[065] In alternative embodiments, the skirt can be formed from woven elastic fibers that can stretch in the axial direction during crimping of the prosthetic valve. The warp and weft fibers can run perpendicularly and parallel to the upper and lower edges of the skirt, or alternatively, they can extend at angles between 0 and 90 degrees relative to the upper and lower edges of the skirt, as described above.

[066] The inner skirt 16 can be sutured to the frame 12 at locations away from the suture line 154 so that the skirt can be more pliable in that area. This configuration can avoid stress concentrations at the suture line 154, which attaches the lower edges of the leaflets to the inner skirt 16.

[067] As noted above, the leaflet structure 14 in the illustrated embodiment includes three flexible leaflets 40 (although a greater or a smaller number of leaflets can be used). Additional information regarding the leaflets, as well as additional information regarding skirt material, can be found, for example, in U.S. Patent Application No. 14/704,861, filed May 05, 2015, which is incorporated by reference in its entirety.

[068] The leaflets 40 can be secured to one another at their adjacent sides to form commissures 122 of the leaflet structure (FIG. 20). A plurality of flexible connectors 124 (one of which is shown in FIG. 16) can be used to interconnect pairs of adjacent sides of the leaflets and to mount the leaflets to the commissure window frame portions 30 (FIG. 5). FIG. 16 shows the adjacent sides of two leaflets 40 interconnected by a flexible connector 124. Three leaflets 40 can be secured to each other side-to-side using three flexible connectors 124, as shown in FIG. 17. Additional information regarding connecting the leaflets to each other, as well as connecting the leaflets to the frame, can be found, for example, in U.S. Patent Application Publication No. 2012/0123529, which is incorporated by reference herein in its entirety.

[069] As noted above, the inner skirt 16 can be used to assist in suturing the leaflet structure 14 to the frame. The inner skirt 16 can have an undulating temporary marking suture to guide the attachment of the lower edges of each leaflet 40. The inner skirt 16 itself can be sutured to the struts of the frame 12 using sutures 70, as noted above, before securing the leaflet structure 14 to the skirt 16. The struts that intersect the marking suture desirably are not attached to the inner

skirt 16. This allows the inner skirt 16 to be more pliable in the areas not secured to the frame and minimizes stress concentrations along the suture line that secures the lower edges of the leaflets to the skirt. As noted above, when the skirt is secured to the frame, the fibers 78, 80 of the skirt (see FIG. 12) generally align with the angled struts of the frame to promote uniform crimping and expansion of the frame.

[070] FIG. 18 shows one specific approach for securing the commissure portions 122 of the leaflet structure 14 to the commissure window frame portions 30 of the frame. The flexible connector 124 (FIG. 17) securing two adjacent sides of two leaflets is folded widthwise and the upper tab portions 112 are folded downwardly against the flexible connector. Each upper tab portion 112 is creased lengthwise (vertically) to assume an L-shape having an inner portion 142 folded against the inner surface of the leaflet and an outer portion 144 folded against the connector 124. The outer portion 144 can then be sutured to the connector 124 along a suture line 146. Next, the commissure tab assembly is inserted through the commissure window 20 of a corresponding window frame portion 30, and the folds outside of the window frame portion 30 can be sutured to portions 144.

[071] FIG. 18 also shows that the folded down upper tab portions 112 can form a double layer of leaflet material at the commissures. The inner portions 142 of the upper tab portions 112 are positioned flat against layers of the two leaflets 40 forming the commissures, such that each commissure comprises four layers of leaflet material just inside of the window frames 30. This four-layered portion of the commissures can be more resistant to bending, or articulating, than the portion of the leaflets 40 just radially inward from the relatively more-rigid four-layered portion. This causes the leaflets 40 to articulate primarily at inner edges 143 of the folded-down inner portions 142 in response to blood flowing through the prosthetic valve during operation within the body, as opposed to articulating about or proximal to the axial struts of the window frames 30. Because the leaflets articulate at a location spaced radially inwardly from the window frames 30, the leaflets can avoid contact with and damage from the frame. However, under high forces, the four layered portion of the commissures can splay apart about a longitudinal axis adjacent to the window frame 30, with each inner portion 142 folding out against the respective outer portion 144. For example, this can occur when the prosthetic valve 10 is compressed and

mounted onto a delivery shaft, allowing for a smaller crimped diameter. The four-layered portion of the commissures can also splay apart about the longitudinal axis when the balloon catheter is inflated during expansion of the prosthetic valve, which can relieve some of the pressure on the commissures caused by the balloon, reducing potential damage to the commissures during expansion.

[072] After all three commissure tab assemblies are secured to respective window frame portions 30, the lower edges of the leaflets 40 between the commissure tab assemblies can be sutured to the inner skirt 16. For example, as shown in FIG. 19, each leaflet 40 can be sutured to the inner skirt 16 along suture line 154 using, for example, Ethibond Excel® PET thread. The sutures can be in-and-out sutures extending through each leaflet 40, the inner skirt 16, and each reinforcing strip 72. Each leaflet 40 and respective reinforcing strip 72 can be sewn separately to the inner skirt 16. In this manner, the lower edges of the leaflets are secured to the frame 12 via the inner skirt 16. As shown in FIG. 19, the leaflets can be further secured to the skirt with blanket sutures 156 that extend through each reinforcing strip 72, leaflet 40 and the inner skirt 16 while looping around the edges of the reinforcing strips 72 and leaflets 40. The blanket sutures 156 can be formed from PTFE suture material. FIG. 20 shows a side view of the frame 12, leaflet structure 14 and the inner skirt 16 after securing the leaflet structure 14 and the inner skirt 16 to the frame 12 and the leaflet structure 14 to the inner skirt 16.

[073] FIG. 21 is a flattened view of the outer skirt 18 prior to its attachment to the frame 12, showing the outer surface of the skirt. FIG. 22 is a flattened view of the outer skirt 18 prior to its attachment to the frame 12, showing the inner surface of the skirt. FIG. 23 is a perspective view of the outer skirt prior to its attachment to the frame 12. The outer skirt 18 can be laser cut or otherwise formed from a strong, durable material such as PET or various other suitable synthetic or natural materials configured to restrict and/or prevent blood-flow therethrough. The outer skirt 18 can comprise a substantially straight lower (inflow or upstream) edge portion 160 and an upper (outflow or downstream) edge portion 162 defining a plurality of alternating projections 164 and notches 166, or castellations, that generally follow the shape of a row of struts of the frame. The lower and upper edge portions 160, 162 can have other shapes in alternative embodiments. For example, in one implementation, the lower edge portion 160 can be formed

with a plurality of projections generally conforming to the shape of a row of struts of the frame 12, while the upper edge portion 162 can be straight.

[074] In particular embodiments, the outer skirt 18 can comprise at least one soft, plush surface 168 oriented radially outward so as to cushion and seal against native tissues surrounding the prosthetic valve. In certain examples, the outer skirt 18 can be made from any of a variety of woven or knitted fabrics wherein the surface 168 is the surface of a plush nap or pile of the fabric. Exemplary fabrics having a pile include velour, velvet, velveteen, corduroy, terrycloth, fleece, etc. As best shown in FIG. 23, the outer skirt can have a base layer 170 (a first layer) from which a pile layer 172 (a second layer) extends. The base layer 170 can comprise warp and weft yarns woven or knitted into a mesh-like structure. For example, in a representative configuration, the yarns of the base layer 170 can be flat yarns and can have a denier range of from about 7 dtex to about 100 dtex, and can be knitted with a density of from about 20 to about 100 wales per inch and from about 30 to about 110 courses per inch. The yarns can be made from, for example, biocompatible thermoplastic polymers such as PET, PTFE (polytetrafluoroethylene), Nylon, etc., or any other suitable natural or synthetic fibers.

[075] The pile layer 172 can comprise pile yarns 174 woven or knitted into loops. In certain configurations, the pile yarns 174 can be the warp yarns or the weft yarns of the base layer 170 woven or knitted to form the loops. The pile yarns 174 can also be separate yarns incorporated into the base layer, depending upon the particular characteristics desired. In a representative configuration, the pile yarns 174 can be flat yarns and can have a denier range of from about 7 dtex to about 100 dtex, and can be knitted with a density of from about 20 to about 100 wales per inch and from about 30 to about 110 courses per inch. The pile yarns can be made from, for example, biocompatible thermoplastic polymers such as PET, PTFE, Nylon, etc., or any other suitable natural or synthetic fibers.

[076] In certain embodiments, the loops can be cut such that the pile layer 172 is a cut pile in the manner of, for example, a velour fabric. FIGS. 1 and 21 illustrate a representative embodiment of the outer skirt 18 configured as a velour fabric. In other embodiments, the loops can be left intact to form a looped pile in the manner of, for example, terrycloth. FIG. 23

illustrates a representative embodiment of the outer skirt 18 in which the pile yarns 174 are knitted to form loops 176.

[077] The height of the pile yarns 174 (e.g., the loops 176) can be the same for all pile yarns across the entire extent of the outer skirt so as to provide an outer skirt having a constant thickness. In alternative embodiments, the height of the pile yarns 174 can vary along the height and/or circumference of the outer skirt so as to vary the thickness of the outer skirt along its height and/or circumference, as further described below.

[078] The pile layer 172 has a much greater surface area than similarly sized skirts formed from flat or woven materials, and therefore can enhance tissue ingrowth compared to known skirts. Promoting tissue growth into the pile layer 172 can decrease perivaluvular leakage, increase retention of the valve at the implant site and contribute to long-term stability of the valve. In some configurations, the surface area of the pile yarns 174 can be further increased by using textured yarns having an increased surface area due to, for example, a wavy or undulating structure. In configurations such as the looped pile embodiment of FIG. 23, the loop structure and the increased surface area provided by the textured yarn of the loops 176 can allow the loops to act as a scaffold for tissue growth into and around the loops of the pile.

[079] The outer skirt embodiments described herein can also contribute to improved compressibility and shape memory properties of the outer skirt over known valve coverings and skirts. For example, the pile layer 172 can be compliant such that it compresses under load (e.g., when in contact with tissue, other implants, or the like), and returns to its original size and shape when the load is relieved. This can help to improve sealing between the outer skirt and the tissue of the native annulus, or a surrounding support structure in which the prosthetic valve is deployed. Embodiments of an implantable support structure that is adapted to receive a prosthetic valve and retain it within the native mitral valve are disclosed in co-pending Application No. 62/449,320, filed January 23, 2017, which is incorporated herein by reference. The compressibility provided by the pile layer 172 of the outer skirt 18 is also beneficial in reducing the crimp profile of the valve. Additionally, the skirt 18 can prevent the leaflets 40 or portions thereof from extending through spaces between the struts of the frame 12 as the

prosthetic valve is crimped, thereby protecting against damage to the leaflets due to pinching of the leaflets between struts.

[080] In alternative embodiments, the outer skirt 18 be made of non-woven fabric such as felt, or fibers such as non-woven cotton fibers. The outer skirt 18 can also be made of porous or spongey materials such as, for example, any of a variety of compliant polymeric foam materials, or woven fabrics, such as woven PET.

[081] Various techniques and configurations can be used to secure the outer skirt 18 to the frame 12 and/or the inner skirt 16. As best shown in FIG. 3, a lower edge portion 180 of the inner skirt 16 can be wrapped around the inflow end 15 of the frame 12, and the lower edge portion 160 of the outer skirt 18 can be attached to the lower edge portion 180 of the inner skirt 16 and/or the frame 12, such as with one or more sutures or stitches 182 (as best shown in FIG. 2) and/or an adhesive. In lieu of or in addition to sutures, the outer skirt 18 can be attached to the inner skirt 16, for example, by ultrasonic welding. In the illustrated embodiment, the lower edge portion 160 of the outer skirt 18 can be free of loops, and the lower edge portion 180 of the inner skirt 16 can overlap and can be secured to the base layer 170 of the outer skirt 18. In other embodiments, the lower edge portion 160 of the inner skirt 16 can extend over one or more rows of loops 176 of the pile layer 172 (see FIG. 27), as further described below.

[082] As shown in FIG. 1, each projection 164 of the outer skirt 18 can be attached to the third row III of struts 26 (FIG. 5) of the frame 12. The projections 164 can, for example, be wrapped over respective struts 26 of row III and secured with sutures 184. The outer skirt 18 can be further secured to the frame 12 by suturing an intermediate portion of the outer skirt (a portion between the lower and upper edge portions) to struts of the frame, such as struts 24 of the second row II of struts.

[083] The height of the outer skirt (as measured from the lower edge to the upper edge) can vary in alternative embodiments. For example, in some embodiments, the outer skirt can cover the entire outer surface of the frame 12, with the lower edge portion 160 secured to the inflow end of the frame 12 and the upper edge portion secured to the outflow end of the frame. In another embodiment, the outer skirt 18 can extend from the inflow end of the frame to the second

row II of struts 24, or to the fourth row IV of struts 28, or to a location along the frame between two rows of struts. In still other embodiments, the outer skirt 18 need not extend all the way to the inflow end of the frame, and instead the inflow end of the outer skirt can secured to another location on the frame, such as to the second row II of struts 24.

[084] The outer skirt 18 desirably is sized and shaped relative to the frame such that when the prosthetic valve 10 is in its radially expanded state, the outer skirt 18 fits snugly (in a tight-fitting manner) against the outer surface of the frame. When the prosthetic valve 10 is radially compressed to a compressed state for delivery, the portion of the frame on which the outer skirt is mounted can elongate axially. The outer skirt 18 has sufficient elasticity to stretch in the axial direction upon radial compression of the frame so that it does not to prevent full radial compression of the frame or deform the struts during the crimping process.

[085] Known skirts that have material slack or folds when the prosthetic valve is expanded to its functional size are difficult to assemble because the material must be adjusted as it is sutured to the frame. In contrast, because the outer skirt 18 is sized to fit snugly around the frame in its fully expanded state, the assembly process of securing the skirt to the frame is greatly simplified. During the assembly process, the outer skirt can be placed around the frame with the frame in its fully expanded state and the outer skirt in its final shape and position when the valve is fully functional. In this position, the skirt can then be sutured to the frame and/or the inner skirt. This simplifies the suturing process compared to skirts that are designed to have slack or folds when radially expanded.

[086] As shown in FIG. 3, the height of the loops of the pile layer 172 can be constant across the entire extent of the outer skirt such that the outer skirt 18 has a constant thickness, except along the upper and lower edge portions which can be free of loops to facilitate attachment of the outer skirt to the frame and/or the inner skirt 16. In another embodiment, as shown in FIG. 24, the loops can comprise lower loops 176a along the lower or upstream portion of the skirt that are relatively shorter in height (as represented by a thinner line) than upper loops 176b (as represented by a thicker line) along the upper or downstream portion of the skirt. The skirt 18 can further include a group of intermediate loops 176c that gradually increase in height from the

lower loops 176a to the upper loops 176b. Thus, in the embodiment of FIG. 24, the thickness of outer skirt 18 increases from a minimum thickness along the lower portion to a maximum thickness along the upper portion.

[087] FIG. 25 shows another embodiment in which the loops of the outer skirt comprise lower loops 176d along the lower portion of the skirt that are relatively higher or longer in height than upper loops 176e along the upper portion of the skirt. The skirt 18 can further include a group of intermediate loops 176f that gradually decrease in height from the lower loops 176d to the upper loops 176e. Thus, in the embodiment of FIG. 25, the thickness of outer skirt 18 decreases from a maximum thickness along the lower portion to a minimum thickness along the upper portion.

[088] FIG. 26 shows another embodiment in which the loops comprise lower loops 176g, upper loops 176h, and intermediate loops 176i that are relative shorter in height than the lower and upper loops. As shown, the lower loops 176g can gradually decrease in height from the lower edge of the skirt toward the intermediate loops 176i, and the upper loops 176h can gradually decrease in height from the upper edge of the skirt toward the intermediate loops 176i. Thus, in the embodiment of FIG. 26, the thickness of the outer skirt decreases from a maximum thickness along the lower portion to a minimum thickness along the intermediate portion, and then increases from the intermediate portion to the maximum thickness along the upper portion.

[089] In lieu of or in addition to having loops that vary in height along the height of the skirt, the height of the loops 176 (and therefore the thickness of the outer skirt) can vary along the circumference of the outer skirt. For example, the height of the loops can be increased along circumferential sections of the skirt where larger gaps might be expected between the outer skirt and the native annulus, such as circumferential sections of the skirt that are aligned with the commissures of the native valve.

[090] FIGS. 27 and 28 show an alternative configuration for mounting the outer skirt 18 to the frame 12. In this embodiment, as best shown in FIG. 27, the lower edge portion 180 of the inner skirt 16 is wrapped around the inflow end of the frame and extended over one or more rows of loops along the lower edge portion 160 of the outer skirt. The lower edge portion 180 of the inner skirt 16 can then be secured to the lower edge portion 160 of the outer skirt, such as with

sutures or stitching 186 (FIG. 28), an adhesive, and/or welding (e.g., ultrasonic welding). The stitching 186 can also extend around selected struts adjacent the inflow end of the frame. The lower edge portion 180 of the inner skirt is effective to partially compress the loops of the pile layer 172, which creates a tapered edge at the inflow end of the prosthetic valve. The tapered edge reduces the insertion force required to push the prosthetic valve through an introducer sheath when being inserted into a patient's body. In one specific implementation, the stitching 186 secures the lower edge portion 180 of the inner skirt to the outer skirt 18 at a distance of at least 1 mm from the lowermost edge of the outer skirt. The upper edge portion 162 and the intermediate portion of the outer skirt can then be secured to the frame as previously described.

[091] FIGS. 29-32 show another configuration for mounting the outer skirt 18 to the frame 12. In this embodiment, the outer skirt 18 is initially placed in a tubular configuration with the base layer 170 facing outwardly and the lower edge portion 160 (which can be free of loops 176) can be placed between the inner surface of the frame 12 and the lower edge portion 180 of the inner skirt 16, as depicted in FIG. 30. The lower edge portions of the outer skirt and the inner skirt can be secured to each other, such as with stitches, an adhesive, and/or welding (e.g., ultrasonic welding). In one implementation, the lower edge portions of the outer skirt and the inner skirt are secured to each other with in-and-out stitches and locking stitches. The outer skirt 18 is then inverted and pulled upwardly around the outer surface of the frame 12 such that the base layer 170 is placed against the outer surface of the frame and the pile layer 172 faces outwardly, as depicted in FIG. 29. In this assembled configuration, the lower edge portion 160 of the outer skirt wraps around the inflow end of the frame and is secured to the inner skirt inside of the frame. The upper edge portion 162 and the intermediate portion of the outer skirt can then be secured to the frame as previously described.

[092] The prosthetic valve 10 can be configured for and mounted on a suitable delivery apparatus for implantation in a subject. Several catheter-based delivery apparatuses are known; a non-limiting example of a suitable catheter-based delivery apparatus includes that disclosed in U.S. Patent Application Publication No. 2013/0030519, which is incorporated by reference herein in its entirety, and U.S. Patent Application Publication No. 2012/0123529.

[093] To implant a plastically-expandable prosthetic valve 10 within a patient, the prosthetic valve 10 including the outer skirt 18 can be crimped on an elongated shaft of a delivery apparatus. The prosthetic valve, together with the delivery apparatus, can form a delivery assembly for implanting the prosthetic valve 10 in a patient's body. The shaft can comprise an inflatable balloon for expanding the prosthetic valve within the body. With the balloon deflated, the prosthetic valve 10 can then be percutaneously delivered to a desired implantation location (e.g., a native aortic valve region). Once the prosthetic valve 10 is delivered to the implantation site (e.g., the native aortic valve) inside the body, the prosthetic valve 10 can be radially expanded to its functional state by inflating the balloon or equivalent expansion mechanism.

[094] The outer skirt 18 can fill-in gaps between the frame 12 and the surrounding native annulus to assist in forming a good, fluid-tight seal between the prosthetic valve 10 and the native annulus. The outer skirt 18 therefore cooperates with the inner skirt 16 to avoid perivalvular leakage after implantation of the prosthetic valve 10. Additionally, as discussed above, the pile layer of the outer skirt further enhances perivalvular sealing by promoting tissue ingrowth with the surrounding tissue.

[095] Alternatively, a self-expanding prosthetic valve 10 can be crimped to a radially collapsed configuration and restrained in the collapsed configuration by inserting the prosthetic valve 10, including the outer skirt 18, into a sheath or equivalent mechanism of a delivery catheter. The prosthetic valve 10 can then be percutaneously delivered to a desired implantation location. Once inside the body, the prosthetic valve 10 can be advanced from the delivery sheath, which allows the prosthetic valve to expand to its functional state.

[096] FIG. 33 illustrates a sealing member 200 for a prosthetic valve, according to another embodiment. The sealing member 200 in the illustrated embodiment is formed from a spacer fabric. The sealing member 200 can be positioned around the outer surface of the frame 12 of a prosthetic valve (in place of the outer skirt 18) and secured to the inner skirt 16 and/or the frame using stitching, an adhesive, and/or welding (e.g., ultrasonic welding).

[097] As best shown in FIG. 34, the spacer fabric can comprise a first, inner layer 206, a second, outer layer 208, and an intermediate spacer layer 210 extending between the first and

second layers to create a three-dimensional fabric. The first and second layers 206, 208 can be woven fabric or mesh layers. In certain configurations, one or more of the first and second layers 206, 208 can be woven such that they define a plurality of openings 212. In some examples, openings such as the openings 212 can promote tissue growth into the covering 202. In other embodiments, the layers 206, 208 need not define openings, but can be porous, as desired.

[098] The spacer layer 210 can comprise a plurality of pile yarns 214. The pile yarns 214 can be, for example, monofilament yarns arranged to form a scaffold-like structure between the first and second layers 206, 208. For example, FIGS. 34 and 35 illustrate an embodiment in which the pile yarns 214 extend between the first and second layers 206, 208 in a sinusoidal or looping pattern.

[099] In certain examples, the pile yarns 214 can have a rigidity that is greater than the rigidity of the fabric of the first and second layers 206, 208 such that the pile yarns 214 can extend between the first and second layers 206, 208 without collapsing under the weight of the second layer 208. The pile yarns 214 can also be sufficiently resilient such that the pile yarns can bend or give when subjected to a load, allowing the fabric to compress, and return to their non-deflected state when the load is removed.

[0100] The spacer fabric can be warp-knitted, or weft-knitted, as desired. Some configurations of the spacer cloth can be made on a double-bar knitting machine. In a representative example, the yarns of the first and second layers 206, 208 can have a denier range of from about 10 dtex to about 70 dtex, and the yarns of the monofilament pile yarns 214 can have a denier range of from about 2 mil to about 10 mil. The pile yarns 214 can have a knitting density of from about 20 to about 100 wales per inch, and from about 30 to about 110 courses per inch. Additionally, in some configurations (e.g., warp-knitted spacer fabrics) materials with different flexibility properties may be incorporated into the spacer cloth to improve the overall flexibility of the spacer cloth.

General Considerations

[0101] It should be understood that the disclosed embodiments can be adapted to deliver and implant prosthetic devices in any of the native annuluses of the heart (e.g., the pulmonary, mitral, and tricuspid annuluses), and can be used with any of various approaches (e.g., retrograde, antegrade, transseptal, transventricular, transatrial, etc.). The disclosed embodiments can also be used to implant prostheses in other lumens of the body. Further, in addition to prosthetic valves, the delivery assembly embodiments described herein can be adapted to deliver and implant various other prosthetic devices such as stents and/or other prosthetic repair devices.

[0102] For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The disclosed methods, apparatus, and systems should not be construed as being limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The methods, apparatus, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed embodiments require that any one or more specific advantages be present or problems be solved.

[0103] Although the operations of some of the disclosed embodiments are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods. Additionally, the description sometimes uses terms like “provide” or “achieve” to describe the disclosed methods. These terms are high-level abstractions of the actual operations that are performed. The actual operations that correspond to these terms may vary depending on the particular implementation and are readily discernible by one of ordinary skill in the art.

[0104] As used in this application and in the claims, the singular forms "a," "an," and "the" include the plural forms unless the context clearly dictates otherwise. Additionally, the term "includes" means "comprises." Further, the terms "coupled" and "associated" generally mean electrically, electromagnetically, and/or physically (*e.g.*, mechanically or chemically) coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items absent specific contrary language.

[0105] As used herein, the term "proximal" refers to a position, direction, or portion of a device that is closer to the user and further away from the implantation site. As used herein, the term "distal" refers to a position, direction, or portion of a device that is further away from the user and closer to the implantation site. Thus, for example, proximal motion of a device is motion of the device toward the user, while distal motion of the device is motion of the device away from the user. The terms "longitudinal" and "axial" refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.

[0106] As used herein, the terms "integrally formed" and "unitary construction" refer to a construction that does not include any welds, fasteners, or other means for securing separately formed pieces of material to each other.

[0107] As used herein, operations that occur "simultaneously" or "concurrently" occur generally at the same time as one another, although delays in the occurrence of one operation relative to the other due to, for example, spacing, play or backlash between components in a mechanical linkage such as threads, gears, etc., are expressly within the scope of the above terms, absent specific contrary language.

[0108] In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only preferred examples of the invention and should not be taken as limiting the scope of the invention. Rather, the scope of the invention is defined by the following claims. We therefore claim as our invention all that comes within the scope and spirit of these claims.

We claim:

1. A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto; and

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a mesh layer and pile layer comprising a plurality of pile yarns extending outwardly from the mesh layer.

2. The prosthetic heart valve of claim 1, wherein the mesh layer comprises a knit or woven fabric.

3. The prosthetic heart valve of any preceding claim, wherein the pile yarns are arranged to form a looped pile.

4. The prosthetic heart valve of any preceding claim, wherein the pile yarns are cut to form a cut pile.

5. The prosthetic heart valve of any preceding claim, wherein the height of the pile yarns varies along a height and/or a circumference of the outer skirt.

6. The prosthetic heart valve of claim 5, wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is less than a height of the yarns of the second group.

7. The prosthetic heart valve of claim 5, wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is greater than a height of the yarns of the second group.

8. The prosthetic heart valve of claim 5, wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt, a second group of yarns along a downstream portion of the outer skirt, and a third group of yarns between the first and second group of yarns, wherein the yarns of the first and second groups have a height that is greater than a height of the yarns of the third group.

9. The prosthetic heart valve of any preceding claim, further comprising an inner skirt mounted on an inner surface of the frame, the inner skirt having an inflow end portion that is secured to an inflow end portion of the outer sealing member.

10. The prosthetic heart valve of claim 9, wherein the inflow end portion of the inner skirt is wrapped around an inflow end of the frame and overlaps the inflow end portion of the outer sealing member on the outside of the frame.

11. The prosthetic heart valve of any preceding claim, wherein the mesh layer comprises a first mesh layer and the outer sealing member further comprises a second mesh layer disposed radially outside of the pile layer.

12. The prosthetic heart valve of any preceding claim, wherein the outer sealing member is configured to stretch axially when the frame is radially compressed to the radially compressed state.

13. A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto; and

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a fabric having a variable thickness.

14. The prosthetic heart valve of claim 13, wherein the thickness of the fabric layer varies along a height and/or a circumference of the outer sealing member.

15. The prosthetic heart valve of claims 13 or 14, wherein the fabric comprises a plush fabric.

16. The prosthetic heart valve of any of claims 13-15, wherein the fabric comprises a plurality of pile yarns and the height of the pile yarns varies along a height and/or a circumference of the outer skirt.

17. The prosthetic heart valve of claim 16, wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is less than a height of the yarns of the second group.

18. The prosthetic heart valve of claim 16, wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is greater than a height of the yarns of the second group.

19. The prosthetic heart valve of claim 16, wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt, a second group of yarns along a downstream portion of the outer skirt, and a third group of yarns between the first and second group of yarns, wherein the yarns of the first and second groups have a height that is greater than a height of the yarns of the third group.

SEALING MEMBER FOR PROSTHETIC HEART VALVE

ABSTRACT

A prosthetic heart valve includes an annular frame that has an inflow end and an outflow end and is radially compressible and expandable between a radially compressed configuration and a radially expanded configuration. The prosthetic heart valve further includes a leaflet structure positioned within the frame and secured thereto, and an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient. The sealing member can include a mesh layer and pile layer comprising a plurality of pile yarns extending outwardly from the mesh layer.

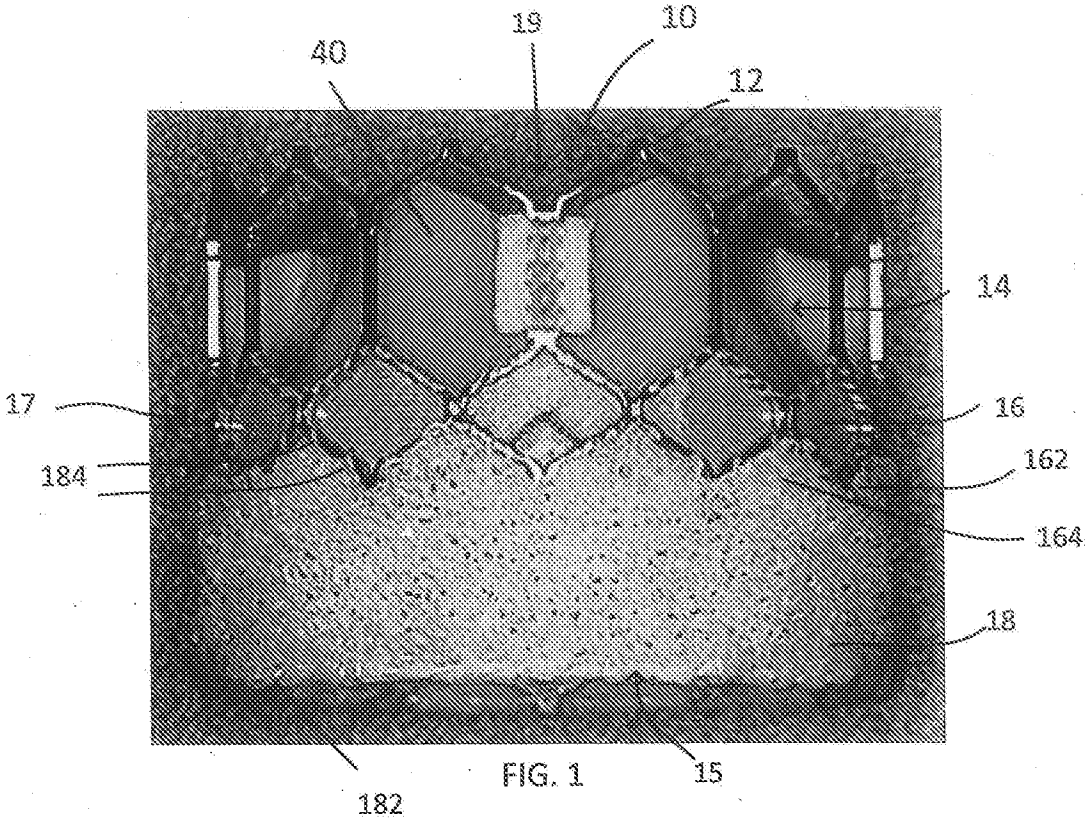


FIG. 1

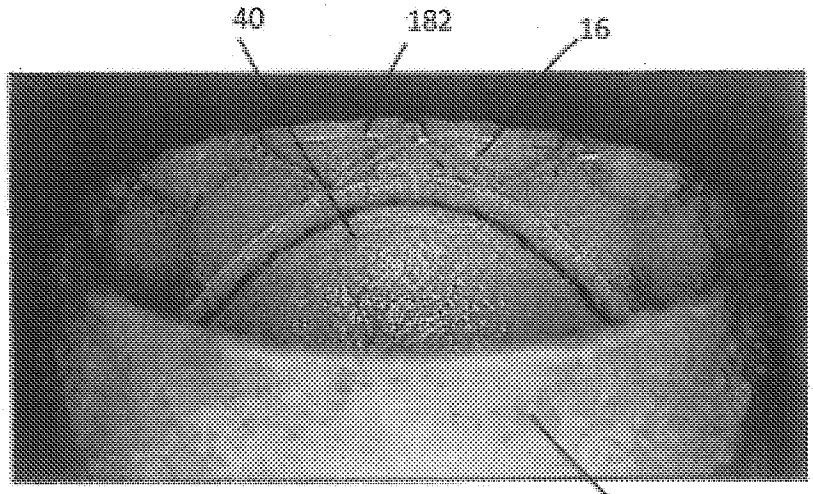


FIG. 2

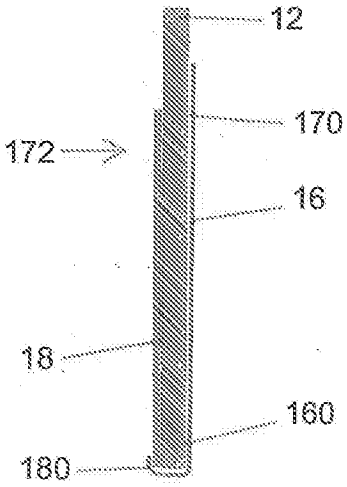


FIG. 3

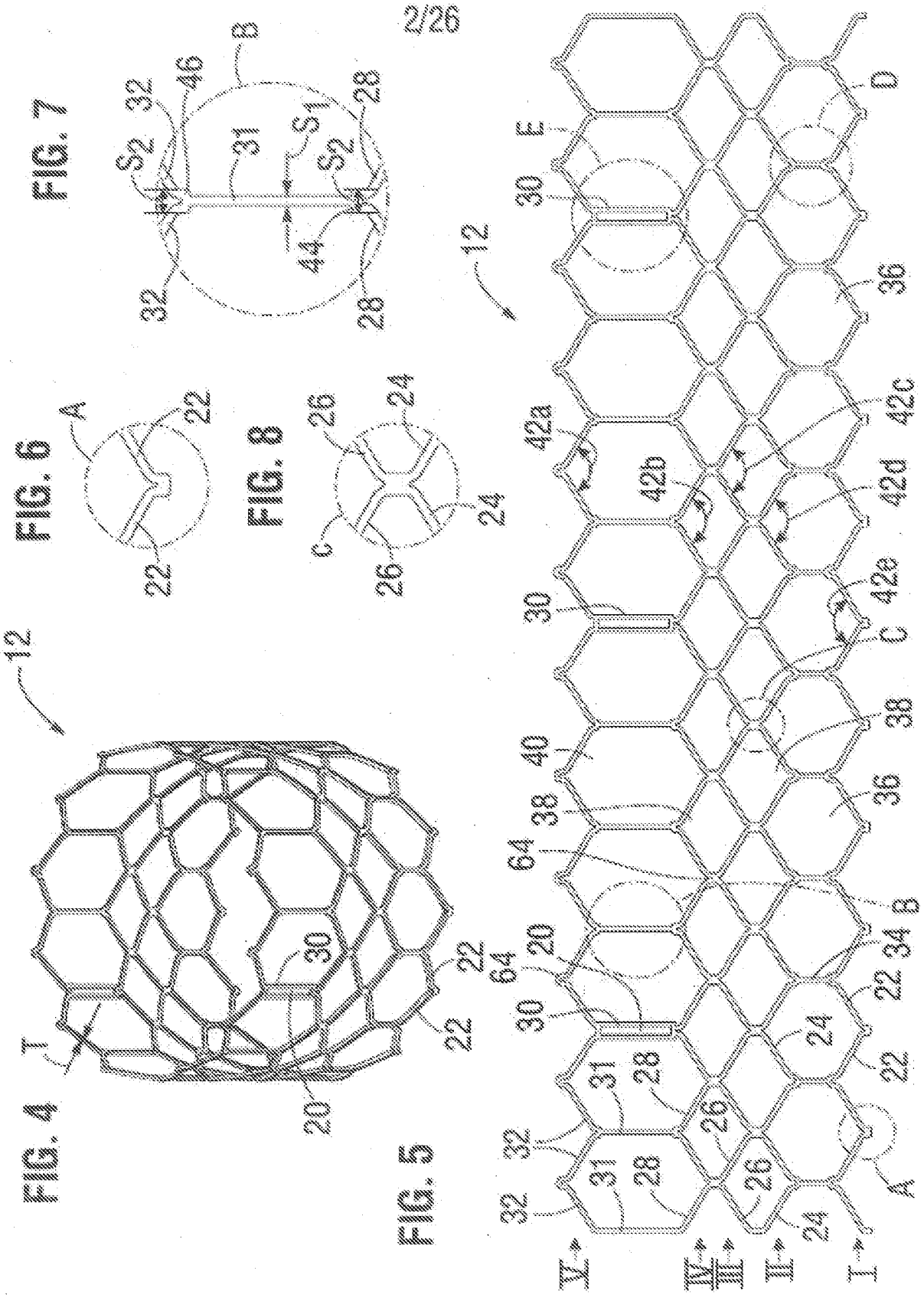

FIG. 4
12
T
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22
FIG. 5
12
D
E
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36
42a
42b
42c
42d
42e
C
38
40
64
20
B
34
22
24
A
31
28
32
26
I
II
III
IV
V
FIG. 6
A
22
FIG. 7
a
46
32
S2
31
S1
28
44
FIG. 8
26
24
C

FIG. 9

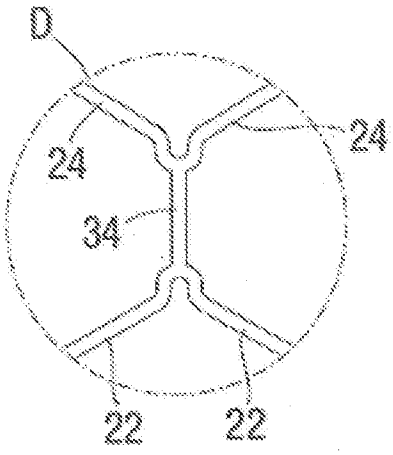
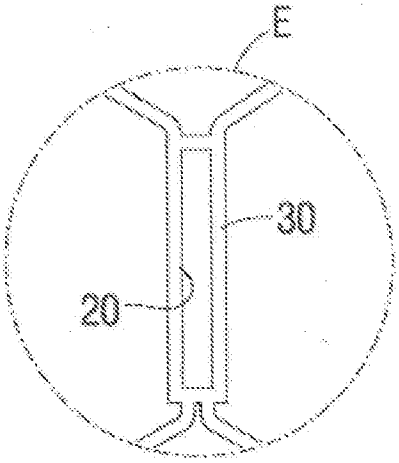


FIG. 10



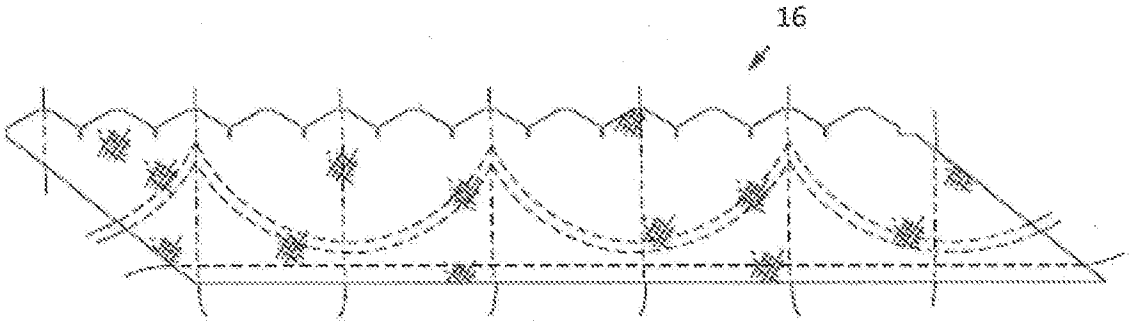


FIG. 11

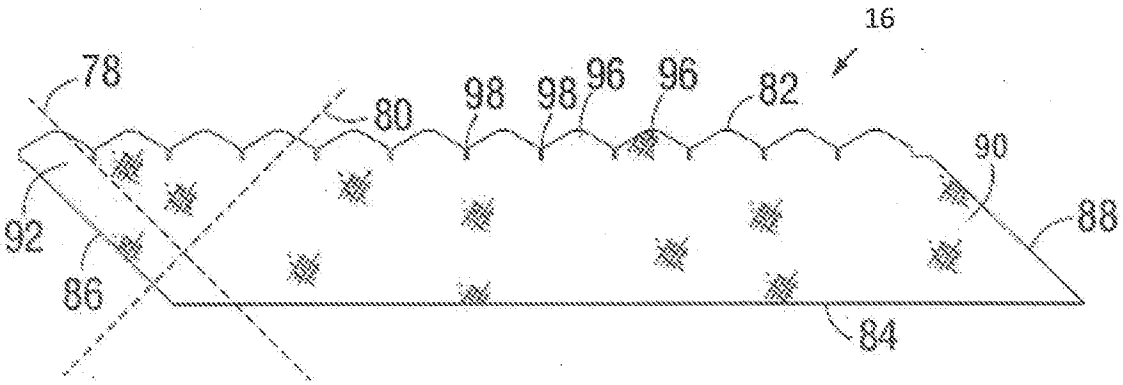


FIG. 12

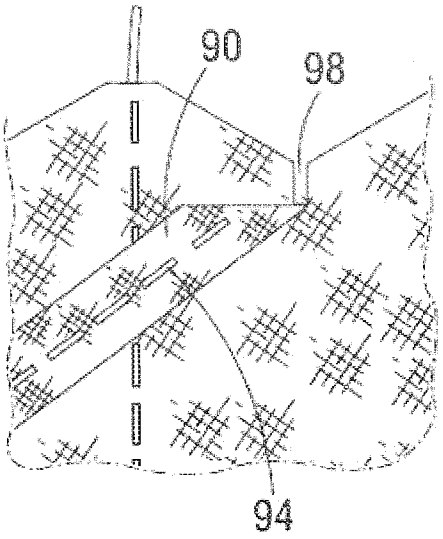


FIG. 13

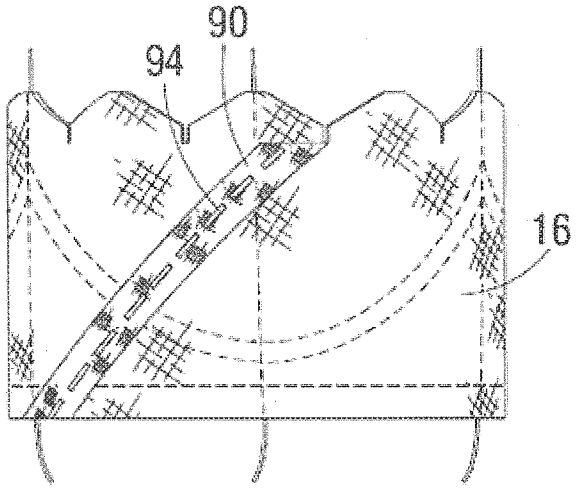


FIG. 14

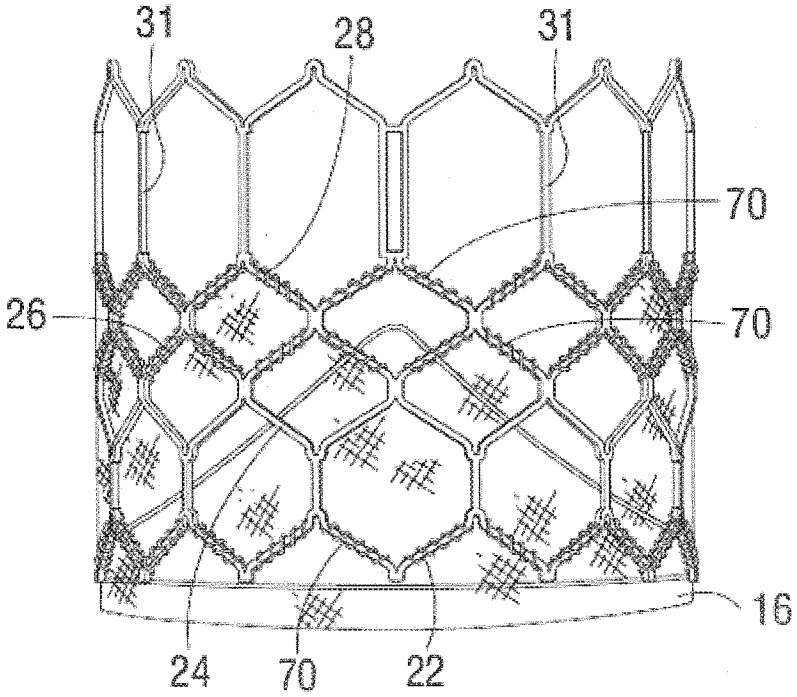


FIG. 15

FIG. 16

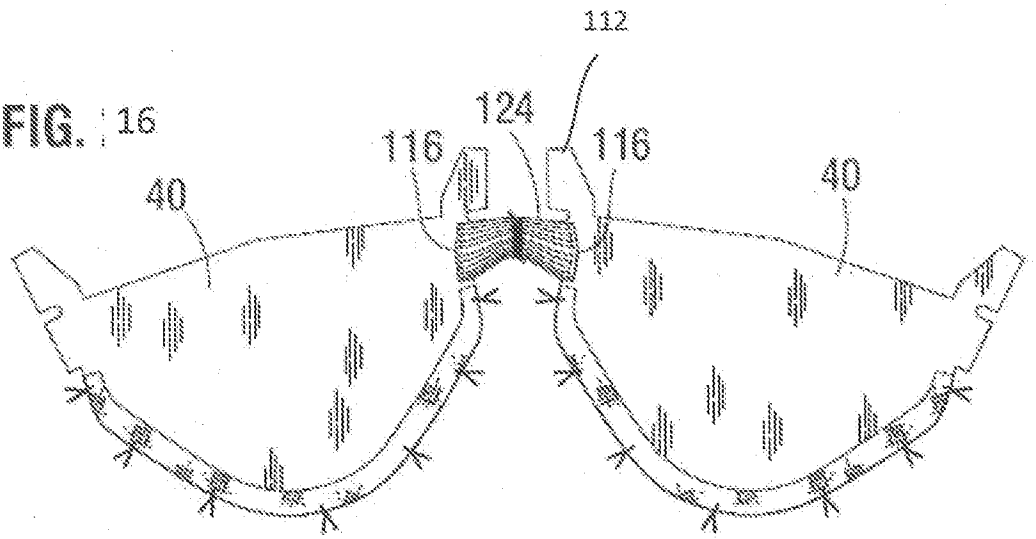
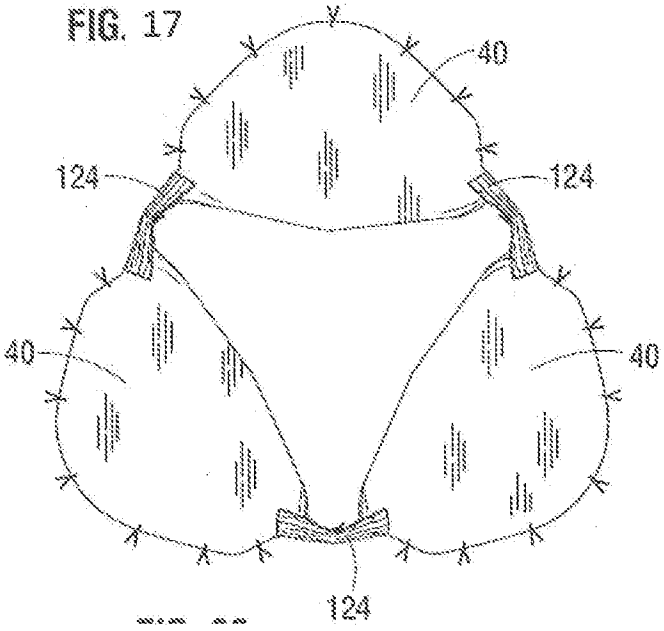


FIG. 17



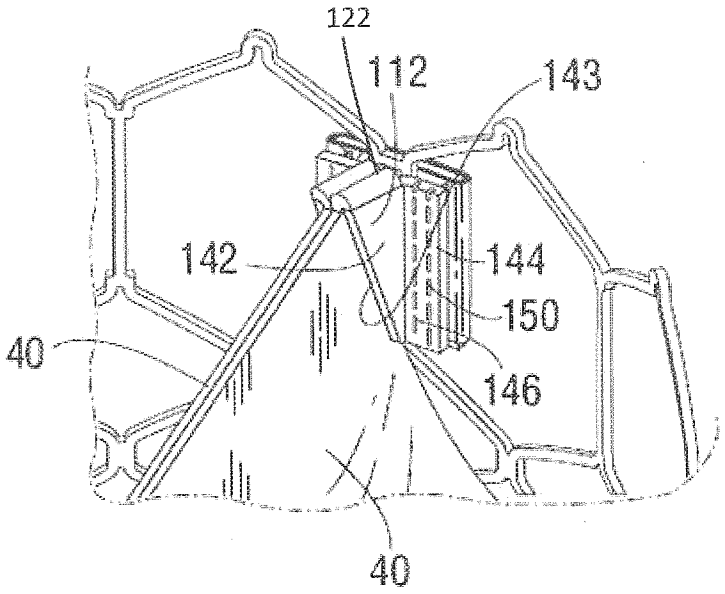


FIG. 18

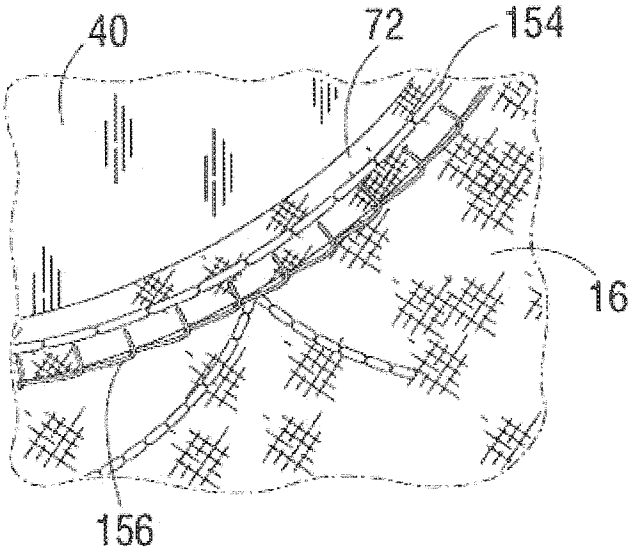


FIG. 19

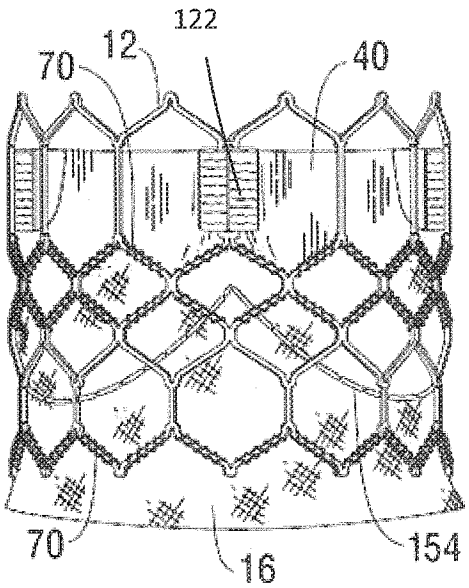


FIG. 20

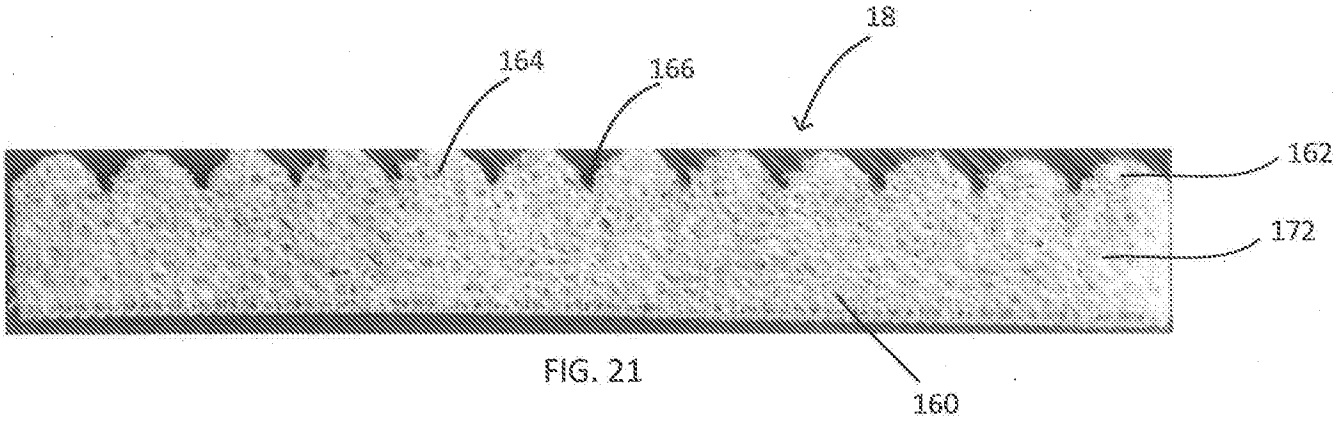


FIG. 21

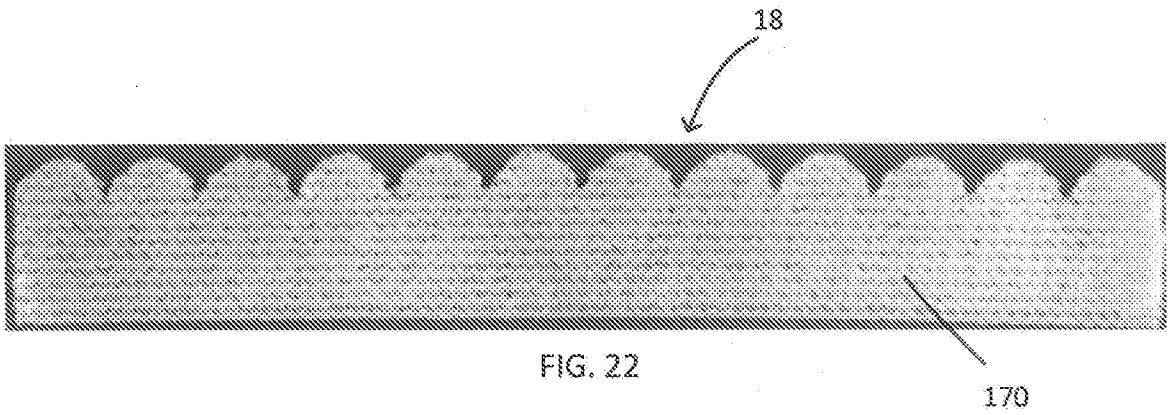


FIG. 22

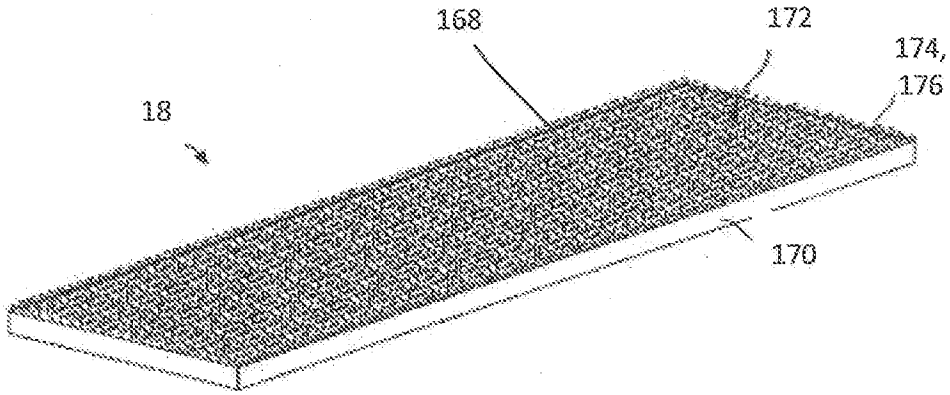


FIG. 23

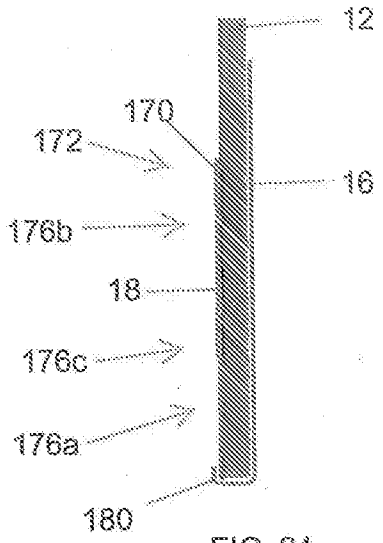


FIG. 24

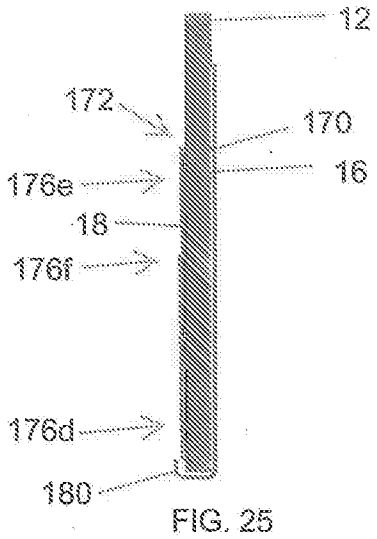


FIG. 25

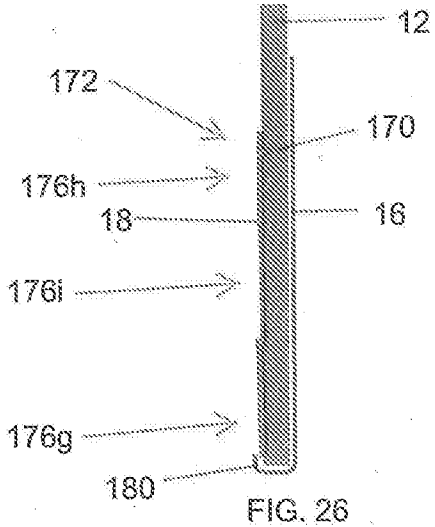


FIG. 26

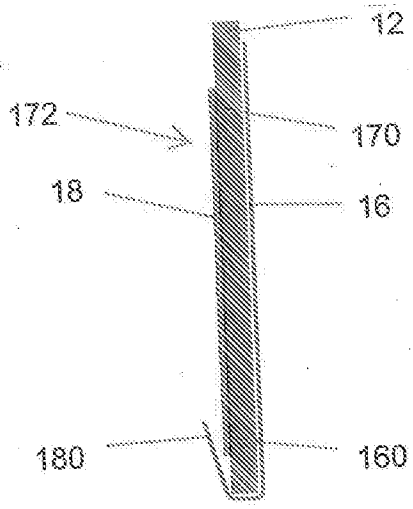


FIG. 27

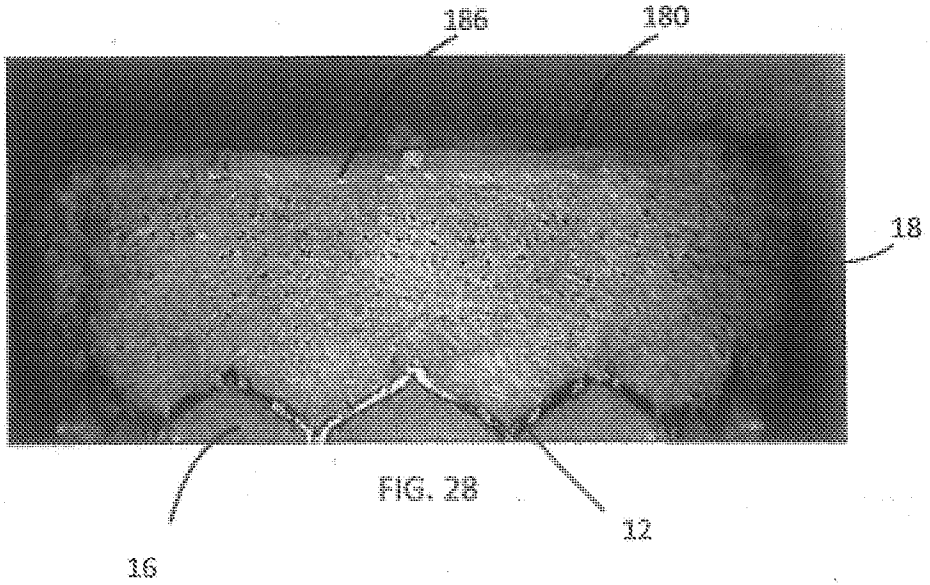


FIG. 28

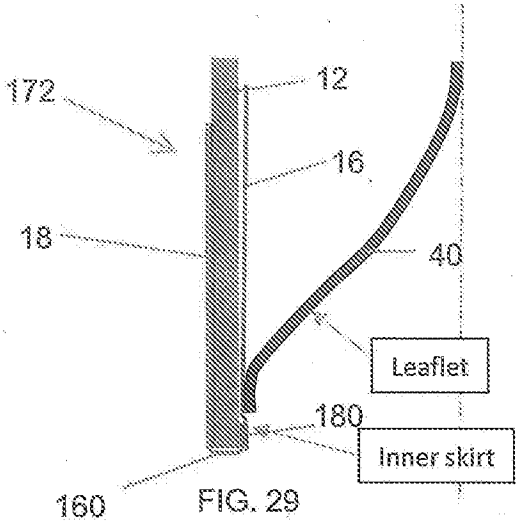


FIG. 29

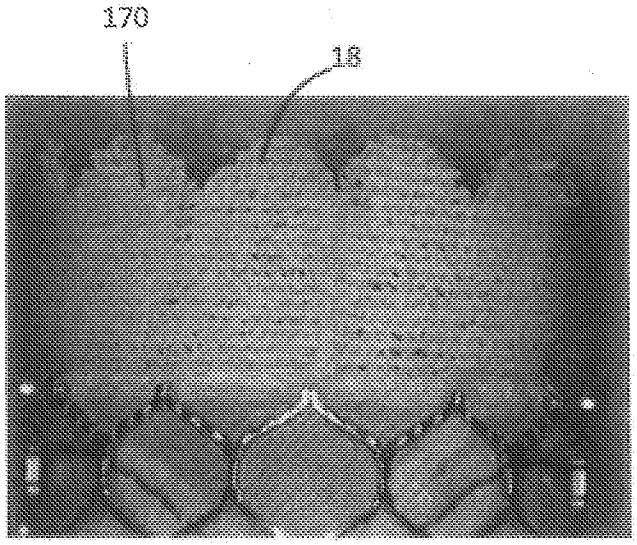


FIG. 30

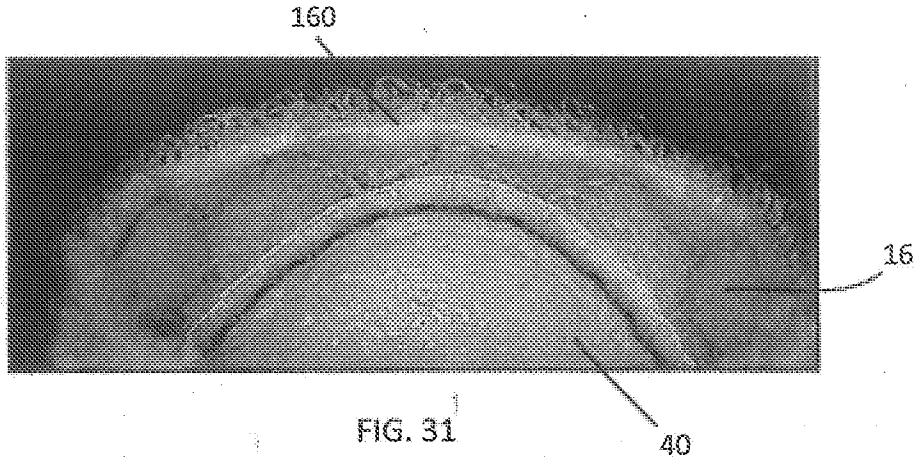


FIG. 31

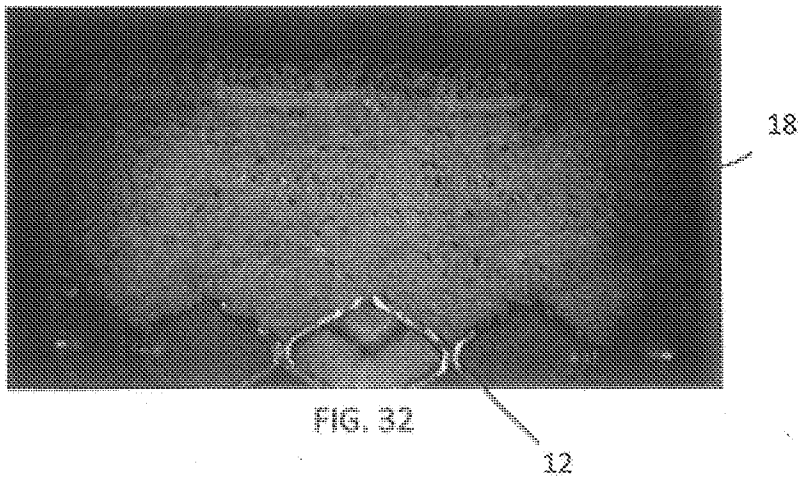


FIG. 32

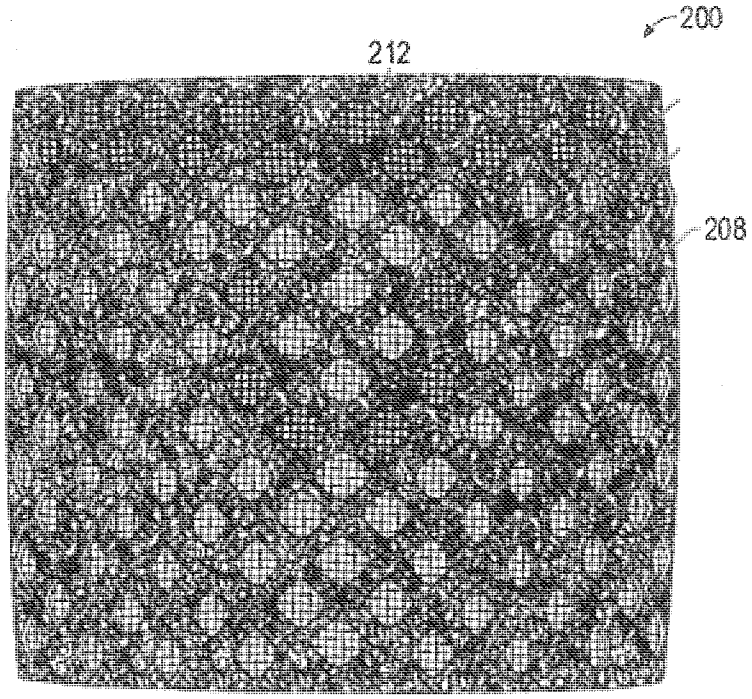


FIG. 33

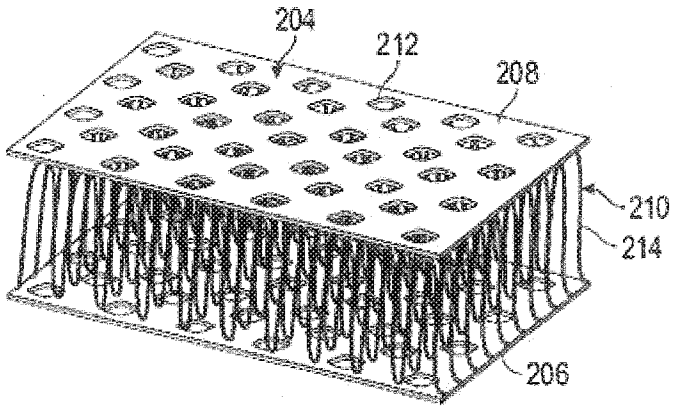


FIG. 34

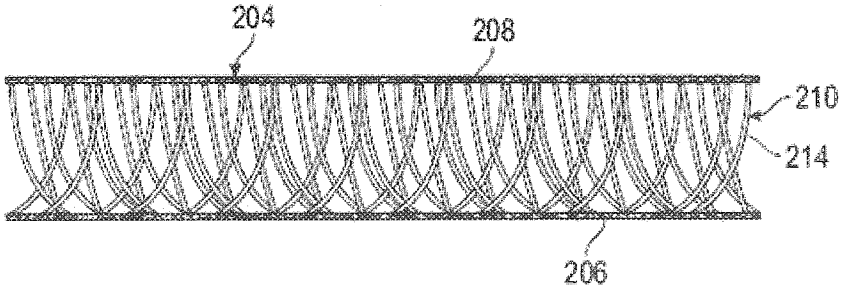


FIG. 35

EXHIBIT 18

From: **Ascyrus** <phil.nowell@ascyrus.com>
Date: Thu, Oct 12, 2017 at 3:43 AM
Subject: Ascyrus Medical Update
To: <Don.bobo@edwards.com>
Cc: Ali Shahriari <ali.shahriari@ascyrus.com>

Dear Mr Bobo

My name is Philip Nowell and I have joined Dr Ali Shahriari at Ascyrus Medical. With many years of senior executive experience in the aortic device commercial space my goal is to take the Ascyrus Dissection Stent (ADS) forward to market.

I am contacting you to follow up on the conversations you had with Dr Shahriari in April. The ADS project is moving ahead rapidly and I would like to update you on our progress:

1) The first patient to be implanted with the ADS was in March 2017 in Edmonton Alberta Canada. The patient reached the key six-month milestone in September and the review confirmed all clinical trial end points had been achieved – Dr Monk (the Principal Investigator) commented that the dissection had been cured

2) We have continued the single center study and, following the success of the first few patients, have moved forward toward a Multi-Center clinical trial and have made initial overtures to the FDA

3) Cardiothoracic surgeons from many parts of the world have contacted Ascyrus seeking early involvement in the project & access to the ADS

So onto my purpose in contacting you.

The Value Proposition of the ADS is established and the clinical trial is proving it out: the ADS heals the dissected aorta.

Currently, patients having a surgical replacement of their dissected ascending aorta survive the acute phase but then suffer ongoing serious complications & reinterventions, with 50% mortality within ten years. This is a serious unmet clinical need affecting more than 200,000 patients every year.

These patients currently have no alternative. We believe the ADS gives these patients – and their families – the opportunity to thrive, not just survive, after their acute type A dissection. We are indeed helping patients live longer, healthier and more productive lives!

Ascyrus Medical, under Dr Shahriari's leadership, has developed the product and is now moving forward to gain key market regulatory approval, driven first by the CE Mark and secondarily via

FDA approval. Whilst we move forward through this process more than 200,000 patients and families every year face an uncertain future due to acute type A dissection. Our goal is to get this device to as many patients as possible in the quickest time. The clear truth is that to achieve this purpose we need to upscale sales and market penetration as quickly as possible post approval. We believe the best way to achieve this objective demands we find an established global medical device company to take over post-approval responsibility for market scaleup.

We are actively talking, therefore, to appropriate medical device companies seeking a Joint Venture with the purpose of achieving this important objective. We believe Edwards Lifesciences has products complementary to the ADS …20% of patients with acute type A dissection require replacement of their aortic valve. We are therefore contacting you to see if you are interested in further discussions. These discussions can also include other devices we have in development of which you are already aware following your earlier discussions with Dr Shahriari.

I would like to set up a call in the near future to more fully update you on our progress and to discuss the JV I have in mind. If this is of interest to you please let me know when this call might be possible. We look forward to hearing your feedback on our request.

Best Regards

Philip Nowell
Vice President, Global Business Strategy & Commercialization
M: +61 417 464 638
E: Phil.Nowell@ascyrus.com
www.ascyrus.com

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EXHIBIT 19

From: **Ali Shahriari** <ali.shahriari@ascyrus.com>
Date: Mon, Jul 1, 2019 at 3:30 PM
Subject: Ascyrus Medical
To: Don Bobo <Don_bobo@edwards.com>

Dear Mr. Bobo,
I hope this email finds you well. Since we spoke last in late 2017, Ascyrus Medical has made a great amount of progress. We completed the largest prospective trial for type A dissections conducted to date with excellent results. We are now CE marked and approved in Canada. We started sales as part of a postmarket registry and without a sales rep in Germany we generated $1.5M in revenues during the first 3 months of sales. I would like to invite you to visit our website www.ascyrus.com to learn more about the product. The product is used excIusively by cardiac surgeons and is fits well within the standard cardiac surgical product portfolios. The pricing of the product in the market has been well received. I would like to set up a time to update you on our progress as I can now also answer some of the questions that you had in our previous conversation with the data and information that we have generated. I am also attaching a brief slide deck for your review. I am looking forward to hearing from you.

Kind regards,
Ali

--
Ali Shahriari M.D.
President/ CEO
2385 NW Executive Center Drive
Suite 100
Boca Raton, FL 33431, USA
Phone: 1 (617) 839-8525
www.ascyrus.com

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EXHIBIT 20

Listing of Claims

1. (Previously Presented) A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto;

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a mesh layer and pile layer comprising a plurality of pile yarns extending outwardly from the mesh layer; and

a fabric inner skirt, separate from the outer sealing member, mounted to an inner surface the frame, the inner skirt having an upper edge portion and a lower edge portion, wherein the upper edge portion of the inner skirt is sutured to struts of the frame and the lower edge portion of the inner skirt is wrapped around the inflow end of the frame and extends over an outer surface of a lower edge portion of the outer sealing member, and wherein the lower edge portion of the inner skirt is stitched to the lower edge portion of the outer sealing member.

2. (Original) The prosthetic heart valve of claim 1, wherein the mesh layer comprises a knit or woven fabric.

3. (Previously Presented) The prosthetic heart valve of claim 1, wherein the mesh layer comprises a plurality of first yarns knitted together to form the mesh layer and the pile yarns are second yarns incorporated into the mesh layer arranged to form a looped pile comprising a plurality of rows of loops extending outwardly from the mesh layer.

4. (Canceled)

5. (Original) The prosthetic heart valve of claim 1, wherein the height of the pile yarns varies along a height and/or a circumference of the outer skirt.

6. (Previously Presented) A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto; and

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a mesh layer and pile layer comprising a plurality of pile yarns extending outwardly from the mesh layer;

wherein the height of the pile yarns varies along a height and/or a circumference of the outer skirt;

wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is less than a height of the yarns of the second group.

7. (Previously Presented) A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto; and

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a mesh layer and pile layer comprising a plurality of pile yarns extending outwardly from the mesh layer;

wherein the height of the pile yarns varies along a height and/or a circumference of the outer skirt;

wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is greater than a height of the yarns of the second group.

8. (Previously Presented) A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto; and

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a mesh layer and pile layer comprising a plurality of pile yarns extending outwardly from the mesh layer;

wherein the height of the pile yarns varies along a height and/or a circumference of the outer skirt;

wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt, a second group of yarns along a downstream portion of the outer skirt, and a third group of yarns between the first and second group of yarns, wherein the yarns of the first and second groups have a height that is greater than a height of the yarns of the third group.

9. (Canceled)

10. (Canceled)

11. (Previously Presented) A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto; and

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a mesh layer and pile layer comprising a plurality of pile yarns extending outwardly from the mesh layer;

wherein the mesh layer comprises a first mesh layer and the outer sealing member further comprises a second mesh layer disposed radially outside of the pile layer.

12. (Original) The prosthetic heart valve of claim 1, wherein the outer sealing member is configured to stretch axially when the frame is radially compressed to the radially compressed state.

13. (Original) The prosthetic heart valve of claim 1, wherein the mesh layer comprises warp yarns and weft yarns woven with the warp yarns, and the pile layer comprises the warp yarns or the weft yarns of the mesh layer that are woven or knitted to form the pile yarns.

14. (Original) The prosthetic heart valve of claim 1, wherein the mesh layer comprises a woven fabric layer and the pile layer comprises a separate pile layer that is stitched to the woven fabric layer.

15. (Original) The prosthetic heart valve of claim 1, wherein the mesh layer has a first height extending axially along the frame and the pile layer comprises a second height extending axially along the frame, wherein the first height is greater than the second height.

16. (Original) The prosthetic heart valve of claim 15, wherein the mesh layer extends closer to the outflow end of the frame than the pile layer.

17. (Canceled)

18. (Canceled)

19. (Canceled)

20. (Canceled)

21. (Previously Presented) A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto; and

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a fabric having a variable thickness

wherein the fabric comprises a plurality of pile yarns and the height of the pile yarns varies along a height and/or a circumference of the outer skirt;

wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is less than a height of the yarns of the second group.

22. (Previously Presented) A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto; and

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a fabric having a variable thickness

wherein the fabric comprises a plurality of pile yarns and the height of the pile yarns varies along a height and/or a circumference of the outer skirt;

wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is greater than a height of the yarns of the second group.

23. (Previously Presented) A prosthetic heart valve, comprising:

an annular frame comprising an inflow end and an outflow end and being radially compressible and expandable between a radially compressed configuration and a radially expanded configuration;

a leaflet structure positioned within the frame and secured thereto; and

an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient, the sealing member comprising a fabric having a variable thickness

wherein the fabric comprises a plurality of pile yarns and the height of the pile yarns varies along a height and/or a circumference of the outer skirt;

wherein the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt, a second group of yarns along a downstream portion of the outer skirt, and a third group of yarns between the first and second group of yarns, wherein the yarns of the first and second groups have a height that is greater than a height of the yarns of the third group.

24. (Previously Presented) The prosthetic heart valve of claim 1, wherein the pile yarns are arranged to form a looped pile comprising a plurality of rows of loops extending outwardly from the mesh layer, wherein the lower edge portion of the inner skirt extends over one or more rows of loops along the lower edge portion of the outer sealing member.

25. (Previously Presented) The prosthetic heart valve of claim 24, wherein the lower edge portion of the inner skirt is stitched to the lower edge portion of the outer sealing member so as to compress the one or more rows of loops covered by the lower edge portion of the inner skirt.

26. (Previously Presented) The prosthetic heart valve of claim 1, wherein the frame comprises a plurality of circumferentially extending rows of struts including a first row of struts defining the inflow end of the frame, a second row of struts downstream of the first row of struts, a third row of struts downstream of the second row of struts, a fourth row of struts downstream of the third row of struts, and a fifth row of struts downstream of the fourth row of struts and defining the outflow end of the frame, wherein a first row of frame openings is defined between

the first and second row of struts, a second row of frame openings is defined between the second and third row of struts, a third row of frame openings is defined between third and fourth row of struts, a fourth row of frame openings is defined between the fourth and fifth row of struts, wherein the upper edge of the inner skirt is sutured to each strut of the fourth row of struts and the inner skirt covers the first, second, and third rows of frame openings, and wherein an upper edge portion of the outer sealing member is sutured to each strut of the third row of struts and the outer sealing member covers the first and second rows of frame openings.

27. (Previously Presented) The prosthetic valve of claim 26, wherein the outer sealing member is sized that when the frame is in the radially expanded configuration, the outer sealing member conforms to the outer surface of the frame without any slack in the outer sealing member and when the frame is the radially compressed configuration, the outer sealing member is stretched axially between the first row of struts and the third row of struts.

FIG. 1

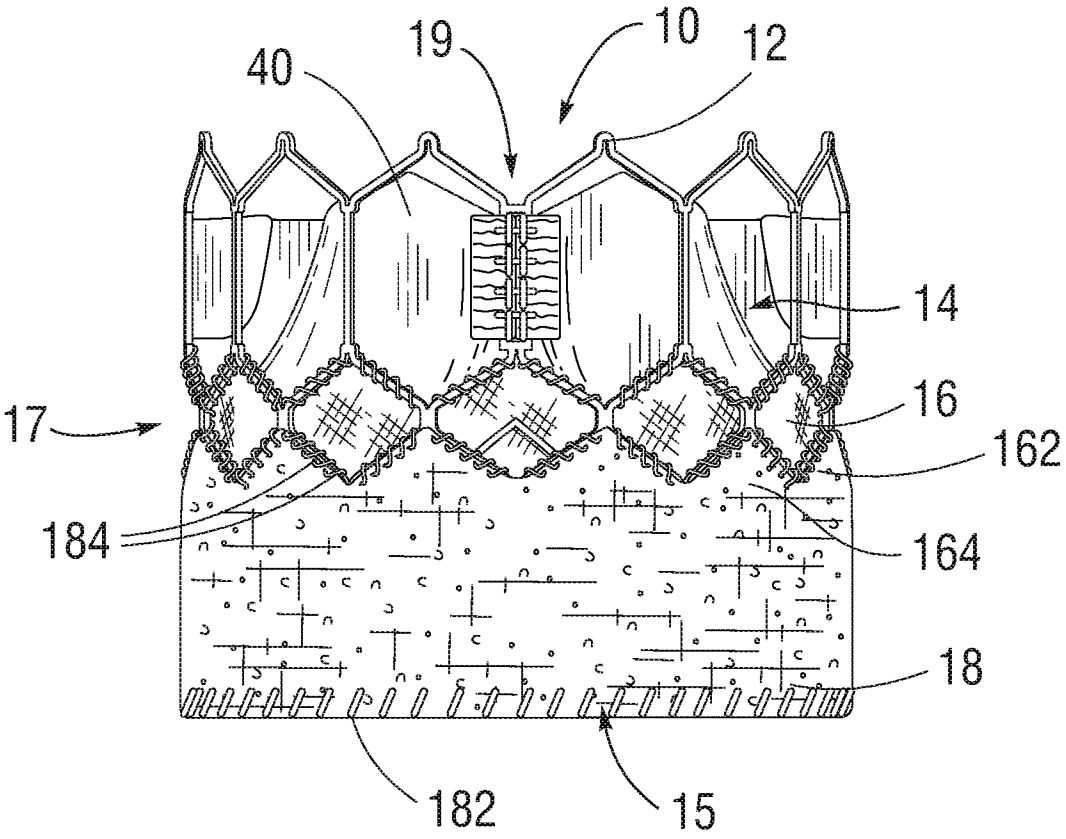


FIG. 2

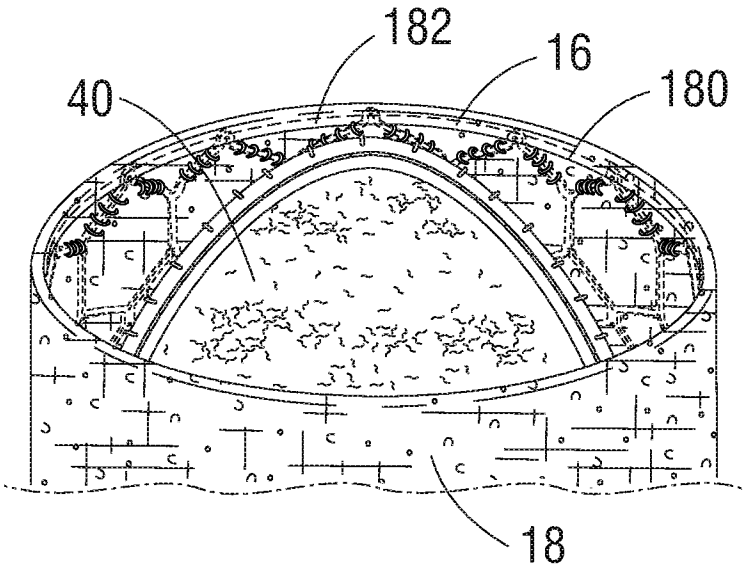


FIG. 3

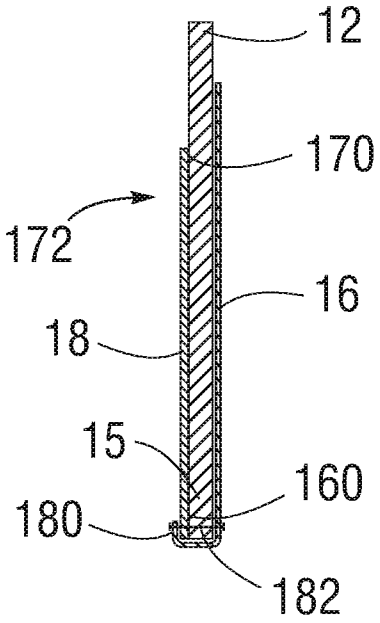


FIG. 4

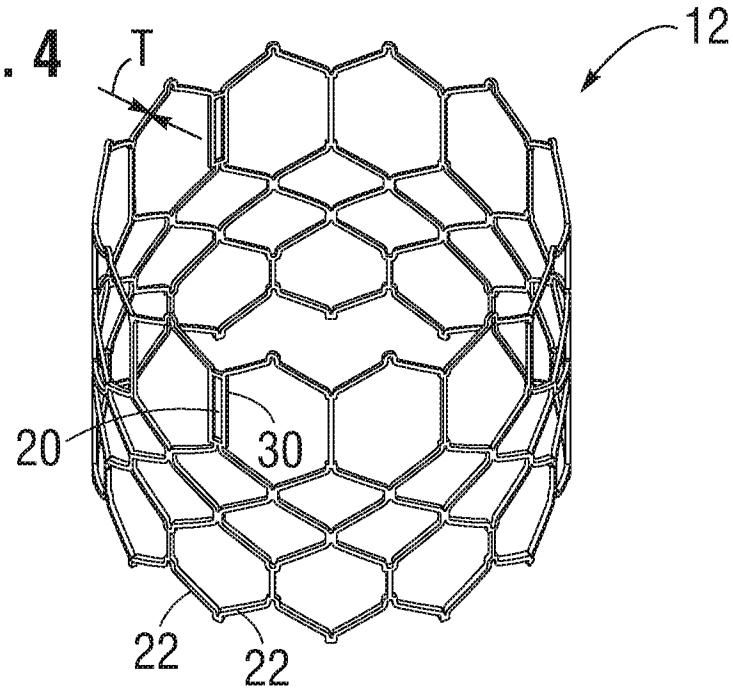


FIG. 6

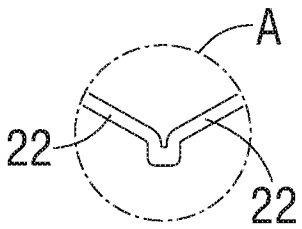


FIG. 7

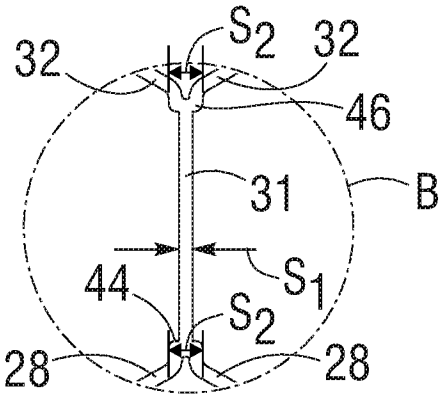


FIG. 8

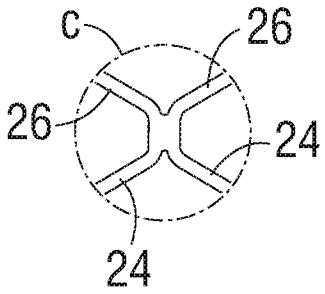
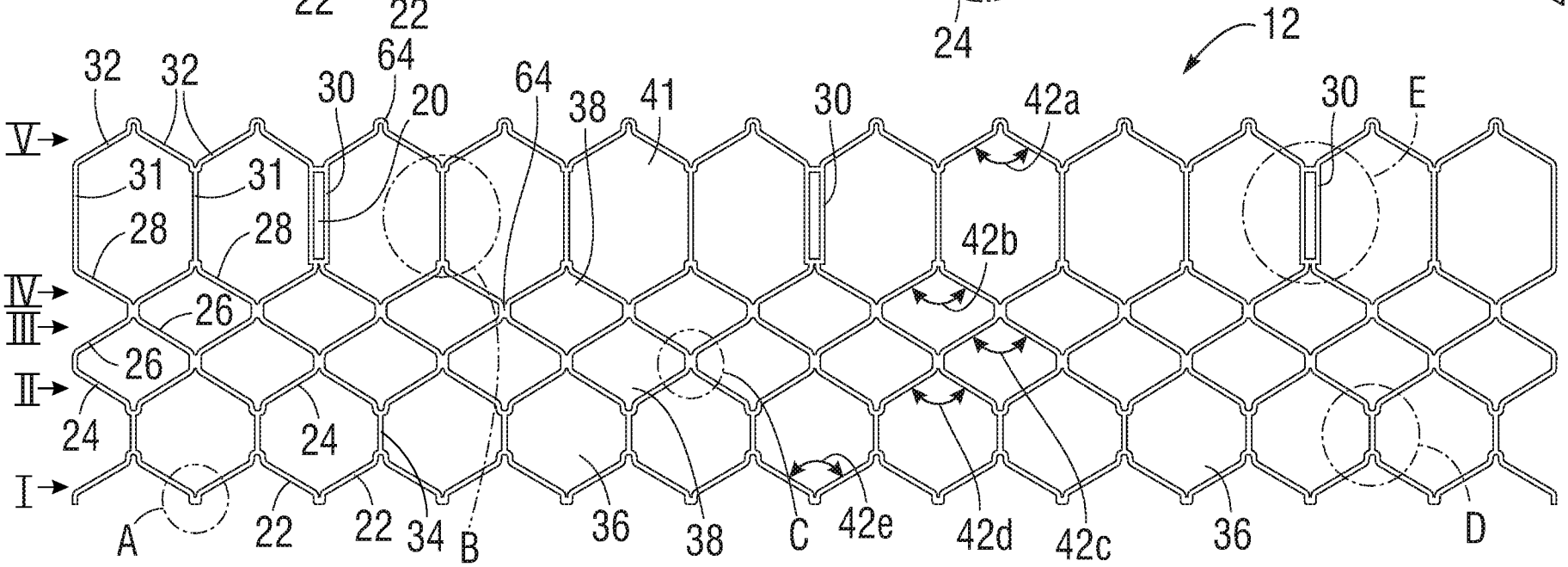


FIG. 5



Docket No.: 9034

FIG. 9

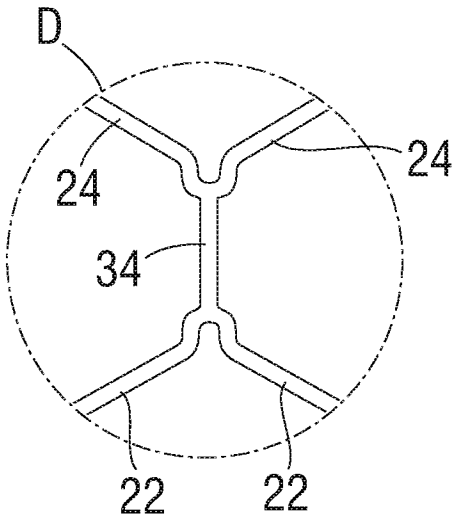


FIG. 10

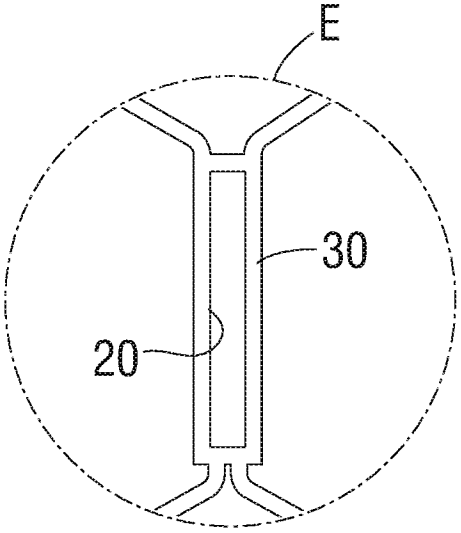


FIG. 11

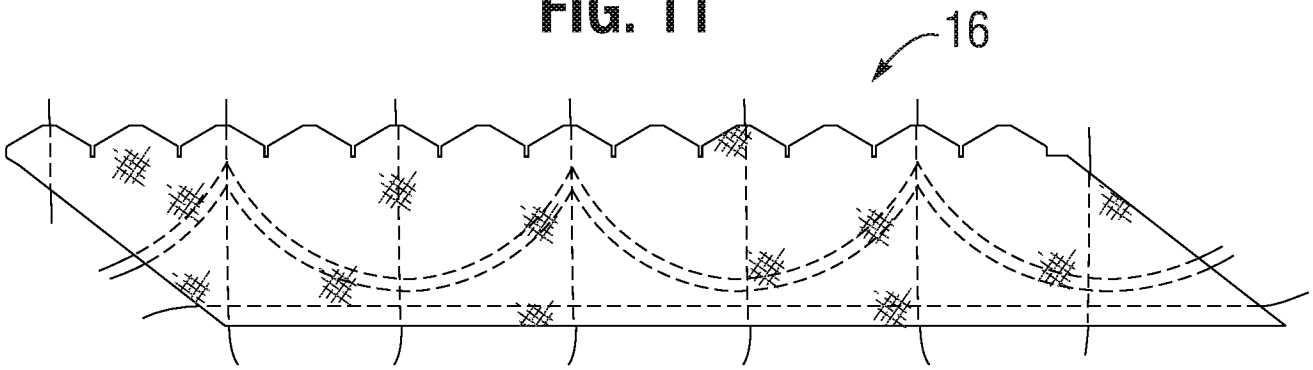


FIG. 12

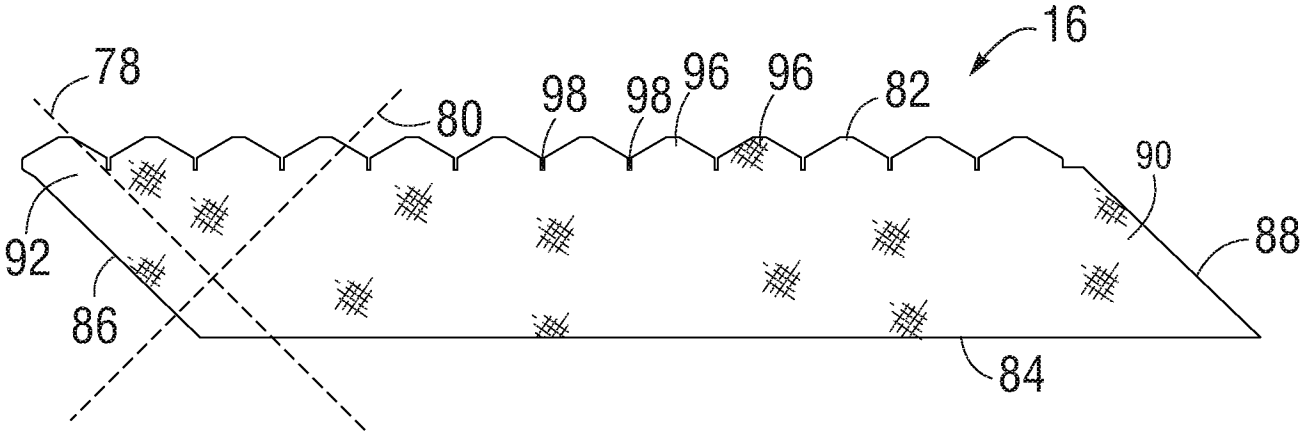


FIG. 13

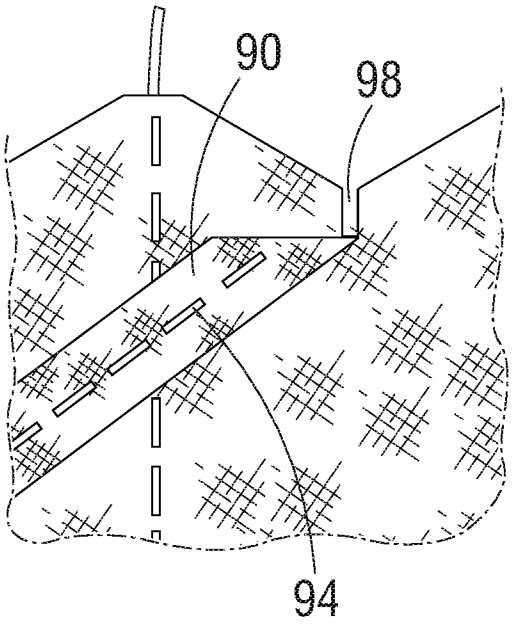


FIG. 14

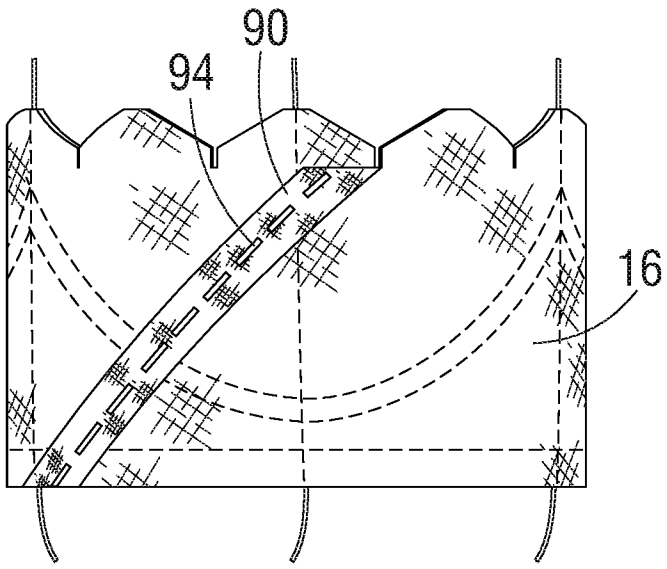


FIG. 15

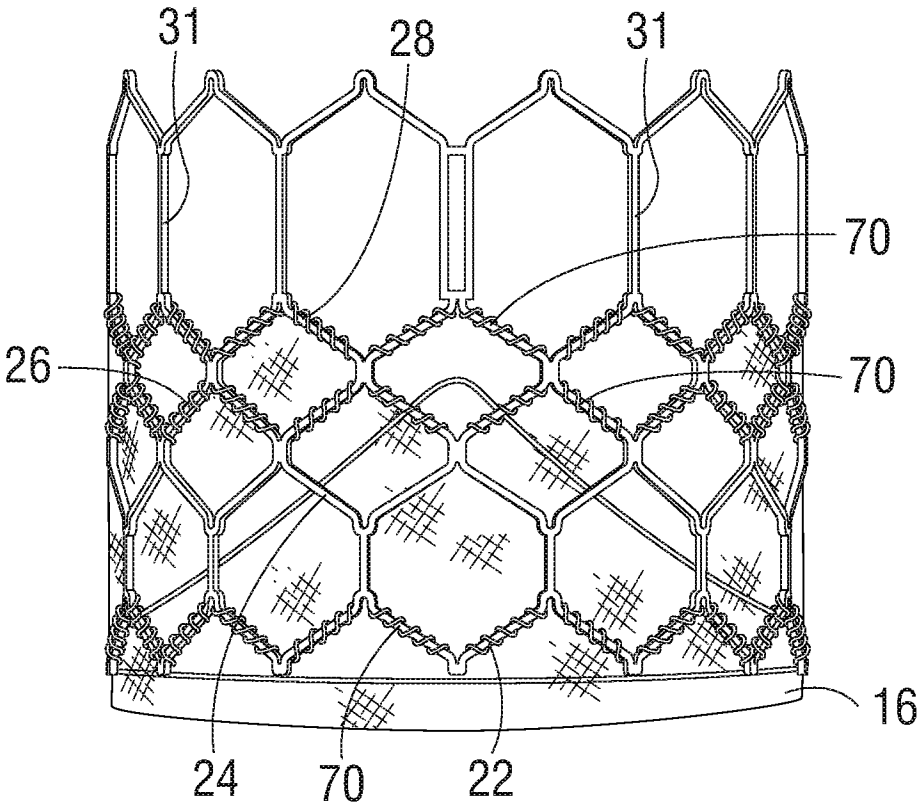


FIG. 16

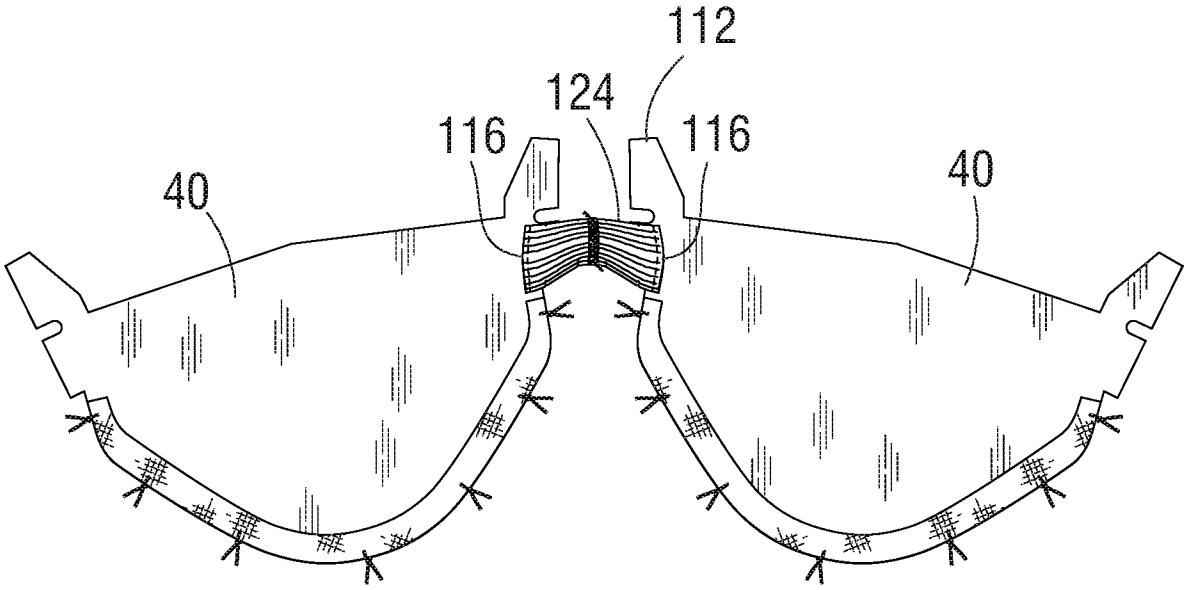


FIG. 17

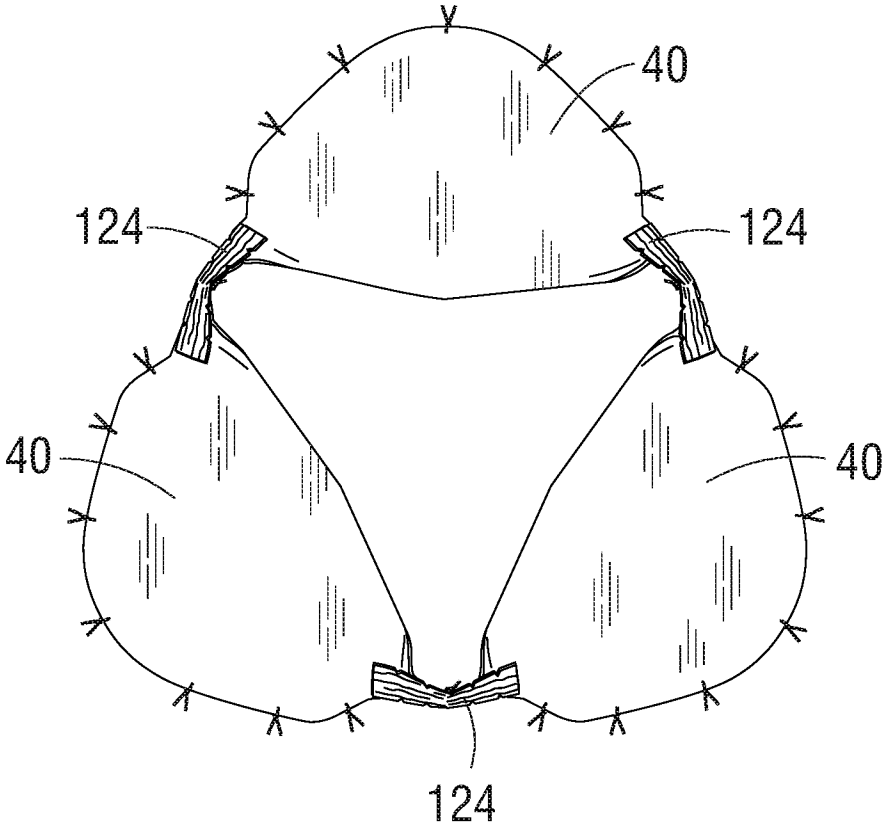


FIG. 18

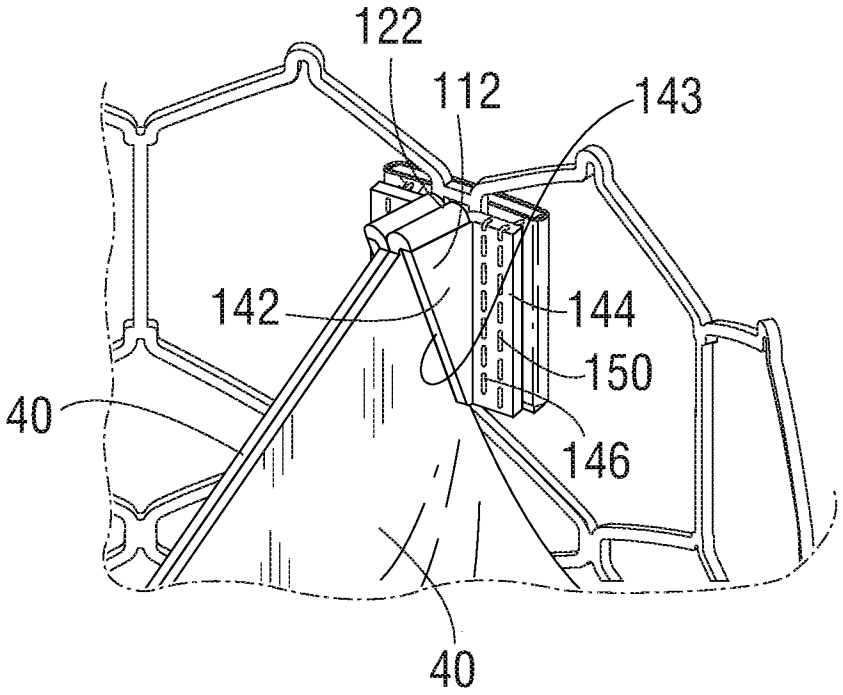


FIG. 19

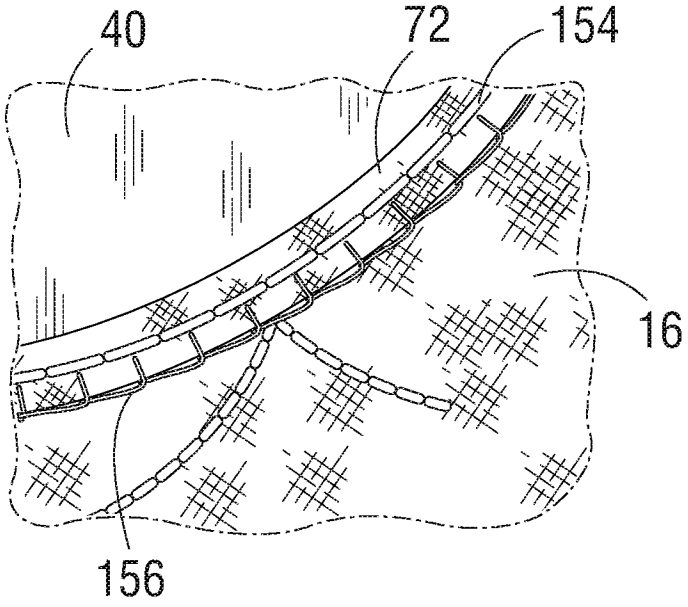


FIG. 20

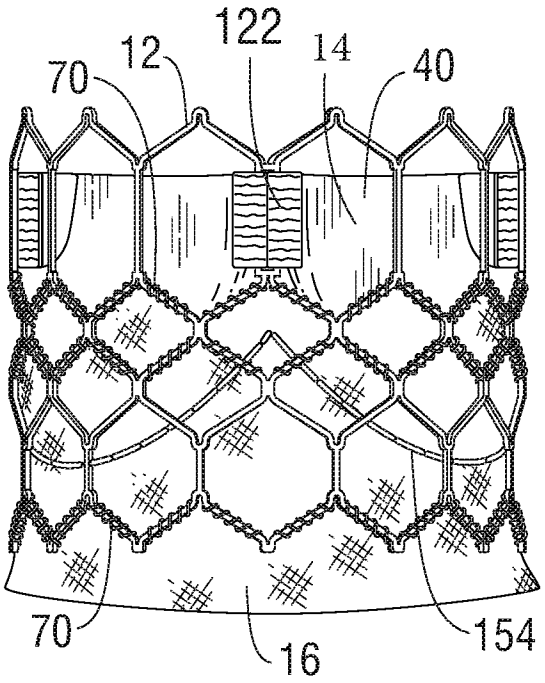


FIG. 21

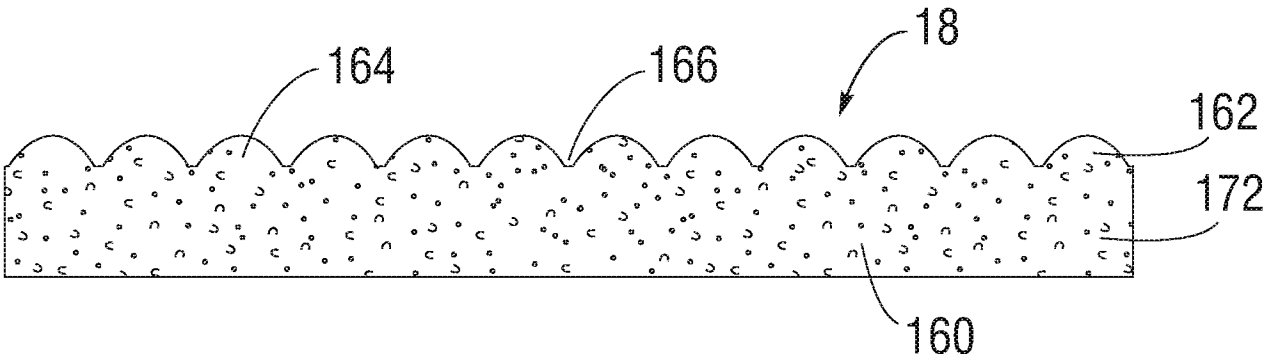


FIG. 22

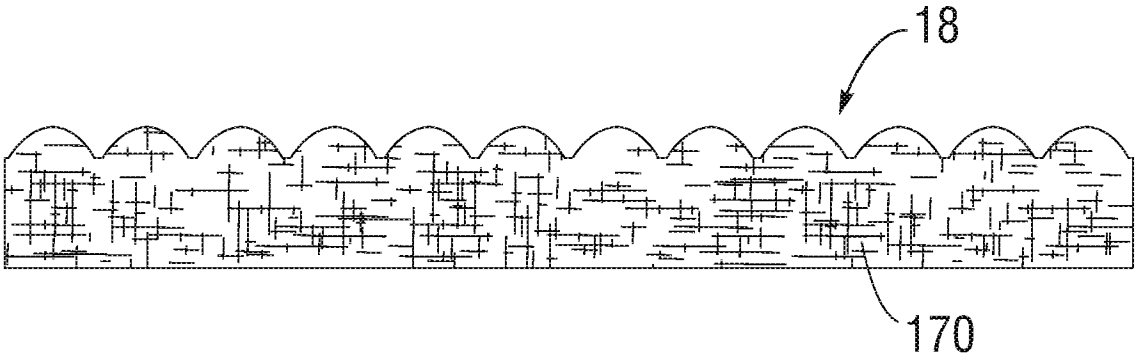


FIG. 23

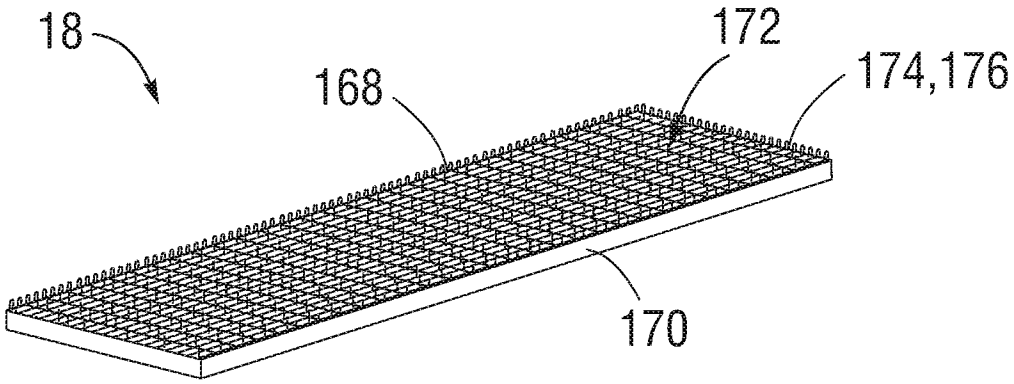


FIG. 24

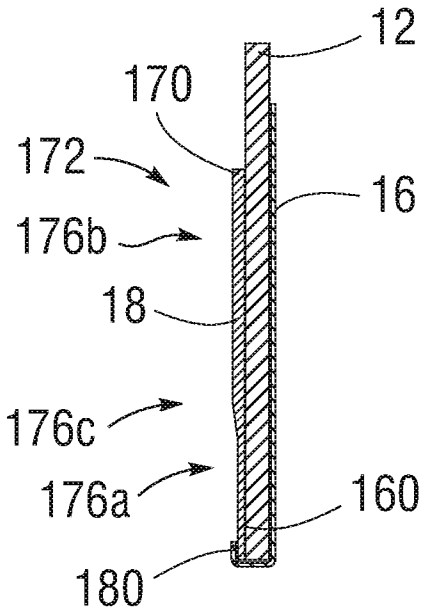


FIG. 25

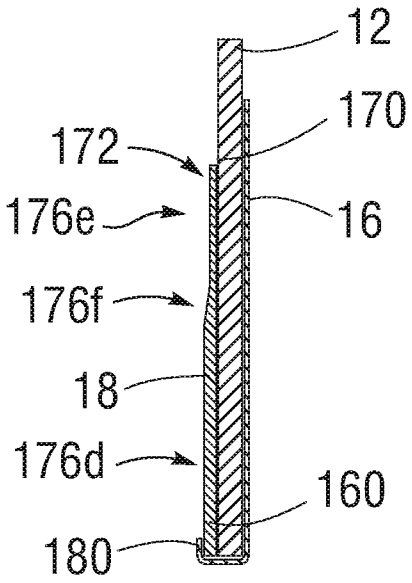


FIG. 26

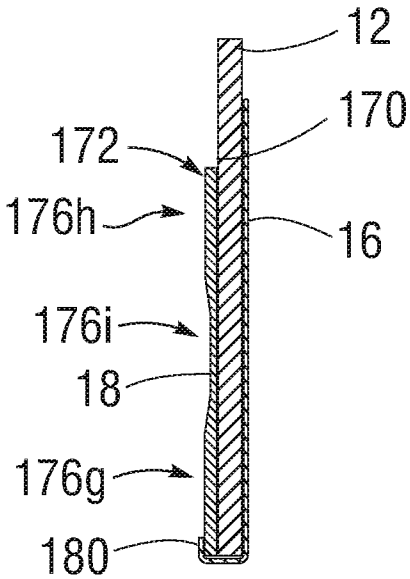


FIG. 27

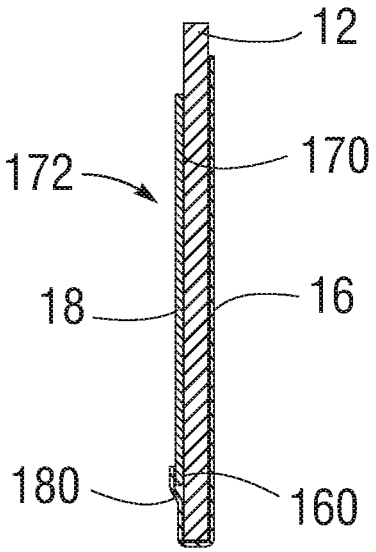


FIG. 28

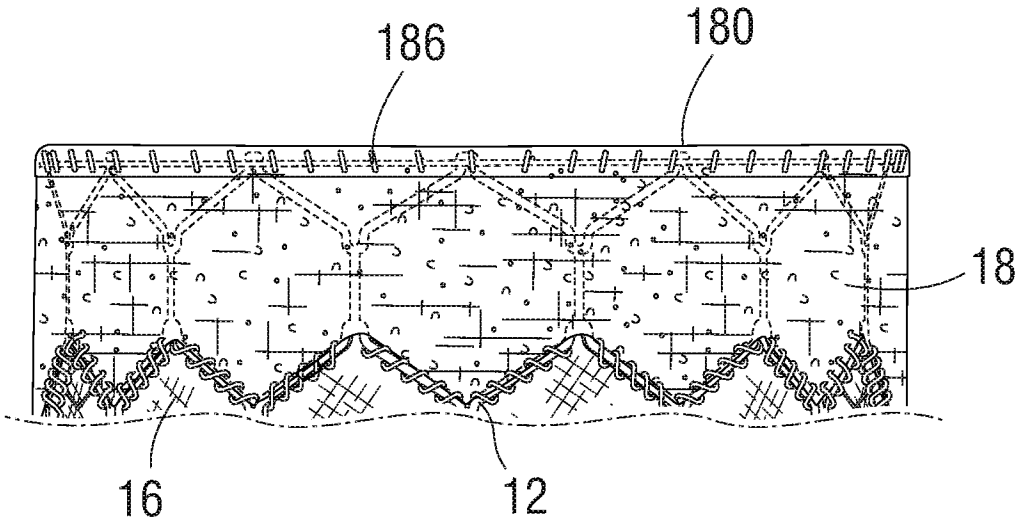


FIG. 29

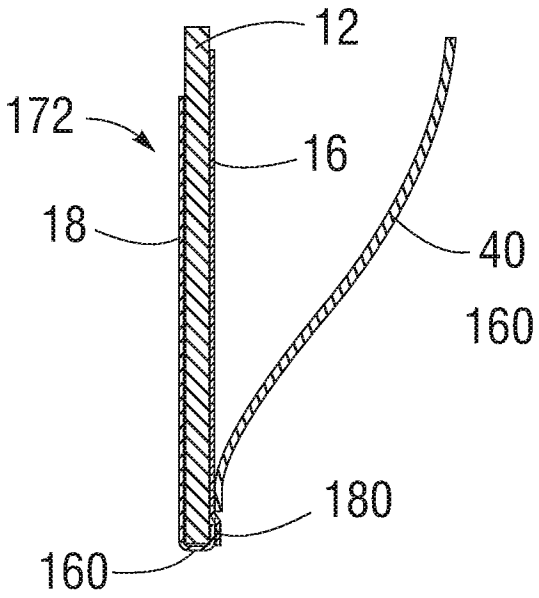


FIG. 30

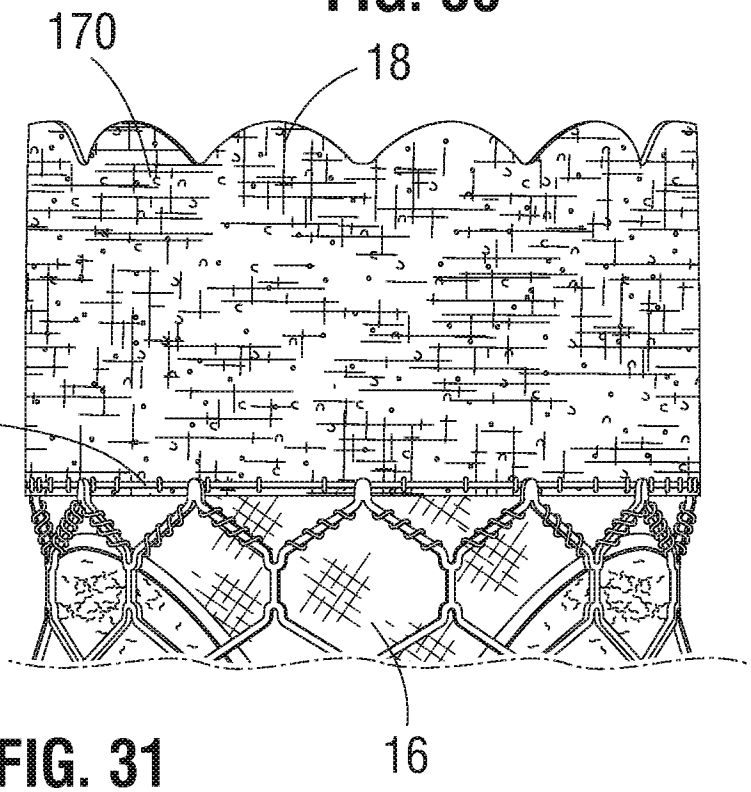


FIG. 31

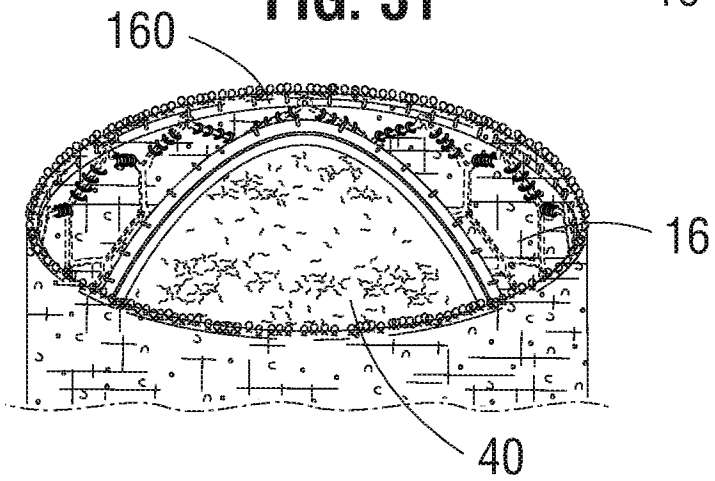


FIG. 32

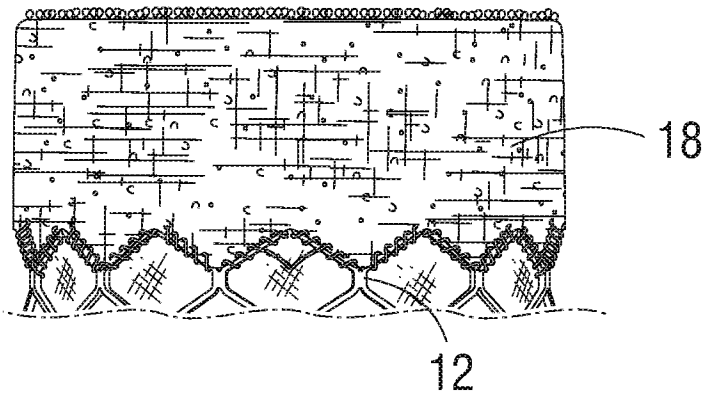


FIG. 33

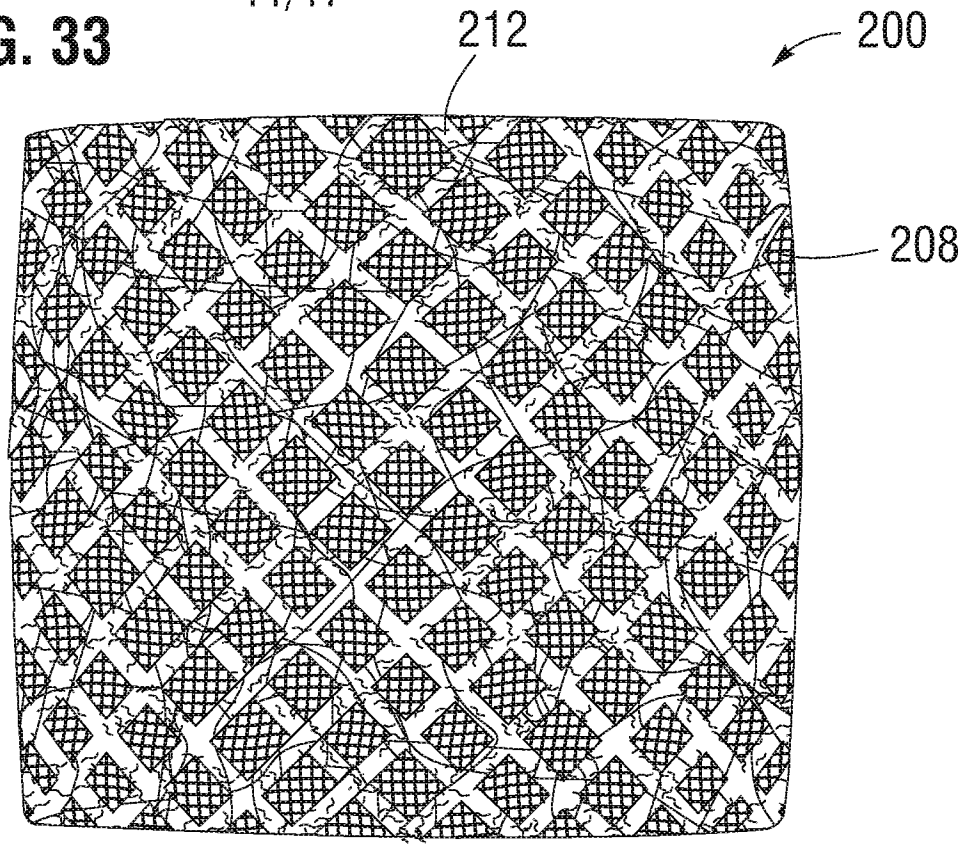


FIG. 34

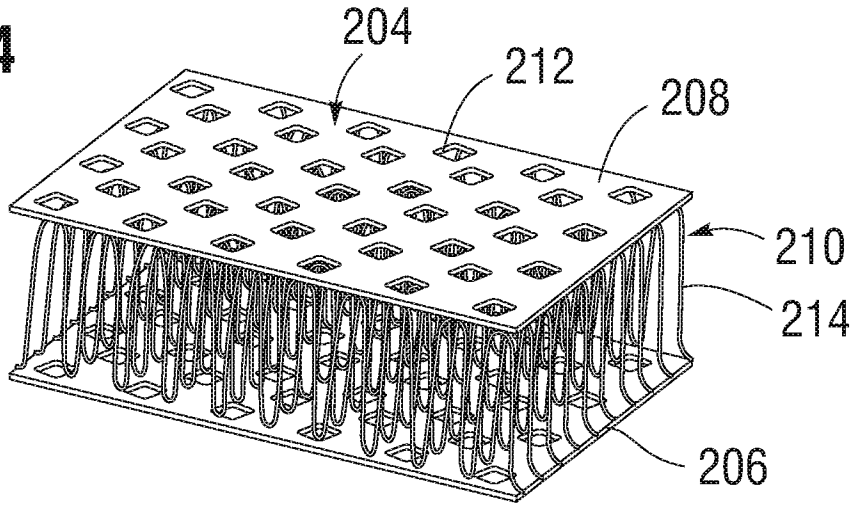


FIG. 35

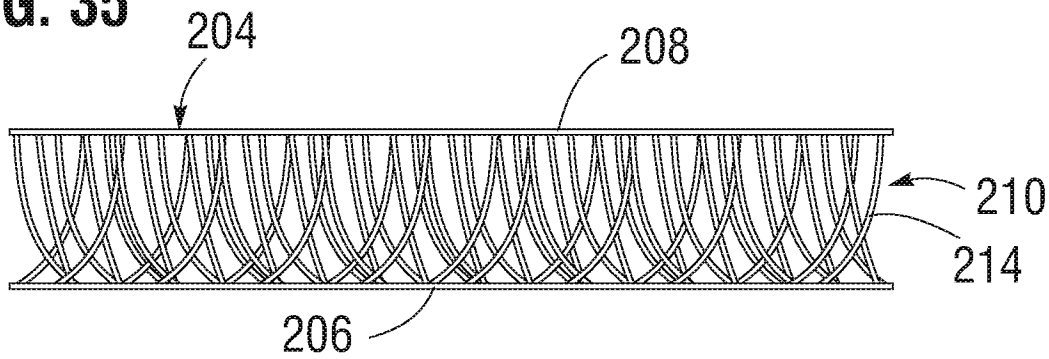


FIG. 36

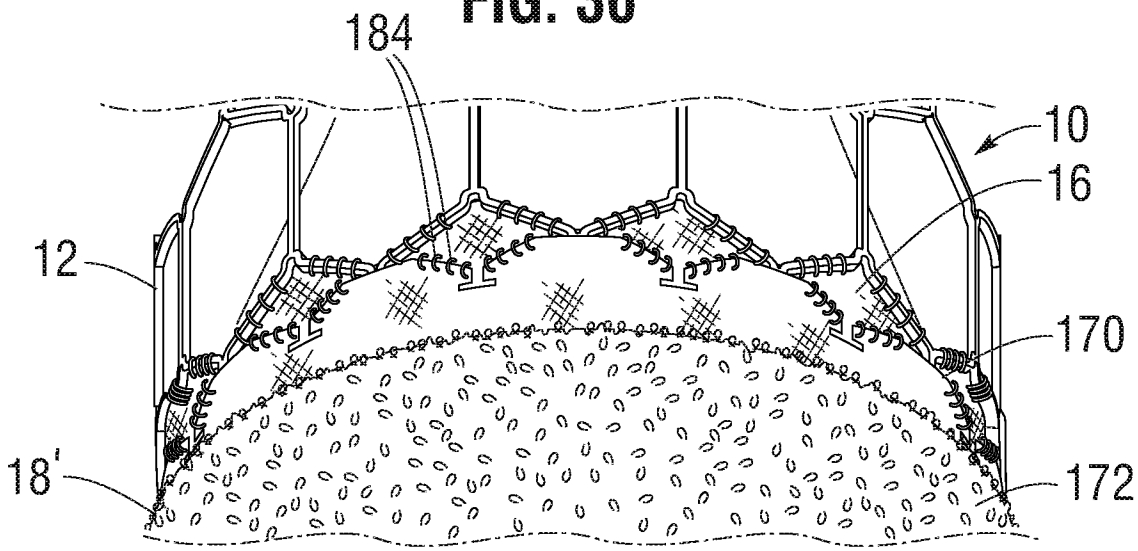


FIG. 37

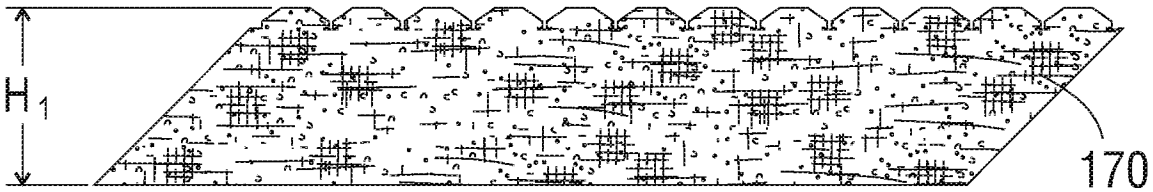


FIG. 38

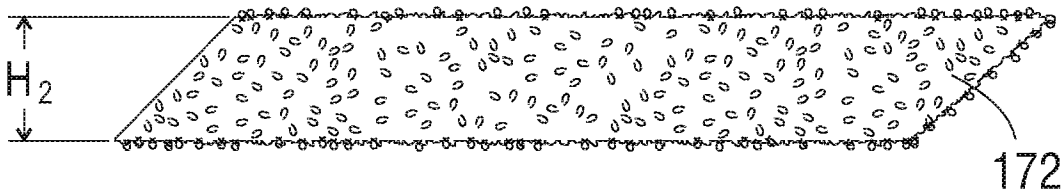


FIG. 39

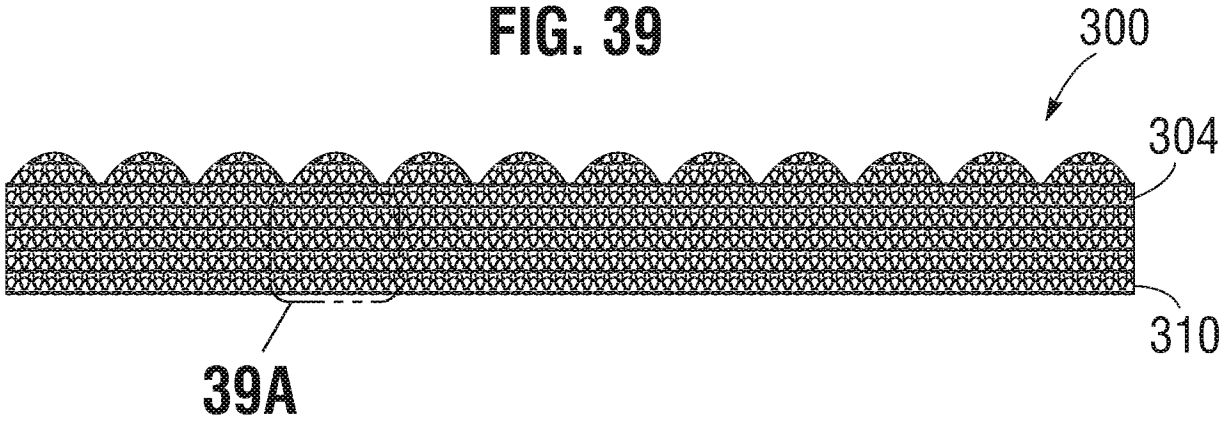


FIG. 40

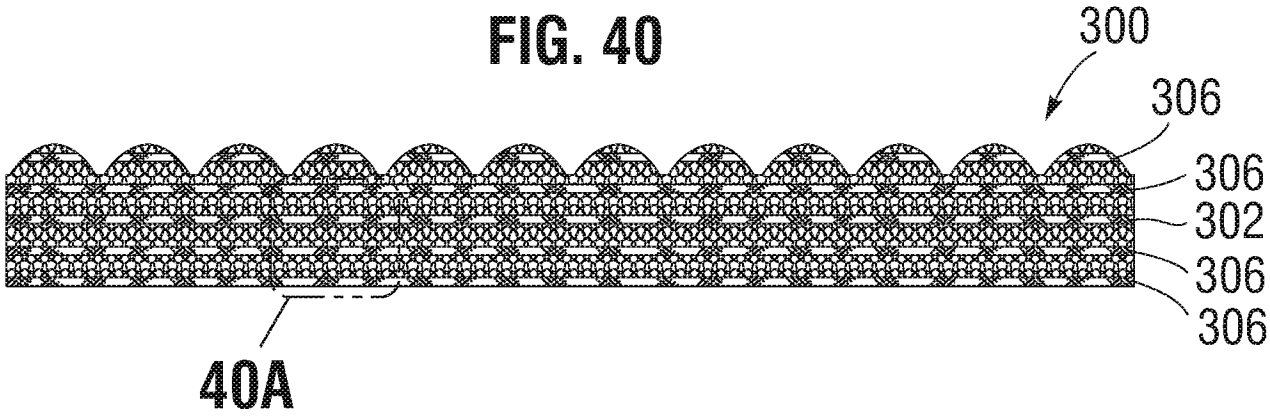


FIG. 39A

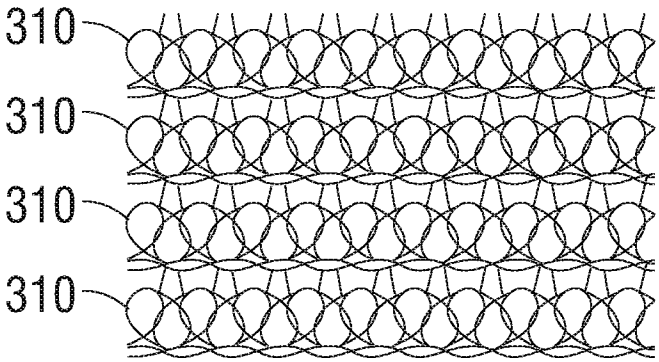


FIG. 40A

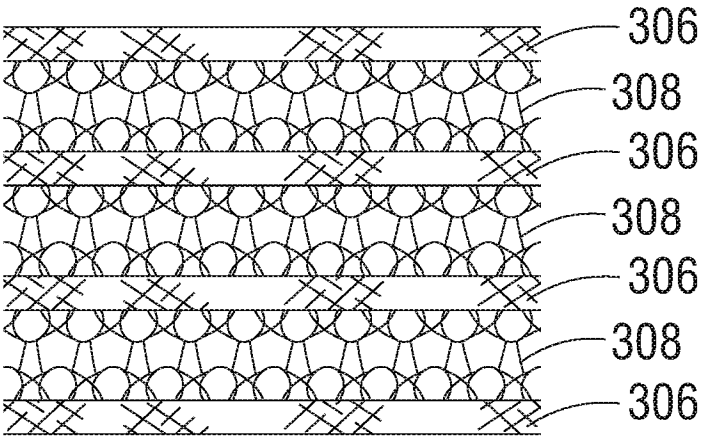


FIG. 41

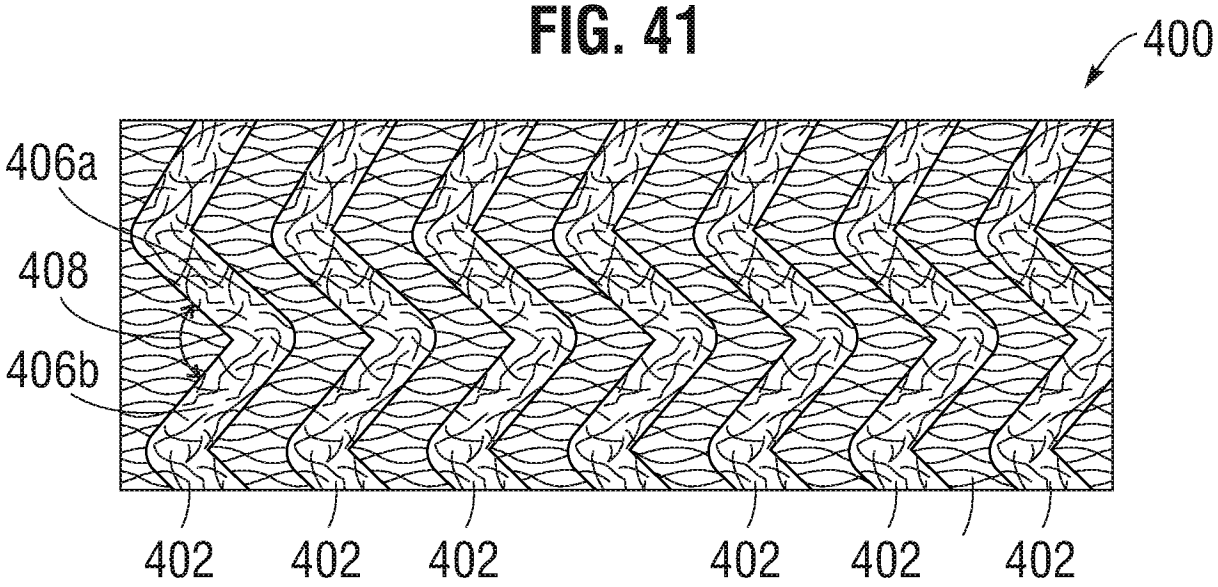

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FIG. 42

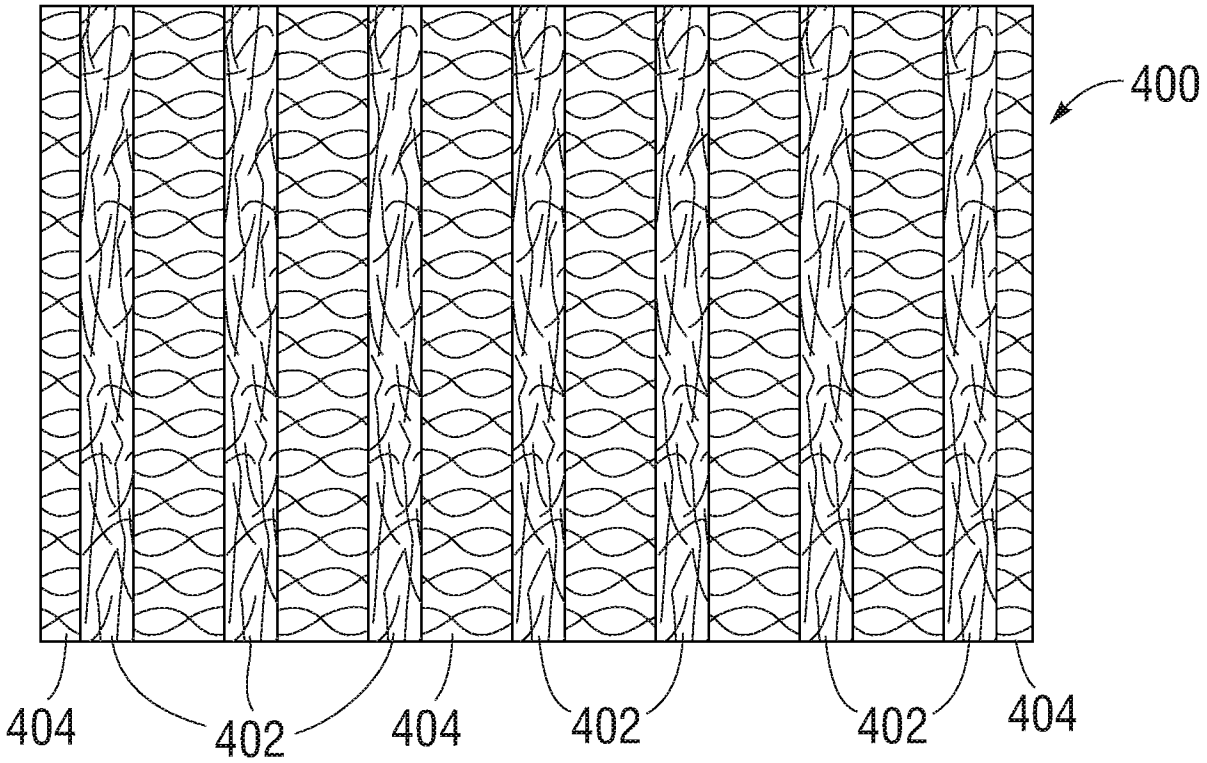

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FIG. 43A

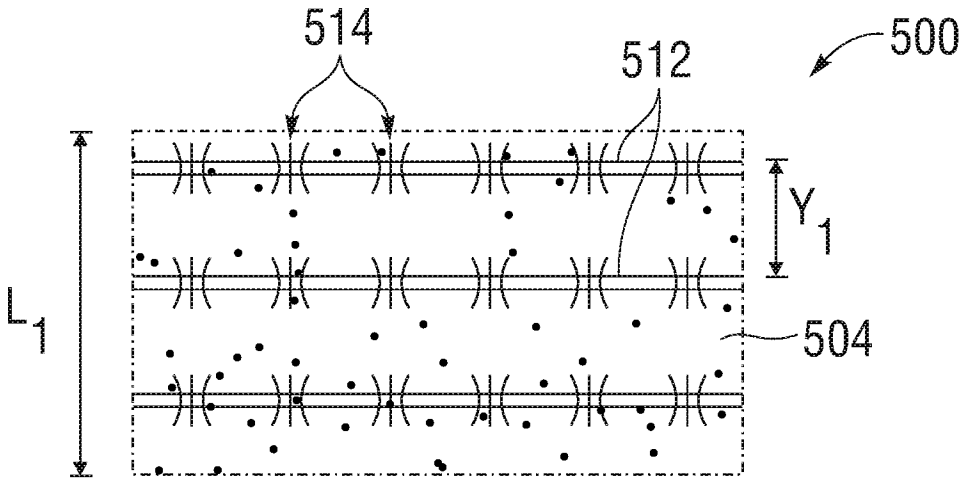


FIG. 43B

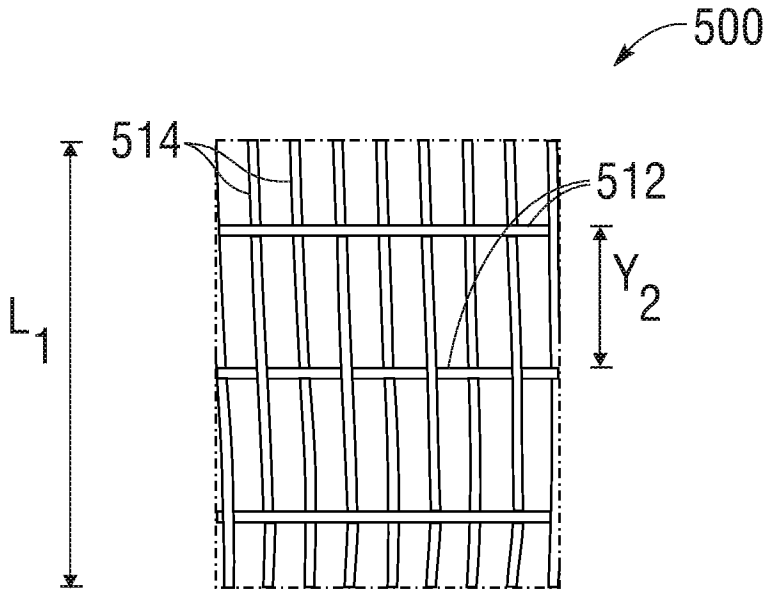


FIG. 44A

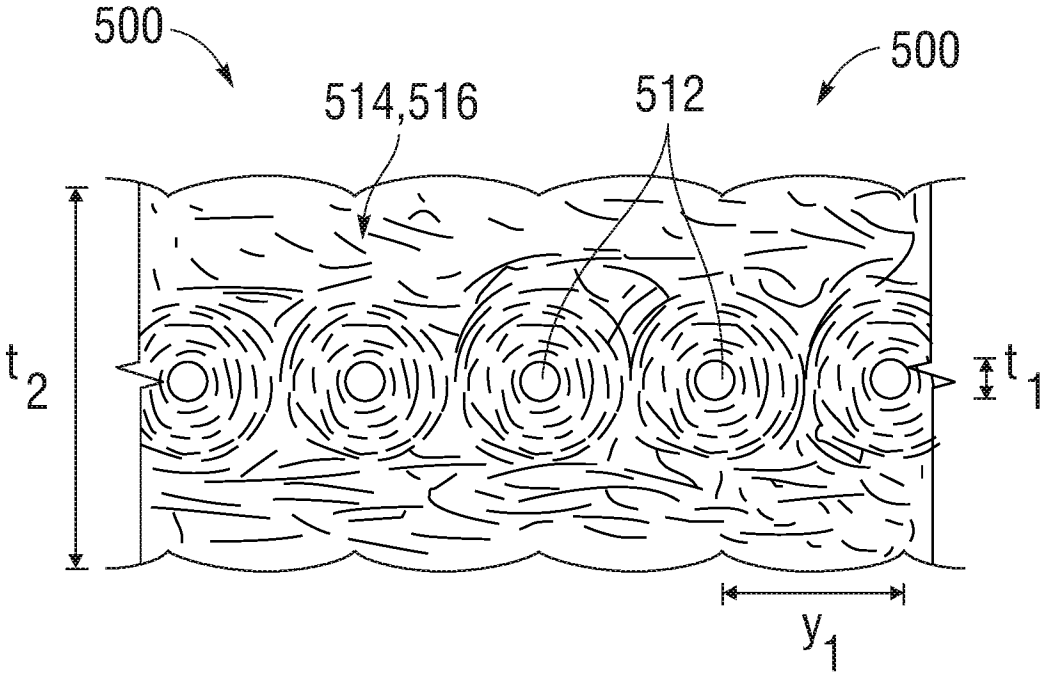
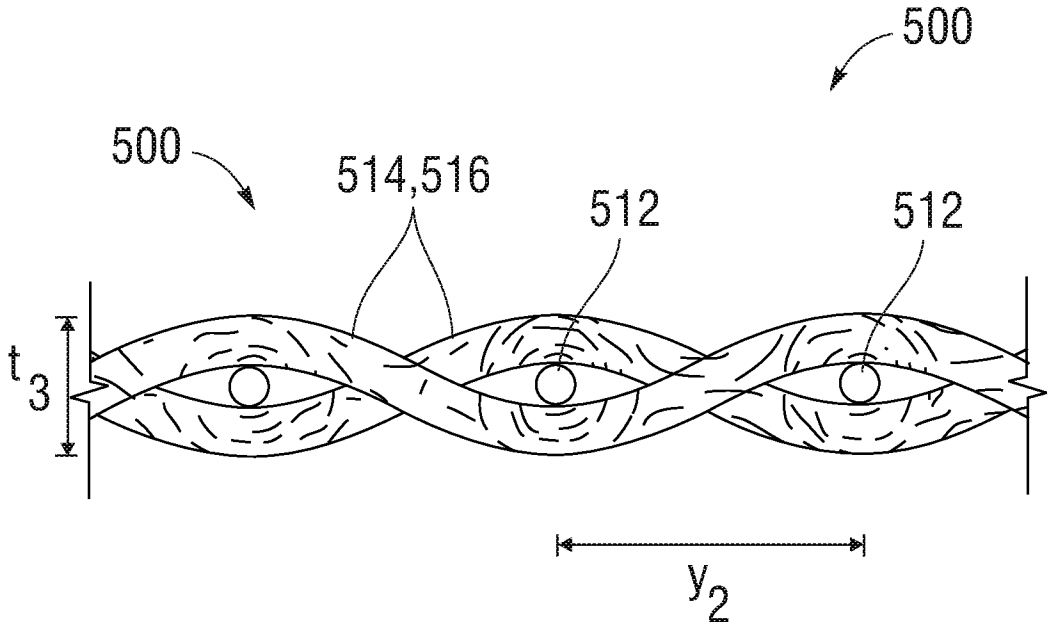


FIG. 44B



SEALING MEMBER FOR PROSTHETIC HEART VALVE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation-in-part of U.S. Patent Application No. 15/991,325 filed on May 29, 2018, which claims the benefit of U.S. Patent Application No. 62/513,348, filed on May 31, 2017. The entire contents of the foregoing applications are incorporated herein by reference.

FIELD

[0002] The present disclosure relates to implantable, expandable prosthetic devices and to methods and apparatuses for such prosthetic devices.

BACKGROUND

[0003] The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require replacement of the native valve with an artificial valve. There are a number of known artificial valves and a number of known methods of implanting these artificial valves in humans. Because of the drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches are garnering intense attention. In one technique, a prosthetic valve is configured to be implanted in a much less invasive procedure by way of catheterization. For example, collapsible transcatheter prosthetic heart valves can be crimped to a compressed state and percutaneously introduced in the compressed state on a catheter and expanded to a functional size at the desired position by balloon inflation or by utilization of a self-expanding frame or stent.

[0004] A prosthetic valve for use in such a procedure can include a radially collapsible and expandable frame to which leaflets of the prosthetic valve can be coupled. For example, U.S. Patent Nos. 6,730,118, 7,393,360, 7,510,575, and 7,993,394, which are incorporated herein by reference, describe exemplary collapsible transcatheter heart valves (THVs).

[0005] A challenge in catheter-implanted prosthetic valves is the process of crimping such a prosthetic valve to a profile suitable for percutaneous delivery to a subject. Another challenge is

EXHIBIT 21

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-6563US05
	Application Number	
Title of Invention	PROSTHETIC HEART VALVE	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Alexander	J.	Siegel	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

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Inventor 2 Remove

Legal Name

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-6563US05
	Application Number	
Title of Invention	PROSTHETIC HEART VALVE	

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Application Information:

Title of the Invention	PROSTHETIC HEART VALVE		
Attorney Docket Number	THVVA-6563US05	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-6563US05
	Application Number	
Title of Invention	PROSTHETIC HEART VALVE	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
	Continuation of	16/827612	2020-03-23	

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/827612	Continuation of	16/150035	2018-10-02	10595993	2020-03-24

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16/150035	Division of	14/561102	2014-12-04	10098734	2018-10-16

Prior Application Status	Expired			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
14/561102	Claims benefit of provisional	61/912231	2013-12-05	

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This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-6563US05
	Application Number	
Title of Invention	PROSTHETIC HEART VALVE	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-6563US05
	Application Number	
Title of Invention	PROSTHETIC HEART VALVE	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-6563US05
	Application Number	
Title of Invention	PROSTHETIC HEART VALVE	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

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Organization Name	Edwards Lifesciences Corporation		
Mailing Address Information For Applicant:			
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Address 2			
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Country	US	Postal Code	92614
Phone Number		Fax Number	
Email Address			

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Assignee Information including Non-Applicant Assignee Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-6563US05
	Application Number	
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Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

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If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

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Country i		Postal Code	
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This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Hans P. Smith/			Date (YYYY-MM-DD)	2020-06-16
First Name	Hans	Last Name	Smith	Registration Number	67,259

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-6563US05
	Application Number	
Title of Invention	PROSTHETIC HEART VALVE	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PROSTHETIC HEART VALVE

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application is a continuation of U.S. Patent Application No. 16/827,612, filed March 23, 2020, which is a continuation of U.S. Patent Application No. 16/150,035, filed October 2, 2018, now granted as U.S. Patent No. 10,595,993, which is a division of U.S. Patent Application No. 14/561,102 filed December 4, 2014, now granted as U.S. Patent No. 10,098,734, which claims the benefit of U.S. Provisional Application No. 61/912,231, filed December 5, 2013. Each of the foregoing is incorporated herein by reference.

FIELD

[002] The present disclosure concerns embodiments of a prosthetic valve (*e.g.*, prosthetic heart valve) and a delivery apparatus for implanting a prosthetic valve, including introducer sheaths.

BACKGROUND

[003] Prosthetic cardiac valves have been used for many years to treat cardiac valvular disorders. The native heart valves (such as the aortic, pulmonary and mitral valves) serve critical functions in assuring the forward flow of an adequate supply of blood through the cardiovascular system. These heart valves can be rendered less effective by congenital, inflammatory, or infectious conditions. Such damage to the valves can result in serious cardiovascular compromise or death. For many years the definitive treatment for such disorders was the surgical repair or replacement of the valve during open-heart surgery, but such surgeries are prone to many complications. More recently, a transvascular technique has been developed for introducing and implanting a prosthetic heart valve using a flexible catheter in a manner that is less invasive than open heart surgery.

[004] In this technique, a prosthetic valve is mounted in a crimped state on the end portion of a flexible catheter and advanced through a blood vessel of the patient until the prosthetic valve reaches the implantation site. The prosthetic valve at the catheter tip is then expanded to its functional size at the site of the defective native valve, such as by inflating a balloon on which the prosthetic valve is mounted. Alternatively, the prosthetic valve can have a resilient, self-expanding stent or frame that expands the prosthetic valve to its functional size when it is advanced from a delivery sheath at the distal end of the catheter.

[005] The native valve annulus in which an expandable prosthetic valve is deployed typically has an irregular shape mainly due to calcification. As a result, small gaps may exist between the expanded frame of the prosthetic valve and the surrounding tissue. The gaps can allow for regurgitation (leaking) of blood flowing in a direction opposite the normal flow of blood through the valve. To minimize regurgitation, various sealing devices have been developed that seal the interface between the prosthetic valve and the surrounding tissue.

SUMMARY

[006] The present disclosure is directed to embodiments of catheter-based prosthetic heart valves, and in particular, prosthetic heart valves having sealing members configured to seal the interface between the prosthetic valve and the surrounding tissue of the native annulus in which the prosthetic valve is implanted. The present disclosure also discloses new methods of making an introducer sheath with an inner liner for percutaneous insertion of a medical device into a patient.

[007] In one representative embodiment, a prosthetic heart valve comprises a collapsible and expandable annular frame that is configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body. The frame has an inflow end, an outflow end, and a longitudinal axis extending from the inflow end to the outflow end, and comprises a plurality of struts defining a plurality of rows of a plurality of cells. The prosthetic heart valve also comprises a collapsible and expandable valve member mounted within the annular frame, and a collapsible and expandable skirt assembly mounted within the annular frame. The skirt assembly comprises an upper skirt, a lower skirt, and a sealing skirt. The upper and lower skirts prevent the sealing skirt from contacting the valve member and can also couple the valve member to the annular frame. When the annular frame is expanded to its radially expanded state, portions of the sealing skirt protrude outwardly through cells of the frame.

[008] In particular embodiments, the sealing skirt is made of loop yarn. In further embodiments, the sealing skirt is mounted within the annular frame of the prosthetic heart valve by sutures that secure the sealing skirt and the lower skirt to the frame of the prosthetic heart valve. In additional embodiments, from the longitudinal axis of the prosthetic heart valve, the valve member is positioned radially outward from the lower skirt, the upper skirt is

positioned radially outward from the valve member; and the sealing skirt is positioned radially outward from the upper skirt. In more embodiments, an outflow portion of the lower skirt is sutured to an inflow portion of the valve member; and the inflow portion of the valve member is sutured to an inflow portion of the upper skirt.

[009] In another representative embodiment, a method of making an introducer sheath with an inner liner for percutaneous insertion of a medical device into a patient is provided. The method comprises inserting a metal sleeve into a mold, inserting a polymer tube comprising a closed end and an open end into the metal sleeve, and pressurizing and heating the polymer tube to cause the polymer tube to expand against an inner surface of the metal sleeve so as to form the inner liner of the sheath.

[010] In particular embodiments of the method, the preform cylindrical polymer tube is made of nylon-12, polyethylene, or fluorinated ethylene propylene (FEP). In further embodiments, the inner liner formed from the polymer tube has a radial wall thickness of from about 0.025 mm (about 0.001 inch) to about 0.075 mm (about 0.003 inch). In still more embodiments, the metal sleeve has a radial wall thickness of from about 0.05 mm (about 0.002 inch) to about 0.15 mm (about 0.006 inch). Pressurizing and heating the polymer tube can comprise injecting heated compressed gas into the polymer tube. Alternatively, pressurizing the polymer tube can comprise injecting compressed gas into the polymer tube and heating the polymer tube can comprise heating with a heat source separate from the pressurized gas. In several embodiments, the introducer sheath is configured for percutaneous insertion of a prosthetic heart valve through the femoral artery of the patient.

[011] In several embodiments, the method can include forming an introducer sheath with an inner liner and an outer liner for percutaneous insertion of the medical device into the patient. In some embodiments of the method, a preform cylindrical polymer tube is used to form the outer liner. In particular embodiments, the preform cylindrical polymer tube used to form the outer liner can be made of nylon-12, polyether block amides, or polyethylene. In further embodiments, the outer liner has a radial wall thickness of from about 0.012 mm (about 0.0005 inch) to about 0.075 mm (about 0.003 inch).

[012] The foregoing and other objects, features, and advantages of the invention will become more apparent from the following detailed description, which proceeds with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[013] FIG. 1 is a perspective view of a prosthetic valve that can be used to replace the native aortic valve of the heart, according to one embodiment.

[014] FIG. 2 is a perspective view of a portion of the prosthetic valve of FIG. 1 illustrating the connection of two leaflets to the support frame of the prosthetic valve.

[015] FIG. 3 is side elevation view of the support frame of the prosthetic valve of FIG. 1.

[016] FIG. 4 is a perspective view of the support frame of the prosthetic valve of FIG. 1.

[017] FIG. 5A is a cross-sectional view of the heart showing the prosthetic valve of FIG. 1 implanted within the aortic annulus.

[018] FIG. 5B is an enlarged view of FIG. 5A illustrating the prosthetic valve implanted within the aortic annulus, shown with the leaflet structure of the prosthetic valve removed for clarity.

[019] FIG. 6 is a perspective view of the leaflet structure of the prosthetic valve of FIG. 1 shown prior to being secured to the support frame.

[020] FIG. 7 is a cross-sectional view of the prosthetic valve of FIG. 1.

[021] FIG. 8 is a cross-sectional view of an embodiment of a delivery apparatus that can be used to deliver and implant a prosthetic valve, such as the prosthetic valve shown in FIG. 1.

[022] FIGS. 8A–8C are enlarged cross-sectional views of sections of FIG. 8.

[023] FIG. 9 is an exploded view of the delivery apparatus of FIG. 8.

[024] FIG. 10 is a side view of the guide catheter of the delivery apparatus of FIG. 8.

[025] FIG. 11 is a perspective, exploded view of the proximal end portion of the guide catheter of FIG. 10.

[026] FIG. 12 is a perspective, exploded view of the distal end portion of the guide catheter of FIG. 10.

[027] FIG. 13 is a side view of the torque shaft catheter of the delivery apparatus of FIG. 8.

[028] FIG. 14 is an enlarged side view of the rotatable screw of the torque shaft catheter of FIG. 13.

[029] FIG. 15 is an enlarged perspective view of a coupling member disposed at the end of the torque shaft.

[030] FIG. 16 is an enlarged perspective view of the threaded nut used in the torque shaft catheter of FIG. 13.

[031] FIG. 17 is an enlarged side view of the distal end portion of the nose cone catheter of the delivery apparatus of FIG. 8.

[032] FIG. 17A is an enlarged, cross-sectional view of the nose cone of the catheter shown FIG. 17.

[033] FIG. 17B is an enlarged cross-sectional view of the distal end portion of the delivery apparatus of FIG. 8 showing the stent of a prosthetic valve retained in a compressed state within a delivery sheath.

[034] FIG. 18 is an enlarged side view of the distal end portion of the delivery apparatus of FIG. 8 showing the delivery sheath in a delivery position covering a prosthetic valve in a compressed state for delivery into a patient.

[035] FIG. 19 is an enlarged cross-sectional view of a section of the distal end portion of the delivery apparatus of FIG. 8 showing the valve-retaining mechanism securing the stent of a prosthetic valve to the delivery apparatus.

[036] FIG. 20 is an enlarged cross-sectional view similar to FIG. 19, showing the inner fork of the valve-retaining mechanism in a release position for releasing the prosthetic valve from the delivery apparatus.

[037] FIGS. 21 and 22 are enlarged side views of distal end portion of the delivery apparatus of FIG. 8, illustrating the operation of the torque shaft for deploying a prosthetic valve from a delivery sheath.

[038] FIGS. 23–26 are various views of an embodiment of a motorized delivery apparatus that can be used to operate the torque shaft of the delivery apparatus shown in FIG. 8.

[039] FIG. 27 is a perspective view of an alternative motor that can be used to operate the torque shaft of the delivery apparatus shown in FIG. 8.

[040] FIG. 28A is an enlarged view of a distal segment of the guide catheter shaft of FIG. 10.

[041] FIG. 28B shows the cut pattern for forming the portion of the shaft shown in FIG. 28A, such as by laser cutting a metal tube.

[042] FIG. 29A is an enlarged view of a distal segment of a guide catheter shaft, according to another embodiment.

[043] FIG. 29B shows the cut pattern for forming the shaft of FIG. 29A, such as by laser cutting a metal tube.

[044] FIG. 30 is a perspective view of a prosthetic valve secured to the end of a delivery apparatus, according to one embodiment.

[045] FIG. 31 is a perspective view of a prosthetic valve that can be used to replace the native aortic valve of the heart, according to another embodiment.

[046] FIG. 32 is a perspective view of the leaflet structure, also showing the skirt including an upper and lower skirt, of the prosthetic valve of FIG. 31 shown prior to being secured to the support frame.

[047] FIG. 33 is a cross-sectional view of the prosthetic valve of FIG. 31 illustrating the configuration of the valve frame, the leaflets, the upper skirt, the lower skirt, and the sealing skirt, in one embodiment.

[048] FIG. 34 is a diagram of the sealing skirt before attachment to the valve frame, in one embodiment.

[049] FIG. 35 is a perspective view of a prosthetic valve including a sealing skirt that can be used to replace the native aortic valve of the heart, according to one embodiment.

[050] FIG. 36 is a perspective view of a portion of the prosthetic valve of FIG. 35 illustrating the sealing skirt and its connection to the support frame of the prosthetic valve, in one embodiment.

[051] FIG. 37 is a perspective view similar to FIG. 36 illustrating a modification of the sealing skirt.

[052] FIG. 38 is a perspective view similar to FIG. 36 illustrating a modification of the sealing skirt.

[053] FIG. 39 is a perspective view of a portion of the prosthetic valve of FIG. 35 illustrating another configuration of the sealing skirt.

[054] FIG. 40A is a perspective view of an introducer sheath, according to another embodiment.

[055] FIG. 40B is an enlarged, perspective view of the sleeve of the introducer sheath of FIG. 40A.

[056] FIG. 41 is an enlarged, perspective view of another embodiment of a sleeve that can be used with the introducer sheath of FIG. 40A.

[057] FIG. 42 is an end view of a sleeve that can be used with the introducer sheath of FIG. 40A.

[058] FIG. 43 is a perspective view of a segment of a sleeve of an introducer sheath, according to another embodiment.

[059] FIG. 44 is a side elevation view of a metal sleeve for an introducer sheath, according to another embodiment.

[060] FIG. 45 shows the cut pattern for forming the metal sleeve of FIG. 43.

[061] FIG. 46 shows the cut pattern for forming the metal sleeve of FIG. 44.

[062] FIG. 47 shows a cut pattern similar to FIG. 46 but having narrower apertures.

[063] FIGS. 48 and 49 are cross-sectional views illustrating a method of molding an inner liner for a metal sleeve of an introducer sheath.

DETAILED DESCRIPTION

[064] For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The described methods, systems, and apparatus should not be construed as limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The disclosed methods, systems, and apparatus are not limited to any specific aspect, feature, or combination thereof, nor do the disclosed methods, systems, and apparatus require that any one or more specific advantages be present or problems be solved.

[065] Although the operations of some of the disclosed methods are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached drawings may not show the various ways in which the disclosed methods, systems, and apparatus can be used in conjunction with other systems, methods, and apparatus.

[066] As used herein, the terms “a”, “an”, and “at least one” encompass one or more of the specified element. That is, if two of a particular element are present, one of these elements is also present and thus “an” element is present. The terms “a plurality of” and “plural” mean two or more of the specified element.

[067] As used herein, the term “and/or” used between the last two of a list of elements means any one or more of the listed elements. For example, the phrase “A, B, and/or C” means “A”, “B”, “C”, “A and B”, “A and C”, “B and C”, or “A, B, and C”.

[068] As used herein, the term “coupled” generally means physically coupled or linked and does not exclude the presence of intermediate elements between the coupled items absent specific contrary language.

[069] Referring first to FIG. 1, there is shown a prosthetic aortic heart valve 10, according to one embodiment. The prosthetic valve 10 includes an expandable frame member, or stent, 12 that supports an expandable valve member, which in the illustrated embodiment comprises a flexible leaflet section 14. The prosthetic valve 10 is radially compressible to a compressed state for delivery through the body to a deployment site and expandable to its functional size shown in FIG. 1 at the deployment site. In certain embodiments, the prosthetic valve 10 is self-expanding; that is, the prosthetic valve can radially expand to its functional size when advanced from the distal end of a delivery sheath. Apparatuses particularly suited for percutaneous delivery and implantation of a self-expanding prosthetic valve are described in detail below. In other embodiments, the prosthetic valve can be a balloon-expandable prosthetic valve that can be adapted to be mounted in a compressed state on the balloon of a delivery catheter. The prosthetic valve can be expanded to its functional size at a deployment site by inflating the balloon, as known in the art.

[070] The illustrated prosthetic valve 10 is adapted to be deployed in the native aortic annulus, although it also can be used to replace the other native valves of the heart (the mitral, tricuspid, and pulmonary valves). Moreover, the prosthetic valve 10 can be adapted to replace other valves within the body, such venous valves.

[071] FIGS. 3 and 4 show the stent 12 without the leaflet section 14 for purposes of illustration. As shown, the stent 12 can be formed from a plurality of longitudinally extending, generally sinusoidal-shaped frame members, or struts, 16. The struts 16 are formed with alternating bends and are welded or otherwise secured to each other at nodes 18 formed from the vertices of adjacent bends so as to form a mesh structure. The struts 16 can be made of a suitable shape memory material, such as the nickel titanium alloy known as Nitinol, that allows the prosthetic valve to be compressed to a reduced diameter for delivery in a delivery apparatus (such as described below) and then causes the prosthetic valve to expand to its functional size inside the patient's body when deployed from the delivery apparatus. If the prosthetic valve is a balloon-expandable prosthetic valve that is adapted to be crimped onto an inflatable balloon of a delivery apparatus and expanded to its functional size by inflation of the balloon, the stent 12 can be made of a suitable ductile material, such as stainless steel.

[072] The stent 12 has an inflow end 26 and an outflow end 27. The mesh structure formed by struts 16 comprises a generally cylindrical "upper" or outflow end portion 20, an outwardly bowed or distended intermediate section 22, and an inwardly bowed "lower" or inflow end portion 24. The intermediate section 22 desirably is sized and shaped to extend into the sinuses of Valsalva in the aortic root to assist in anchoring the prosthetic valve in place once implanted. As shown, the mesh structure desirably has a curved shape along its entire length that gradually increases in diameter from the outflow end portion 20 to the intermediate section 22, then gradually decreases in diameter from the intermediate section 22 to a location on the inflow end portion 24, and then gradually increases in diameter to form a flared portion terminating at the inflow end 26.

[073] When the prosthetic valve is in its expanded state, the intermediate section 22 has a diameter D_1, the inflow end portion lower section 24 has a minimum diameter D_2, the inflow end 26 has a diameter D_3, and the outflow end portion 20 has a diameter D_4, where D_2 is less than D_1 and D_3, and D_4 is less than D_2. In addition, D_1 and D_3 desirably are greater than the diameter of the native annulus in which the prosthetic valve is to be implanted. In this manner, the overall shape of the stent 12 assists in retaining the prosthetic valve at the implantation site. More specifically, and referring to FIGS. 5A and 5B, the prosthetic valve 10 can be implanted within a native valve (the aortic valve in the illustrated example) such that the lower section 24 is positioned within the aortic annulus 28, the intermediate section 22 extends above the aortic annulus into the sinuses of Valsalva 56, and the lower flared end 26 extends below the aortic annulus. The prosthetic valve 10 is retained within the native valve by the radial outward force of the lower section 24 against the surrounding tissue of the aortic annulus 28 as well as the geometry of the stent. Specifically, the intermediate section 22 and the flared lower end 26 extend radially outwardly beyond the aortic annulus 28 to better resist against axial dislodgement of the prosthetic valve in the downstream and upstream directions (toward and away from the aorta). Depending on the condition of the native leaflets 58, the prosthetic valve typically is deployed within the native annulus 28 with the native leaflets 58 folded upwardly and compressed between the outer surface of the stent 12 and the walls of the sinuses of Valsalva 56, as depicted in FIG. 5B. In some cases, it may be desirable to excise the leaflets 58 prior to implanting the prosthetic valve 10.

[074] Known prosthetic valves having a self-expanding frame typically have additional anchoring devices or frame portions that extend into and become fixed to non-diseased areas of the vasculature. Because the shape of the stent 12 assists in retaining the prosthetic valve, additional anchoring devices are not required and the overall length L of the stent can be minimized to prevent the stent upper portion 20 from extending into the non-diseased area of the aorta, or to at least minimize the extent to which the upper portion 20 extends into the non-diseased area of the aorta. Avoiding the non-diseased area of the patient's vasculature helps avoid complications if future intervention is required. For example, the prosthetic valve can be more easily removed from the patient because the stent is primarily anchored to the diseased part of the native valve. Furthermore, a shorter prosthetic valve is more easily navigated around the aortic arch.

[075] In particular embodiments, for a prosthetic valve intended for use in a 22-mm to 24-mm annulus, the diameter D1 is from about 28 mm to about 32 mm, with about 30 mm being a specific example; the diameter D2 is from about 24 mm to about 28 mm, with about 26 mm being a specific example; the diameter D3 is from about 28 mm to about 32 mm, with about 30 mm being a specific example; and the diameter D4 is from about 24 mm to about 28 mm, with about 26 mm being a specific example. The length L in particular embodiments is from about 20 mm to about 24 mm, with about 22 mm being a specific example.

[076] Referring to FIG. 1, the stent 12 can have a plurality of angularly spaced retaining arms, or projections, in the form of posts 30 (three in the illustrated embodiment) that extend from the stent upper portion 20. Each retaining arm 30 has a respective aperture 32 that is sized to receive prongs of a valve-retaining mechanism that can be used to form a releasable connection between the prosthetic valve and a delivery apparatus (described below). In alternative embodiments, the retaining arms 30 need not be provided if a valve-retaining mechanism is not used.

[077] As best shown in FIGS. 6 and 7, the leaflet assembly 14 in the illustrated embodiment comprises three leaflets 34a, 34b, 34c made of a flexible material. Each leaflet has an inflow end portion 60 and an outflow end portion 62. The leaflets can comprise any suitable biological material (*e.g.*, pericardial tissue, such as bovine or equine pericardium), bio-compatible synthetic materials, or other such materials, such as those described in U.S.

Patent No. 6,730,118, which is incorporated herein by reference. The leaflet assembly 14 can include an annular reinforcing skirt 42 that is secured to the inflow end portions of the leaflets 34a, 34b, 34c at a suture line 44 adjacent the inflow end of the prosthetic valve. The inflow end portion of the leaflet assembly 14 can be secured to the stent 12 by suturing the skirt 42 to struts 16 of the lower section 24 of the stent (best shown in FIG. 1). As shown in FIG. 7, the leaflet assembly 14 can further include an inner reinforcing strip 46 that is secured to the inner surfaces of the inflow end portions 60 of the leaflets.

[078] Referring to FIGS. 1 and 2, the outflow end portion of the leaflet assembly 14 can be secured to the upper portion of the stent 12 at three angularly spaced commissure attachments of the leaflets 34a, 34b, and 34c. As best shown in FIG. 2, each commissure attachment can be formed by wrapping a reinforcing section 36 around adjacent upper edge portions 38 of a pair of leaflets at the commissure formed by the two leaflets and securing the reinforcing section 36 to the edge portions 38 with sutures 48. The sandwiched layers of the reinforcing material and leaflets can then be secured to the struts 16 of the stent 12 with sutures 50 adjacent the outflow end of the stent. The leaflets therefore desirably extend the entire length or substantially the entire length of the stent from the inflow end 26 to the outflow end 27. The reinforcing sections 36 reinforces the attachment of the leaflets to the stent so as to minimize stress concentrations at the suture lines and avoid "needle holes" on the portions of the leaflets that flex during use. The reinforcing sections 36, the skirt 42, and the inner reinforcing strip 46 (FIG. 7) desirably are made of a bio-compatible synthetic material, such as polytetrafluoroethylene (PTFE), or a woven fabric material, such as woven polyester (*e.g.*, polyethylene terephthalate) (PET), DACRON®).

[079] FIG. 7 shows the operation of the prosthetic valve 10. During diastole, the leaflets 34a, 34b, 34c collapse to effectively close the prosthetic valve. As shown, the curved shape of the intermediate section 22 of the stent 12 defines a space between the intermediate section and the leaflets that mimics the sinuses of Valsalva. Thus, when the leaflets close, backflow entering the "sinuses" creates a turbulent flow of blood along the upper surfaces of the leaflets, as indicated by arrows 52. This turbulence assists in washing the leaflets and the skirt 42 to minimize or reduce clot formation.

[080] The prosthetic valve 10 can be implanted in a retrograde approach where the prosthetic valve, mounted in a crimped state at the distal end of a delivery apparatus, is introduced into the body via the femoral artery and advanced through the aortic arch to the heart, as further described in U.S. Patent Application Publication No. 2008/0065011, which is incorporated herein by reference.

[081] FIGS. 8 and 9 show a delivery apparatus 100, according to one embodiment, that can be used to deliver a self-expanding prosthetic valve, such as prosthetic valve 10 described above, through a patient's vasculature. The delivery apparatus 100 comprises a first, outermost or main catheter 102 (shown alone in FIG. 10) having an elongated shaft 104, the distal end of which is coupled to a delivery sheath 106 (FIG. 18; also referred to as a delivery cylinder). The proximal end of the main catheter 102 is connected to a handle of the delivery apparatus. FIGS. 23–26 show an embodiment of a handle mechanism having an electric motor for operating the delivery apparatus. The handle mechanism is described in detail below. During delivery of a prosthetic valve, the handle can be used by a surgeon to advance and retract the delivery apparatus through the patient's vasculature. Although not required, the main catheter 102 can comprise a guide catheter that is configured to allow a surgeon to guide or control the amount the bending or flexing of a distal portion of the shaft 104 as it is advanced through the patient's vasculature, such as further described below. Another embodiment of a guide catheter is disclosed in U.S. Patent Application Publication No. 2008/0065011, which is incorporated herein by reference.

[082] As best shown in FIG. 9, the delivery apparatus 100 also includes a second, intermediate catheter 108 (also referred to herein as a torque shaft catheter) having an elongated shaft 110 (also referred to herein as a torque shaft) and an elongated screw 112 connected to the distal end of the shaft 110. The shaft 110 of the intermediate catheter 108 extends coaxially through the shaft 104 of the main catheter 102. The delivery apparatus 100 can also include a third, nose-cone catheter 118 having an elongated shaft 120 and a nose piece, or nose cone, 122 secured to the distal end portion of the shaft 120. The nose piece 122 can have a tapered outer surface as shown for atraumatic tracking through the patient's vasculature. The shaft 120 of the nose-cone catheter extends through the prosthetic valve 10 (not shown in FIGS. 8–9) and the shaft 110 of the intermediate catheter 108. In the illustrated configuration, the innermost shaft 120 is configured to be moveable axially and rotatably

relative to the shafts 104, 110, and the torque shaft 110 is configured to be rotatable relative to the shafts 104, 120 to effect valve deployment and release of the prosthetic valve from the delivery apparatus, as described in detail below. Additionally, the innermost shaft 120 can have a lumen for receiving a guide wire so that the delivery apparatus can be advanced over the guide wire inside the patient's vasculature.

[083] As best shown in FIG. 10, the outer catheter 102 can comprise a flex control mechanism 168 at a proximal end thereof to control the amount the bending or flexing of a distal portion of the outer shaft 104 as it is advanced through the patient's vasculature, such as further described below. The outer shaft 104 can comprise a proximal segment 166 that extends from the flex control mechanism 168 and a distal segment 126 that comprises a slotted metal tube that increases the flexibility of the outer shaft at this location. The distal end portion of the distal segment 126 can comprises an outer fork 130 of a valve-retaining mechanism 114 (FIGS. 8 and 8B) that is configured to releasably secure a prosthetic valve 10 to the delivery apparatus 100 during valve delivery, as described in detail below.

[084] FIG. 28A is an enlarged view of a portion of the distal segment 126 of the outer shaft 104. FIG. 28B shows the cut pattern that can be used to form the distal segment 126 by laser cutting the pattern in a metal tube. The distal segment 126 comprises a plurality of interconnected circular bands or links 160 forming a slotted metal tube. A pull wire 162 can be positioned inside the distal segment 126 and can extend from a location 164 of the distal segment 126 (FIGS. 10 and 12) to the flex control mechanism. The distal end of the pull wire 162 can be secured to the inner surface of the distal segment 126 at location 164, such as by welding. The proximal end of the pull wire 162 can be operatively connected to the flex control mechanism 168, which is configured to apply and release tension to the pull wire in order to control bending of the shaft, as further described below. The links 160 of the shaft and the gaps between adjacent links are shaped to allow bending of the shaft upon application of light pulling force on the pull wire 162. In the illustrated embodiment, as best shown in FIG. 12, the distal segment 126 is secured to a proximal segment 166 having a different construction (*e.g.*, one or more layers of polymeric tubing). In the illustrated embodiment, the proximal segment 166 extends from the flex control mechanism 168 to the distal segment 126 and therefore makes up the majority of the length of the outer shaft 104. In alternative embodiments, the entire length or substantially the entire length of the outer

shaft 104 can be formed from a slotted metal tube comprising one or more sections of interconnected links 160. In any case, the use of a main shaft having such a construction can allow the delivery apparatus to be highly steerable.

[085] The width of the links 160 can be varied to vary the flexibility of the distal segment along its length. For example, the links within the distal end portion of the slotted tube can be relatively narrower to increase the flexibility of the shaft at that location while the links within the proximal end portion of the slotted tube can be relatively wider so that the shaft is relatively less flexible at that location.

[086] FIG. 29A shows an alternative embodiment of a distal segment, indicated at 126', which can be formed, for example, by laser cutting a metal tube. The segment 126' can comprise the distal segment of an outer shaft of a delivery apparatus (as shown in FIG. 12) or substantially the entire length of an outer shaft can have the construction shown in FIG. 29A. FIG. 29B shows the cut pattern for forming the segment 126'. In another embodiment, a delivery apparatus can include a composite outer shaft comprising a laser-cut metal tube laminated with a polymeric outer layer that is fused within the gaps in the metal layer. In one example, a composite shaft can comprise a laser cut metal tube having the cut pattern of FIGS. 29A and 29B and a polymeric outer layer fused in the gaps between the links 160 of the metal tube. In another example, a composite shaft can comprise a laser cut metal tube having the cut pattern of FIGS. 28A and 28B and a polymeric outer layer fused in the gaps between the links 160 of the metal tube. A composite shaft also can include a polymeric inner layer fused in the gaps between the links 160 of the metal tube.

[087] Referring to FIGS. 8A and 11, the flex control mechanism 168 can comprise a rotatable housing, or handle portion, 186 that houses a slide nut 188 mounted on a rail 192. The slide nut 188 is prevented from rotating within the housing by one or more rods 192, each of which is partially disposed in a corresponding recess within the rail 192 and a slot or recess on the inside of the nut 188. The proximal end of the pull wire 162 is secured to the nut 188. The nut 188 has external threads that engage internal threads of the housing. Thus, rotating the housing 186 causes the nut 188 to move axially within the housing in the proximal or distal direction, depending on the direction of rotation of the housing. Rotating the housing in a first direction (*e.g.*, clockwise), causes the nut to travel in the proximal

direction, which applies tension to the pull wire 162, which causes the distal end of the delivery apparatus to bend or flex. Rotating the housing in a second direction (*e.g.*, counterclockwise), causes the nut to travel in the distal direction, which relieves tension in the pull wire 162 and allows the distal end of the delivery apparatus to flex back to its pre-flexed configuration under its own resiliency.

[088] As best shown in FIG. 13, the torque shaft catheter 108 includes an annular projection in the form of a ring 128 (also referred to as an anchoring disc) mounted on the distal end portion of the torque shaft 110 adjacent the screw 112. The ring 128 is secured to the outer surface of the torque shaft 110 such that it cannot move axially or rotationally relative to the torque shaft. The inner surface of the outer shaft 104 is formed with a feature, such as a slot or recess, that receives the ring 128 in such a manner that the ring and the corresponding feature on the inner surface of the outer shaft 104 allow the torque shaft 110 to rotate relative to the outer shaft 104 but prevent the torque shaft from moving axially relative to the outer shaft. The corresponding feature on the outer shaft 104 that receives the ring 128 can be inwardly extending tab portions formed in the distal segment 126, such as shown at 164 in FIG. 12. In the illustrated embodiment (as best shown in FIG. 14), the ring 128 is an integral part of the screw 112 (*i.e.*, the screw 112 and the ring 128 are portions of single component). Alternatively, the screw 112 and the ring are separately formed components but are both fixedly secured to the distal end of the torque shaft 110.

[089] The torque shaft 110 desirably is configured to be rotatable relative to the delivery sheath 106 to effect incremental and controlled advancement of the prosthetic valve 10 from the delivery sheath 106. To such ends, and according to one embodiment, the delivery apparatus 100 can include a sheath retaining ring in the form of a threaded nut 150 mounted on the external threads of the screw 112. As best shown in FIG. 16, the nut 150 includes internal threads 152 that engage the external threads of the screw and axially extending legs 154. Each leg 154 has a raised distal end portion that extends into and/or forms a snap fit connection with openings 172 in the proximal end of the sheath 106 (as best shown in FIG. 18) so as to secure the sheath 106 to the nut 150. As illustrated in FIGS. 17B and 18, the sheath 106 extends over the prosthetic valve 10 and retains the prosthetic valve in a radially compressed state until the sheath 106 is retracted by the user to deploy the prosthetic valve.

[090] As best shown in FIGS. 21 and 22, the outer fork 130 of the valve-retaining mechanism comprises a plurality of prongs 134, each of which extends through a region defined between two adjacent legs 154 of the nut so as to prevent rotation of the nut relative to the screw 112 upon rotation of the screw. As such, rotation of the torque shaft 110 (and thus the screw 112) causes corresponding axial movement of the nut 150. The connection between the nut 150 and the sheath 106 is configured such that axially movement of the nut along the screw 112 (in the distal or proximal direction) causes the sheath 106 to move axially in the same direction relative to the screw and the valve-retaining mechanism. FIG. 21 shows the nut 150 in a distal position wherein the sheath 106 (not shown in FIG. 21) extends over and retains the prosthetic valve 10 in a compressed state for delivery. Movement of the nut 150 from the distal position (FIG. 21) to a proximal position (FIG. 22) causes the sheath 106 to move in the proximal direction, thereby deploying the prosthetic valve from the sheath 106. Rotation of the torque shaft 110 to effect axial movement of the sheath 106 can be accomplished with a motorized mechanism or by manually turning a crank or wheel (*e.g.*, as described in U.S. Patent Application Publication No. 2012/0239142, which is incorporated by reference herein in its entirety).

[091] FIG. 17 shows an enlarged view of the nose cone 122 secured to the distal end of the innermost shaft 120. The nose cone 122 in the illustrated embodiment includes a proximal end portion 174 that is sized to fit inside the distal end of the sheath 106. An intermediate section 176 of the nose cone is positioned immediately adjacent the end of the sheath in use and is formed with a plurality of longitudinal grooves or recessed portions 178. The diameter of the intermediate section 176 at its proximal end 180 desirably is slightly larger than the outer diameter of the sheath 106. The proximal end 180 can be held in close contact with the distal end of the sheath 106 to protect surrounding tissue from coming into contact with the metal edge of the sheath. The grooves 178 allow the intermediate section to be compressed radially as the delivery apparatus is advanced through an introducer sheath. This allows the nose cone 122 to be slightly oversized relative to the inner diameter of the introducer sheath. FIG. 17B shows a cross-section the nose cone 122 and the sheath 106 in a delivery position with the prosthetic valve retained in a compressed delivery state inside the sheath 106 (for purposes of illustration, only the stent 12 of the prosthetic valve is shown). As shown, the proximal end 180 of the intermediate section 176 can abut the distal end of the

sheath 106 and a tapered proximal surface 182 of the nose cone can extend within a distal portion of the stent 12.

[092] As noted above, the delivery apparatus 100 can include a valve-retaining mechanism 114 (FIG. 8B) for releasably retaining a stent 12 of a prosthetic valve. The valve-retaining mechanism 114 can include a first valve-securement component in the form of an outer fork 130 (as best shown in FIG. 12) (also referred to as an "outer trident" or "release trident"), and a second valve-securement component in the form of an inner fork 132 (as best shown in FIG. 17) (also referred to as an "inner trident" or "locking trident"). The outer fork 130 cooperates with the inner fork 132 to form a releasably connection with the retaining arms 30 of the stent 12.

[093] The proximal end of the outer fork 130 is connected to the distal segment 126 of the outer shaft 104 and the distal end of the outer fork is releasably connected to the stent 12. In the illustrated embodiment, the outer fork 130 and the distal segment 126 can be integrally formed as a single component (*e.g.*, the outer fork and the distal segment can be laser cut or otherwise machined from a single piece of metal tubing), although these components can be separately formed and subsequently connected to each other. The inner fork 132 can be mounted on the nose catheter shaft 120 (as best shown in FIG. 17). The inner fork 132 connects the stent to the distal end portion of the nose catheter shaft 120. The nose catheter shaft 120 can be moved axially relative to the outer shaft 104 to release the prosthetic valve from the valve-retaining mechanism, as further described below.

[094] As best shown in FIG. 12, the outer fork 130 includes a plurality of angularly-spaced prongs 134 (three in the illustrated embodiment) corresponding to the retaining arms 30 of the stent 12, which prongs extend from the distal end of distal segment 126. The distal end portion of each prong 134 includes a respective opening 140. As best shown in FIG. 17, the inner fork 132 includes a plurality of angularly-spaced prongs 136 (three in the illustrated embodiment) corresponding to the retaining arms 30 of the stent 12, which prongs extend from a base portion 138 at the proximal end of the inner fork. The base portion 138 of the inner fork is fixedly secured to the nose catheter shaft 120 (*e.g.*, with a suitable adhesive) to prevent axial and rotational movement of the inner fork relative to the nose catheter shaft 120.

[095] Each prong of the outer fork 130 cooperates with a corresponding prong 136 of the inner fork to form a releasable connection with a retaining arm 30 of the stent. In the illustrated embodiment, for example, the distal end portion of each prong 134 is formed with an opening 140. When the prosthetic valve is secured to the delivery apparatus (as best shown in FIG. 19), each retaining arm 30 of the stent 12 extends inwardly through an opening 140 of a prong 134 of the outer fork and a prong 136 of the inner fork is inserted through the opening 32 of the retaining arm 30 so as to retain the retaining arm 30 from backing out of the opening 140. FIG. 30 also shows the prosthetic valve 10 secured to the delivery apparatus by the inner and outer forks before the prosthetic valve is loaded into the sheath 106. The threaded nut 150 can be seen positioned between the prongs of the outer fork 130. The prosthetic valve 10 is ready to be compressed and loaded into the sheath 106 of a delivery apparatus. Retracting the inner prongs 136 proximally (in the direction of arrow 184 in FIG. 20) to remove the prongs from the openings 32 is effective to release the prosthetic valve 10 from the retaining mechanism. When the inner fork 132 is moved to a proximal position (FIG. 20), the retaining arms 30 of the stent can move radially outwardly from the openings 140 in the outer fork 130 under the resiliency of the stent. In this manner, the valve-retaining mechanism 114 forms a releasable connection with the prosthetic valve that is secure enough to retain the prosthetic valve relative to the delivery apparatus to allow the user to fine tune or adjust the position of the prosthetic valve after it is deployed from the delivery sheath. When the prosthetic valve is positioned at the desired implantation site, the connection between the prosthetic valve and the retaining mechanism can be released by retracting the nose catheter shaft 120 relative to the outer shaft 104 (which retracts the inner fork 132 relative to the outer fork 130).

[096] Once the prosthetic valve 10 is loaded in the delivery sheath 106, the delivery apparatus 100 can be inserted into the patient's body for delivery of the prosthetic valve. In one approach, the prosthetic valve can be delivered in a retrograde procedure where delivery apparatus is inserted, for example, into a femoral artery and advanced through the patient's vasculature to the heart. Prior to insertion of the delivery apparatus, an introducer sheath can be inserted into the femoral artery followed by a guide wire, which is advanced through the patient's vasculature through the aorta and into the left ventricle. The delivery apparatus 100 can then be inserted through the introducer sheath and advanced over the guide wire until the

distal end portion of the delivery apparatus containing the prosthetic valve 10 is advanced to a location adjacent to or within the native aortic valve.

[097] Thereafter, the prosthetic valve 10 can be deployed from the delivery apparatus 100 by rotating the torque shaft 110 relative to the outer shaft 104. As described below, the proximal end of the torque shaft 110 can be operatively connected to a manually rotatable handle portion or a motorized mechanism that allows the surgeon to effect rotation of the torque shaft 110 relative to the outer shaft 104. Rotation of the torque shaft 110 and the screw 112 causes the nut 150 and the sheath 106 to move in the proximal direction toward the outer shaft (FIG. 22), which deploys the prosthetic valve from the sheath. Rotation of the torque shaft 110 causes the sheath to move relative to the prosthetic valve in a precise and controlled manner as the prosthetic valve advances from the open distal end of the delivery sheath and begins to expand. Hence, unlike known delivery apparatus, as the prosthetic valve begins to advance from the delivery sheath and expand, the prosthetic valve is held against uncontrolled movement from the sheath caused by the expansion force of the prosthetic valve against the distal end of the sheath. In addition, as the sheath 106 is retracted, the prosthetic valve 10 is retained in a stationary position relative to the ends of the inner shaft 120 and the outer shaft 104 by virtue of the valve-retaining mechanism 114. As such, the prosthetic valve 10 can be held stationary relative to the target location in the body as the sheath is retracted. Moreover, after the prosthetic valve is partially advanced from the sheath, it may be desirable to retract the prosthetic valve back into the sheath, for example, to reposition the prosthetic valve or to withdraw the prosthetic valve entirely from the body. The partially deployed prosthetic valve can be retracted back into the sheath by reversing the rotation of the torque shaft, which causes the sheath 106 to advance back over the prosthetic valve in the distal direction.

[098] In known delivery devices, the surgeon must apply push-pull forces to the shaft and/or the sheath to unsheathe the prosthetic valve. It is therefore difficult to transmit forces to the distal end of the device without distorting the shaft (*e.g.*, compressing or stretching the shaft axially), which in turn causes uncontrolled movement of the prosthetic valve during the unsheathing process. To mitigate this effect, the shaft and/or sheath can be made more rigid, which is undesirable because the device becomes harder to steer through the vasculature. In contrast, the manner of unsheathing the prosthetic valve described above eliminates the

application of push-pull forces on the shaft, as required in known devices, so that relatively high and accurate forces can be applied to the distal end of the shaft without compromising the flexibility of the device. In certain embodiments, as much as about 90 N (about 20 lb) of force can be transmitted to the end of the torque shaft without adversely affecting the unsheathing process. In contrast, prior art devices utilizing push-pull mechanisms typically cannot exceed about 20 N (5 lb) of force during the unsheathing process.

[099] After the prosthetic valve 10 is advanced from the delivery sheath and expands to its functional size (the expanded prosthetic valve 10 secured to the delivery apparatus is depicted in FIG. 30), the prosthetic valve remains connected to the delivery apparatus via the retaining mechanism 114. Consequently, after the prosthetic valve is advanced from the delivery sheath, the surgeon can reposition the prosthetic valve relative to the desired implantation position in the native valve such as by moving the delivery apparatus in the proximal and distal directions or side to side, or rotating the delivery apparatus, which causes corresponding movement of the prosthetic valve. The retaining mechanism 114 desirably provides a connection between the prosthetic valve and the delivery apparatus that is secure and rigid enough to retain the position of the prosthetic valve relative to the delivery apparatus against the flow of the blood as the position of the prosthetic valve is adjusted relative to the desired implantation position in the native valve. Once the surgeon positions the prosthetic valve at the desired implantation position in the native valve, the connection between the prosthetic valve and the delivery apparatus can be released by retracting the innermost shaft 120 in the proximal direction relative to the outer shaft 104, which is effective to retract the inner fork 132 to withdraw its prongs 136 from the openings 32 in the retaining arms 30 of the prosthetic valve (FIG. 20). Slightly retracting of the outer shaft 104 allows the outer fork 130 to back off the retaining arms 30 of the prosthetic valve, which slide outwardly through openings 140 in the outer fork to completely disconnect the prosthetic valve from the retaining mechanism 114. Thereafter, the delivery apparatus can be withdrawn from the body, leaving the prosthetic aortic valve 10 implanted within the native valve (such as shown in FIGS. 5A and 5B).

[0100] The delivery apparatus 100 has at its distal end a semi-rigid segment comprised of relatively rigid components used to transform rotation of the torque shaft into axial movement of the sheath. In particular, this semi-rigid segment in the illustrated embodiment

is comprised of the prosthetic valve and the screw 112. An advantage of the delivery apparatus 100 is that the overall length of the semi-rigid segment is minimized because the nut 150 is used rather than internal threads on the outer shaft to affect translation of the sheath. The reduced length of the semi-rigid segment increases the overall flexibility along the distal end portion of the delivery catheter. Moreover, the length and location of the semi-rigid segment remains constant because the torque shaft does not translate axially relative to the outer shaft. As such, the curved shape of the delivery catheter can be maintained during valve deployment, which improves the stability of the deployment. A further benefit of the delivery apparatus 100 is that the ring 128 prevents the transfer of axial loads (compression and tension) to the section of the torque shaft 110 that is distal to the ring.

[0101] In an alternative embodiment, the delivery apparatus can be adapted to deliver a balloon-expandable prosthetic valve. As described above, the valve retaining mechanism 114 can be used to secure the prosthetic valve to the end of the delivery apparatus. Since the stent of the prosthetic valve is not self-expanding, the sheath 106 can be optional. The retaining mechanism 114 enhances the pushability of the delivery apparatus and prosthetic valve assembly through an introducer sheath.

[0102] FIGS. 23–26 illustrate the proximal end portion of the delivery apparatus 100, according to one embodiment. The delivery apparatus 100 can comprise a handle 202 that is configured to be releasably connectable to the proximal end portion of a catheter assembly 204 comprising catheters 102, 108, 118. It may be desirable to disconnect the handle 202 from the catheter assembly 204 for various reasons. For example, disconnecting the handle can allow another device to be slid over the catheter assembly, such as a valve-retrieval device or a device to assist in steering the catheter assembly. It should be noted that any of the features of the handle 202 and the catheter assembly 204 can be implemented in any of the embodiments of the delivery apparatuses disclosed herein.

[0103] FIGS. 23 and 24 show the proximal end portion of the catheter assembly 204 partially inserted into a distal opening of the handle 202. The proximal end portion of the main shaft 104 is formed with an annular groove 212 (as best shown in FIG. 24) that cooperates with a holding mechanism, or latch mechanism, 214 inside the handle. When the proximal end portion of the catheter assembly is fully inserted into the handle, as shown in

FIGS. 25 and 26, an engaging portion 216 of the holding mechanism 214 extends at least partially into the groove 212. One side of the holding mechanism 214 is connected to a button 218 that extends through the housing of the handle. The opposite side of the holding mechanism 214 is contacted by a spring 220 that biases the holding mechanism to a position engaging the main shaft 104 at the groove 212. The engagement of the holding mechanism 214 within the groove 212 prevents axial separation of the catheter assembly from the handle. The catheter assembly can be released from the handle by depressing button 218, which moves the holding mechanism 214 from locking engagement with the main shaft. Furthermore, the main shaft 104 can be formed with a flat surface portion within the groove 212. The flat surface portion is positioned against a corresponding flat surface portion of the engaging portion 216. This engagement holds the main shaft 104 stationary relative to the torque shaft 110 as the torque shaft is rotated during valve deployment.

[0104] The proximal end portion of the torque shaft 110 can have a driven nut 222 (FIG. 26) that is slidably received in a drive cylinder 224 (FIG. 25) mounted inside the handle. The nut 222 can be secured to the proximal end of the torque shaft 100 by securing the nut 222 over a coupling member 170 (FIG. 15). FIG. 26 is a perspective view of the inside of the handle 202 with the drive cylinder and other components removed to show the driven nut and other components positioned within the drive cylinder. The cylinder 224 has a through opening (or lumen) extending the length of the cylinder that is shaped to correspond to the flats of the nut 222 such that rotation of the drive cylinder is effective to rotate the nut 222 and the torque shaft 110. The drive cylinder can have an enlarged distal end portion 236 that can house one or more seals (*e.g.*, O-rings 246) that form a seal with the outer surface of the main shaft 104 (FIG. 25). The handle can also house a fitting 238 that has a flush port in communication with the lumen of the torque shaft and/or the lumen of the main shaft.

[0105] The drive cylinder 224 is operatively connected to an electric motor 226 through gears 228 and 230. The handle can also house a battery compartment 232 that contains batteries for powering the motor 226. Rotation of the motor in one direction causes the torque shaft 110 to rotate, which in turn causes the sheath 106 to retract and uncover a prosthetic valve at the distal end of the catheter assembly. Rotation of the motor in the opposite direction causes the torque shaft to rotate in an opposite direction, which causes the sheath to

move back over the prosthetic valve. An operator button 234 on the handle allows a user to activate the motor, which can be rotated in either direction to un-sheath a prosthetic valve or retrieve an expanded or partially expanded prosthetic valve.

[0106] As described above, the distal end portion of the nose catheter shaft 120 can be secured to an inner fork 132 that is moved relative to an outer fork 130 to release a prosthetic valve secured to the end of the delivery apparatus. Movement of the shaft 120 relative to the main shaft 104 (which secures the outer fork 130) can be effected by a proximal end portion 240 of the handle that is slidable relative to the main housing 244. The end portion 240 is operatively connected to the shaft 120 such that movement of the end portion 240 is effective to translate the shaft 120 axially relative to the main shaft 104 (causing a prosthetic valve to be released from the inner and outer forks). The end portion 240 can have flexible side panels 242 on opposite sides of the handle that are normally biased outwardly in a locked position to retain the end portion relative to the main housing 244. During deployment of the prosthetic valve, the user can depress the side panels 242, which disengage from corresponding features in the housing and allow the end portion 240 to be pulled proximally relative to the main housing, which causes corresponding axial movement of the shaft 120 relative to the main shaft. Proximal movement of the shaft 120 causes the prongs 136 of the inner fork 132 to disengage from the apertures 32 in the stent 12, which in turn allows the retaining arms 30 of the stent to deflect radially outwardly from the openings 140 in the prongs 134 of the outer fork 130, thereby releasing the prosthetic valve.

[0107] FIG. 27 shows an alternative embodiment of a motor, indicated at 300, that can be used to drive a torque shaft (*e.g.*, torque shaft 110). In this embodiment, a catheter assembly can be connected directly to one end of a shaft 302 of the motor, without gearing. The shaft 302 includes a lumen that allows for passage of an innermost shaft (*e.g.*, shaft 120) of the catheter assembly, a guide wire, and/or fluids for flushing the lumens of the catheter assembly.

[0108] Alternatively, the power source for rotating the torque shaft 110 can be a hydraulic power source (*e.g.*, hydraulic pump) or pneumatic (air-operated) power source that

is configured to rotate the torque shaft. In another embodiment, the handle can have a manually movable lever or wheel that is operable to rotate the torque shaft 110.

[0109] In another embodiment, a power source (*e.g.*, an electric, hydraulic, or pneumatic power source) can be operatively connected to a shaft, which is turn is connected to a prosthetic valve 10. The power source is configured to reciprocate the shaft longitudinally in the distal direction relative to a valve sheath in a precise and controlled manner in order to advance the prosthetic valve from the sheath. Alternatively, the power source can be operatively connected to the sheath in order to reciprocate the sheath longitudinally in the proximal direction relative to the prosthetic valve to deploy the prosthetic valve from the sheath.

[0110] Referring to FIG. 31, there is shown a prosthetic aortic heart valve 410, according to another embodiment. Similar to the prosthetic valve 10, the prosthetic valve 410 includes an expandable frame member, or stent, 412 that supports an expandable valve member, which in the illustrated embodiment comprises a flexible leaflet section 414. Also, the prosthetic valve 410 is radially compressible to a compressed state for delivery through the body to a deployment site and expandable to its functional size shown in FIG. 31 at the deployment site. In certain embodiments, the prosthetic valve 410 is self-expanding; that is, the prosthetic valve can radially expand to its functional size when advanced from the distal end of a delivery sheath. In other embodiments, the prosthetic valve can be a balloon-expandable prosthetic valve that can be adapted to be mounted in a compressed state on the balloon of a delivery catheter. The prosthetic valve can be expanded to its functional size at a deployment site by inflating the balloon, as known in the art. Apparatuses particularly suited for percutaneous delivery and implantation of the prosthetic valve 10 (such as those described herein) are also suitable for percutaneous delivery and implantation of the prosthetic valve 410. The illustrated prosthetic valve 410 is adapted to be deployed in the native aortic annulus, although it also can be used to replace the other native valves of the heart (the mitral, tricuspid and pulmonary valves). Moreover, the prosthetic valve 410 can be adapted to replace other valves within the body, such venous valves.

[0111] The frame member 412 of the prosthetic valve 410 can have the same overall shape and construction as the frame member 12 of the prosthetic valve 10. Thus, similar to

the frame member 12, the frame member 412 can be formed from a plurality of longitudinally extending, generally sinusoidal shaped frame members, or struts, 416. Referring to FIG. 31, the stent 412 has an inflow end 426 and an outflow end 427, and the mesh structure formed by the struts 416 comprises a generally cylindrical "upper" or outflow end portion 420, an outwardly bowed or distended intermediate section 422, and an inwardly bowed "lower" or inflow end portion 424. Further, the stent 412 can have a plurality of angularly spaced retaining arms, or projections, in the form of posts 430 (three in the illustrated embodiment) that extend from upper portion of the stent 412. Each retaining arm 430 has a respective aperture 432 that is sized to receive prongs of a valve-retaining mechanism that can be used to form a releasable connection between the prosthetic valve and a delivery apparatus (described above). In alternative embodiments, the retaining arms 430 need not be provided if a valve-retaining mechanism is not used. In further embodiments, the retaining arms 430 can extend from the lower portion of the stent 424, for example, for applications involving antegrade implantation of the valve (*e.g.*, the delivery apparatus is inserted through a surgical opening in the wall of the left ventricle of the heart in a transventricular approach, such as an opening made at the bare spot on the lower anterior ventricle wall).

[0112] The leaflet assembly 414 of the prosthetic aortic heart valve 410 is similar to the leaflet assembly 14 of the prosthetic aortic heart valve 10, although there are several differences, described below. For example, with reference to FIGS. 32 and 33, the leaflet assembly 414 comprises three leaflets 434a, 434b, 434c made of a flexible material. Each leaflet has an inflow end portion 460 and an outflow end portion 462. The leaflets can comprise any suitable biological material (*e.g.*, pericardial tissue, such as bovine or equine pericardium), bio-compatible synthetic materials, or other such materials, such as those described in U.S. Patent No. 6,730,118, which is incorporated herein by reference. The leaflet assembly 414 can include an annular reinforcing skirt assembly 442 that is secured to the inflow end portions of the leaflets 434a, 434b, 434c at a suture line 444 adjacent the inflow end of the prosthetic valve. The inflow end portion of the leaflet assembly 414 can be secured to the stent 412 by suturing the skirt assembly 442 to the struts 416 of the lower section 424 of the stent (best shown in FIG. 31).

[0113] With reference to FIG. 33, the skirt assembly 442 can include an upper skirt 443 and a lower skirt 445. The inflow end portions 460 of the leaflets 434a, 434b, and 434c can be positioned between an upper portion 447 of the lower skirt 445 and a lower portion 454 of the upper skirt 443, with the upper skirt desirably having an outward placement compared to the lower skirt. The upper skirt 443, the inflow end portions 460 of the leaflets 434a, 434b, 434c, and the lower skirt 445 can be secured by sutures along a scalloped or undulating suture line 444 adjacent the inflow end of the prosthetic valve (FIG. 31). The inflow end portion of the leaflet assembly 414 can be secured to the stent 412 by suturing the upper skirt 443, the lower skirt 445, or both the upper skirt 443 and the lower skirt 445 to the struts 416 of the lower section 424 of the stent via sutures 455 (best shown in FIG. 31). The skirt assembly 442 (including the upper skirt 443 and the lower skirt 445), desirably can be made of a bio-compatible synthetic material, such as polytetrafluoroethylene (PTFE), or a woven fabric material, such as woven polyester (*e.g.*, polyethylene terephthalate) (PET), DACRON®). The upper skirt 443 and the lower skirt 445 can be made of the same, or different, material.

[0114] As best shown in FIG. 32, the outflow end portion of upper skirt 443 can be shaped to substantially align with the undulating or zigzag shape formed by the struts 416 of the lower section 424 of the stent, *e.g.*, for ease of securing the upper skirt to the struts of the stent by suture. For example, the upper skirt 443 can include an upper edge 456 shaped to correspond to the shape of the second lowermost row of cells of the frame member 412. The inflow end portion of upper skirt 443 can have an undulating lower edge 458 that substantially aligns with the undulating suture line 444 and the scalloped or undulating shape of the inflow portions of the leaflets 443a, 443b, and 443c. The outflow end portion of the lower skirt 445 can be shaped to have an undulating shape that substantially corresponds with the undulating suture line 444. The inflow end portion 454 of the upper skirt 443 and the outflow end portion 447 of the lower skirt 445 overlap each other on opposite sides of the leaflet inflow end portions at least enough to secure the upper skirt and lower skirt by sutures along the suture line 444. The inflow end portion of the lower skirt 445 typically extends to the inflow end 426 of the stent, although other configurations are possible. For example, the inflow end portion of the lower skirt 445 can be shaped to include a lower edge shaped to correspond to the shape of a lowermost row of cells of the frame.

[0115] The outflow end portion of the leaflet assembly 414 can be secured to the upper portion of the stent 412 at three angularly spaced commissure attachments of the leaflets 434a, 434b, 434c, in a manner similar to the configuration used to secure the outflow end portion of the leaflet assembly 14 to the upper portion of the stent 12 at three angularly spaced commissure attachments of the leaflets 34a, 34b, 34c (as best shown in FIG. 2).

[0116] FIG. 33 shows the operation of the prosthetic valve 410. During diastole, the leaflets 434a, 434b, 434c collapse to effectively close the prosthetic valve. As shown, the curved shape of the intermediate section 422 of the stent 412 defines a space between the intermediate section and the leaflets that mimics the sinuses of Valsalva. Thus, when the leaflets close, backflow entering the "sinuses" creates a turbulent flow of blood along the upper surfaces of the leaflets, as indicated by arrows 452. This turbulence assists in washing the leaflets and the skirt assembly 442 to minimize clot formation.

[0117] Referring to FIGS. 33 and 35, the prosthetic valve 410 can further include a sealing skirt 449 positioned at the lower section 424 of the stent. The sealing skirt 449 provides an additional barrier against paravalvular leakage following implantation of the stent in a subject by providing material at the inflow end portion of the stent that protrudes outwardly through the openings of the cells of the frame and contacts surrounding tissue of the native annulus, thereby minimizing or reducing paravalvular leakage. The sealing skirt is desirably supported by the upper skirt 443 and the lower skirt 445, which prevent the sealing skirt 449 from contacting the leaflets 434a, 434b, and 434c of the leaflet assembly 414. The upper skirt 443 and the lower skirt 445 additionally provide support to ensure that the material of the sealing skirt 449 extends outwardly between cells formed by the struts 416 of the stent 412 to seal against the surrounding annulus.

[0118] FIG. 34 depicts an embodiment of the sealing skirt 449 prior to attachment to the stent. The outflow end portion 451 of the sealing skirt 449 can have an undulating or zigzag shape that has an upper edge shaped to correspond to the shape of the upper boundary of a lower most row of cells of the frame formed by the struts 416 of the stent 412. In alternative embodiments, the outflow end portion 451 of the sealing skirt 449 can have a substantially straight edge that does not align with the undulating or zigzag shape formed by the struts 416 of the stent 412; instead the outflow end portion 451 of the sealing skirt 449 can transect the

lower most row of cells of the frame formed by the struts 416 of the stent 412 (see, *e.g.*, FIG. 38). The inflow end portion 453 of the sealing skirt 449 typically extends to the inflow end 426 of the stent (see, *e.g.*, FIGS. 35 and 36), although other configurations are possible. For example, the sealing skirt 449 can have an upper edge and a lower edge shaped to correspond to the shape of a lower most row of cells formed by the struts 416 of the inflow end 426 of the stent such that the sealing skirt 449 only occludes the openings in the lowermost row of cells (see, *e.g.*, FIG. 37). In additional embodiments, the inflow end portion of the sealing skirt 449 can be constructed to extend beyond the inflow end 426 of the stent (see, *e.g.*, FIG. 38). In several embodiments, the inflow end portion 453 of the sealing skirt 449 can be shaped to substantially align with the inflow end portion of the lower skirt 445.

[0119] Referring to FIGS. 35–39, the sealing skirt 449 can be secured to the struts 416 of the lower portion of the stent 412 with sutures 455. The sutures 455 can secure the sealing skirt 449 to the struts 416 of the lower portion of the stent 412, and optionally can also secure the upper skirt 443 and/or the lower skirt 445 to the struts 416 of the lower portion of the stent 412. The sealing skirt 449 desirably is made of a bio-compatible synthetic material, such as polytetrafluoroethylene (PTFE), or a woven fabric material, such as woven polyester (*e.g.*, polyethylene terephthalate) (PET), DACRON®). In several embodiments, the sealing skirt comprises a plush or pile material, such as a loop yarn, which functions as a filler material in that fibers of the sealing skirt can extend outwardly through openings in the frame and fill spaces between the frame and the native annulus. The plush or pile material is also compressible, thus minimizing the crimp profile of the sealing skirt 449. In some embodiments, the sealing skirt can be made of a PET loop yarn or polyester 70/20 textured yarn. In additional embodiments, the sealing skit can be made of polyester multifilament partially oriented yarn (poy); a polyester 2-ply multifilament yarn; a polyester film; a knitted polyester; a woven polyester; and/or a felted polyester. Such materials are available commercially, for example, from Biomedical Structures (Warwick, RI) and ATEX Technologies (Pinebluff, NC).

[0120] With reference to FIG. 39, the illustrated embodiment of the sealing skirt 449 can be made of a relatively less bulky, non-plush or non-pile material (*e.g.*, woven PET fabric) and secured (*e.g.*, with sutures 455) to the frame member 412 such that portions of the

sealing skirt protrude radially outwardly through the cells of the frame member 412 to seal against the surrounding annulus. In such embodiments, the sealing skirt can be secured by sutures 455 such that slack material of sealing skirt 449 bulges or protrudes through the lowermost cells formed by the struts 416 of the frame member 412. The lower skirt 445 supports the sealing skirt 449 (and can be secured to the frame member 412 with the same sutures 455 as used to secure the sealing skirt 449) to prevent the slack material of the sealing skirt from protruding inwardly towards the longitudinal axis of the valve 410 and contacting the leaflets. In such embodiments, the length of the sealing skirt 449 is typically longer than that of the inner circumference of the lower portion of the frame member 412. FIG. 39 provides a perspective view depicting a portion of the frame member 412 and the sealing skirt 449; however, for clarity of illustration, the upper skirt 443, the lower skirt 445 and the leaflet assembly 434 are not depicted.

[0121] The dimensions of the sealing skirt 449 can be adjusted to obtain the desired amount of material protruding from an expanded annular frame, depending on the type of material used for the sealing skirt. For example, in embodiments where the sealing skirt 449 is constructed of a plush or pile material (such as a loop yarn) having fibers that protrude outwardly between the cells of the frame member 412, the length of the sealing skirt (in an unrolled or flattened configuration prior to mounting on the frame) can be substantially the same as the circumference of the lower portion of the frame member 412. In other embodiments, the length of the sealing skirt prior to mounting on the annular frame is at least about 5% (such as at least about 10%, at least about 15%, at least about 20%, at least about 25%) longer than the circumference of the expanded annular frame of the stent, to allow for additional material to protrude between the cells of the frame member 412.

[0122] Although description of the sealing skirt 449 above is made with reference to prosthetic heart valve 410, the sealing skirt can also be included on prosthetic heart valve 10, for example, by modifying the dimensions of the sealing skirt 449 as needed to secure the sealing skirt 449 to skirt assembly 42 of heart valve 10.

[0123] The prosthetic valve 410 can be implanted in a retrograde approach where the prosthetic valve, mounted in a crimped state at the distal end of a delivery apparatus (*e.g.*, the delivery apparatus 100), is introduced into the body via the femoral artery and advanced

through the aortic arch to the heart, as further described in U.S. Patent Application Publication No. 2008/0065011, which is incorporated herein by reference. The prosthetic valve 410 can also be implanted in a retrograde approach where the prosthetic valve, mounted in a crimped state at the distal end of a delivery apparatus (*e.g.*, the delivery apparatus 100), is introduced into the body via the left or right subclavian artery and advanced to the heart. In further embodiments, the prosthetic valve 410 can be implanted in an antegrade approach where the prosthetic valve, mounted in a crimped state at the distal end of a delivery apparatus, is introduced into the body and advanced transventricularly (see, *e.g.*, U.S. Patent No. 8,439,970, which is incorporated herein by reference. For transventricular implant applications, the retaining arms 430 can be included on the lower portion of the stent.

[0124] Prior to insertion of the delivery apparatus, an introducer sheath can be inserted into the artery followed by a guide wire, which is advanced through the patient's vasculature through the aorta and into the left ventricle. The delivery apparatus can then be inserted through the introducer sheath and advanced over the guide wire until the distal end portion of the delivery apparatus containing the prosthetic valve 410 is advanced to a location adjacent to or within the native aortic valve.

[0125] Known introducer sheaths typically employ a sleeve made from polymeric tubing having a radial wall thickness of from about 0.025 mm (about 0.010 inch) to about 0.04 mm (about 0.015 inch). FIG. 40A shows an embodiment of an introducer sheath, indicated at 500, that employs a thin metallic tubular layer that has a much smaller wall thickness compared to known devices. In particular embodiments, the wall thickness of the sheath 500 is from about 0.0012 mm (about 0.0005 inch) to about 0.05 mm (about 0.002 inch). The introducer sheath 500 includes a proximally located housing or hub 502 and a distally extending sleeve or cannula 504. The housing 502 can house a seal or a series of seals as known in the art to minimize blood loss. The sleeve 504 comprises a tubular layer or sleeve 506 that is formed from a metal or metal alloy, such as Nitinol or stainless steel, and desirably is formed with a series of circumferentially extending or helically extending slits or openings to impart a desired degree of flexibility to the sleeve.

[0126] As shown in FIG. 40B, for example, the tubular layer 506 is formed (*e.g.*, laser cut) with an "I-beam" pattern of alternating circular bands 507 and openings 508 with axially extending connecting portions 510 connecting adjacent bands 507. Two adjacent bands 507 can be connected by a plurality of angularly spaced connecting portions 510, such as four connecting portions 510 spaced about 90 degrees from each other around the axis of the sleeve, as shown in the illustrated embodiment. The sleeve 504 exhibits sufficient flexibility to allow the sleeve to flex as it is pushed through a tortuous pathway without kinking or buckling. FIG. 41 shows another pattern of openings that can be laser cut or otherwise formed in the tubular layer 506. The tubular layer in the embodiment of FIG. 41 has a pattern of alternating bands 512 and openings 514 with connecting portions 516 connecting adjacent bands 512, the openings 514 and connecting portions 516 each arranged in a helical pattern along the length of the sleeve. In alternative embodiments, the pattern of bands and openings and/or the width of the bands and/or openings can vary along the length of the sleeve in order to vary stiffness of the sleeve along its length. For example, the width of the bands can decrease from the proximal end to the distal end of the sleeve to provide greater stiffness near the proximal end and greater flexibility near the distal end of the sleeve.

[0127] As shown in FIG. 42, the sleeve 504 can have a thin outer layer or liner 518 extending over the tubular layer 506, the outer layer 518 made of a low friction material to reduce friction between the sleeve and the vessel wall into which the sleeve is inserted. The sleeve 504 can also have a thin inner layer or liner 520 covering the inner surface of the tubular layer 506 and made of a low friction material to reduce friction between the sleeve and the delivery apparatus that is inserted into the sleeve. The inner and outer layers can be made from a suitable polymer, such as PET, PTFE, FEP, and/or polyether block amide (PEBAX®). The inner and outer liners, and the tubular layer, are sized appropriately for the desired application of the introducer sheath 500. In particular embodiments, the inner liner 520 can have a radial wall thickness in the range of from about 0.0012 mm (about 0.0005 inch) to about 0.012 mm (about 0.005 inch) (such as from about 0.025 mm (about 0.001 inch) to about 0.075 mm (0.003 inch), for example about 0.06 mm (about 0.0025 inch)). In particular embodiments, the outer liner 518 has a radial wall thickness in the range of about from about 0.0012 mm (0.0005 inch) to about 0.012 mm (about 0.005 inch) (such as from about 0.012 mm (about 0.0005 inch) to about 0.075 mm (0.003 inch), for example

about 0.025 mm (about 0.001 inch)). In particular embodiments, the tubular layer 506 can have a radial wall thickness in the range of from about 0.0012 mm (about 0.0005 inch) to about 0.025 mm (about 0.01 inch) (such as from about 0.05 mm (about 0.002 inch) to about 0.15 mm (about 0.006 inch), for example about 0.05 mm (about 0.002 inch) or about 0.1 mm (about 0.004 inch)).

[0128] Together, the inner liner 520, the tubular layer 506, and the outer layer 518, have a wall thickness that can vary based on the desired final product. In some embodiments, the inner liner 520, the tubular layer 506, and the outer layer 518, together can have a radial wall thickness in the range of from about 0.05 mm (about 0.002 inch) to about 0.5 mm (about 0.02 inch) (such as from about 0.09 mm (about 0.0035 inch) to about 0.3 mm (about 0.012 inch). As such, the sleeve 504 can be provided with an outer diameter that is about 1–2 Fr smaller than known devices. The relatively smaller profile of the sleeve 504 improves ease of use, lowers risk of patient injury via tearing of the arterial walls, and increases the potential use of minimally invasive procedures (*e.g.*, heart valve replacement) for patients with highly calcified arteries, tortuous pathways or small vascular diameters.

[0129] The inner liner 520 can be applied to the interior of the tubular layer 506, for example, using a two-stage molding process. In one step, a preform, cylindrical polymer tube or parison 522 (FIG. 48) with an open end 524 and a closed end 526 is formed, *e.g.*, by an injection molding or extrusion process. The tube 522 has an outer diameter less than that of the inner diameter of the tubular layer 506, and a wall thickness designed to provide an appropriate thickness for the inner liner 520 of the tubular layer 506, following blow molding. In one embodiment, the tube 522 can have a wall thickness of from about 0.025 mm (about 0.001 inch) to about 0.1 mm (about 0.004 inch) (such as from about 0.05 mm (about 0.002 inch) to about 0.075 mm (about 0.003 inch), such as about 0.06 mm (about 0.0025 inch)). Appropriate material for the polymer tube can be selected based on the desired finished product. In some embodiments, the polymer tube 522 is made of nylon-12, polyethylene, fluorinated ethylene propylene, and/or polyether block amide (, *e.g.*, PEBAX® 72D). The length of the tube 522 can be varied depending on the length of the tubular layer 506, and is typically longer than that of the tubular layer 506. In another step, heat and pressure are applied to the tube 522 to form the inner liner 520 by blow molding.

[0130] FIGS. 48 and 49 depict an exemplary method of using blow molding to apply the tube 522 to the tubular layer 506 to form the inner liner 520. The tubular layer 506 is inserted into mold 528. The mold 528, which has an inner diameter that is slightly larger than the outer diameter of the tubular layer 506 such that the sleeve can be easily inserted into and removed from the mold, prevents any appreciable radial expansion of the sleeve during the pressurization step (described below). The mold 528 can be constructed to be non-expandable during blow molding of the tube 522. The mold 528 can have a cylindrical inner surface 529 that corresponds to the shape of the outer surface of the tubular layer 506. Thus, when the tube 522 is pressurized (discussed in detail below), the inner surface of the mold prevents the tubular layer 506 from expanding/deforming under pressure from the expanding tube 522 and prevents portions of the tube 522 from expanding radially outwardly through the openings 508 in the tubular layer 506.

[0131] The tube 522 with the open end 524 and the closed end 526 is inserted into the tubular layer 506, as shown in FIG. 48. The closed end 526 can extend beyond one end of the tubular layer 506, and the open end 524 can extend beyond the other end of tubular layer 506.

[0132] Heat and pressure are applied to the tube 522 to cause the tube to expand against the inner surface of the tubular layer 506 to form an expanded polymer tube 530. The heat and pressure can be applied sequentially (*e.g.*, heat is applied, then pressure), or simultaneously. For example, the heat and pressure can be applied simultaneously by injecting heated compressed gas or liquid into the open end 524 of the tube 522. Alternatively, the heat can be applied by heating the mold 528, and the tube 522 can be pressurized by injecting compressed gas or liquid into the open end 524 of the tube 522. For example, the entire assembly including the mold 528, the tubular layer 506, and the tube 522 can be immersed in a heated fluid. In this regard, the wall of the mold can have one or more apertures that allow the heated fluid (*e.g.*, a heated liquid such as water) to flow through the apertures and contact the tube 522 to facilitate heating of the tube. Various other types of heat sources, such as resistive, conductive, convective, and infrared heat sources, can be used to apply heat to the tube 522. Optionally, the tube 522 can be stretched axially concurrently with heating and/or pressurizing, or in one or more separate stretching steps performed at separate times from heating and/or pressurizing.

[0133] Portions of the expanded tube 530 extending beyond the either end of tubular layer 506 can be trimmed to form the inner liner 520 of tubular layer 506. In some embodiments, the inner liner 520 can expand into the openings 508 of the tubular layer 506 during the molding process, and remain in the openings following the molding process. In other embodiments, the inner liner 520 does not expand into and/or remain into the openings 508 of the tubular layer 506 during the molding process. The specific heat and pressure conditions (including the duration for which the heat and pressure should be applied, as well as cooling conditions) for blow molding the inner liner 520 of the tubular layer 506 can be varied as desired, and typically will depend on the starting materials and desired finished product. In some embodiments, the tube 522 is heated to about 125 °C (about 255 °F) and pressurized to about 80 kPa (about 12 psi) for a period of time sufficient to form inner liner 520. Further, general methods of blow molding are known to the person of ordinary skill in the art (*see, e.g.*, U.S. Patent Application Publication No. 2011/0165284, which is incorporated by reference herein in its entirety).

[0134] The outer layer 518 of the sheath can be applied over and secured to the outer surface of the tubular layer 506 using conventional techniques or mechanisms (*e.g.*, using an adhesive or by thermal welding). In one embodiment, the outer layer is formed by shrink wrapping a polymer tubular layer to tubular layer 506. Appropriate material for the outer layer 518 can be selected based on the desired finished product. In some embodiments, the outer layer 518 is made of nylon-12, polyether block amide (PEBAX®, *e.g.*, PEBAX® 72D), and/or polyethylene. The outer layer 518 can be applied to the tubular layer 506 before or after the inner layer 520 has been formed using the molding process described above.

[0135] In a modification of the introducer sheath 500, the sheath can have inner and outer layers 520, 518, respectively, which are secured to a metal sleeve (*e.g.*, sleeve 504) only at the proximal and distal ends of the metal sleeve. The inner and outer polymeric layers can be bonded to the metal sleeve (or to each other through the gaps in the metal sleeve), for example using a suitable adhesive or by thermal welding. In this manner, the metal sleeve is unattached to the inner and outer polymeric layers between the proximal and distal ends of the sleeve along the majority of the length of the sleeve, and therefore is "free-floating" relative to the polymeric layers along the majority of the length of the sleeve. This

construction allows the adjacent bands of metal to bend more easily relative to the inner and outer layers, providing the sheath with greater flexibility and kink-resistance than if the inner and outer layers were bonded along the entire length of the sleeve.

[0136] FIG. 43 shows a segment of an alternative metal sleeve, indicated at 600, that can be used in the introducer sheath 500. The sheath 500 in this embodiment desirably includes inner and outer polymeric layers, which desirably are secured to the metal sleeve only at its proximal and distal ends as discussed above. The sleeve 600 includes a plurality of circular bands or rings 602 interconnected by two links, or connecting portions, 604, extending between each pair of adjacent rings. Each pair of links connecting two adjacent bands 602 desirably are spaced about 180 degrees from each other and desirably are rotationally offset by about 90 degrees from an adjacent pair of links, which allows for multi-axial bending.

[0137] FIG. 44 shows side view of a segment of another embodiment of a metal sleeve, indicated at 700, that can be used in the introducer sheath 500. The sleeve 700 has the same cut pattern as the sleeve 600, and therefore has circular bands 702 and two links 704 connecting adjacent bands, and further includes two cutouts, or apertures, 706 formed in each band 702 to increase the flexibility of the sleeve. The cutouts 706 desirably have a generally elliptical or oval shape, but can have other shapes as well. Each cutout 706 desirably extends about 180 degrees in the circumferential direction of the sleeve and desirably is rotational offset by about 90 degrees from a cutout 706 in an adjacent band 702.

[0138] In particular embodiments, the metal sleeve of an introducer sheath has a wall thickness in the range of from about 0.05 mm (about 0.002 inch) to about 0.015 mm (about 0.006 inch). In one implementation, a sheath has a metal sleeve having a wall thickness of about 0.05 mm (about 0.002 inch) and an inner diameter of about 5.8 mm (about 0.229 inch), an inner polymeric layer having a wall thickness of about 0.06 mm (about 0.0025 inch), an outer polymeric layer having a wall thickness of about 0.025 mm (about 0.001 inch), and a total wall thickness (through all three layers) of about 0.14 mm (about 0.0055 inch). In another implementation, a sheath has a metal sleeve having a wall thickness of about 0.1 mm (about 0.004 inch) and an inner diameter of about 5.8 mm (about 0.229 inch), an inner polymeric layer having a wall thickness of about 0.06 mm (about 0.0025 inch), an outer polymeric layer having a wall thickness of about 0.025 mm (about 0.001 inch), and a total

wall thickness (through all three layers) of about 0.2 mm (about 0.0075 inch). FIG. 45 shows the cut pattern for forming the metal sleeve 600 of FIG. 43. FIG. 46 shows the cut pattern for forming the metal sleeve 700 of FIG. 44. FIG. 47 shows a cut pattern similar to the cut pattern of FIG. 46, but including cutouts 706 that are narrower than the cutouts shown in FIG. 46.

TABLE 1

Wall thickness of metal sleeve	*Material*	*Minimum bend radius without visual kink*	*Minimum bend radius allowing passage of 16-Fr dilator*
0.1 mm (0.004")	Nitinol	2.5 cm (1")	2.5 cm (1")
0.1 mm (0.004")	Stainless steel	2.5 cm (1")	2.5 cm (1")
0.1 mm (0.002")	Nitinol	15 cm (6")	2.5 cm (1")
0.05 mm (0.002")	Stainless steel	15 cm (6")	2.5 cm (1")
0.05 mm (0.002")	Stainless steel (wide rings)	5 cm (2")	2.5 cm (1")

[0139] Table 1 above demonstrates the bend performance of several metal sleeves. Each metal sleeve had an inner diameter of about 5.8 mm (about 0.229 inch). Each sleeve was formed with the cut pattern shown in FIG. 44, except for the last sleeve in Table 1, which was formed with the cut pattern shown in FIG. 43. All of the sleeves in Table 1 provide device deliverability at a relatively small bend radius (2.5 cm, 1 inch). Furthermore, it was found that the metal sleeves recover their circular cross-sectional shapes even after passing a delivery device through a visibly kinked section of the sleeve.

[0140] In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only preferred examples and should not be taken as limiting the scope of the disclosure. Moreover, additional embodiments are disclosed in U.S. Patent Application Publication No. 2010/0049313 (U.S. Patent Application No. 12/429,040) and U.S. Patent Application Publication No. 2012/0239142 (U.S. Patent Application No. 13/405,119), each of which is incorporated herein by reference. Accordingly, the scope of the disclosure is defined by the following claims. We therefore claim all that comes within the scope and spirit of these claims.

WHAT IS CLAIMED IS:

1. A prosthetic heart valve, comprising:

a collapsible and expandable annular frame that is configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body, the frame having an inflow end, an outflow end, and a longitudinal axis extending from the inflow end to the outflow end, the frame comprising a plurality of struts defining a plurality of rows of a plurality of cells;

a collapsible and expandable valve member mounted within the annular frame; and

a collapsible and expandable sealing skirt mounted on the annular frame, wherein the sealing skirt comprises a pile fabric and can contact tissue surrounding the prosthetic valve when the prosthetic valve is implanted within a native valve annulus.

2. The prosthetic heart valve of claim 1, wherein the pile fabric is made of loop yarn.

3. The prosthetic heart valve of claim 2, wherein the loop yarn comprises polyethylene terephthalate loop yarn.

4. The prosthetic heart valve of claim 1, wherein the sealing skirt is sutured to the struts of the frame.

5. The prosthetic heart valve of claim 1, wherein the sealing skirt extends beyond the inflow end of the prosthetic heart valve.

6. The prosthetic heart valve of claim 1, wherein the struts of the frame are arranged in a plurality of circumferentially extending rows of struts, and wherein the sealing skirt comprises an upper edge and a lower edge, wherein the upper edge has an undulating shape that corresponds to one of the circumferentially extending rows of struts and the lower edge is straight.

7. The prosthetic heart valve of claim 1, wherein the sealing skirt covers an entirety of a row of cells at the inflow end of the frame.

8. The prosthetic heart valve of claim 1, further comprising an additional fabric skirt positioned radially outward from the valve member and radially inward from the sealing skirt.

9. The prosthetic heart valve of claim 8, wherein the valve member comprises a plurality of leaflets, each having an inflow end portion sutured to the additional fabric skirt along a scalloped shaped suture line.

10. The prosthetic heart valve of claim 9, wherein the sealing skirt covers an entirety of a row of cells at the inflow end of the frame and wherein the additional fabric skirt covers an entirety of another row of cells above an upper edge of the sealing skirt.

11. The prosthetic heart valve of claim 1, wherein the pile fabric is made of textured yarn.

12. A prosthetic heart valve, comprising:

a collapsible and expandable annular frame that is configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body, the frame having an inflow end, an outflow end, and a longitudinal axis extending from the inflow end to the outflow end, the frame comprising a plurality of struts defining a plurality of rows of a plurality of cells;

a collapsible and expandable valve member mounted within the annular frame, wherein the valve member comprises a plurality of leaflets;

a collapsible and expandable first fabric skirt sutured to the struts of the frame, wherein each leaflet has an inflow end portion sutured to the first fabric skirt along a scalloped shaped suture line; and

a collapsible and expandable second fabric skirt positioned radially outward from the first fabric skirt, wherein the second fabric skirt comprises a pile fabric and can contact tissue

surrounding the prosthetic valve when the prosthetic valve is implanted within a native valve annulus.

13. The prosthetic heart valve of claim 12, wherein the pile fabric is made of loop yarn.

14. The prosthetic heart valve of claim 13, wherein the loop yarn comprises polyethylene terephthalate loop yarn.

15. The prosthetic heart valve of claim 12, wherein the struts of the frame are arranged in a plurality of circumferentially extending rows of struts, including a first row of struts and a second row of struts positioned above the first row of struts, and wherein the second fabric skirt comprises an upper edge and a lower edge, wherein the upper edge has an undulating shape that corresponds to the first rows of struts and the lower edge is straight.

16. The prosthetic heart valve of claim 15, wherein the first fabric skirt comprises an upper edge and a lower edge, wherein the upper edge of the first fabric skirt has an undulating shape that corresponds to the second row of struts.

17. The prosthetic heart valve of claim 16, wherein the second fabric skirt covers an entirety of a row of cells at the inflow end of the frame.

18. The prosthetic heart valve of claim 17, wherein the first fabric skirt covers an entirety of a row of cells defined between the first and second row of struts.

19. A prosthetic heart valve, comprising:

a collapsible and expandable annular frame that is configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body, the frame having an inflow end, an outflow end, and a longitudinal axis extending from the inflow end to the outflow end, the frame comprising a plurality of circumferentially extending rows of struts defining a plurality of rows of a

plurality of cells, wherein the rows of struts include a first row of struts and a second row of struts positioned above the first row of struts;

a collapsible and expandable valve member mounted within the annular frame, wherein the valve member comprises a plurality of leaflets;

a collapsible and expandable first fabric skirt comprising an upper edge and a lower edge, wherein the upper edge of the first fabric skirt has an undulating shape that corresponds to first row of struts, wherein the upper edge of the first fabric skirt is sutured to the struts of the first row of struts, wherein each leaflet has an inflow end portion sutured to the first fabric skirt along a scalloped shaped suture line; and

a collapsible and expandable second fabric skirt positioned radially outward from the first fabric skirt, wherein the second fabric skirt comprises an upper edge and a lower edge, wherein the upper edge of the second fabric skirt has an undulating shape that corresponds to the second row of struts, wherein the upper edge of the second fabric skirt is sutured to the struts of the second row of struts, wherein the second fabric skirt comprises a pile fabric made of loop yarn and can contact tissue surrounding the prosthetic valve when the prosthetic valve is implanted within a native valve annulus.

PROSTHETIC HEART VALVE

ABSTRACT

The present disclosure is directed to embodiments of catheter-based prosthetic heart valves, and in particular, prosthetic heart valves having sealing members configured to seal the interface between the prosthetic valve and the surrounding tissue of the native annulus in which the prosthetic valve is implanted. In one embodiment, a prosthetic heart valve includes a collapsible and expandable annular frame, a collapsible and expandable valve member mounted within the annular frame, and a collapsible and expandable sealing skirt mounted on the annular frame, wherein the sealing skirt is a pile fabric and can contact tissue surrounding the prosthetic valve when the prosthetic valve is implanted within a native valve annulus.

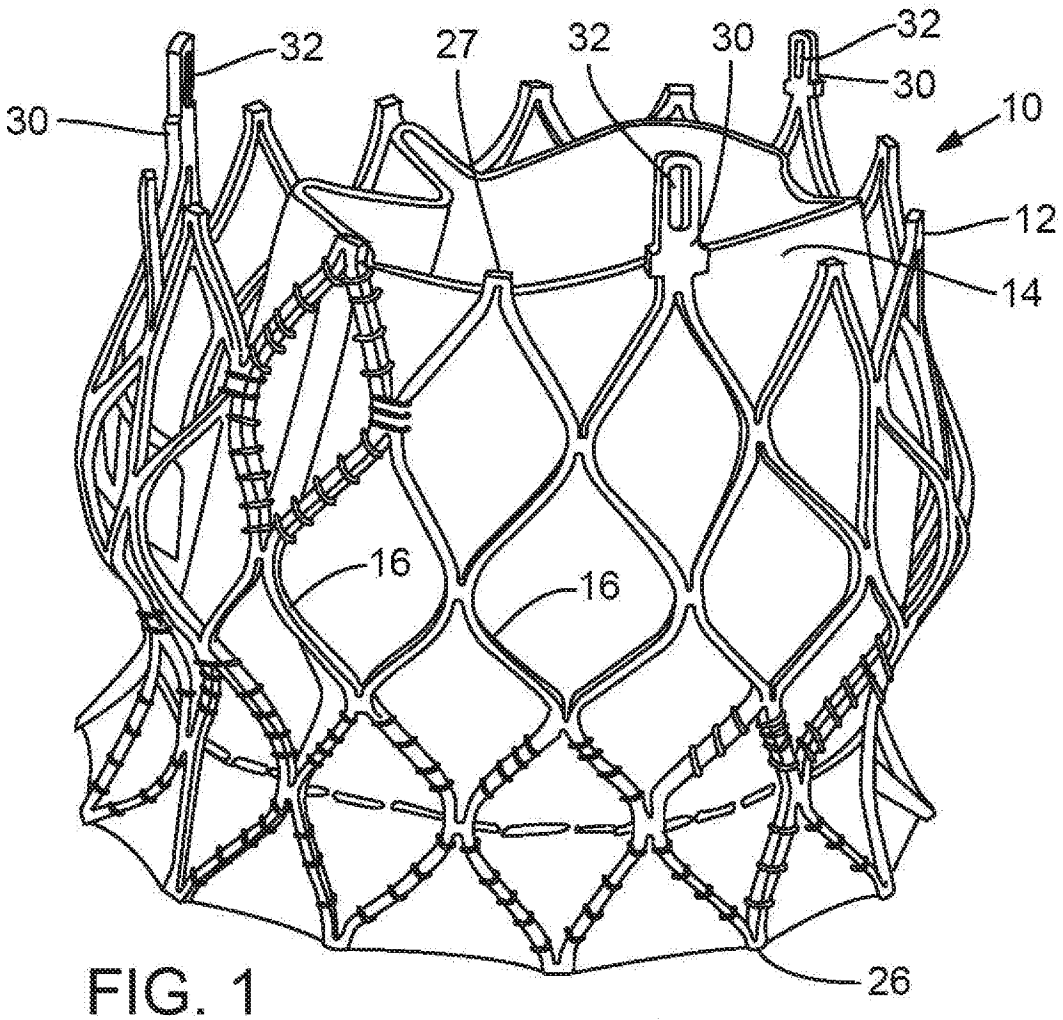


FIG. 1

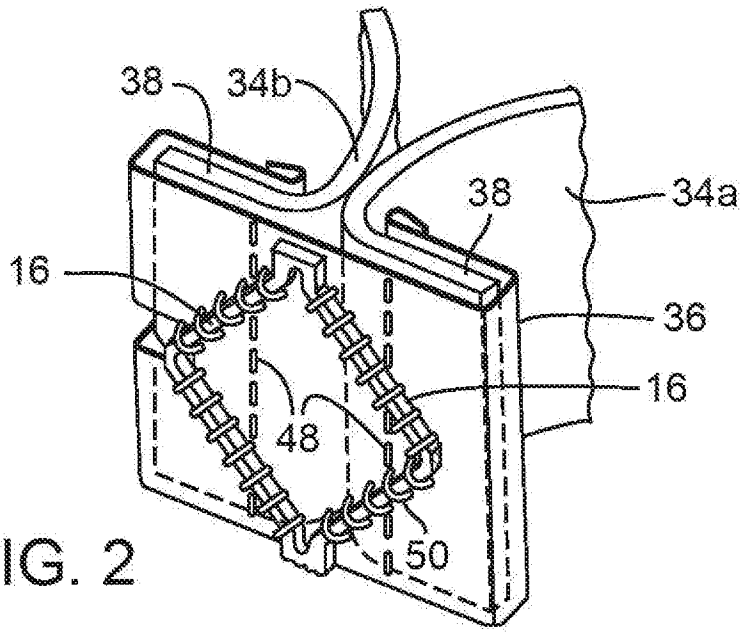


FIG. 2

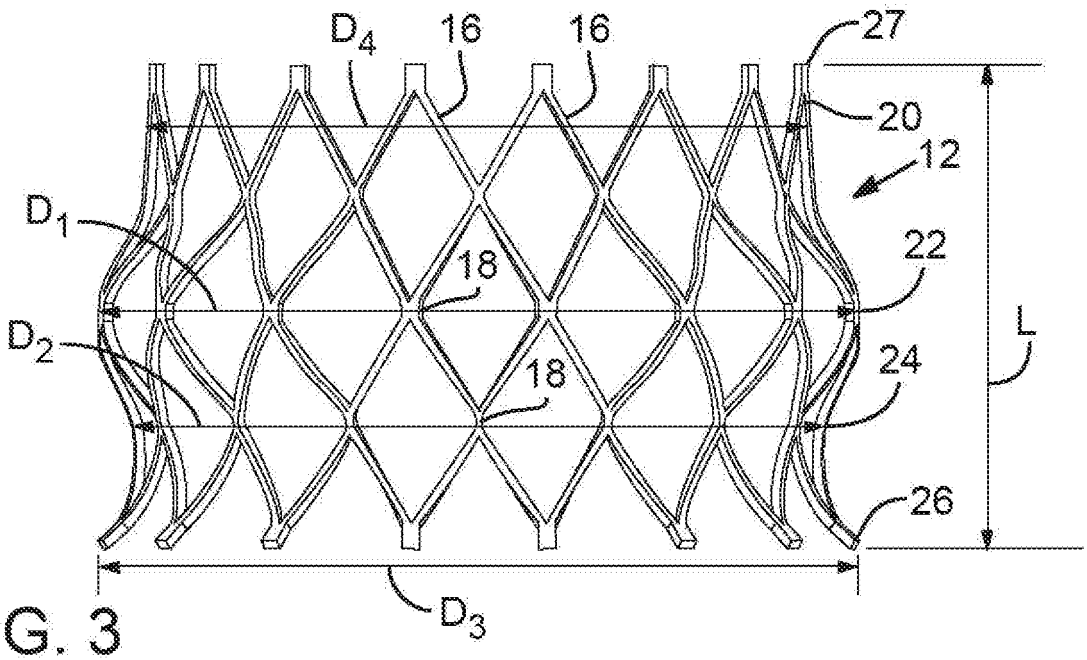


FIG. 3

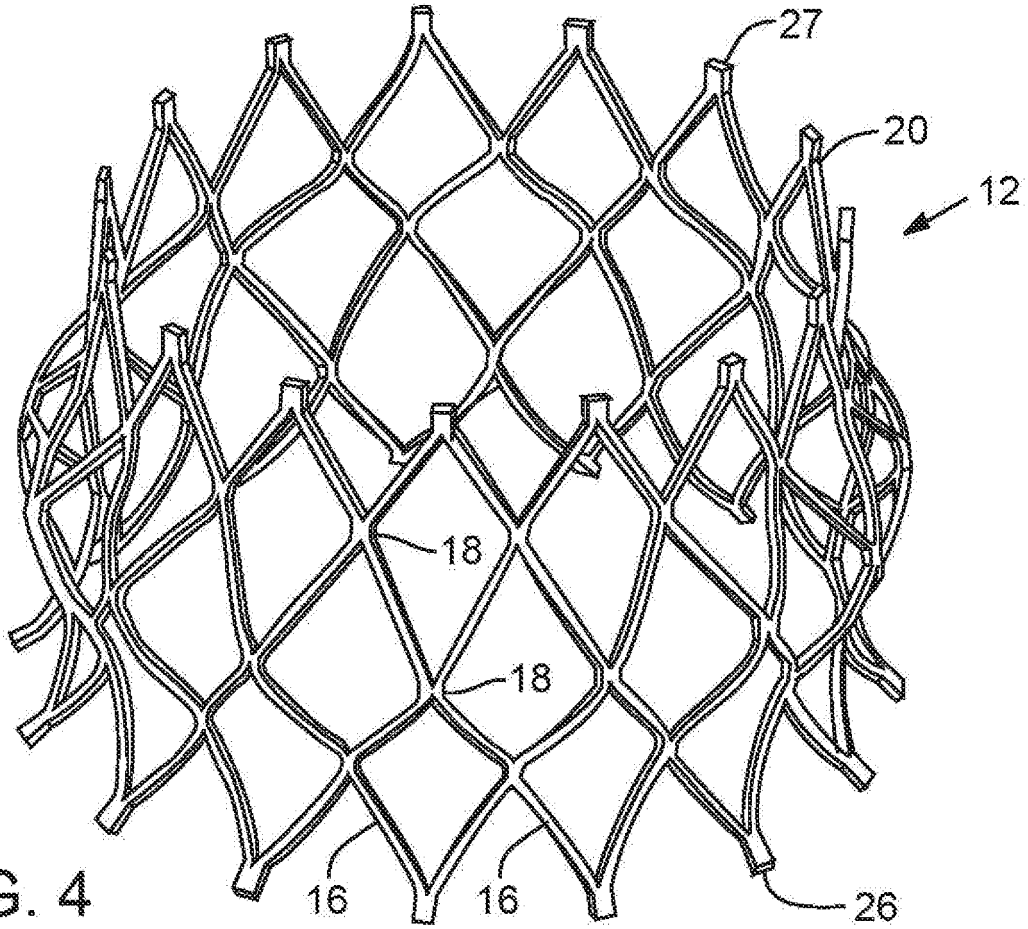


FIG. 4

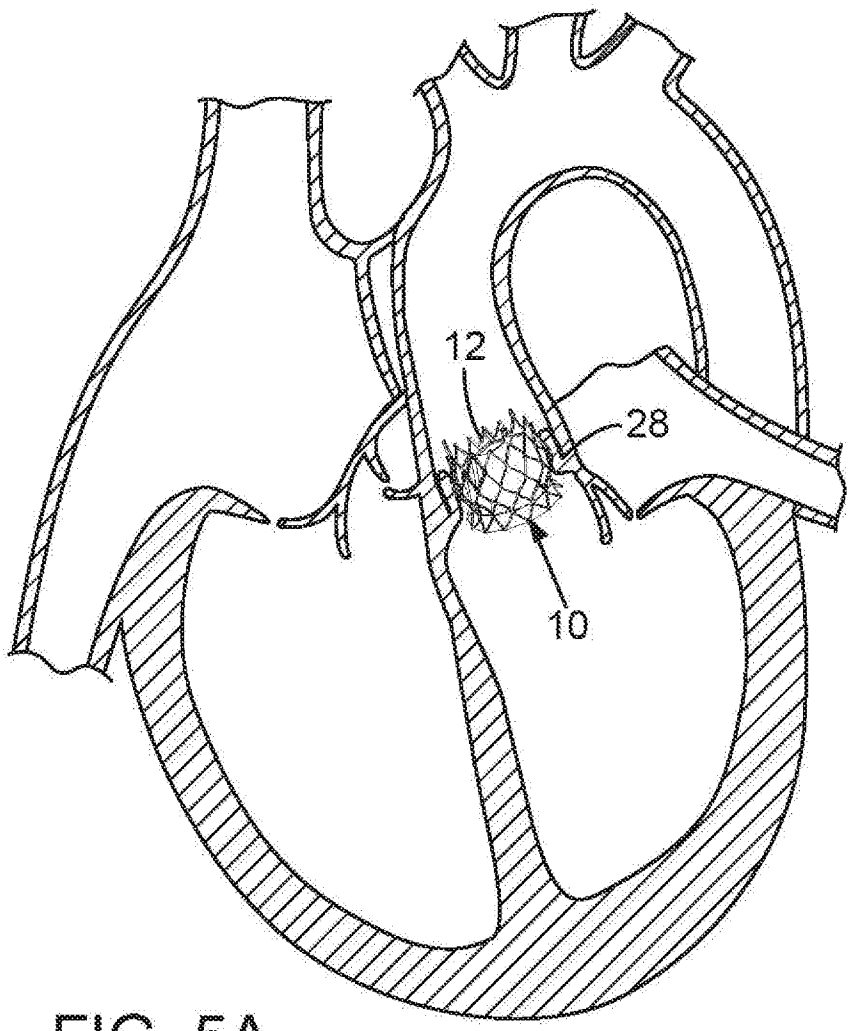


FIG. 5A

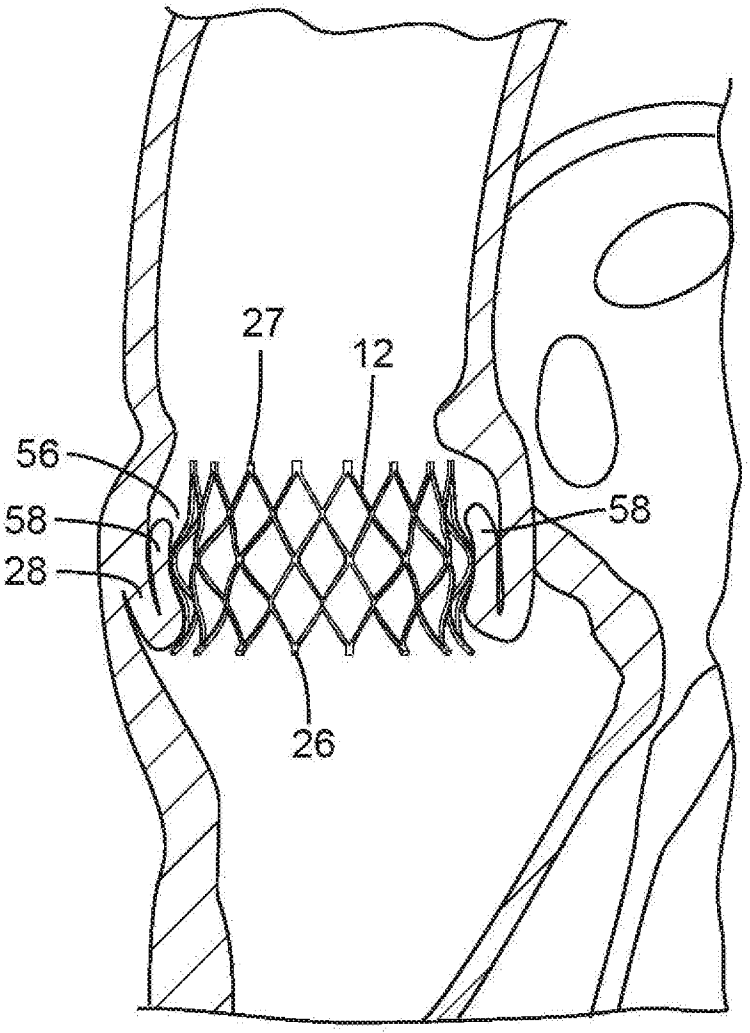


FIG. 5B

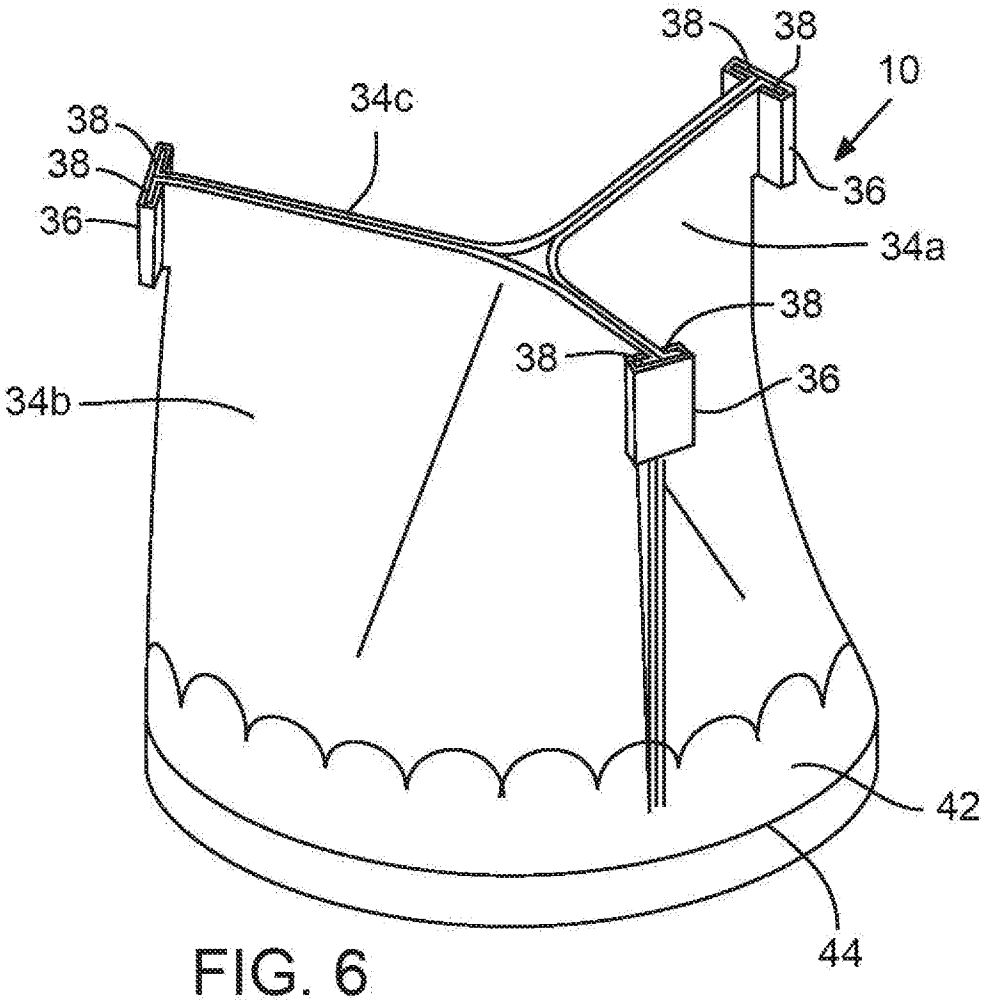

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FIG. 6

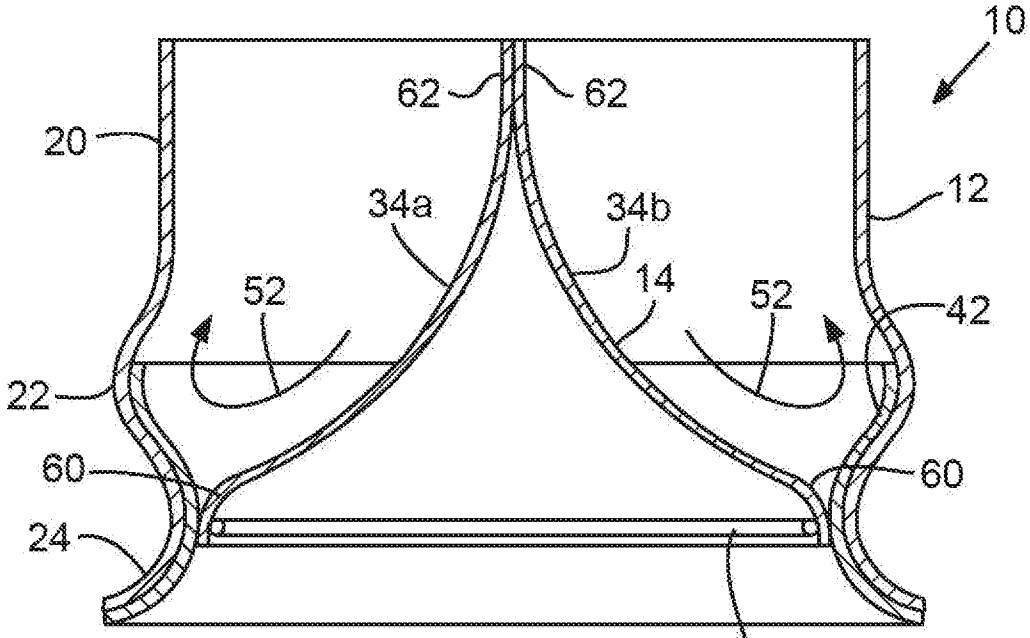

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FIG. 7

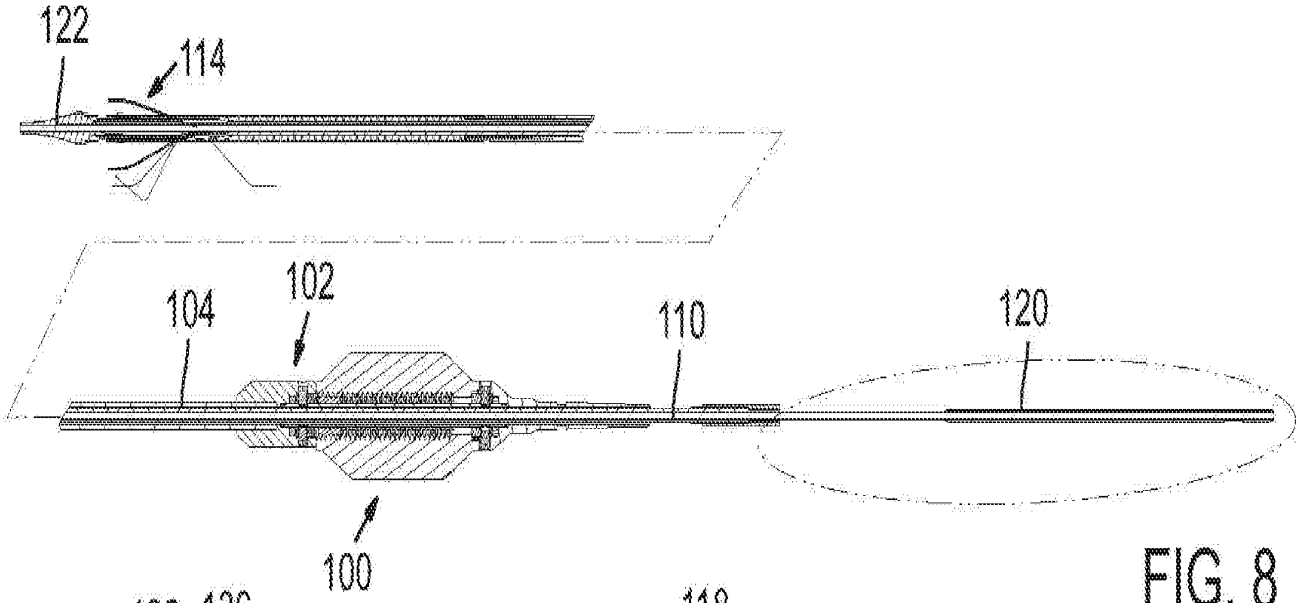


FIG. 8

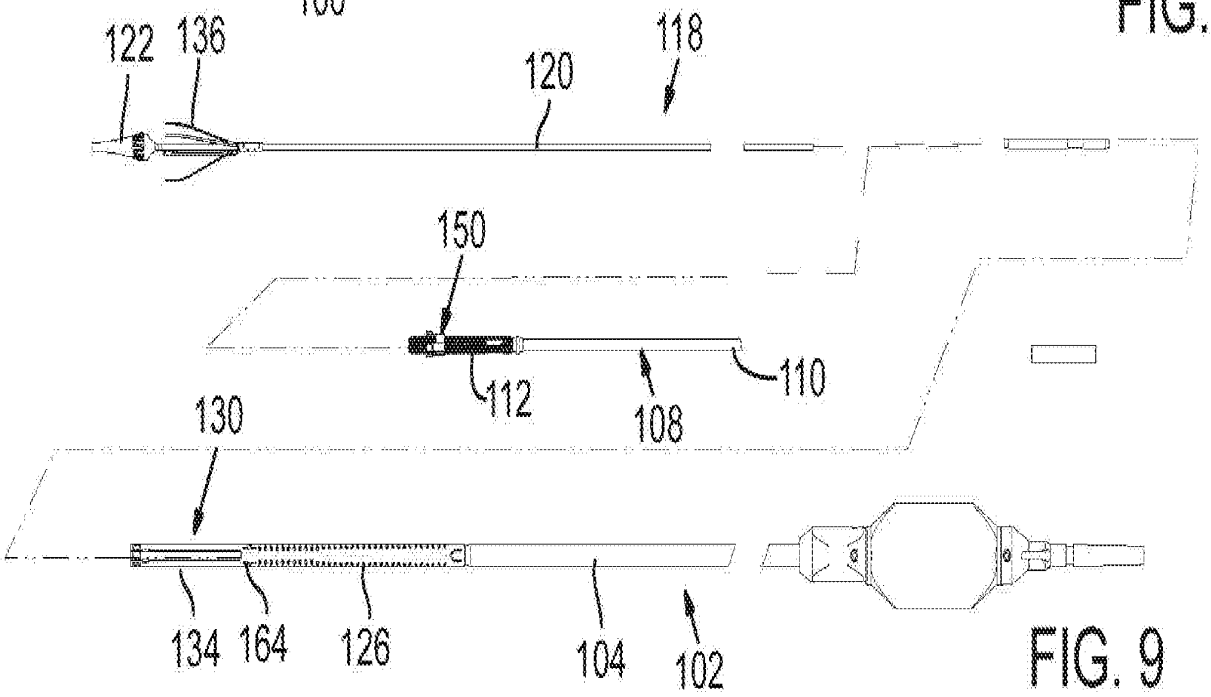


FIG. 9

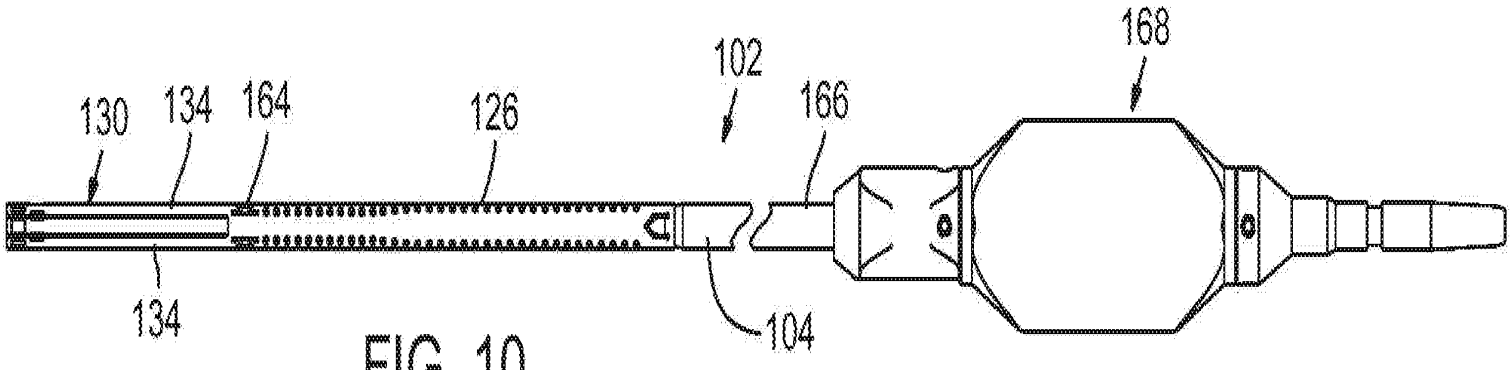


FIG. 10

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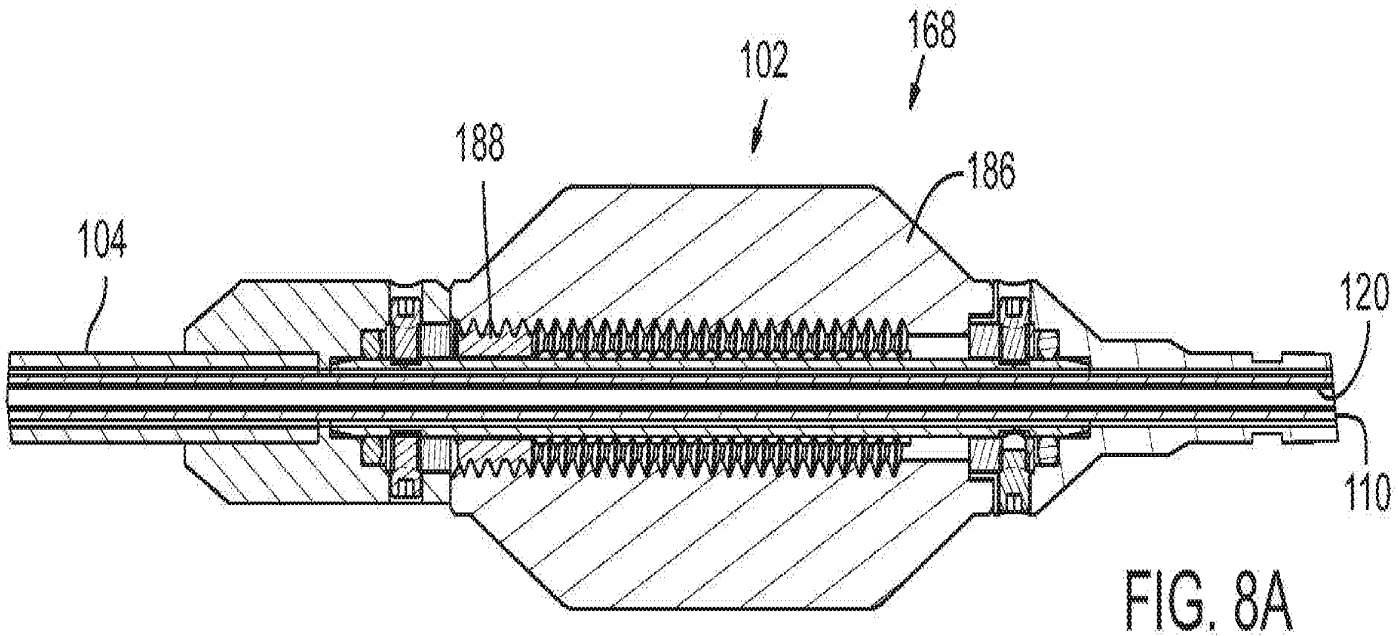


FIG. 8A

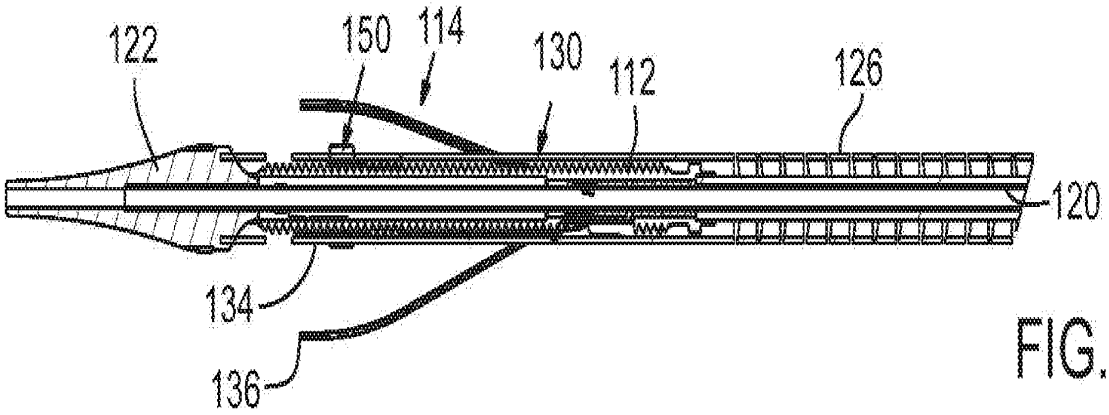


FIG. 8B

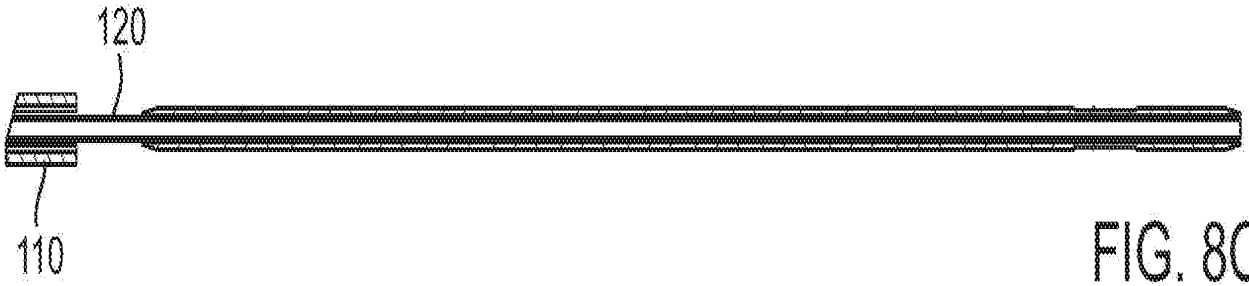


FIG. 8C

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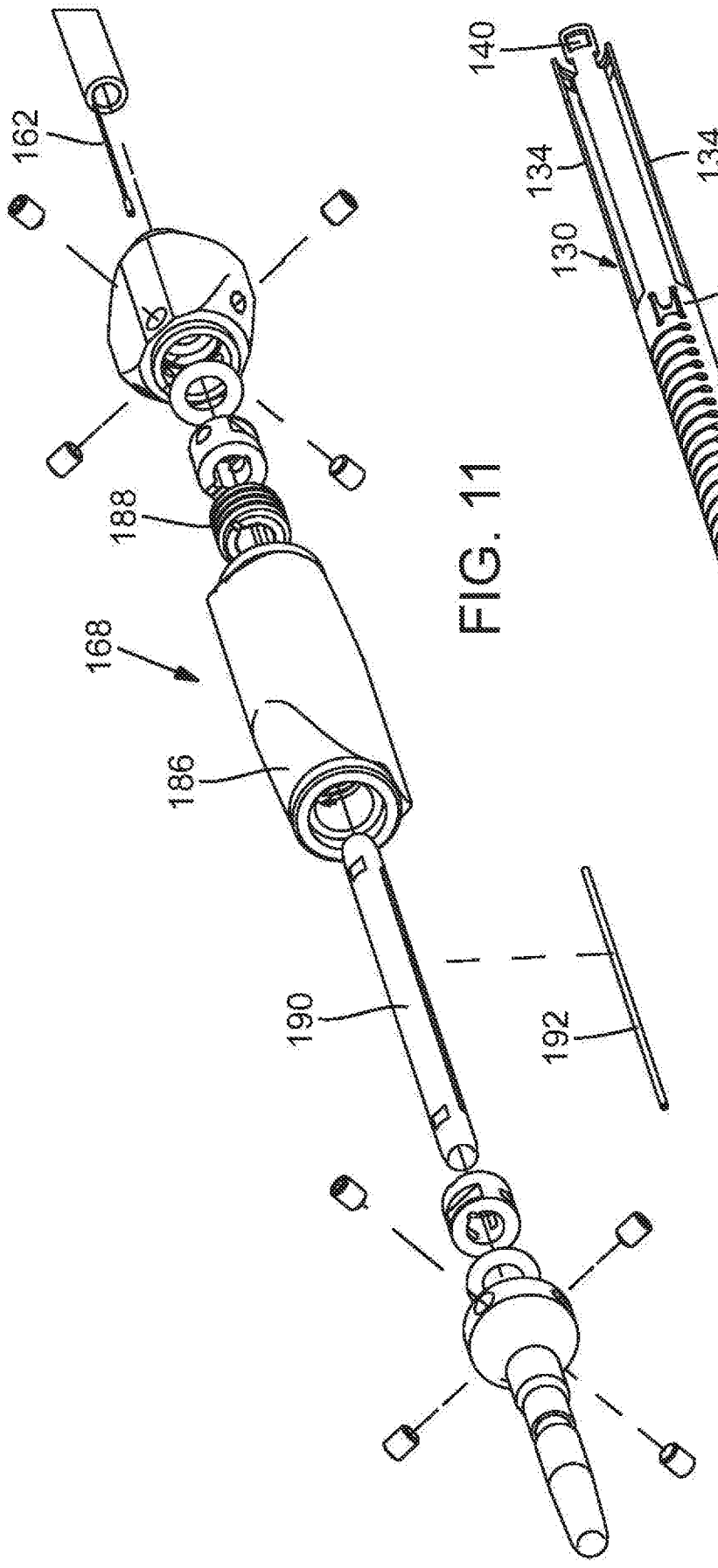


FIG. 11

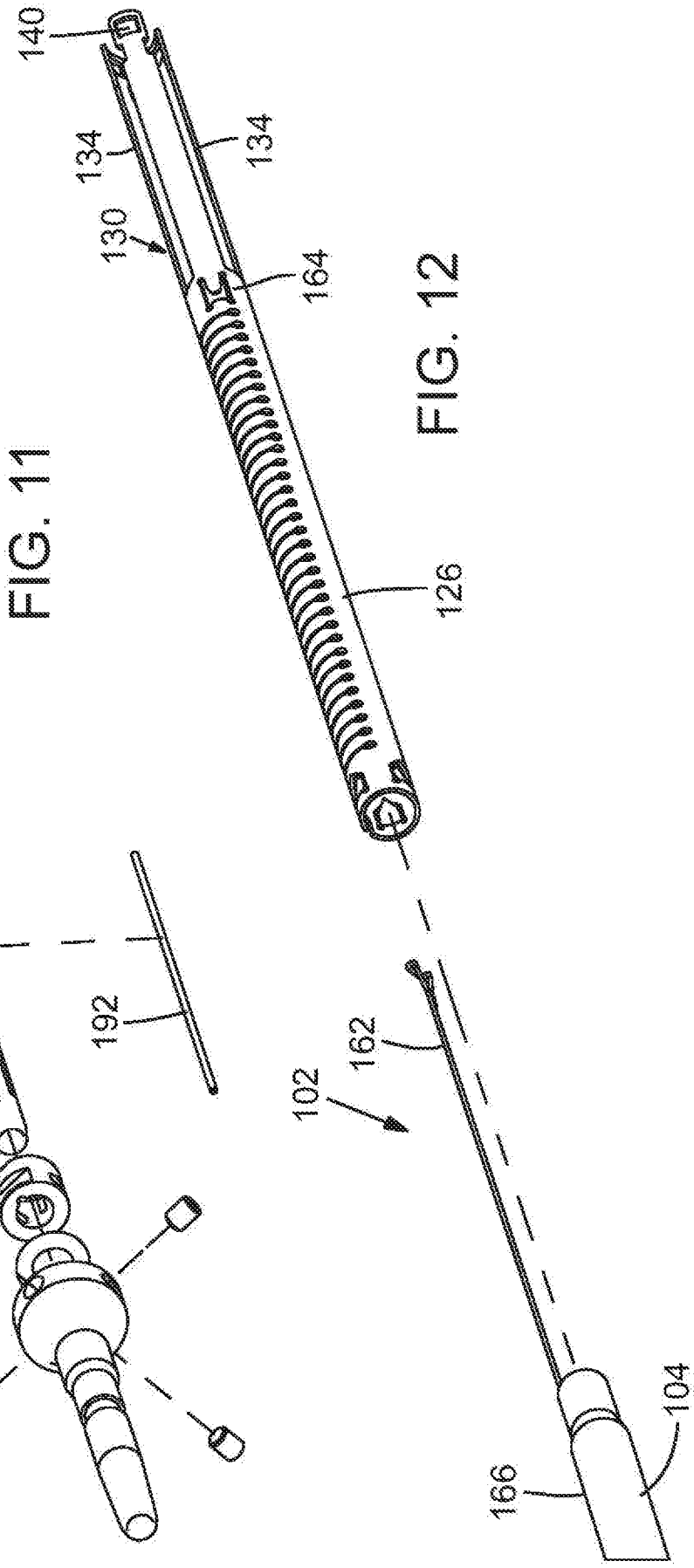


FIG. 12

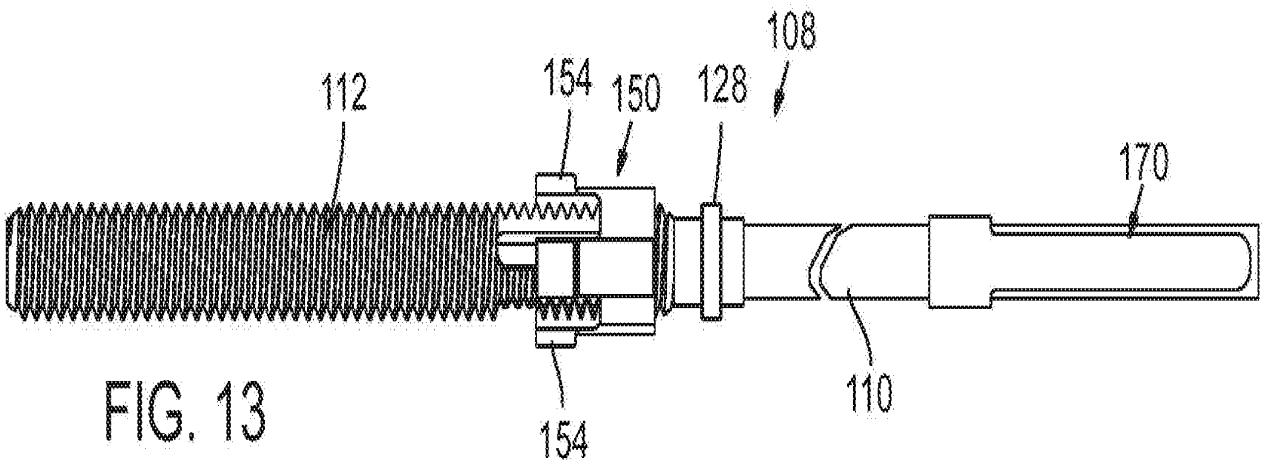


FIG. 13

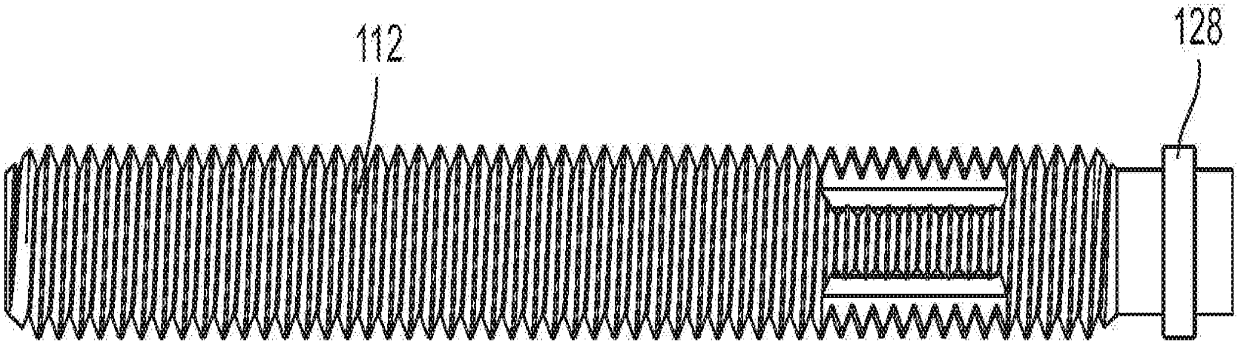


FIG. 14

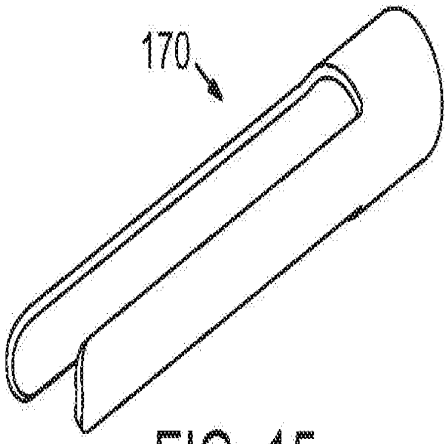


FIG. 15

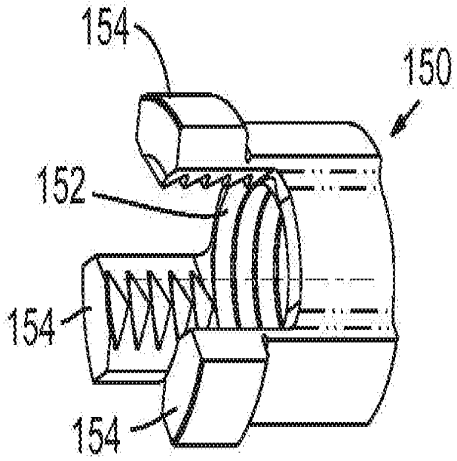


FIG. 16

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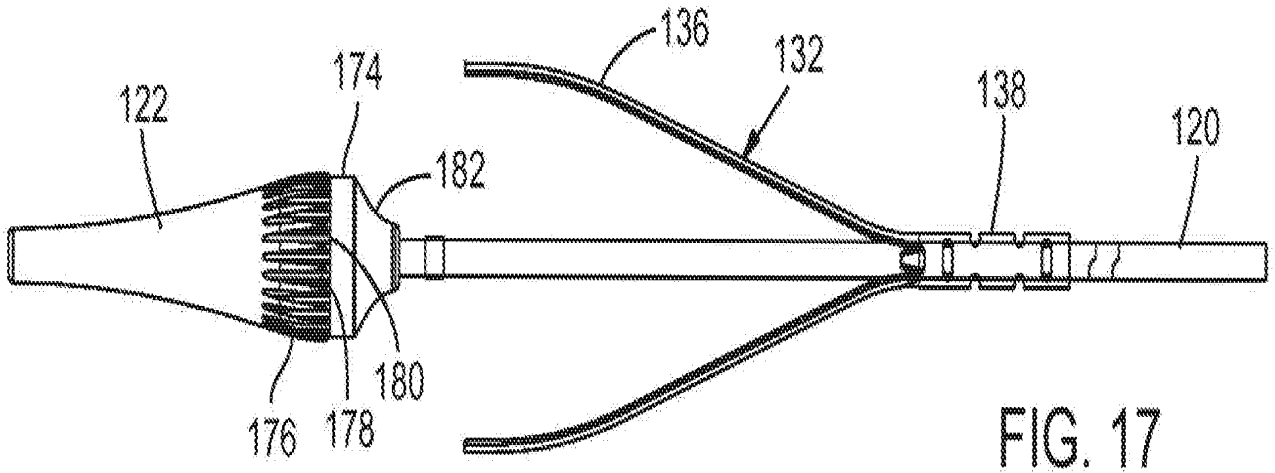


FIG. 17

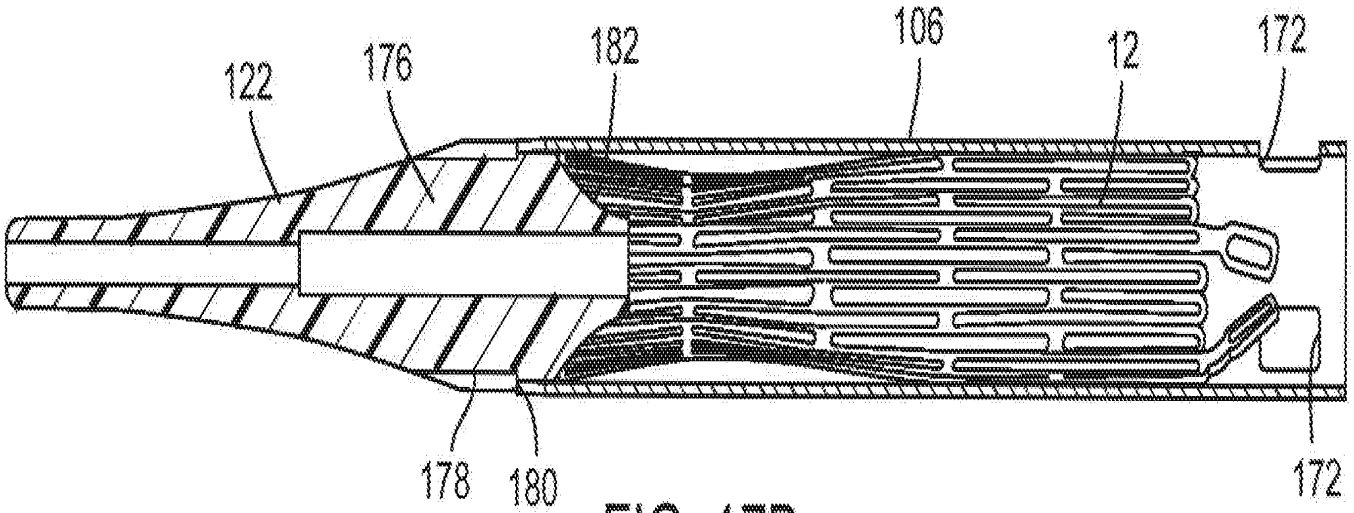


FIG. 17B

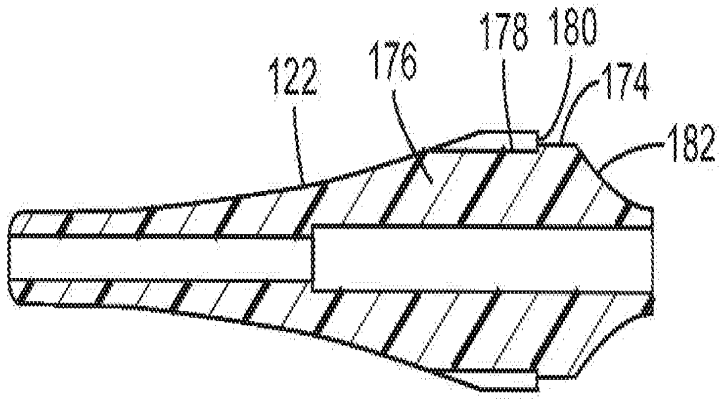


FIG. 17A

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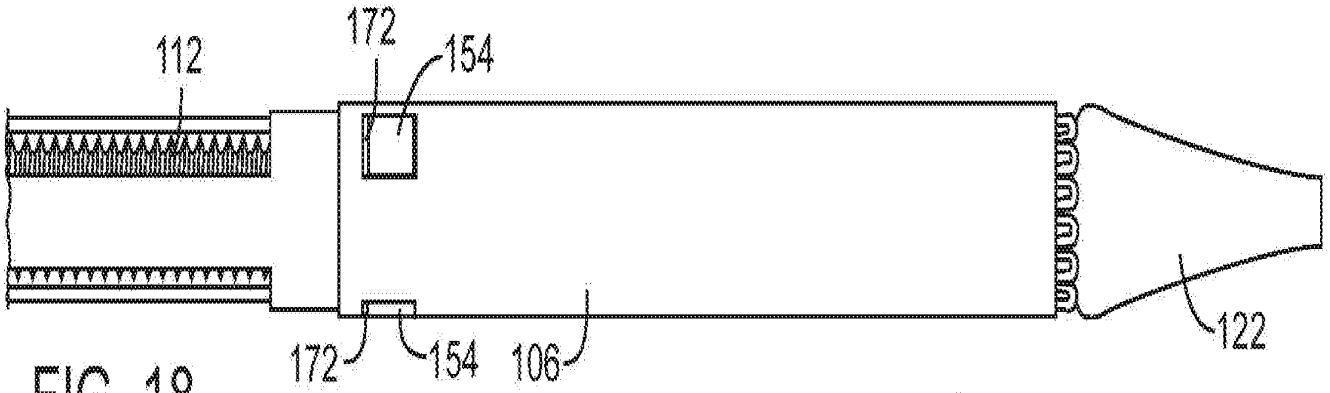


FIG. 18

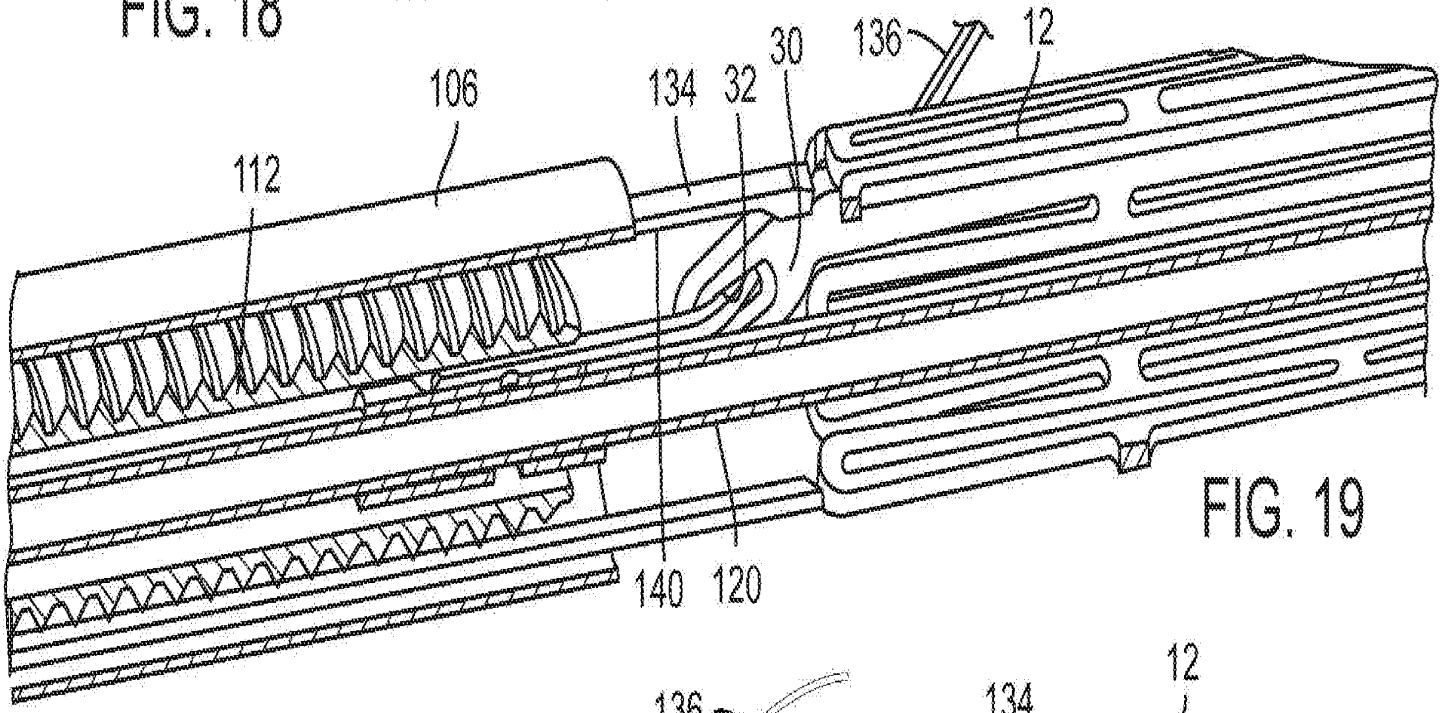


FIG. 19

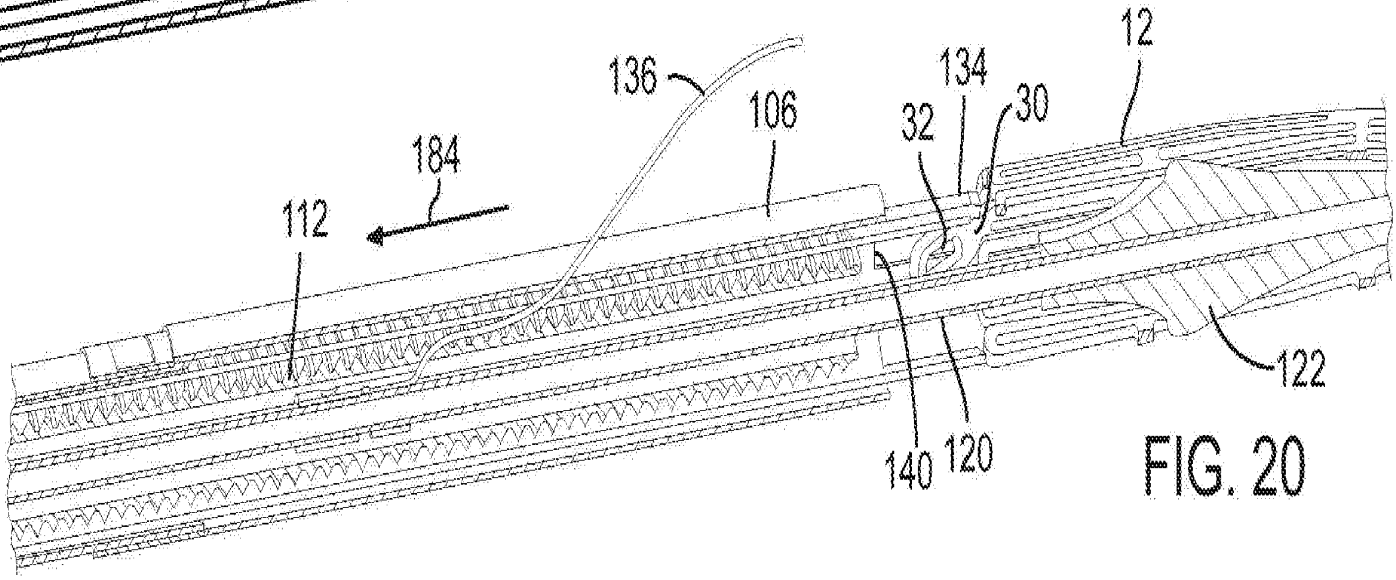


FIG. 20

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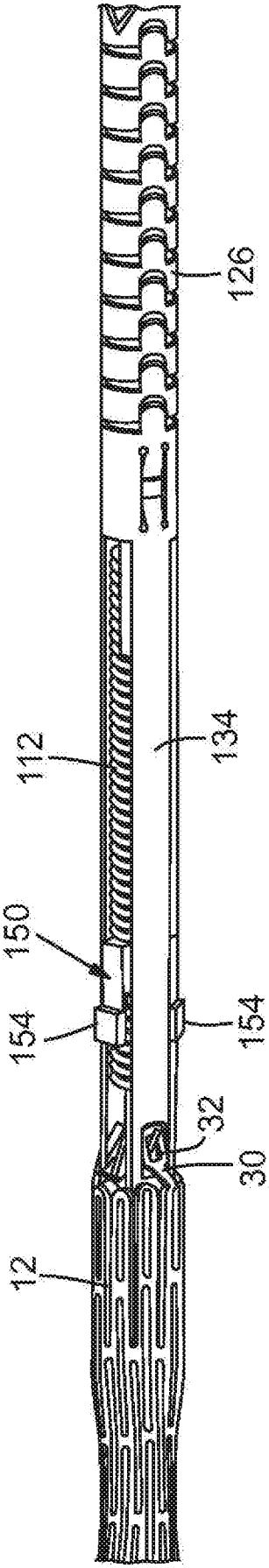

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FIG. 21

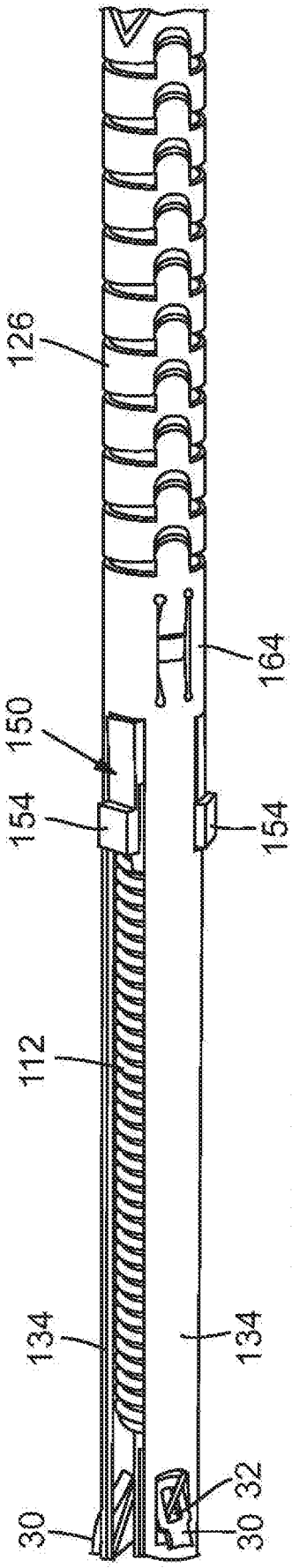

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FIG. 22

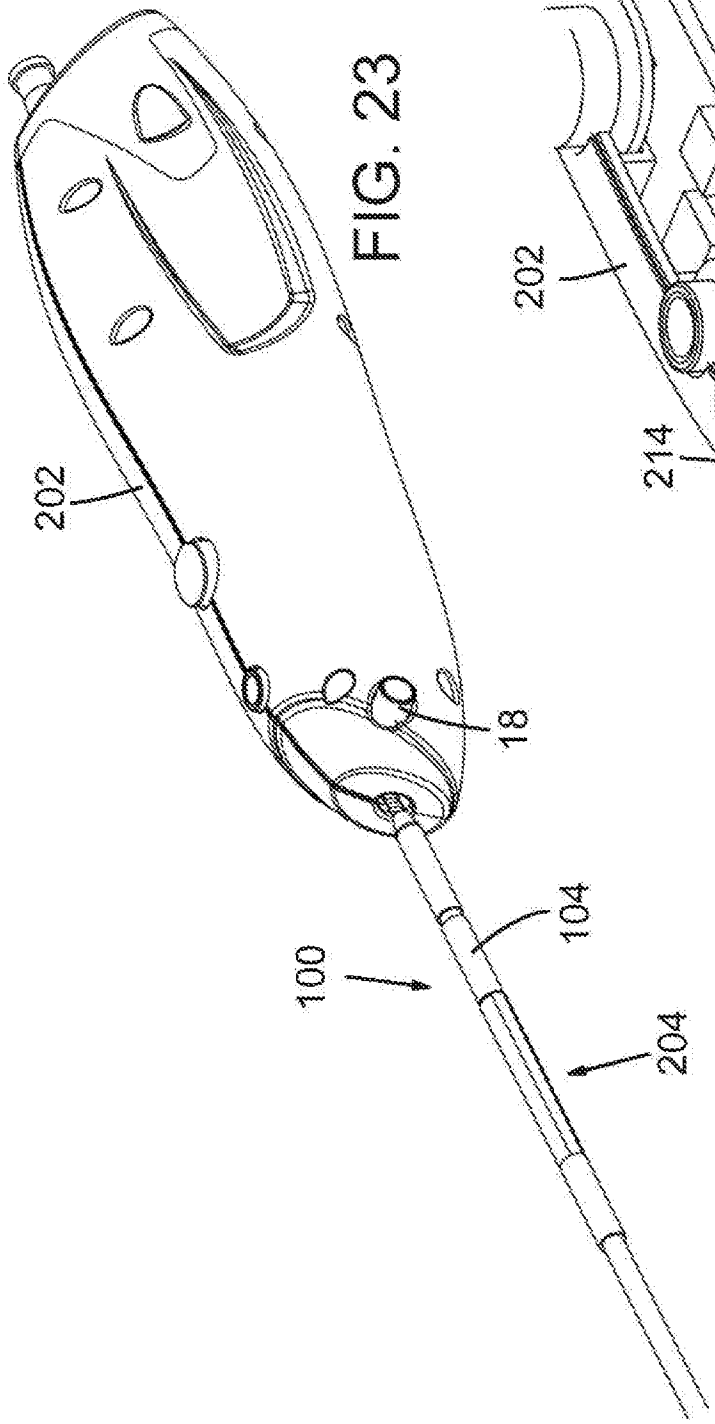


FIG. 23

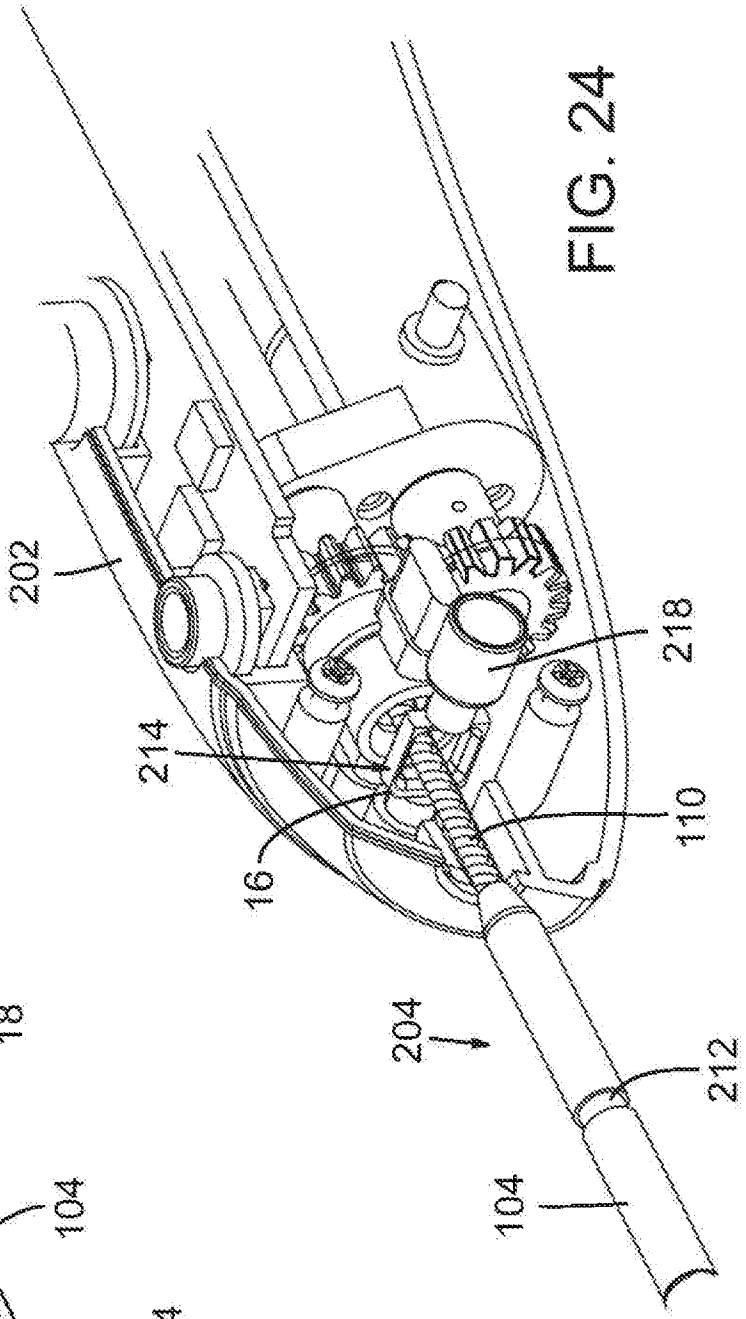


FIG. 24

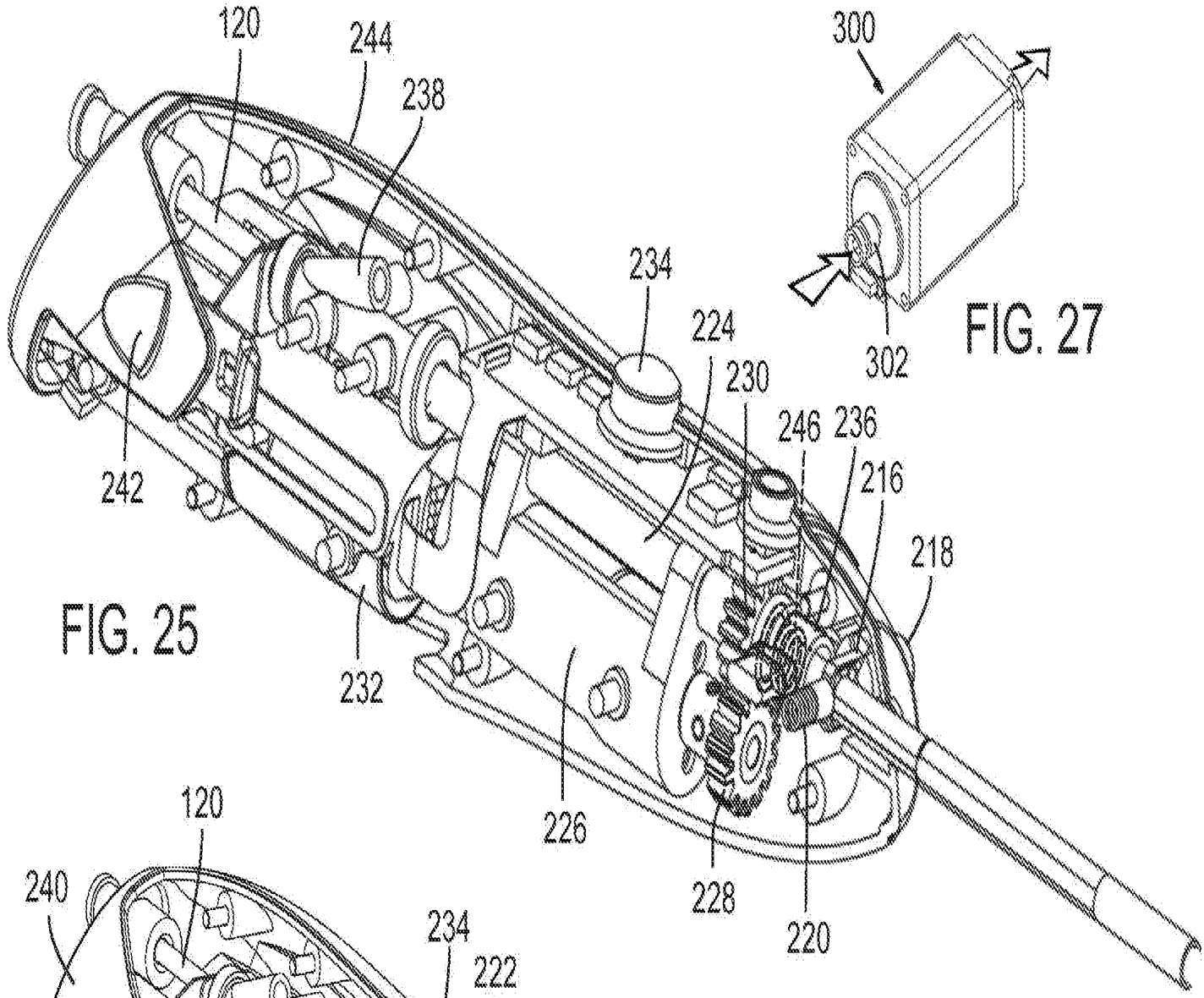


FIG. 25

FIG. 27

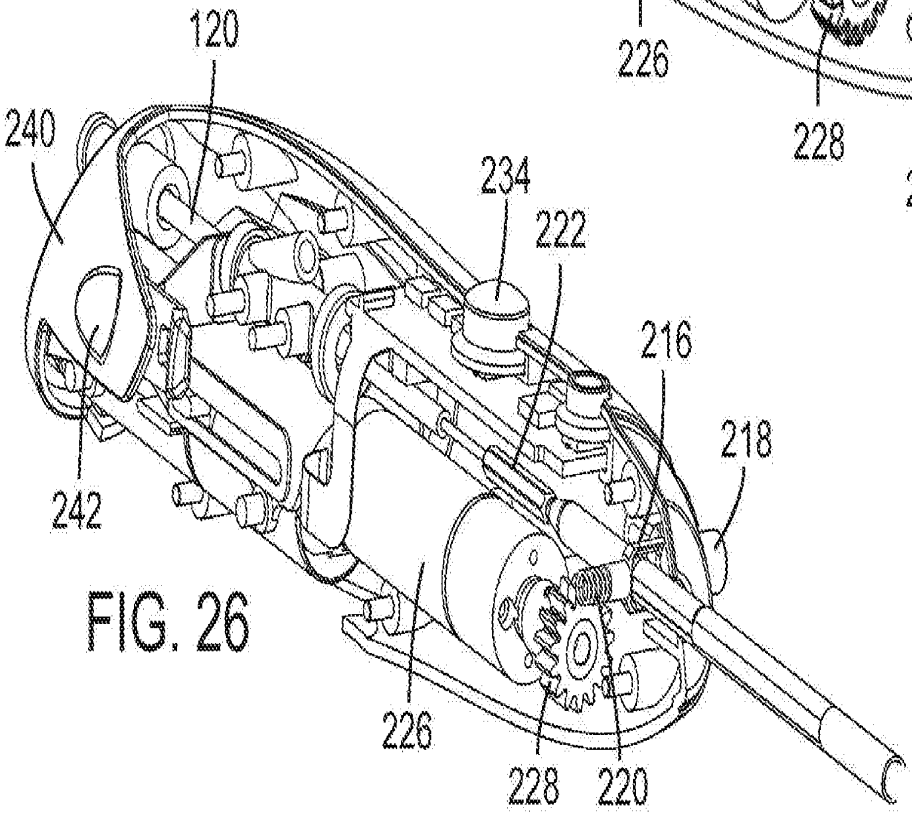


FIG. 26

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14/23

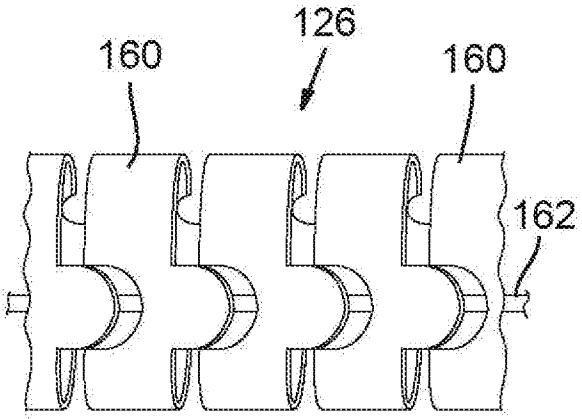


FIG. 28A

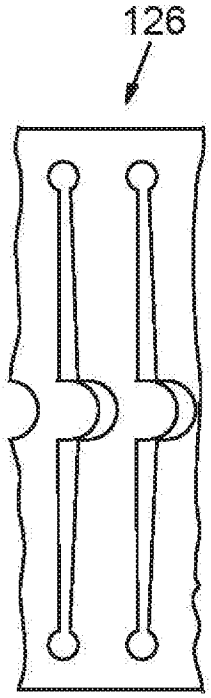


FIG. 28B

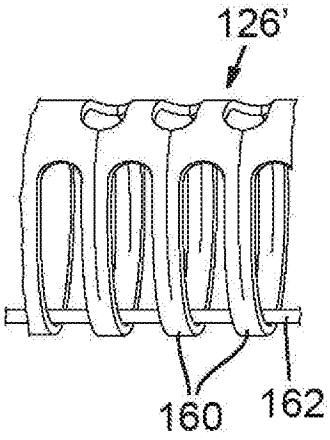


FIG. 29A

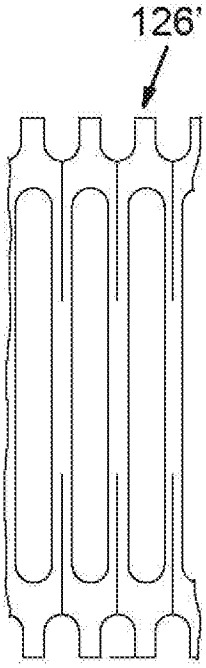


FIG. 29B

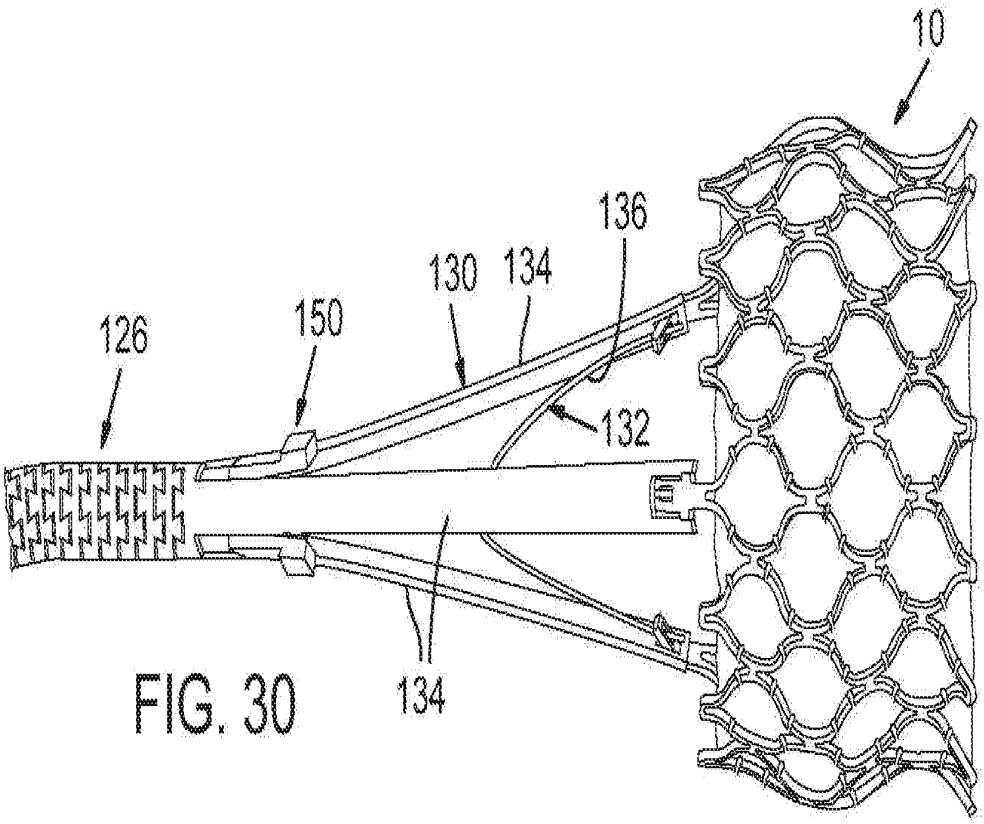


FIG. 30

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16/23

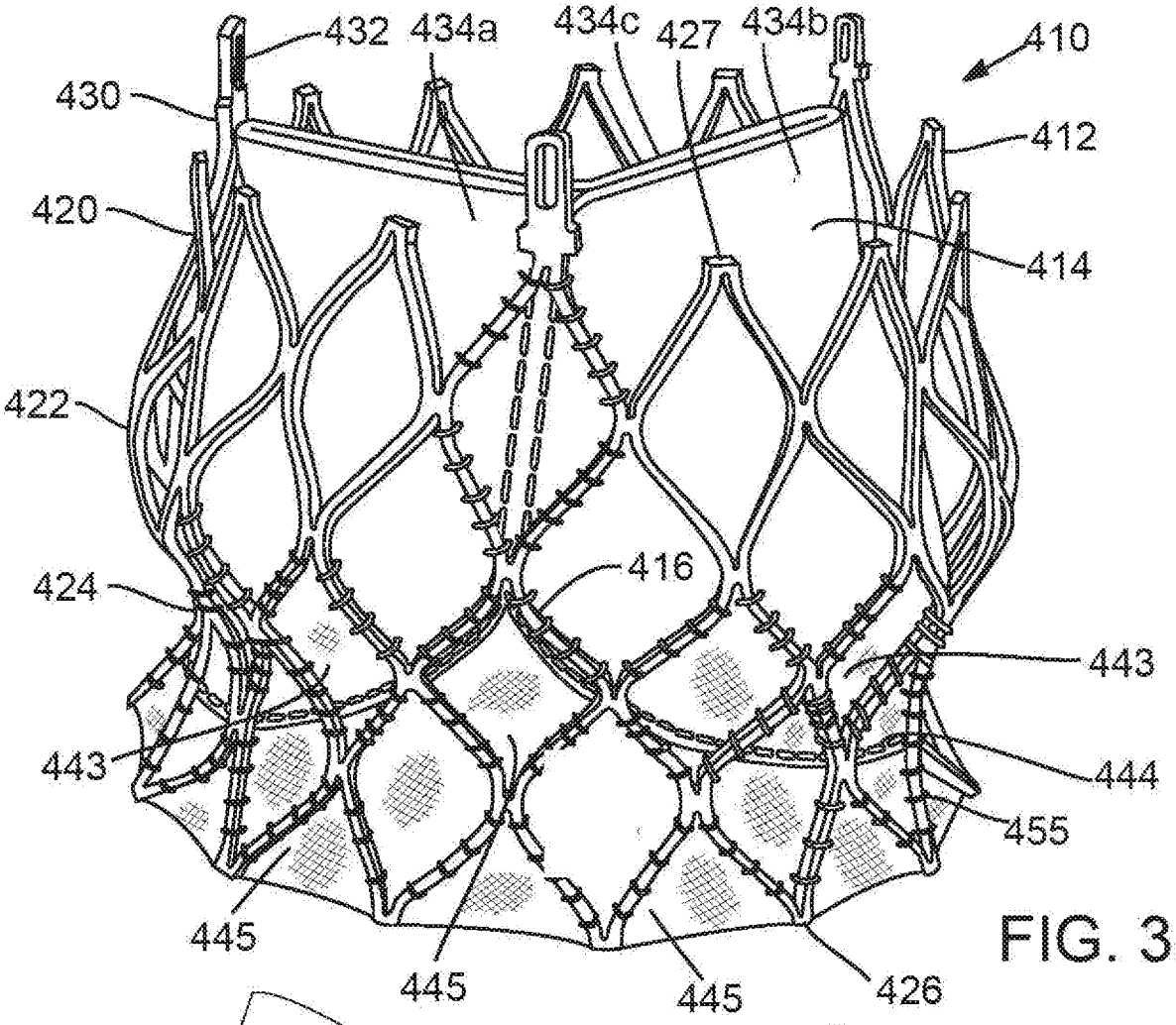

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FIG. 31

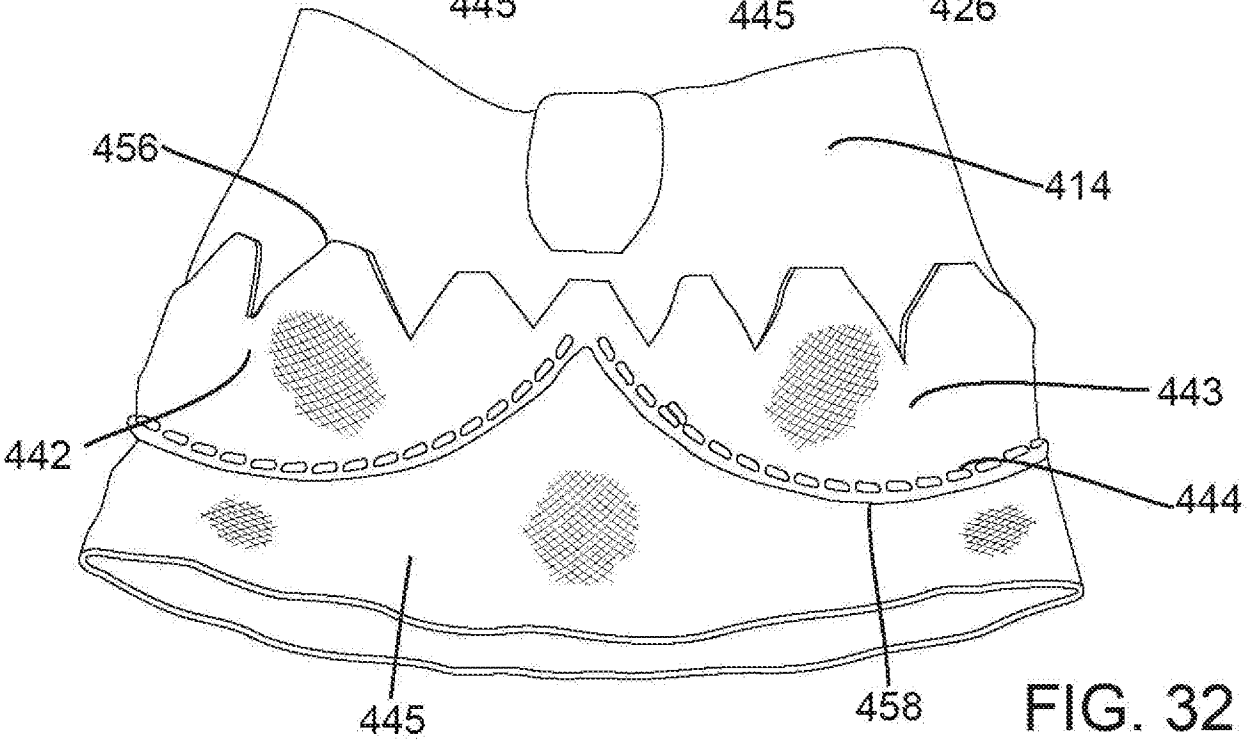

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FIG. 32

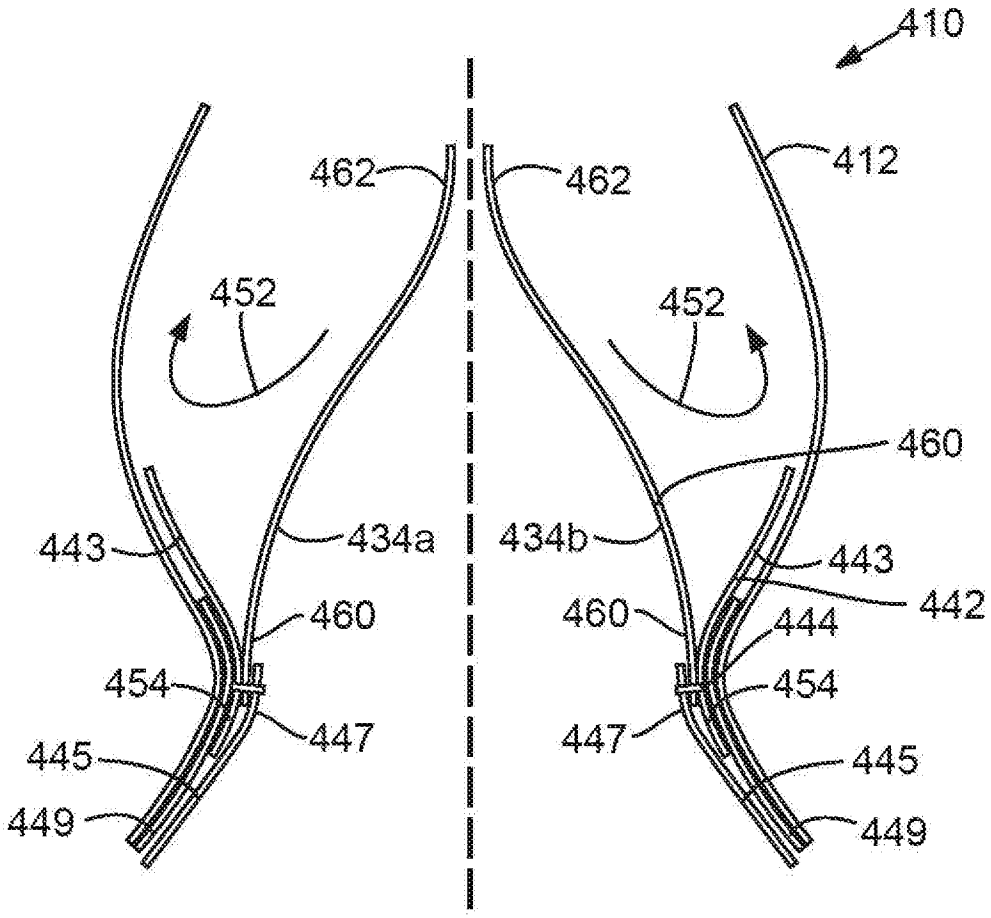

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FIG. 33

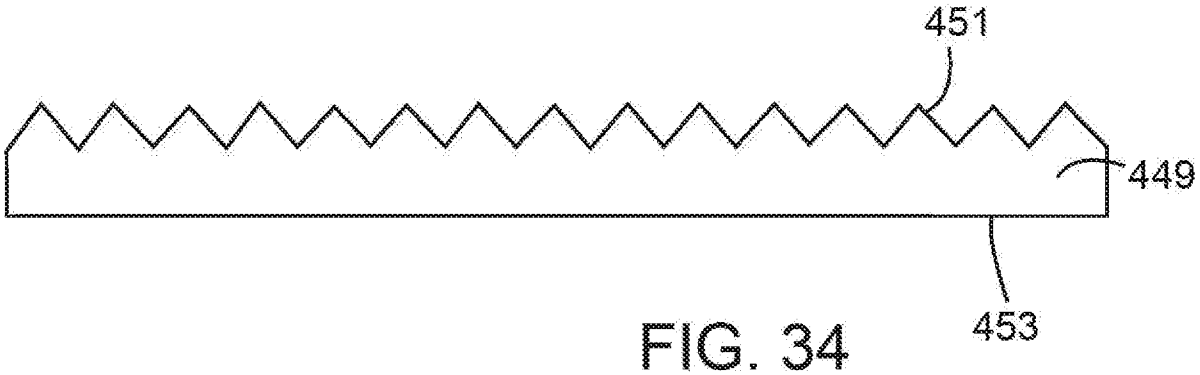

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FIG. 34

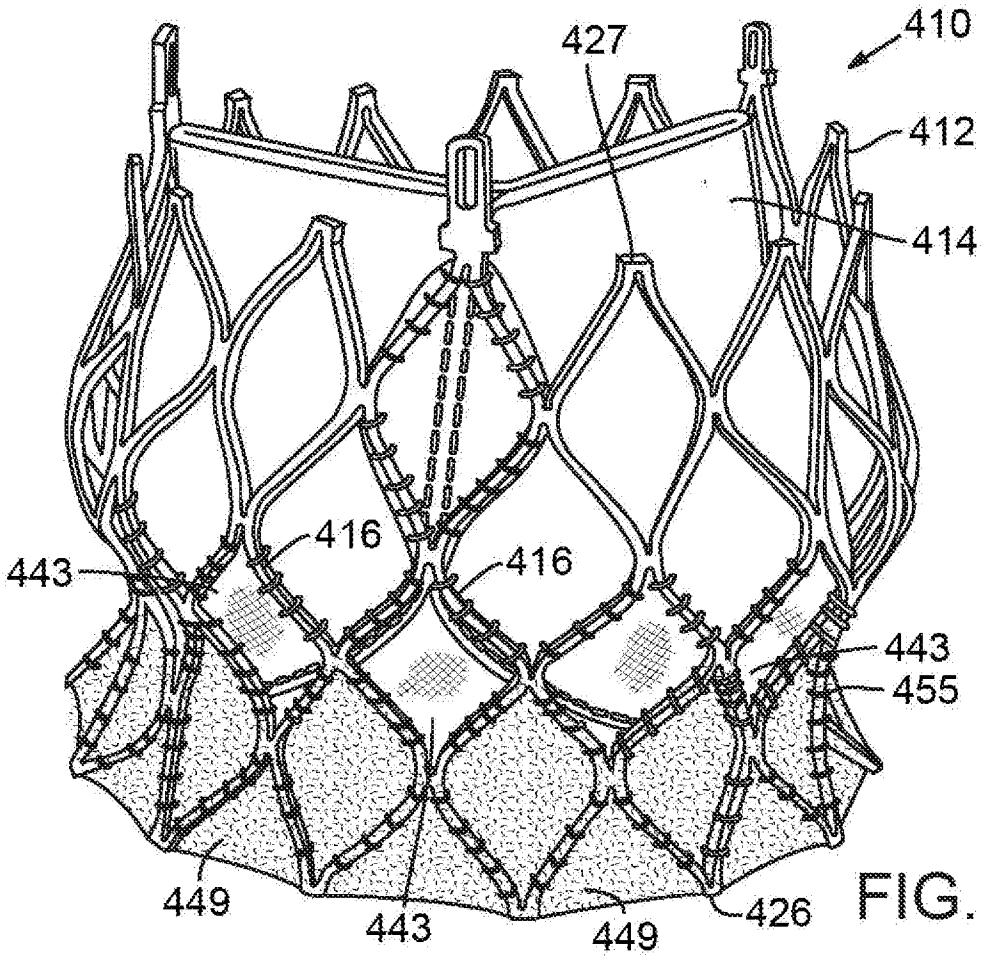


FIG. 35

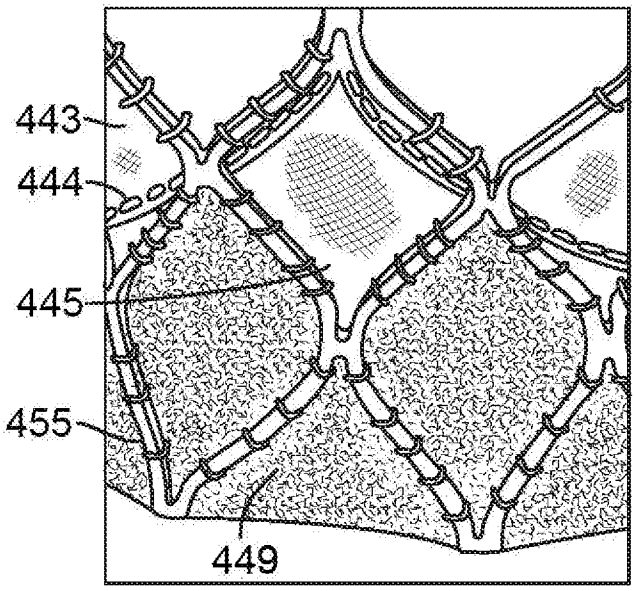


FIG. 36

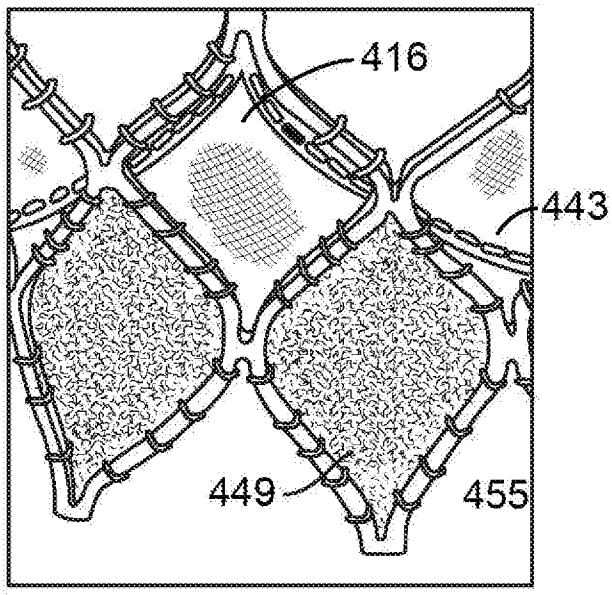


FIG. 37

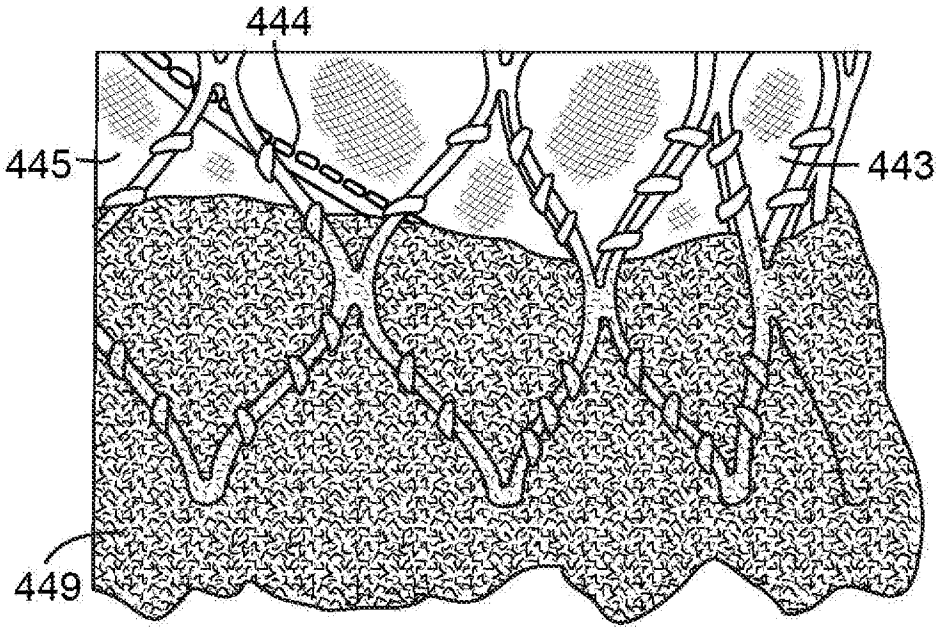


FIG. 38

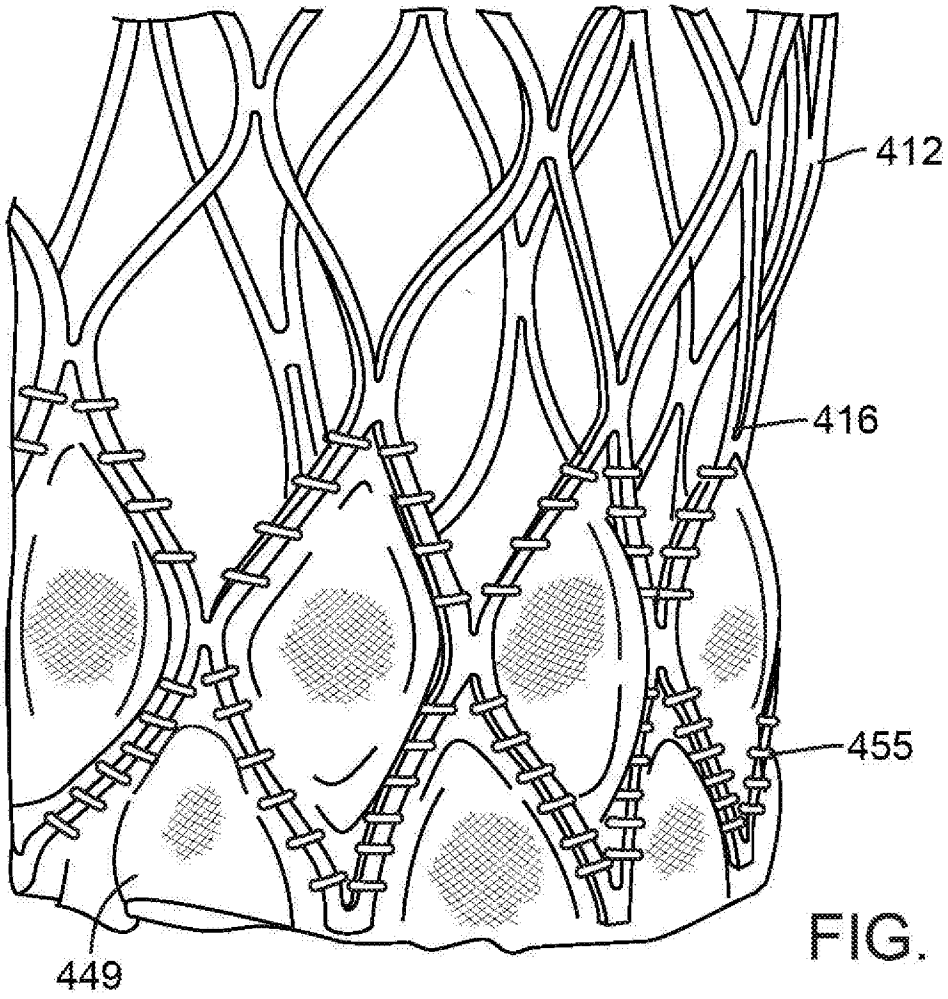


FIG. 39

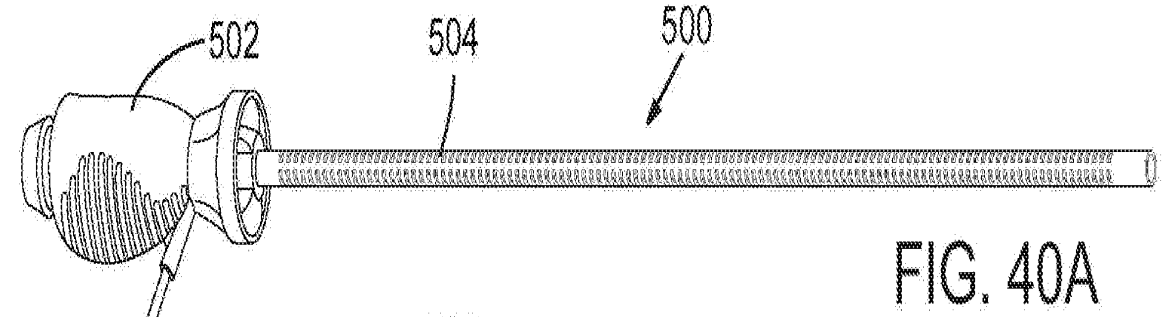


FIG. 40A

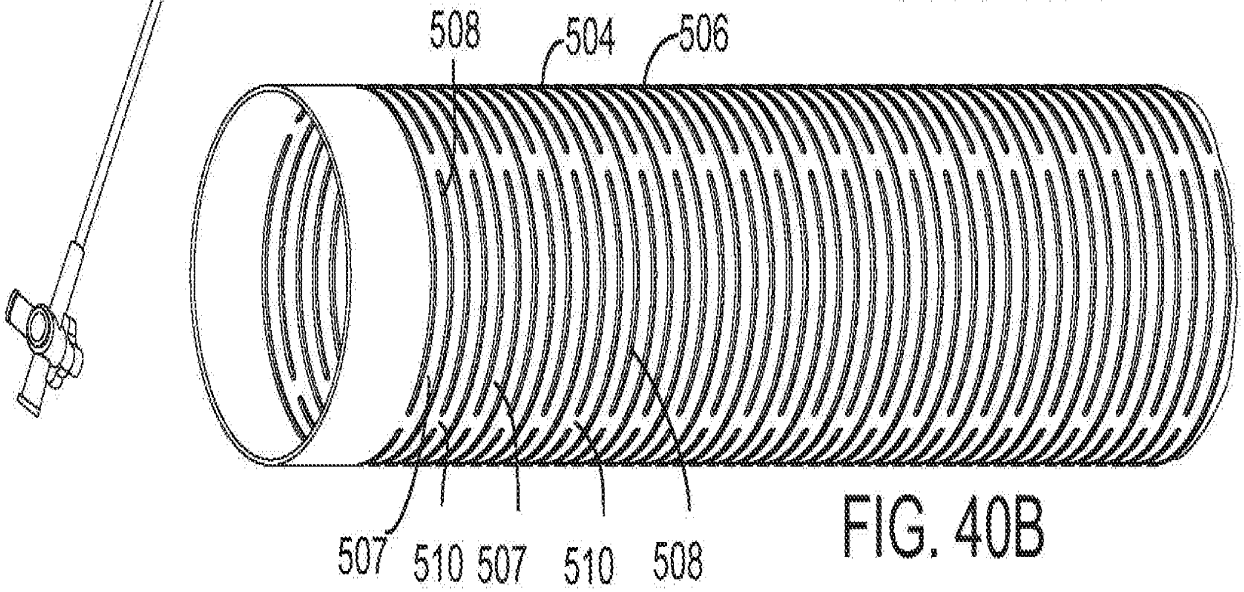


FIG. 40B

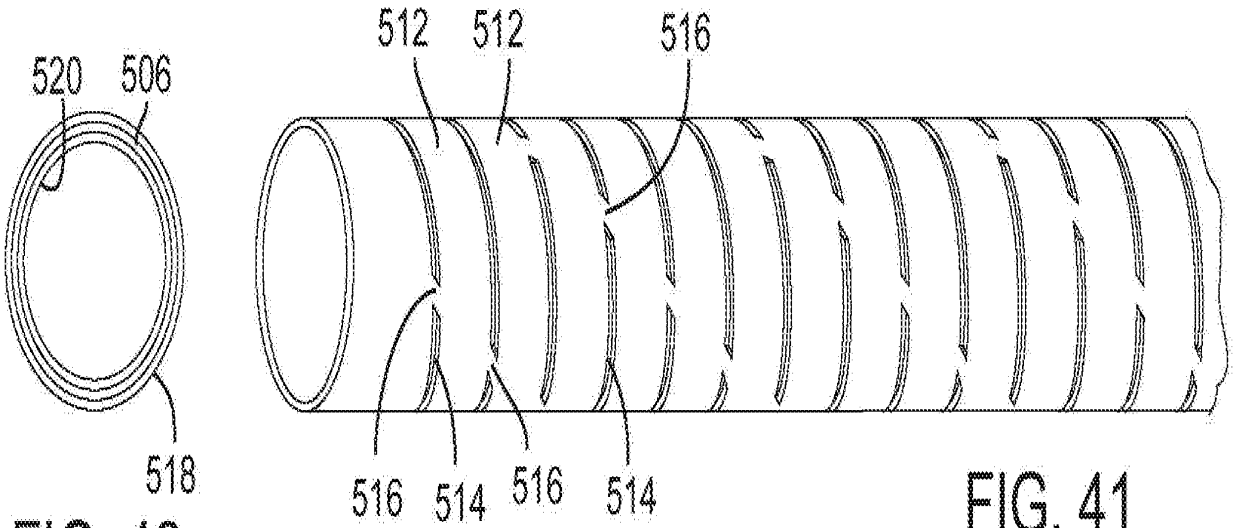


FIG. 42

FIG. 41

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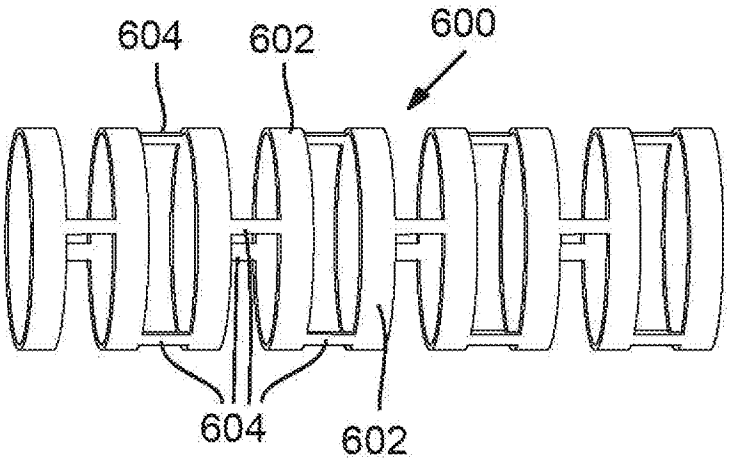


FIG. 43

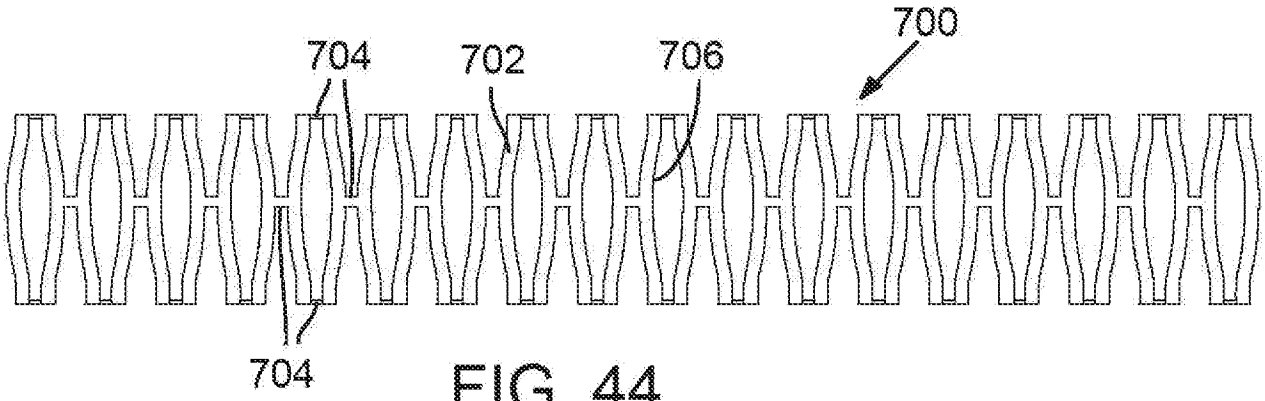


FIG. 44

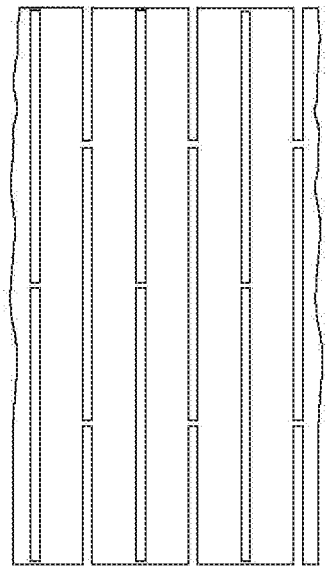


FIG. 45

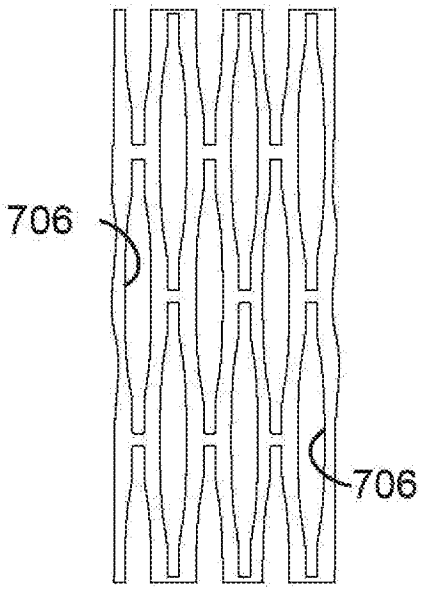


FIG. 46

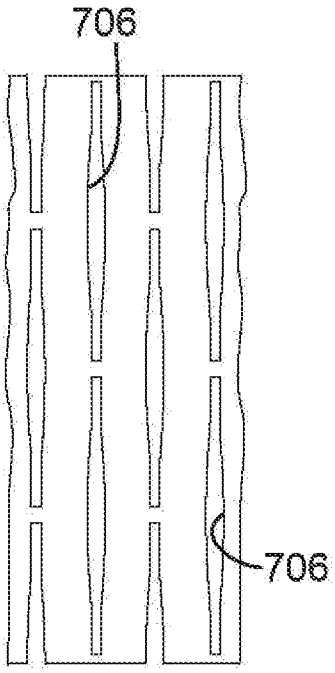


FIG. 47

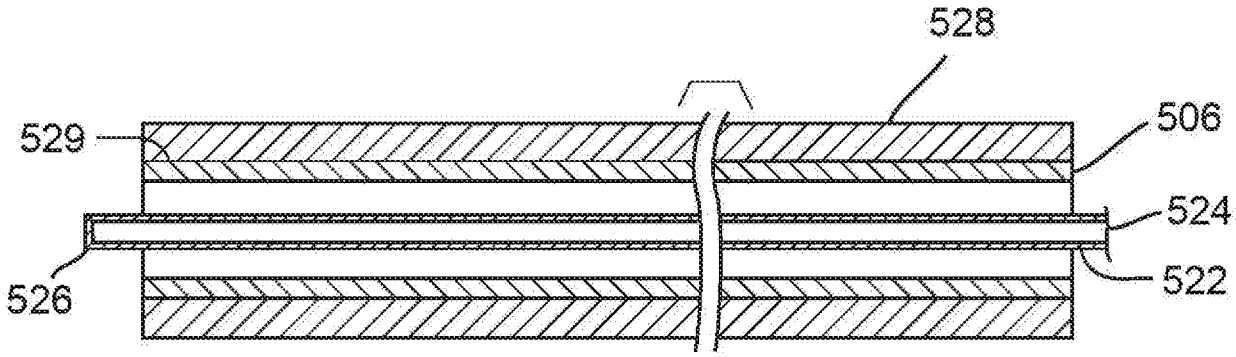


FIG. 48

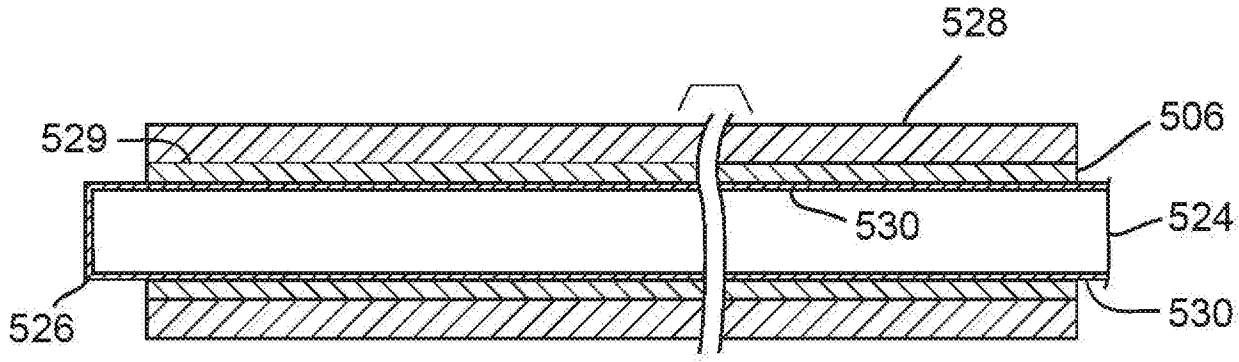


FIG. 49

EXHIBIT 22

From: **Ali Shahriari** <ali.shahriari@aorticinnovations.com>
Date: Mon, Jul 19, 2021 at 11:48 AM
Subject: Aortic Innovations LLC
To: Don_bobo@edwards.com <Don_bobo@edwards.com>, keith_newburry@edwards.com <keith_newburry@edwards.com>

Donald Bobo

Corporate Vice President, Strategy and Development

Edwards Lifesciences Corp.

1 Edwards Way

Irvine, CA 92614

RE: Aortic Innovations Patents for Transcatheter Valve Replacement

Dear Don:

I hope all is well since we last spoke in 2017 with you and many of your team. At that time, I was focused on Ascyrus Medical, LLC, which has now been sold. During our conversations, your team indicated an interest in Aortic Innovations ("AI"). As you are aware, I invented transcatheter aortic valve replacement ("TAVR") and transcatheter mitral valve replacement ("TMVR") devices and systems, including those covered by at least the following patents:

- United States Patent No. 10,792,172
- United States Patent No. 10,857,011
- United States Patent No. 10,881,538
- United States Patent No. 10,888,441
- United States Patent No. 10,966,846
- United States Patent No. 10,987,236
- United States Patent No. 11,026,817
- United States Patent Publication No. 2021-0212846
- United States Patent Publication No. 2021-0161688
- Related patents and patent applications in Europe, Canada, Germany, and Japan

Each of these patents is owned by AI. It appears that the Sapien 3 Ultra and/or Sapien M3 practice one or more claims from these patents. You may wish to have your patent counsel examine the above patents in order to determine whether a license is needed.

I look forward to hearing from you and welcome a discussion regarding a potential license to the AI patent portfolio, a portfolio that we think could be very valuable to Edwards going forward. If you have any questions, please feel free to reach out.

Best,

Dr. Ali Shahriari

Chief Executive Officer

Aortic Innovations, LLC

977 Hillsboro Mile

Hillsboro Beach, FL 33062

Ali.Shahriari@aorticinnovations.com

CC; Keith Newburry, Chief IP Counsel

--
Ali Shahriari
CEO
Aortic Innovations LLC.

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EXHIBIT 23

FDA U.S. FOOD & DRUG ADMINISTRATION

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	SAPIEN 3 Ultra Transcatheter Heart Valve
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered
Applicant	EDWARDS LIFESCIENCES, LLC. One Edwards Way Irvine, CA 92614
PMA Number	P140031
Supplement Number	S085
Date Received	04/01/2019
Decision Date	08/16/2019
Product Code	NPT[24]
Docket Number	19m-3845
Notice Date	08/16/2019
Advisory Committee	Cardiovascular
Supplement Type	Panel Track
Supplement Reason	Labeling Change - Indications/Instructions/Shelf Life/Tradename
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval for the Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System for expanding the indication to include patients at low risk for surgical aortic valve replacement. The devices are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

Approval Order	Approval Order[25]
Summary Labeling	Summary Of Safety And Effectiveness[26]

Labeling[27]

Labeling Part 2[28]

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Page Last Updated: 07/19/2021

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EXHIBIT 24

Paravalvular Aortic Leak After Transcatheter Aortic Valve Replacement

Current Knowledge

Stamatios Lerakis, MD; Salim S. Hayek, MD; Pamela S. Douglas, MD

Transcatheter aortic valve replacement (TAVR) is now well-established as the standard of care for patients with severe symptomatic aortic stenosis who are deemed inoperable,[1] and is seen as an alternative treatment option to surgical aortic valve replacement (SAVR) in a subset of patients with high postoperative mortality.[2] The native valve is typically not removed but instead crushed by the superimposed bioprosthesis, which can result in an incomplete seal of the bioprosthetic valve and aortic annulus, with subsequent occurrence of paravalvular leak (PVL). Two types of Transcatheter Heart Valves (THV) that have been widely used, the balloon-expandable Edwards valve (Cribier-Edwards, Edwards SAPIEN and Edwards SAPIEN XT) by Edwards Lifesciences, and the self-expandable CoreValve by Medtronic, have been described in detail elsewhere.[3,4] Despite the evolving technology of transcatheter valves, PVL post-TAVR is common, with a wide range of reported incidences (Table 1). Most importantly, PVL has been associated with increased short- and long-term mortality post-TAVR, and is seen as a barrier to more widespread use of this promising technique.[5–13] This article describes the incidence, causes, and predictors of PVL, as well as its impact on clinical outcomes. Methods of prevention, diagnosis, and treatment of PVL are also reviewed.

Definition and Incidence

Aortic regurgitation is characterized as either central or paravalvular. Pathological central regurgitation occurs in diseased native valves or damaged prosthetic valves, whereas minor central regurgitation is often a physiological feature of some bioprosthetic valves by virtue of their design. On the other hand, PVL is a complication only of aortic valve prostheses and occurs more commonly post-TAVR (Figure 1) than after SAVR.

Various multicenter registries and trials have reported data on incidence of PVL post-TAVR at different time points (Table 1). The overall incidence of PVL post-TAVR ranges between 50% and 85%, which is significantly higher than what has been observed in SAVR, reported between 1% and 47.6%, with only 4.2% consisting of more than mild PVL.[14] Although the majority of post-TAVR PVL is mild (7.8–40.8%), moderate (5–37.9%) and severe (0.5–13.6%) PVL occur frequently.[1,2,6,8,10,11,13,15–26] The largest meta-analysis of TAVR outcomes estimates the incidence of residual moderate or severe aortic regurgitation after TAVR to be 7.4%.[27] The UK TAVR registry suggests moderate-severe PVL occurred more commonly with CoreValve implants (17.3%, versus 9.6% with the Edwards implants).[13] This finding has not been replicated in other studies. One study by Ewe et al[21] did not find a statistically significant difference in incidence of PVL between transfemoral and transapical TAVR at 30 days and 6 months. The wide range of PVL incidence reported is not surprising and is likely a result of the lack of standardization across centers in the TAVR technique, differences in operator experience, types and sizes of valves used, in addition to the different imaging modalities used and challenges in grading PVL. Unbehaun et al[6] used a modified TAVR procedure after which no patient had severe PVL and only 2 had moderate PVL, of a relatively large cohort of 358 patients.

It is unclear whether PVL progresses in severity with time. The studies reporting the rate of PVL for multiple follow-up time points show decreasing incidences of moderate–severe PVL. Although the decrease could be attributed to the death of patients with higher-grade PVL who are at higher mortality risk, a reduction of severity from moderate to mild may also relate to geometric remodeling of the annulus[2,5,20,21] (Table 1). Rates of mild PVL generally remained stable; there was no evidence of an increase in PVL over time.

Clinical Impact of Paravalvular Leak

Despite the difficulties in accurately characterizing PVL, the wide range of incidences reported, and the relative short period of follow-up, its impact on short- and long-term mortality has been consistently reported across studies (Table 2). Data from a large cohort of 3201 SAVR patients with a mean follow-up of 4.5±3.4 years confirm that patients with moderate–severe aortic regurgitation (AR>1/4) had lower survival at 1, 5, and 10 years (91.4 versus 96.7%, 77.5 versus 82.4%, and 44.1 versus 54.5%; $P<0.01$).[14] Other data on clinical outcomes related to PVL extend from the postoperative period to up to 2 years. Moderate–severe PVL is an independent predictor of mortality in the postoperative period to 30 days, at 1 year, and at 2 years[5–11,13] (Table 2). Recently, Kodali et al from the Placement of AoRTic

From the Department of Medicine, Division of Cardiology, Emory University School of Medicine, Atlanta, GA (S.L., S.S.H.); and the Duke University Medical Center, Duke Clinical Research Institute, Durham, NC (P.S.D.).

Correspondence to Stamatios Lerakis, MD, Emory University Hospital, 1365 Clifton Rd NE, Suite AT-503, Atlanta, GA 30322. E-mail:sleraki@emory.edu

(*Circulation*. 2013;127:397-407.)

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Table 1. TAVR Studies and Registries Reporting Incidence of PVL in >100 Patients

Valve	Registry/Trial	Diagnostic Modality	Postprocedure/30 Days	6 Months	1 Year	2 Years	3 Years
Edwards	Rodes-Cabau et al[15] Canadian, 2010	Echocardiography	n=339 Mild: 78% Moderate: 5% Severe: 1%	—	—	—	—
	Thomas et al[16] SOURCE, 2010	Echocardiography	n=1038 Moderate–Severe: 1.9%	—	—	—	—
	Leon et al[1] PARTNER nonoperable cohort, 2010	Echocardiography	n=144 None: 14% Mild: 68% Moderate–Severe: 12%	—	n=98 None: 23% Mild: 59% Moderate–Severe: 11%	—	—
	Smith et al[2] PARTNER high-risk cohort, 2011	Echocardiography	n=287 None: 22.6% Mild: 65.2% Moderate–Severe: 12.2%	n=240 None: 26.3% Mild: 62.5% Moderate–Severe: 11.3%	n=222 None: 32.9% Mild: 60.4% Moderate–Severe: 6.8%	n=143 Moderate–Severe: 6.9%	—
	Nombela-Franco et al,[17] 2012	Echocardiography	n=211 Mild: 30.8% Moderate: 37.9% Severe: 11.3%	—	—	—	—
	Gripari et al,[18] 2012	Echocardiography	n=135 None: 31.1% Mild: 48.1% Moderate: 18.5% Severe: 2.2%	—	—	—	—
	Unbehaun et al,[6] 2012	Echocardiography, Angiography	n=358 None: 51.6% Mild: 47% Moderate: 0.6% Severe: 0%	—	—	—	—
	Walther et al,[19] 2012	Echocardiography	n=150 None: 36% Mild: 30.7% Moderate: 22.8% Severe: 7%	—	—	—	—
	Webb et al,[20] 2009	Echocardiography	n=168 Mild: 58% Moderate: 37% Severe: 5%	None–Mild: 77% Moderate: "Unchanged" Severe: 0%	None–Mild: 66% Moderate: "Unchanged" Severe: 0%	…	…
	Ewe et al,[21] 2011	Echocardiography	TF, n=45 None: 8.9% Mild: 26.7% Moderate: 53.3% Severe: 11.1% TA, n=59 None: 3.4% Mild: 25.4% Moderate: 57.6% Severe:13.6%	TF, n=33 None: 51.5% Mild: 36.4% Moderate: 51.5% Severe: 0% TA, n=39 None: 64.1% Mild: 33.3% Moderate: 2.6% Severe: 0%	TF, n=26 None: 57.7% Mild: 38.5% Moderate: 3.8% Severe: 0% TA, n=23 None: 73.9% Mild: 26.1% Moderate: 0% Severe:0%	…	…

(Continued)

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Table 1. Continued

Valve	Registry/Trial	Diagnostic Modality	Postprocedure/30 Days	6 Months	1 Year	2 Years	3 Years
CoreValve	Ussia et al[22] Italian 3-years, 2012	Echocardiography	n=178 Mild: 52.8% Moderate: 15.2% Severe: None	—	n=129 Mild: 48.1% Moderate: 17.8% Severe: None	—	n=89 Mild: 42% Moderate: 9% Severe: None
	Buellesfeld et al,[23] 2011	Echocardiography	n=126 None: 59% Mild: 32% Moderate: 9% Severe: 0%	n= N/A None: 55% Mild: 39% Moderate: 6% Severe: 0%	n= N/A None: 63% Mild: 34% Moderate: 3% Severe: 0%	n= N/A None: 63% Mild: 34% Moderate: 3% Severe: 0%	—
	Sinning et al,[8] 2012	Echocardiography, Angiography	n=146 None: 36.3% Mild: 48.6% Moderate: 12.3% Severe: 2.7%	—	—	—	—
Mixed	Eltchaninoff et al[24] FRANCE, 2011 Edwards 68% CoreValve 32%	Echocardiography, Angiography	n=244 Absent/Mild: 90.5% Moderate: 9% Severe: 0.5%	—	—	—	—
	Gilard et al[25] FRANCE2, 2012 Edwards 66.9% CoreValve 33.1%	Echocardiography	n=1846 Mild: 47.4% Moderate: 16.3% Severe: 0.8%	n=983 Mild: 46% Moderate: 16.1% Severe: 0.8%	n=426 Mild: 47.2% Moderate: 18.5% Severe: 1.2%	—	—
	Abdel-Wahab et al[11,12] Germany, 2011 Edwards 15.6% CoreValve 88.4%	Angiography	n=689 None: 27.6% Mild: 54.9% Moderate: 15.2% Severe: 2.3%	—	—	—	—
	Moat et al[13] UK, 2011 Edwards 47.1% CoreValve 52.9%	Angiography	n=870 None: 39% Mild: 47.4% Moderate–Severe: 13.6% (Edwards 9.6%, CoreValve 17.3%)	—	Moderate–Severe: 12.3%	—	—
	Fraccaro et al,[26] 2012	Echocardiography	n=384 Moderate–Severe: 4%	—	—	—	—
	Hayashida et al,[10] 2012 Edwards 85.4% CoreValve 14.6%	Echocardiography	n=260 Moderate–Severe: 30.8% Severe: 4.2%	…	…	…	…

PARTNER indicates Placement of AoRTic TraNscathetER valve trial; TA, transapical; and TF, transfemoral.

TraNscathetER (PARTNER) valve trial high-risk cohort suggested that any PVL regurgitation (mild–moderate–severe) was associated with increased mortality at 2 years, although this association was not analyzed in multivariate fashion. So far, most other studies have not reported worse outcomes with mild/trace PVL[5](Table 2).

Causes and Predictors of Paravalvular Regurgitation

During SAVR the positioning of the prosthesis is performed under direct anatomic observation, allowing excision of the calcified valve, followed by optimal placement and alignment

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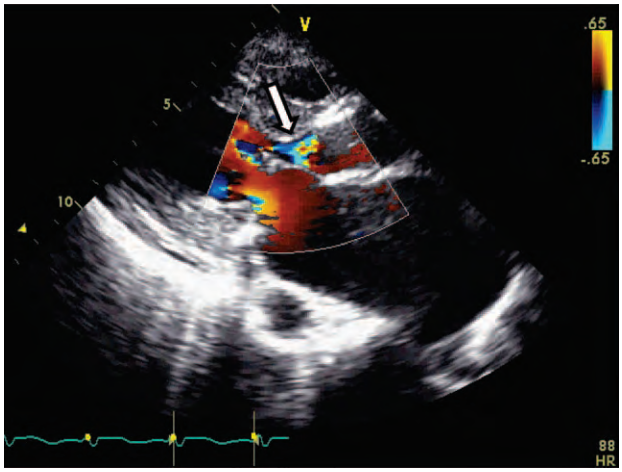


Figure 1. Parasternal longitudinal axis transthoracic echocardiography view showing mild paravalvular leak post–transcatheter heart valve deployment. **Arrow** indicates the site of paravalvular leak.

of the prosthetic valve within the aortic annulus. The minimally invasive nature of TAVR precludes removal of the heavily calcified native valve and direct observation of the annulus. It entails using preprocedural imaging to estimate the size of the aortic root, and indirectly implanting a circular bioprosthesis in a dynamic, oval-shaped aortic annulus. The technique relies on fluoroscopy and intraprocedural echocardiography for positioning. Thus, it is not surprising to expect a higher frequency of PVL in TAVR as a result of the risks of inappropriate sizing of the prosthesis, its malpositioning, and the hindrance of the old calcified valve (Table 3).

The diameter of the aortic annulus is measured before and during the procedure to determine the choice and size of the THV. To assess valve-annulus congruence, a cover index integrating aortic annulus diameter (A) and prosthetic diameter (P; 100×[A−P]/P) was used. Moderate-severe regurgitation was not seen with a cover index >8% in this study of 74 patients. These findings were reproducible in a study using intraprocedural 3D tranesesophageal echocardiography (TEE) in addition to transthoracic echocardiography (TTE) to evaluate the THV.[18] In another prospective study, annulus–prosthesis mismatch was defined as a native annulus diameter larger than normal on label diameter limit for the prosthesis and was associated with higher grade PVL.[28] Larger aortic annulus size measured by MRI and computed tomography (CT) but not TTE was also predictive of PVL.[29] These studies suggest a certain amount of oversizing is indeed necessary to prevent PVL. Indeed, Detaint et al[30] reported that patients with aortic annulus <22 mm by echocardiography had no moderate–severe PVL after TAVR. Although echocardiography is the most widely used method for measuring the annulus, multi-detector computed tomography (MDCT) allows

Table 2. PVL as a Predictor of Outcomes: Reported Mortality/Survival Rates and Hazard Ratios in Studies With >100 Patients

Valve	Registry/Trial	Severity	Outcome	Time	HR/Survival/Mortality
Edwards	Unbehaun et al,[6] 2012, n=358	None, Trace, Mild–Moderate	Survival	2-year	None: 66% Trace: 72%
	Kodali et al[5]; PARTNER high risk cohort, 2012 n=699	Mild–Moderate–Severe	Mortality	2-year	HR 2.11 [1.43–3.10]
CoreValve	Gotzmann et al,[7] 2012 n=198	None–Mild, Moderate–Severe	Mortality	30 day	None–Mild: 6%, Moderate–Severe 21%; HR 3.81 [1.384–10.482]
				1 yr	None–Mild: 16%, Moderate–Severe 57%; HR 5.48 [2.807–10.683]
	Sinning et al,[8] 2012 n=146	None–Mild, Moderate–Severe	Mortality	30 day	None–Mild: 4%, Moderate–Severe: 22.7%
				1 yr	None–Mild: 25%. Moderate–Severe 63.6% HR 3.9 [2.0–7.5]
	Tamburino et al[9] Italian, 2011 n=661	Moderate–Severe	Mortality	30 days – 1 yr	HR 3.785 [1.57–9.10]
Mixed	Hayashida et al,[10] 2011, n=260	Moderate–Severe	Mortality	6 mo	HR 1.97 [1.19–3.28]
	Edwards 85.4%				
	CoreValve 14.6%				
	Abdel-Wahab et al[11,12] German, 2011	None, Mild, Moderate, Severe	Mortality	In-Hospital	None: 4.9%
	Edwards 15.6%				Mild: 6.1%
	CoreValve 88.4%				Moderate 15.5%
	n=689				Severe: 12.5%
					Moderate–Severe: 2.43 [1.22–4.85]
	Moat et al[13] UK, 2011	Moderate–Severe	Mortality	1 yr	HR 1.49 [1.00–2.21]
	Edwards 47.1%				
	CoreValve 52.9%				
	n=870				

HR indicates hazard ratio; and PARTNER, Placement of AoRTic TraNscathetER valve trial.

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Table 3. Risk Factors and Predictors of Postprocedural PVL

Valve	Registry/Trial	Diagnostic Modality	Predictors	Comments
Edwards	Gripari et al,[18] 2012	2D/3D Transesophageal Echocardiography	Area Cover Index* 0.95	—
		n=135	Calcification of commissure between right and NCC (OR 2.66)	
	Nombela-Franco et al,[17] 2012	Transesophageal Echocardiography	Valvular Calcium Volume per 500 mm^3 increase (OR 1.26 [1.11–1.44])	Volume cutoff of 3,874 mm^3 predicted the occurrence of AR (≥2) that did not respond to BPD, with a sensitivity of 82% and specificity of 60% (area under the ROC curve: 0.71, 95% CI: 0.54 to 0.88, P=0.033).
		n=211	Transfemoral approach (OR: 2.49 [1.03–5.97])	Volume cutoff of 2,242 mm^3 predicted the need for BPD with a sensitivity of 78% and specificity of 65% (area under the ROC curve: 0.74, 95% CI; 0.65 to 0.84, P<0.0001).
	Unbehaun et al,[6] 2012	Transesophageal Echocardiography, Angiography, MDCT	Male sex (OR 1.66 [1.06–2.58])	Patients with previous AVR had less risk of PVL
		n=358	NYHA IV (OR 1.58 [1.04–2.42])	
			Previous AVR(OR AVR 0.12 [0.03–0.51])	
			Annular size (on TEE) (OR 1.18 [1.03–1.37])	
	Willson et al,[32] 2012	Transesophageal Echocardiography, MDCT	THV diameter - mean diameter by MDCT (AUC 0.81 [0.68–0.88])	THV oversized to MDCT mean annular diameter by at least 1 mm area and annular area by at least 10% have significantly reduced risk of moderate-severe PVR
		n=109	THV diameter - mean diameter by TEE (AUC 0.70 [0.51–0.88])	
			THV area/annula area by MDCT (AUC 0.80 [0.65–0.90)	
	Détaint et. al,[30] 2009	Echocardiography n=74	Older age	Aortic annulus <22 mm, cover index >8%, had no AR≥2
			Male sex	
			Greater height	
			Larger aortic annulus	
			Operator's experience	
			Low cover index† (OR 1.22 [1.03–1.51])	
CoreValve	Takagi et al,[28] 2011	Echocardiography	Peripheral vascular disease (OR 2.57 [0.99–6.69]	…
		n=79	History of heart failure (OR 2.89 [1.10–7.61]	
			Chronic renal insufficiency (OR 2.62 [1.02–6.71])	
			Larger aortic annulus size (OR 1.66 [1.21–2.29])	
			Prosthesis mismatch (valve <annulus) (OR 5.19 [0.98–27.63])	
			Low implantation(OR3.11 [1.00–9.68])	
			High implantation (OR 0.34 [0.12–0.98])	
	Sherif et al,[36] 2010	Echocardiography, Angiography	Increasing angle of LVOT to ascending aorta (OR 1.24)	$2 \times$ LVOT-AO + (depth to NCC - 10)$^2 \geq 50$, the likelihood of occurrence of significant AR could be predicted with a sensitivity of 85% and a specificity of 87%.
		n=50	Depth of device in relation to NCC (minimum chance of significant AR corresponding to depth = 9.5 mm)	
			Depth of the device in relation to LCC (minimum chance of significant AR corresponding to depth = 10.42 mm)	

AR indicates aortic regurgitation; AUC, area under the curve; AVR, aortic valve replacement; BPD, balloon postdilation; CI, confidence interval; LCC, left coronary cusp; LVOT-AO, angle of left ventricular outflow tract to ascending aorta; MDCT, multi-detector computed tomography; NCC, Non-coronary cusp; NYHA, New York Heart Association; OR, odds ratio; PVL, paravalvular leak; PVR, paravalvular regurgitation; and TEE, transesophageal echocardiography.

*Area Cover Index (1−Annulus area/Prosthesis nominal area).

†Cover Index=(100 × ([prosthesis diameter − TEE annulus diameter]/prosthesis diameter).

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3-dimensional reconstruction of the annulus and multi-planar measurements of annular diameter, area, and circumference.[31] THV oversized by at least 1 mm relative to the mean annular diameter, or by ≥10% of the annular area, as measured by MDCT, have a reduced risk of moderate to severe PVL.[32] The same study suggests that the difference between annular perimeter measurement and THV size by MDCT was a slightly better predictor of PVL when compared with TEE,[32] although this may be partially attributable to differences in the type of measurement obtained (circumference by MDCT versus sagittal diameter by TEE) rather than the imaging modality used. The current TAVR technique systematically oversizes the THV ≈2 to 5 mm larger than the native valve. However, oversizing is not without risks and may cause annular rupture, coronary artery occlusion, and arrhythmias, underscoring the importance of accurately measuring the aortic annulus.

Appropriate positioning of the bioprosthesis is essential to preventing PVL but is challenging in the setting of a beating heart and catheter-guided deployment. The incidence of CoreValve dislocation ranged from 3% to 10% depending on the series.[33] Similar results have been reported for the Edwards valve[34,35] (4% to 11%). Sherif et al[36] set out to identify anatomic predictors of PVL using angiography in patients undergoing TAVR with the CoreValve: the angle of the left ventricular outflow tract to the ascending aorta as well as the depth of the device in relation to the noncoronary cusps were found to be independent predictors of PVL.[36] For all THV, the greater the angle the more likely the device incompletely seals the paravalvular space. Further, if implanted too low, the covered skirt may be situated below the native annulus, allowing blood to regurgitate through the holes of the uncovered portion of the stent frame, whereas high implantation allows blood to flow in the space between prosthesis and annulus. In addition to PVL, malposition and potential valvular dislocation is a serious complication of TAVR, which may cause coronary ischemia, arrhythmias requiring pacemaker implantation, and is associated with excess 30-day mortality (21.5% versus 9.9%).[33] Newer devices in development have an improved ability to reposition the valve during deployment and should reduce the incidence of PVL.

The extent of native aortic valve calcification and its location has been repeatedly shown to be predictive of PVL post-TAVR with both the Edwards and CoreValve THV,[17,18,37–41] because it impairs apposition and complete expansion of the THV by imposing an asymmetrical shape to the valve deployment area. Different studies have quantified calcification of the aortic root using different imaging techniques and scoring systems. The Agatston Score is derived from ECG-gated multislice contrast-enhanced computed tomography and has been used to characterize total valve and individual cusp calcification.[42] High Agatston Score was correlated with higher degrees of PVL as well as the need for repeat maneuvers during implantation.[38,40,41] Cusp calcification at the aortic wall was strongly predictive of PVL at the corresponding site.[38,39] TEE has also been used to assess aortic root calcification semiquantitatively using an echocardiographic calcification score devised by Corciu et al[18,37,43] Application of this score yields results consistent with the MDCT findings, such that valvular calcification and annular size are strongly predictive of PVL as well as the need for additional maneuvers.[18,37,43] Newer devices with more flexible cuffs allowing more complete seal over the retained native valve should mitigate this problem.

Clinical characteristics associated, such as male sex, New York Heart Association functional class IV, and no previous aortic valve replacement, were suggested to be predictive of PVL.[6]

The Role of Imaging in Assessing Paravalvular Regurgitation

Identifying and accurately characterizing paravalvular regurgitation in prosthetic valves is challenging. The shielding and reverberations of the valvular frame as well as the eccentricity of the jets render accurate localization and quantification of PVL difficult. Echocardiography, both TTE and TEE, angiography, MDCT, as well as MRI are modalities that have been used across studies to characterize PVL (Table 1).

Intra-Procedural Imaging

TEE is particularly useful for the detection and assessment of acute aortic regurgitation post-TAVR because it can be performed immediately on deployment.[44] Immediately after valve deployment, stent positioning, shape, leaflet motion, and aortic regurgitation can rapidly be assessed with TEE imaging in biplane mode or a single plane short-axis view. For PVL, the short-axis plane of imaging should be just below the valve stent and skirt and just within the left ventricular outflow tract (LVOT); if the imaging plane is above the stent, regurgitation may not be visualized or color flow just above the annulus but contained within the sinuses of Valsalva may be mistaken for regurgitant jets into the left ventricle. Lower cross sections may erroneously view jet spray rather than vena contracta. Confirmation of the severity of AR should always be performed from multiple echocardiographic views. Because of acoustic shadowing of the anterior THV annulus with mid-esophageal TEE, imaging just below the stent (within the LVOT) avoids most shadowing issues. The deep gastric view also allows imaging of the LVOT without acoustic shadowing. Imaging the entire annulus is mandatory and requires rotating 180 degrees while centered on the valve.

Aortography post-TAVR can provide accurate PVL evaluation and correlate it immediately with the simultaneous TEE evaluation under the same hemodynamic conditions. Hemodynamic data obtained immediately post-TAVR that include measurement of LV end-diastolic pressure and diastolic pressure and compare them with pre-TAVR values can provide additional information about grading the severity of PVL and has recently been shown to be of prognostic value.[45]

Post-Procedural Imaging

Transthoracic echocardiograms can identify the presence, location, and severity of the PVL and are the most common form of imaging because of availability and low cost. The optimal views for detection of regurgitant jets include the parasternal long-axis, short-axis, the apical long-axis, and the 5-chamber views, although as a result of eccentric jets, off-axis views should also be used to ensure accurate determination of the location and severity of regurgitation. Paravalvular jets usually travel along the natural curvature of the

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prosthesis-annular interface, thus imaging in multiple planes is necessary. The transthoracic short-axis view offers the best visualization of the true orifice of PVL and helps prevent the overestimation of AR severity, which can occur when relying solely on apical views.

In quantifying PVL, a comprehensive integrated approach must always be used.The American Society of Echocardiography (ASE) criteria for assessing PVL severity by echocardiography have emphasized describing the jet anatomy (ie, location, circumferential extent, and width[46]; Table 4), particularly when visualized by color Doppler in the aortic short-axis view. These criteria have not been validated in post-TAVR patients, and despite the adoption of these recommendations by the VARC (Valve Academic Research Consortium)[47,48] they have not been uniformly adopted by the different registries and trials. Most commonly, PVL is assessed qualitatively by estimating the proportion of the circumference of the sewing ring occupied by the jet: <10% of the sewing ring suggests mild, 10% to 20% suggests moderate, and >20% suggests severe.[49] Overall aortic regurgitation is classified as absent (0), trace (<I), mild (I), moderate (II), and severe (III or IV).

In addition, quantitative assessments of regurgitant fraction and volume can also be helpful in determining the severity of PVL. These methods rely on the comparison of stroke volumes across the aortic valve and a nonregurgitant valve. Although total stroke volume can be measured by subtracting LV end-systolic volume from end-diastolic volume, the more common method is to calculate the stroke volume across the LVOT.

Three-dimensional echocardiography may become the method of choice for assessing aortic regurgitant volume. Three-dimensional TTE is an additional tool that can be used to evaluate the severity of PVL. Vena-contracta planimetry by 3-dimensional TTE correlates better with regurgitant volume than vena contracta width with 2-dimensional TTE.[50]

Cardiac MRI may be a useful supplement to echocardiography and may be the modality of choice when there is discordance in grading from different echocardiographic windows. Quantified regurgitant volume and fraction by cardiac MRI appears to correlate better with qualitative angiographic evaluation and less with echocardiographic assessment. Qualitative evaluation by echo may underestimate the severity of PVL when compared with quantitative cardiac MRI measurements.[51]

Percutaneous Approaches to Treat Paravalvular Leak

The pathophysiologic consequences of acute valvular regurgitation occurring after valve deployment as well as the clinical impact of chronic moderate-severe PVL warrant early and effective remediation to avoid conversion to open surgery as well as prevent progression into heart failure. Thus far there are no universally established indications or algorithm for the procedural management of PVL, and the method of choice is related to the severity of regurgitation and center and operator expertise. Treatment, however, does depend on the onset and cause of regurgitation. Acute valvular regurgitation resulting from initial malpositioning of the THV has been remediated successfully by either refolding and reinserting the valve, or repositioning of the valve using the snare technique. Both techniques are possible using the CoreValvebioprosthesis and have been described by Vavouranakis et al[52] as bail-out solutions, given the CoreValve was not designed for repositioning.

Table 4. Echocardiographic Criteria for Grading PVL per EAE/ASE and VARC-2

Parameter	Mild	Moderate	Severe
EAE/ASE			
Valve structure and motion			
Mechanical or bioprosthetic	Usually normal	Usually abnormal	Usually abnormal
Structural parameters			
Left ventricular size	Normal	Normal/mildly dilated	Dilated
Doppler parameters (qualitative or semiquantitative)			
Jet width in central jets (% diameter): color	Narrow (≤25%)	Intermediate (26% to 64%)	Large (≥65%)
Jet density: CW Doppler	Incomplete or faint	Dense	Dense
Jet deceleration rate (PHT, ms): CW Doppler	Slow (>500)	Variable (200–500)	Steep (<200)
LV outflow vs. pulmonary flow: PW Doppler	Slightly increased	Intermediate	Greatly increased
VARC-2			
Semi-quantitative parameters*			
Diastolic flow reversal in the descending aorta by pulsed wave	Absent or brief early diastolic	Intermediate	Prominent, holodiastolic
Circumferential extent of PVR (%)	<10%	10% to 29%	≥30%
Quantitative parameters*			
Regurgitant volume (ml/beat)	<30 mL	30–59 mL	≥60 mL
Regurgitant fraction (%)	<30%	30% to 50%	≥50%
EROA (cm^2)	<0.10 cm^2	0.1–0.29 cm^2	≥0.30 cm^2

CW indicates continuous wave Doppler; EROA, effective regurgitant orifice area; PVR, paravalvular regurgitation; and PW, pulse wave Doppler. Adapted from the European Association for Echocardiography and the American Society of Echocardiography (EAE/ASE) Guidelines and the Valve Academic Research Consortium-2.[46, 47]
*Common to both guidelines.

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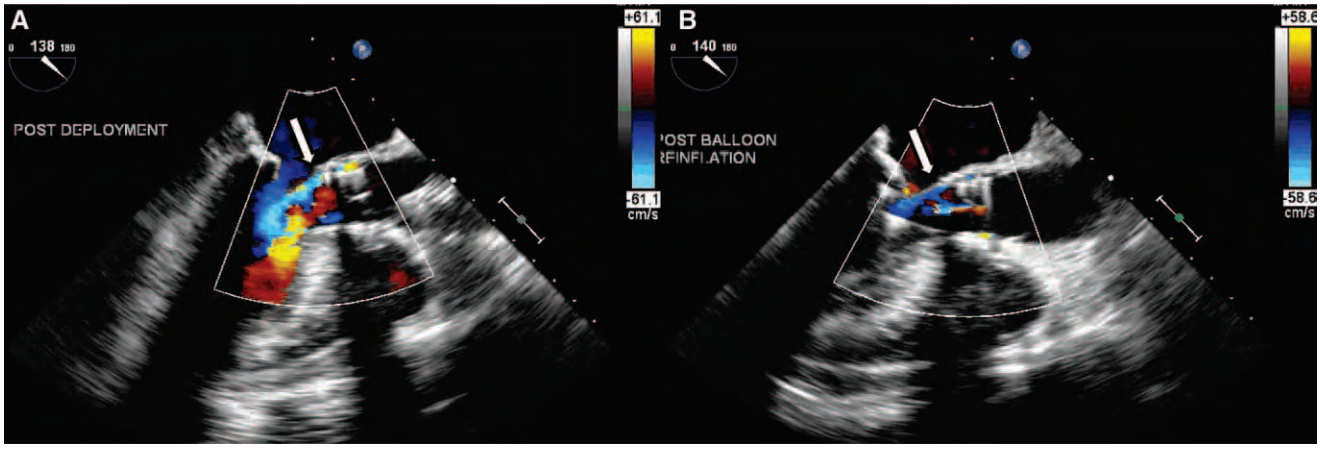


Figure 2. A, Parasternal longitudinal axis tranesesophageal echocardiography (TEE) view showing moderate paravalvular leak post–transcatheter heart valve deployment. **B,** Parasternal longitudinal axis midesophageal TEE view post–balloon dilation showing significant decrease in severity of paravalvular leak from moderate–severe to mild. **Arrows** indicate the site of paravalvular leak.

Utmost importance should be given to correctly placing the THV on the first attempt, because these techniques are not without risk; the valve may embolize, obstruct the coronary ostium, or induce trauma to the aortic wall and subsequent atheroembolization and strokes.

In patients with THV appropriately positioned, incomplete expansion of the bioprosthetic frame is deemed a major cause of PVL, and is routinely mediated with balloon postdilatation in both the self-expandable CoreValve[28,53] and the balloon-expandable Edwards Valve(Figure 2).[17] Success rates have been reproducible, with postdilation regurgitation reduced by ≥1 grade in >70% of patients.[17] Risks of overexpansion include injury to the leaflets, annular rupture, and atrioventricular block. Cerebrovascular events were noted to be significantly increased postdilation, especially in patients with a high burden of valvular calcium.[17] The concern for strokes has mitigated the widespread use of balloon postdilatation.

In cases of suboptimal deployment of the THV and the inability to reposition, valve-in-valve implantation has emerged as an alternative to treat severe PVL.[54] Outcomes data from the Italian CoreValve registry in which 24 patients underwent valve-in-valve are encouraging, showing 100% procedural success and outcomes similar to uneventfully placed valves.[55] The most common reason for redeployment was low positioning of the THV (75% of cases).[55] Hemodynamic performance of the valve-in-valve prosthesis was satisfactory, with no new-onset PVL, embolic events, or impingement on the coronary ostia within the 12-month period.[55] Atrioventricular blocks requiring pacing were, however, more common.[55] Limited outcomes data for valve-in-valve with the Edwards-Sapiens valve are available from a smaller series of 5 patients with severe PVL showing similar results.[56] Data from larger series with longer follow-up are necessary to justify the use of valve-in-valve in patients with less than severe PVL.

Patients with chronic PVL may present asymptomatically, with significant hemolysis or signs of heart failure. The efficacy of paravalvular defect repair using catheter-delivered occluding devices, such as the Amplatzer vascular plugs, is well-established in post-SAVR patients.[57–59] The deployment techniques have been extensively described by Rihal et al,[57] who reported outcomes after closure of 141 defects in 115 patients post-SAVR who presented with heart failure (93%) and hemolysis (37%).[57] Successful device deployment rate was 89%, with a total 30-day complication rate of 8.7%.[57] Seventy-two percent of patients were symptom-free at 3 years.[59] Potential complications relate to embolization of the occluders, leading to obstruction of the prosthetic valve

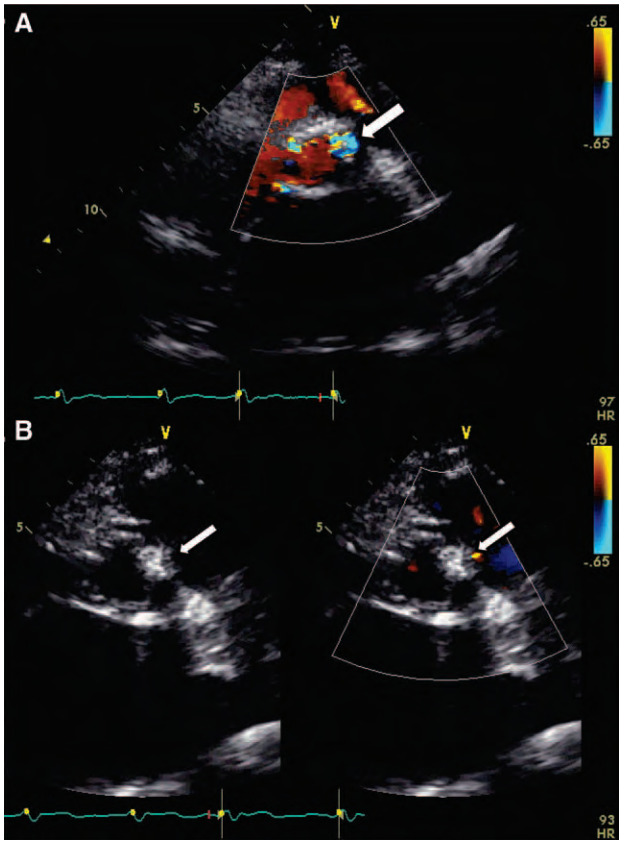


Figure 3. A, Short-axis transthoracic echocardiography (TTE) view at the level of the aortic valve showing 23-mm Edwards SAPIENS valve and moderate paravalvular leak (PVL). **Arrow** indicates site of largest paravalvular leak. **B,** Short-axis TTE view at the level of the aortic valve with and without color showing Amplatzer Vascular II 8-mm plug in place with significant reduction in severity of PVL. **Arrows** indicate occluder device site.

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leaflets or distally in the iliac arteries. Obstruction of the coronary ostia can occur when para-aortic defects are treated. It is important to note that persistent regurgitation postprocedurally is ominous, with patients having poor survival (30.3%) at 3 years.[57]Occluders have been used successfully in treating PVL post-TAVR (Figure 3).[60] However, until outcomes from large series of post-TAVR patients undergoing the procedure are available, its efficacy remains unclear in this group of patients with PVL.

Center expertise and the optimization of the TAVR technique should also impact the incidence of PVL. Unbehaun et al,[6] using a modified 3-step procedural strategy of transapical TAVR, yielded a very low incidence of moderate PVL (0.2%) with absolutely no cases of severe PVL. The development of next-generation THV aims to address several procedural challenges in TAVR.[61] New valves, such as the Edwards CENTERA, the JenaValve, Sadra Medical Lotus, and Saint Jude Portico, allow for repositioning and retrieval. Their designs also include innovative mechanisms to minimize PVL, such as anchors or adaptive skirts in the lower part of the prosthesis that conform to irregular surfaces and provide a seal with the aortic annulus.[61]

Future Directions

Paravalvular regurgitation is common post-TAVR and is an established independent prognostic factor, with even mild PVL appearing to have important negative clinical consequences. However, the risks and impact of PVL can be mitigated by careful preprocedural imaging and device selection, standardization of procedural techniques and imaging, prompt recognition and accurate characterization of acute PVL, and long-term surveillance, prevention, and management of PVL. As the use of TAVR expands to lower risk groups, the need to address PVL through these techniques as well as by the development of THV technology is essential to ensure a favorable risk–benefit ratio for the patient.

Disclosures

Dr Lerakis is a consultant to Edwards LifeSciences. Dr Douglas receives research support from Edwards LifeSciences. Dr Hayek reports no conflicts.

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KEY WORDS: aortic valve ■ aortic valve insufficiency

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EXHIBIT 25

Edwards Lifesciences Launching SAPIEN XT Valve In The U.S.

FDA Approval Includes High-Risk and Inoperable Indications, Transfemoral and Alternative Access Systems

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Jun 16, 2014, 05:23 ET

IRVINE, Calif., June 16, 2014 /PRNewswire/ -- Edwards Lifesciences Corporation (NYSE: EW), the global leader in the science of heart valves and hemodynamic monitoring, today announced that it has received United States Food and Drug Administration (FDA) approval for its Edwards SAPIEN XT transcatheter aortic heart valve for the treatment of high-risk and inoperable patients suffering from severe symptomatic aortic stenosis (AS). This next-generation, lower-profile system, which includes the 29mm valve size for patients with a large native annulus, will allow for the treatment of more patients.



Edwards SAPIEN XT valve (PRNewsFoto/Edwards Lifesciences)

The Edwards SAPIEN XT valve will be immediately available to patients at leading cardiovascular centers across the nation, along with the NovaFlex+ transfemoral delivery system that can be delivered through a low-profile 16-French expandable sheath (eSheath) and the Ascendra+ transapical and transaortic delivery systems.

"There is a substantial and growing body of evidence that the SAPIEN XT valve benefits both high-risk and inoperable patients, and clinicians have documented these consistently positive results in both randomized studies and European country registries," said Martin B. Leon, MD, director, Center for Interventional Vascular Therapy at NewYork-Presbyterian/Columbia University Medical Center and professor of medicine at the Columbia University College of Physicians and Surgeons. Dr. Leon was the co-principal investigator for the PARTNER II Trial, which was Edwards' second randomized controlled trial of a transcatheter valve and evaluated the SAPIEN XT valve. "The results from the PARTNER II Trial in treating U.S. inoperable patients with the SAPIEN XT valve demonstrated a reduction in complications with the TAVR procedure, and improved patient outcomes over earlier trials."

"Clinicians have demonstrated their confidence in the SAPIEN valves by making them the market-leading transcatheter valves, and this approval provides greater options for U.S. patients who can benefit from the substantial enhancements in this proven platform," said Larry L. Wood, Edwards' corporate vice president, transcatheter heart valves. "The SAPIEN family of valves has been used in the treatment of more than 70,000 patients globally – with the majority of those patients treated with SAPIEN XT – and we look forward to Heart Teams across America transforming the lives of even more patients with this advanced transcatheter valve."

The Edwards SAPIEN XT valve has been commercially available in Europe since 2010, and received regulatory and reimbursement approval in Japan in 2013.

About Edwards Lifesciences

Edwards Lifesciences is the global leader in the science of heart valves and hemodynamic monitoring. Driven by a passion to help patients, the company partners with clinicians to develop innovative technologies in the areas of structural heart disease and critical care monitoring, enabling them to save and enhance lives. Additional company information can be found at www.edwards.com.

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements include, but are not limited to, statements of Dr. Leon and Mr. Wood and statements regarding the launch status, availability and benefits of SAPIEN XT. Forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain and

difficult to predict. Our forward-looking statements speak only as of the date on which they are made and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement.

Forward-looking statements involve risks and uncertainties that could cause results to differ materially from those expressed or implied by the forward-looking statements based on a number of factors, including but not limited to, unanticipated delays in the timing or scale of launch, or unexpected clinical outcomes following the U.S. launch, regulatory actions, competitive activity, or quality or manufacturing issues. These factors are detailed in the company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2013.

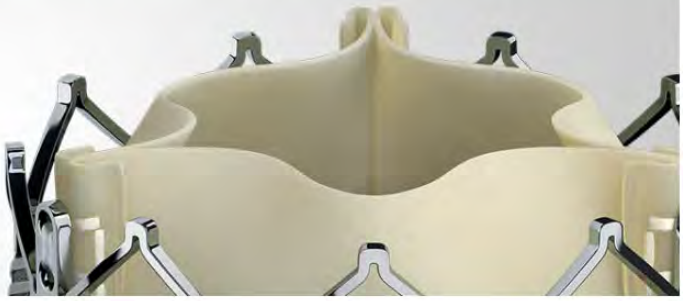
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EXHIBIT 26

SAPIEN XT valve



Design | Expanded indications | Videos

Designed for predictable deployment

- Frame design
- Proven valve tissue
- NovaFlex+ delivery system
- Ascendra+ delivery system



Expanded indications

Valve-in-valve



Aortic

The SAPIEN XT valve may be used in the aortic position via a broad range of access routes - transfemoral, transapical and transaortic.



Mitral

The SAPIEN XT valve may be used in the mitral position via the transapical access route only.

Aortic and mitral valve-in-valve sizing

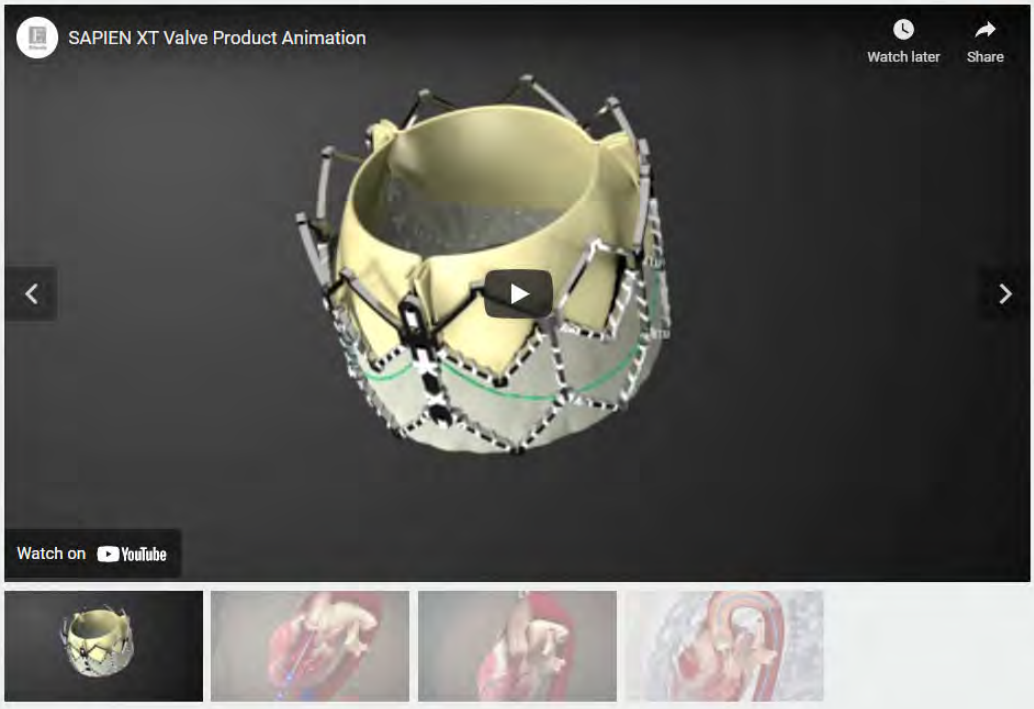
	23 mm	26 mm
Bioprosthesis Internal Orifice Diameter*	18-21 mm	21-23.5 mm

Valve-in-valve indications for 23 mm and 26 mm SAPIEN XT valves

*The internal orifice diameter of the surgical bioprosthesis must be determined prior to the procedure for appropriate transcatheter heart valve sizing.

Video library

SAPIEN XT valve product animation



For professional use

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable). Edwards devices placed on the European market meet the requirements for bearing the CE marking of conformity.

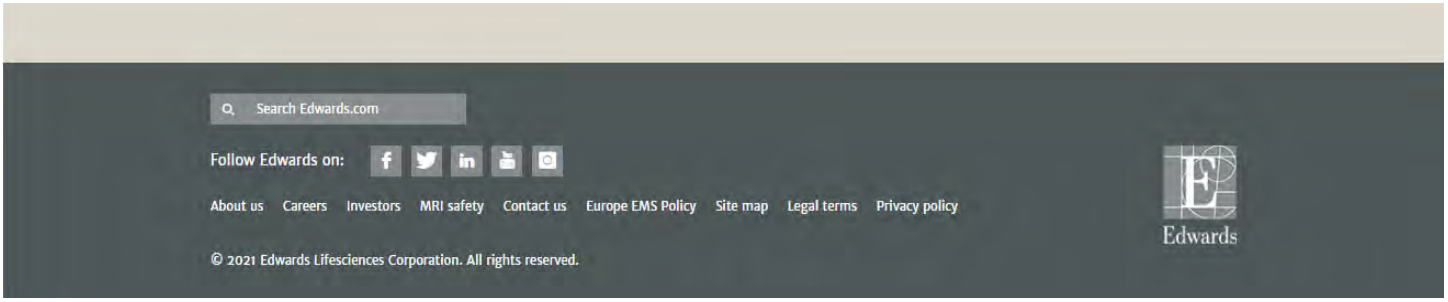

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EXHIBIT 27

Only Edwards SAPIEN 3 TAVR was proven superior to surgery

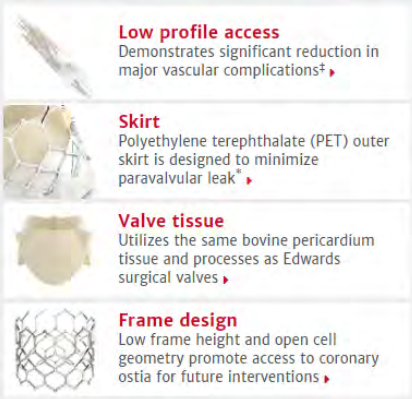
Low-risk patients deserve the lowest-risk procedure

1% death or disabling stroke at 1 year†

PARTNER 3 Trial proved SAPIEN 3 TAVR is superior to surgery on the primary endpoint (all-cause mortality, all stroke, and rehospitalization) and multiple pre-specified secondary endpoints.

†Compared to 2.9% death or disabling stroke at 1 year (P=0.03).

Transformational valve design



Low profile access
Demonstrates significant reduction in major vascular complications‡

Skirt
Polyethylene terephthalate (PET) outer skirt is designed to minimize paravalvular leak*

Valve tissue
Utilizes the same bovine pericardium tissue and processes as Edwards surgical valves

Frame design
Low frame height and open cell geometry promote access to coronary ostia for future interventions



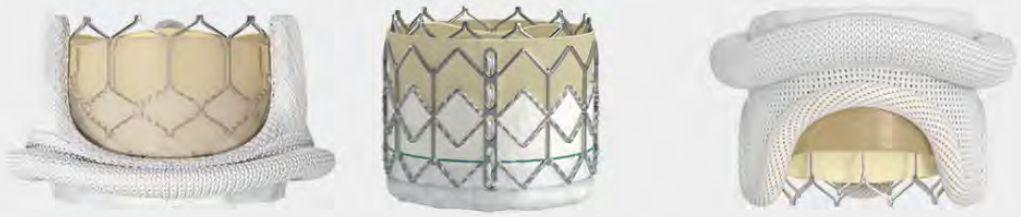
Complete range of valve sizes and access routes expands the treatable patient population



Now approved for aortic and mitral valve-in-valve procedures

The SAPIEN 3 valve is the **only valve approved** for valve-in-valve procedures in both the **aortic and mitral positions**, allowing patients at high or greater surgical risk to avoid an additional open heart procedure.

Aortic **Mitral**

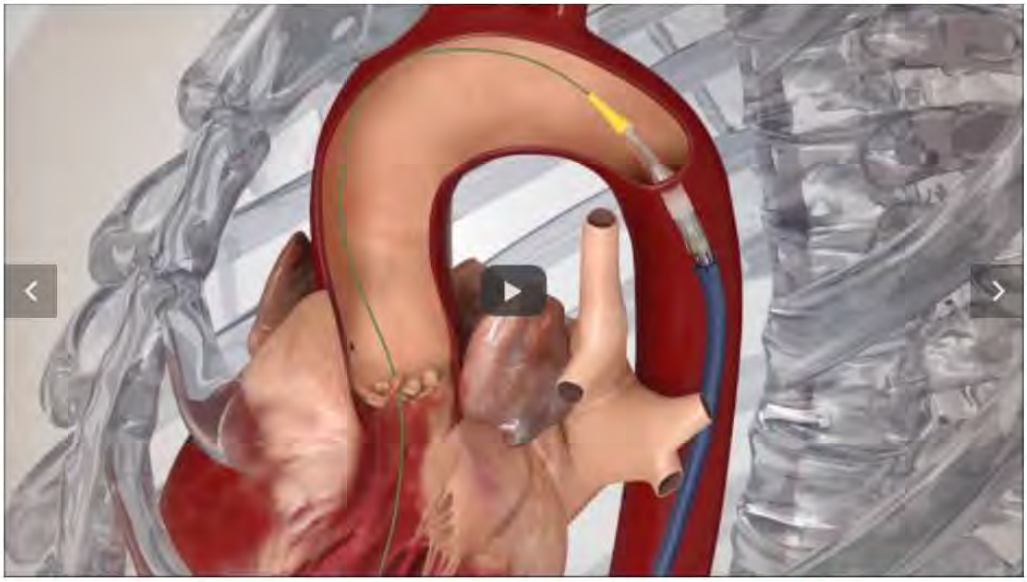


Aortic
Transfemoral, Transapical, and Transaortic

Mitral
Transseptal, Transapical

Video library

Video library









Important safety information

Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications: The valves and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper-evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or if the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some

fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets. Failure to use slow, controlled inflation and prescribed nominal inflation volumes may result in balloon rupture, and lead to patient death or serious injuries associated with difficulty retrieving the delivery system and surgical intervention.

Precautions: Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium or abnormalities in the atrial septum preventing safe transseptal access. Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; pre-existing prosthetic ring in any position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy; hypertrophic cardiomyopathy with or without obstruction (HOCM); echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. For Left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage. Ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor PA pressure in homolateral radial artery. Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthetic valve be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; thoracic bleeding; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury or brachial plexus injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; mechanical failure of delivery system and/or accessories; and non-emergent reoperation.

Edwards Axela Sheath

Indications: The Edwards Axela sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 Ultra delivery system.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm as it may preclude safe placement of the 14F Edwards Axela sheath. For subclavian/axillary vessels with the 29 mm Edwards SAPIEN 3 Ultra delivery system, caution

should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath. Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath. Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed. When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position. When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

Potential Adverse Events: Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 Ultra transcatheter heart valve and the Edwards SAPIEN 3 transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices. There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.**

Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

Caution: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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Edwards

EXHIBIT 28

Premarket Approval (PMA)

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered
Applicant	EDWARDS LIFESCIENCES, LLC. One Edwards Way Irvine, CA 92614
PMA Number	P140031
Supplement Number	S074
Date Received	09/18/2018
Decision Date	12/27/2018
Product Code	NPT[24]
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/Components/Specifications/Material
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval for the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System.

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Page Last Updated: 07/19/2021

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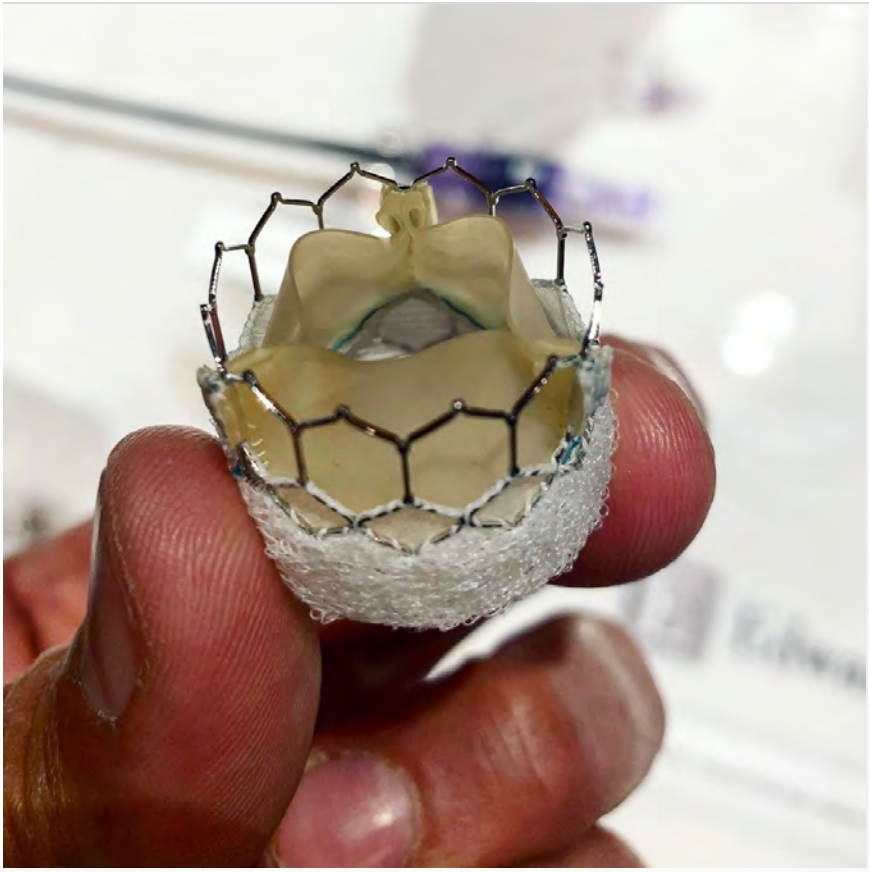
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EXHIBIT 29

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yourheartdoc
Chicago, Illinois

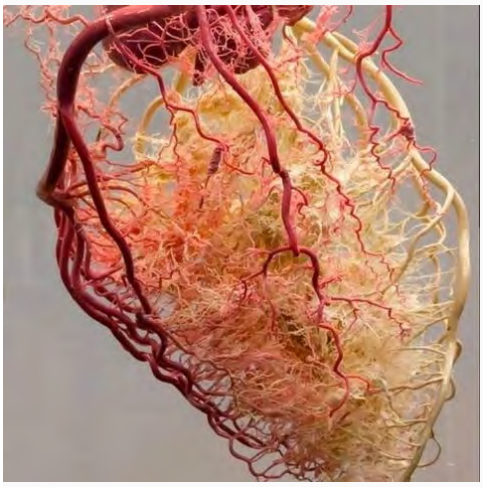
yourheartdoc Playing with some generation TAVR heart valves. Th Sapien S3 Ultra is the next iterati the Edwards valve. The cage is m cobalt-chromium, and the leaflet created out of bovine pericardiur That fluffy cotton-like skirt on the bottom fills any crevices betweer native valve and the TAVR prosth further reduce paravalvular leaks Medical technology is always evc and improving, and still so much come in the world of valvular hea disease. Pretty exciting!

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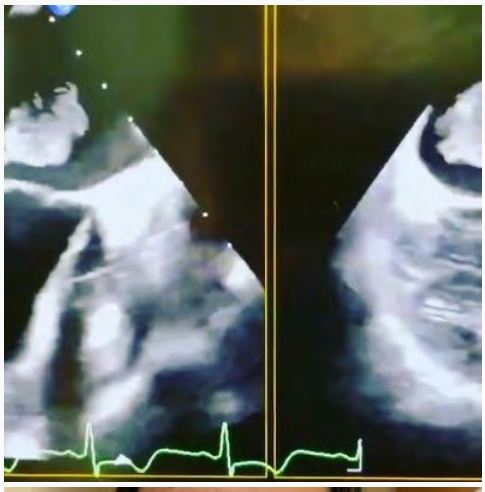
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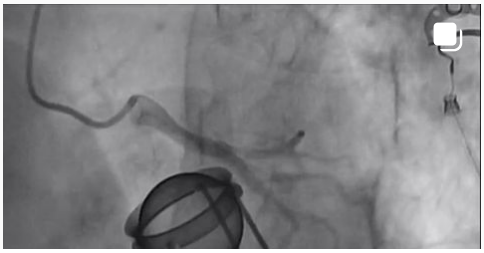
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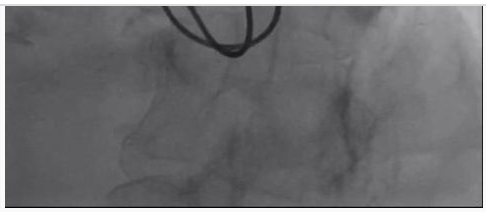




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while on Lipitor 40. And developed unstable angina wirh new 90% LAD lesion compared to 3 years prior.



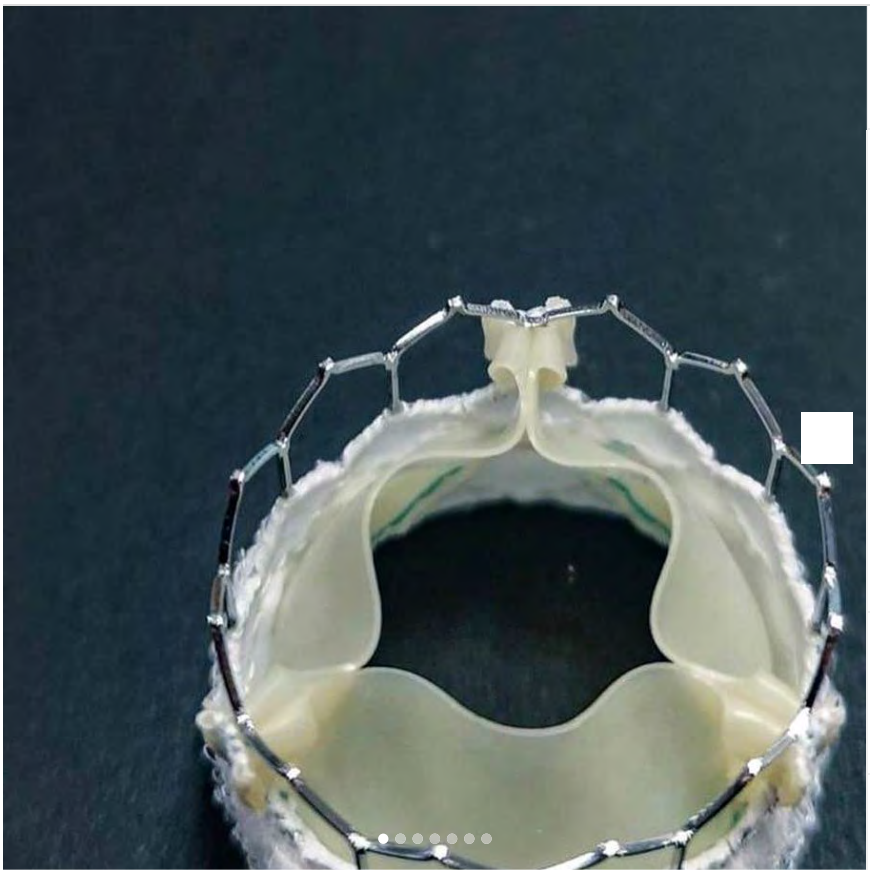


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EXHIBIT 30

Instagram Search



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⏬Transcatheter Aortic Valve Implantation #tavi

● in pictures

▶️ valve: Edwards Sapien 3⏯take your hand and do a carefuly visu inspection ⏸ crimped⏭ position t valve at her place in the heart ⏸ inflate⏭asses the result b angio &eco🔁 repeat the scenar the next case⏮

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EXHIBIT 31

Edwards Lifesciences Corp (EW) Q4 2020 Earnings Call Transcript

EW earnings call for the period ending January 27, 2021.



Motley Fool Transcribers (MFTranscribers)

Jan 27, 2021 at 9:01PM

Edwards Lifesciences Corp (NYSE:EW)
Q4 2020 Earnings Call
Jan 27, 2021, *5:00 p.m. ET*

Contents:

- Prepared Remarks
- Questions and Answers
- Call Participants

IMAGE SOURCE: THE MOTLEY FOOL.

Prepared Remarks:

Operator

Greetings and welcome to the Edwards Lifesciences Corporation's Fourth Quarter 2020 Results Conference Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions].

I will now turn the conference over to our host, Mark Wilterding, Vice President of Investor Relations. Thank you. You may begin.

10 stocks we like better than Edwards Lifesciences Corporation
When our award-winning analyst team has a stock tip, it can pay to listen. After all, the newsletter they have run for over a decade, *Motley Fool Stock Advisor*, has tripled the market.*

They just revealed what they believe are the **ten best stocks** for investors to buy right now... and Edwards Lifesciences Corporation wasn't one of them! That's right -- they think these 10 stocks are even better buys.

Edwards Lifesciences Corp (EW) Q4 2020 Earnings Call Transcript

EW earnings call for the period ending January 27, 2021.

Motley Fool Transcribers (MFTranscribers)
Jan 27, 2021 at 9:01PM

Edwards Lifesciences Corp (NYSE:EW)
Q4 2020 Earnings Call
Jan 27, 2021, *5:00 p.m. ET*

Contents:

- Prepared Remarks
- Questions and Answers
- Call Participants

IMAGE SOURCE: THE MOTLEY FOOL.

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See the 10 stocks

*Stock Advisor returns as of September 17, 2021

Mark Wilterding -- *Vice President, Investor Relations*

Thanks, Diego. Good afternoon and thank you for joining us everyone. With me on today's call are Mike Mussallem, Chairman and Chief Executive Officer; and Scott Ullem, Chief Financial Officer. Just after the close of regular trading, Edwards Lifesciences released fourth quarter 2020 financial results. During today's call, Management will discuss those results included in the press release and accompanying financial schedules and then use the remaining time for Q&A. Please note that Management will be making forward-looking statements that are based on estimates, assumptions, and projections. These statements include, but aren't limited to financial guidance and expectations for longer-term growth opportunities, regulatory approvals, clinical trials, litigation, reimbursement, competitive matters, and foreign currency fluctuations. These statements speak only as of the date when they were made and Edwards does not take -- undertake any obligation to update them after today. Additionally, the statements involve risks and uncertainties, including but not limited to those associated with the pandemic that could cause actual results to differ materially. Information concerning factors that could cause these differences and important safety information may be found in the press release our 2019 Annual Report on Form 10-K and Edwards' other SEC filings, all of which are available on the company's website at edwards.com. Finally, a quick reminder that when using the terms underlying and adjusted, Management is referring to non-GAAP financial measures, otherwise they are referring to GAAP results. Reconciliations between GAAP and non-GAAP numbers mentioned during the call are included in today's press release.

With that, I'd like to turn the call over to Mike for his comments. Mike?

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Thank you, Mark. Before we discuss fourth quarter's results and our expectations for 2021 and beyond, I want to spend a minute reflecting on 2020. Structural heart patients were severely impacted beginning in March, experiencing significant difficulties entering the system, which also had a profound impact on second quarter procedures and even though healthcare systems adapted to the challenge, the resurgence of COVID that began late in the year continues to impact structural heart patients, who need care. Despite unprecedented challenges throughout the year, I'm proud of our team's steadfast dedication to

challenges throughout the year, I'm proud of our team's steadfast dedication to our patient-focused strategy. We continue to invest in developing solutions that extend lives, improve the quality of life and offer greater value for the healthcare system. Along those lines, we celebrated some exciting milestones in 2020 that directly impacted patients. In TAVR, despite headwinds, more than 100,000 patients benefited from treatment with SAPIEN valves worldwide. In Surgical Structural Heart, we launched our KONECT aortic valved conduit and Inspiris became the leading aortic surgical valve worldwide. We've seen early positive clinical evidence across the TMTT platform, physician feedback is encouraging and patient outcomes have been distinguished. And in Critical Care, we met the increased demand for core pressure monitoring products due to the pandemic,

and we're proud that we were able to help over 1 million patients globally with our monitoring technology.

To support our innovation and growth, we continued to invest in our people and our infrastructure. During the year when job losses impacted many families across the globe, Edwards prioritized protecting our employees and we grew our team to 15,000 worldwide. We continue to make strategic R&D investments that enabled us to fuel progress and despite this unique environment and extraordinary prior year growth, underlying sales grew 1% in 2020 to $4.4 billion, which is a reflection of the life-threatening needs of the patients that Edwards serves. Looking into 2021, while we expect the pandemic to continue to impact the global healthcare system, we remain optimistic about the year ahead. As we indicated at our investor conference, we expect full year sales between $4.9 billion and $5.3 billion representing mid-teens underlying growth on a year-over-year basis. Based on our year-to-date experience, we expect Q1 sales to be slightly down sequentially, although in line with the first quarter of last year, which was largely unaffected by COVID.

Our 2021 guidance continues to assume COVID will stress the global healthcare system, it leads through the winter months with procedures ramping later in the year. This expectation assumes that vaccines are effective and widely administered by mid-year 2021 and hospitals continue to improve their ability to treat non-COVID patients, who need care for conditions such as aortic stenosis and even though we expect the COVID impact on sales at the start of the year, we are continuing to invest now in our innovations that have the tremendous opportunity to enhance patients' lives and bring significant value to the healthcare system. We recognize the uncertain impact and timeframe for recovery from this unique global challenge, but we remain confident that our patient-focused strategy of continued investment positions us well and even stronger when the world emerges from the pandemic.

Now turning to our quarterly results, consistent with our guidance at our

Now turning to our quarterly results, consistent with our guidance at our investor conference last month, fourth quarter sales of $1.2 billion were in line with the year ago period when Edwards' grew nearly 20% on an underlying basis, reflecting the strength, even during the ongoing pandemic. Full-year 2020 global sales -- global TAVR sales of 2.9 billion increased 4% on an underlying basis over the prior year. 2020 growth reflected increased sales in every region lifted by greater awareness of the benefits of TAVR therapy and increased adoption of our leading technologies. Based on the strength of the SAPIEN platform, we retained our strong leadership position while also maintaining our disciplined price strategy. In the fourth quarter, global TAVR sales were $776 million, up slightly from the year ago period. We estimate global TAVR procedure growth was

comparable with our growth and globally, average selling prices were stable. Although the rollout was somewhat impacted, SAPIEN 3 Ultra now represents more than two-thirds of our global TAVR sales and physician feedback on ease of use and improved paravalvular leak performance remains outstanding.

In the U.S., our Q4 TAVR sales were approximately level with the third quarter and declined in the mid-single digit range versus last year. We estimate overall Q4 U.S. procedures declined at a comparable rate. Recall that our U.S. TAVR sales in the year ago period increased nearly 40% driven by the strong PARTNER 3 evidence that led to a third quarter 2019 indication expansion and improved patient access under an updated TAVR NCD. We expect these factors to resume lifting treatment rates, as the pandemic subsides. Growth at smaller TAVR centers, which are providing local access to aortic stenosis patients was more than offset by declines in larger accounts, where referrals have been disrupted by the resurgence of COVID. Outside the U.S., in the fourth quarter, we estimated total TAVR procedures grew in the high single digits on a year-over-year basis and Edwards growth was comparable. Edwards' underlying TAVR growth in Europe versus the prior year was in the mid-single digit range. Growth was driven by continued strong adoption of our SAPIEN platform and was more pronounced in countries that were more severely impacted by the first wave of COVID in 2020. Outside of the U.S. and Europe, we continue to see very good TAVR adoption in the fourth quarter. Sales growth in Japan, Australia, and Korea were strong, where therapy adoption is still low. In Japan, we continue to anticipate providing SAPIEN 3 for low-risk patients prior to the end of this year. In China, which was a minor contributor to Q4 sales, we remain focused on growing our dedicated clinical support team to assist leading hospitals, as they build their TAVR programs. In addition to geographic expansion of our TAVR therapies, we remain focused on indication expansion. We talked at our recent Investor Conference about our early TAVR trial, which is focused on the treatment of asymptomatic patients. Enrollment is now two-thirds complete and we remain optimistic that the trial will be fully enrolled in 2021. Separately, we

we remain optimistic that the trial will be fully enrolled in 2021. Separately, we continue to plan to initiate an important pivotal trial for moderate aortic stenosis to determine the optimal time to treat patients, who have this progressive disease. We believe that some patients may benefit from earlier treatment, when they have moderate AS rather than risking irreversible damage as the disease progresses. We're optimistic about the potential of this trial and we anticipate FDA approval to begin enrollment this year.

In November 2020, we are pleased that the American Heart Association announced the launch of an initiative, called Target Aortic Stenosis, a quality improvement program aimed to develop optimal standards of care. The program features a learning collaborative comprised of experts and volunteers from pilot hospital locations around the nation. AHA noticed that if left untreated, the condition worsens and patients with severe aortic stenosis have a survival rate as low as 50% at two years. Aortic stenosis is also a risk factor for heart failure, a costly disease projected the cost the US Healthcare System $70 billion in 2030.

In summary, we continue to anticipate 2021 underlying TAVR sales growth in the 15% to 20% range, as we shared at our Investor Conference. We expect continuing COVID related challenges early in 2021, turning to a more normalized growth environment in the second half of the year. We remain confident in this large global opportunity will exceed $7 billion by 2024, which implies a compounded annual growth rate in the low double-digit range.

Turning to Transcatheter Mitral and Tricuspid Therapies or TMTT, we've made meaningful progress moving from early stage development to clinical use across all of our platforms with over 3,000 patients treated to-date. To transform treatment and unlock the significant long-term growth opportunity, we remain focused on three key value drivers, a portfolio of differentiated therapies, positive pivotal trial results to support approvals and adoption and favorable real-world clinical outcomes. In Europe, PASCAL leaflet repair continues to deliver excellent results. In Q4, we continued the introduction of PASCAL Ace for mitral and tricuspid patients and we're pleased with the early real world results and positive physician feedback regarding its differentiated features and narrower profile. We plan to make both PASCAL Ace and PASCAL available on a single next generation platform called the PASCAL Precision System. This new system is designed to elevate the user experience with enhanced maneuverability, navigation, and stability enabling improved procedural precision. From a clinical perspective, in this challenging near-term environment, we are experiencing a negative impact to clinical trial enrollment. However, our team and research partners are highly motivated to build on the differentiated data presented in 2020 and expand our body of clinical evidence in this exciting field. We will look

forward to presenting meaningful follow-up data across our portfolio at medical meetings later this year.

We progressed in the enrollment of our three CLASP pivotal studies. We also received approval for use of the Edwards PASCAL Precision System in these pivotal studies. The company is still expects U.S. approval of PASCAL for patients with DMR late next year. We continue to enrolling SAPIEN M3 pivotal study and Circle designed to demonstrate strong safety and efficacy for transcatheter mitral replacement and we're on track to initiate our first clinical experience with our next generation EVOQUE Mitral Replacement System. The EVOQUE tricuspid replacement study, TRISCEND continue to enroll in Q4 and we're on track to initiate the TRISCEND II randomized pivotal study based on FDA's Breakthrough pathway designation. We look forward to bringing this important treatment option to more patients that are in significant need.

Turning to recent news, we commenced CMS for ensuring mitral valve disease patients have improved access to therapy options through the updated NCD. This update, which includes coverage with Evidence Development achieves the balance of patient access with high quality outcomes. Fourth quarter global sales were $13 million, representing sequential improvement versus Q3. Full year 2020 sales were $42 million. We expect continuing COVID related challenges early in 2021, but we anticipate a ramp up through the rest of the year. We maintain our beliefs that the total TMTT sales will approximately double in 2021. We continue to estimate the global TMTT opportunity to reach $3 billion by 2025 with significant growth beyond. We remain committed to transforming the treatment of these patients and believe our portfolio strategy positions us well for ultimate leadership.

In Surgical Structural Heart, full-year 2020 global sales of $762 million decreased 10% on an underlying basis over the prior year, in line of our guidance, with our guidance of 5% to 15% decline. Fourth quarter sales of $204 million held steady with Q3 and declined 2% year-over-year on an underlying basis, which was below our previous expectation for positive growth. Over the course of the quarter, hospitals experience an influx of COVID patients limiting surgical procedures. Despite this impact, we are encouraged that the U.S. achieve positive growth in Q4, driven by adoption of our newest premium technologies. We remain very encouraged by the steady global adoption of Edwards Premium RESILIA tissue valves, including the Inspiris aortic surgical valve and the recently launched KONECT aortic valved conduit. In the fourth quarter, Inspiris valve utilization grew in all regions, and we continue to add new centers.

Sales in the U.S. are ramping for KONECT, the first preassembled ready to implant aortic tissue valve conduit for patients who require replacement of the

implant aortic tissue valve conduit for patients, who require replacement of the aortic valve, root, and the ascending aorta, which is a critical unmet patient need. We continue to focus on comprehensive physician training and robust data collection for the HARPOON Beating Heart Mitral Valve Repair System. We are seeing favorable patient outcomes with faster surgery and recovery times with this minimally invasive therapy. The U.S. pivotal trial is now under way and the first patient was treated in December. In summary, we expect full-year 2021 underlying sales growth in the high single-digit range for surgical structural heart driven by market adoption of our newest technologies. After a challenging start, we expect improving year-over-year comparisons, as we progress through the year. We are excited by our ability to provide innovative surgical treatment options for more patients and to extend our global leadership in premium Surgical Structural Heart technologies. We believe the current $1.8 billion Surgical Structural Heart opportunity will grow mid single digits through 2026.

In Critical Care, full year 2020 global sales of $725 million decreased 3% on an underlying basis versus the prior year, in line with our guidance of flat to down 5%. Fourth quarter Critical Care sales of $198 million decreased 2% on an underlying basis, driven by the decline in HemoSphere orders in the U.S., as hospitals limited their capital spending. Sales of our TruWave disposable pressure monitoring devices used in the ICU were lifted by the increased COVID hospitalizations late in the fourth quarter in both the U.S. and Europe. Demand for our products used in more intense surgeries remains strong, but were more than offset by the impact of delayed elective procedures. In summary, we expect full-year 2021 underlying sales growth in the high single-digit range for critical care. We remain excited about our pipeline of Critical Care innovations, as we continue to shift our focus to smart recovery technologies designed to help clinicians make better decisions for their patients.

Now, I'll ask Scott to provide some more detail on the company's financial results.

Scott B. Ullem -- *Corporate Vice President, Chief Financial Officer*

Hey, thanks a lot Mike. Today, I'll provide a wrap-up of 2020 including detailed results from the fourth quarter as well as provide an update on guidance for the first quarter and full year of 2021. Despite the wave of COVID that began during the fourth quarter, we are pleased that we were able to achieve our sales guidance ranges across all product lines. Sales in the fourth quarter were flat year-over-year on an underlying basis and adjusted earnings per share grew 2% to $0.50 versus the prior year. GAAP earnings per share was similar at $0.49. For the full year 2020, sales increased 1% on an underlying basis to $4.4 billion, adjusted earnings per share was flat at $1.86 and we generated over $700 million

of adjusted free cash flow. During 2020, we achieved cost efficiencies, but we intentionally did not take any actions to significantly impact our employees or reduce investments supporting our long-term strategy. I'll now cover the details of our results and then discuss guidance for 2021.

For the fourth quarter, our adjusted gross profit margin was 75.3% compared to 75.8% in the same period last year. This reduction was driven by a negative impact from foreign exchange and incremental costs associated with responding to COVID, partially offset by lower performance-based compensation. We continue to expect our 2021 adjusted gross profit margin to be between 76% and 77%. Our rate should be lifted by an improved product mix, partially offset by a negative impact from foreign exchange. Selling, general and administrative expenses in the fourth quarter were $339 million or 28.4% of sales, compared to $347 million in the prior year. This decrease was primarily driven by reduced spending resulting from COVID and lower performance-based compensation, partially offset by the impact from foreign exchange. We continue to expect full year 2021 SG&A as a percentage of sales, excluding special items to be 28% to 29%, which is similar to pre-COVID levels. Research and development expenses in the quarter grew 1% to $196 million or 16.4% of sales. This small increase was primarily the result of higher investments in TMTT and costs associated with discontinuing our SUTRAFIX program, partially offset by reduced performance-based compensation. For the full year 2021, we continue to expect R&D as a percentage of sales to be in the 17% to 18% range, similar to pre-COVID levels, as we invest in developing new technologies and generating evidence to expand indications for TAVR and TMTT including enrolling seven clinical trials.

Turning to taxes, our reported tax rate this quarter was 13.1% or 13.9% excluding the impact of special items. This rate included a 350 basis point benefit from the accounting for stock-based compensation. Our full-year 2020 tax rate, excluding special items was 12.5%. We continue to expect our full year rate in 2021 excluding special items to be between 11% and 15%, including an estimated benefit of 5 percentage points from stock based compensation accounting. Foreign exchange rates increased fourth quarter reported sales growth by 150 basis points or $18 million compared to the prior year. At current rates, we now expect an approximate $100 million positive impact or about 2% to full year 2021 sales compared to 2020. FX rates negatively impacted our fourth quarter gross profit margin by 150 basis points compared to the prior year. Free cash flow for the fourth quarter was $287 million, defined as cash flow from operating activities of $400 million, less capital spending of $113 million.

Now turning to the balance sheet, we have a strong balance sheet with approximately $2.2 billion in cash and investments as of the end of the year. In

addition, we have an undrawn line of credit of up to $1 billion. We have public bonds outstanding of about $600 million that don't mature until 2028. Average shares outstanding during the fourth quarter were 632 million, relatively consistent with the prior quarter. We now expect average diluted shares outstanding for 2021 to be between 630 million and 635 million.

So before turning the call back over to Mike, I'll finish with financial guidance for 2021. We are maintaining all of our previous sales guidance ranges for 2021. For total Edwards, we expect sales of $4.9 billion to $5.3 billion. For TAVR, we expect sales of $3.2 billion to $3.6 billion. For TMTT, we expect sales of approximately $80 million. We expect Surgical Structural Heart sales of $800 million to $900

million and Critical Care sales of $725 million to $800 million. For the full year 2021, we continue to expect adjusted earnings per share of $2 to $2.20. For the first quarter of 2021, we project total sales to be between $1.1billion and $1.2 billion and adjusted earnings per share of $0.43 to $0.50.

And so with that, I'll pass it back to Mike.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Thanks, Scott. While a year like 2020 could threaten to cause persistent disruptions, our strategy of patient-focused innovations remains unwavering. As we look to 2021 and beyond, I'm as excited as ever about the work happening at Edwards and more importantly what we envision for the future of patient care. I continue to believe we are poised for success and that our innovation and cultural imperative to put patients first will drive strong organic sales growth and create long-term value.

And with that, I'll turn it back over to Mark.

Mark Wilterding -- *Vice President, Investor Relations*

Thanks a lot, Mike. With that, we're ready to take questions. In order to allow for broad participation, we ask that you please limit the number of questions to one plus one follow-up. If you have additional questions, please reenter the queue and Management will answer as many participants as possible during the remainder of the call. Diego?

Questions and Answers:

Operator

Thank you. At this time, we will be conducting a question-and-answer session. [Operator Instructions]. Our first question comes from Bob Hopkins with Bank of America. Please state your question.

Bob Hopkins -- *Bank of America -- Analyst*

Great and good afternoon. Mike, I was wondering, since we just met in December, if you comment on maybe just two quick things, first question would be just how different is the environment out there right now, the selling environment out there right now versus what you seeing at the time of the Analyst Day, kind of on the margins are things getting a little worse, are they getting a little better, just would love some thoughts on that topic and then I have one quick follow-up.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. I would say in general, it's been a little worse. It was already trending negative and we anticipated it was going to be a tough winter and it certainly has turned out to be that way, but probably a little worse since that time.

Bob Hopkins -- *Bank of America -- Analyst*

Okay. And then the other thing I'd love to get your quick comments on is just thinking a little bit long-term on the tricuspid opportunity and the reason I ask is that obviously, Abbott has reported some numbers too and their tricuspid business is already annualizing at over $50 million, if you just take the results this quarter and multiply it times four, so it looks like some pretty robust interest in tricuspid repair right off the bat, so would love your thoughts on that market and how quickly you think that could develop and what hurdles might be. Thank you.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. Thanks, Bob. It's interesting. So the tricuspid market size in terms of number of patients, it's very large, it's certainly as big as the mitral opportunity and we've talked about the fact that that patient group is greatly underserved. So in terms of people actually getting procedures, you're talking about 1%, 2%, 3% very low numbers. So if we can actually develop a great solution for them, it's going to be an important deal. They don't have great answers. And so the burden is going to be on us to develop great solutions and to create evidence that we are actually doing that. We have -- we have a high level of confidence that we can do it, of course mitral is going to be bigger here in the near term. It's got an earlier start, but we think there is a lot of potential in this. The patients themselves are very diverse and that's why we think, when it's all done for tricuspid patients, it's going to require a portfolio.

Operator

Thank you. Our next question comes from David Lewis with Morgan Stanley. Please state your question.

David Lewis -- *Morgan Stanley -- Analyst*

Great. Thanks for taking the question. Mike or Scott, I just want to followup here on guidance for a second. So obviously resurgence trends have probably trended more negatively than when you sort of gave earlier guidance in December, so while things are trending more negatively, you're still sort of holding the outlook for '21. So I guess what's providing that kind of comfort that even though your near term things are heading more difficulty, you still feel very good about the '21 numbers. Is that just what you're seeing here in the first quarter, is that new account recovery, is that just the pace of the recovery you

saw last time, but same confidence, facts have change, what's providing that confidence and a quick follow-up.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah, thanks David. So we always anticipated it was going to be a slow start to the year. It was going to take a while for vaccines to have any impact, it's probably turned out to be a little worse than we thought, but it really hasn't changed our outlook. We really believe that coming out of the winter, we are going to start gaining ground on this that you're going to have vaccines widely distributed by the middle of the year and that we're going to be returning to normalization. So when we put that together, it gives us considerable confidence. Yeah. Is it maybe slightly weaker than it was when we gave the guidance at the investor conference? Yeah, maybe, but we're still very much in the range.

David Lewis -- *Morgan Stanley -- Analyst*

Okay. And then just maybe -- just strategically, this comment of clinical trial enrollment is coming up a lot from you, other companies now, and I wonder two things. The first is, have you rethought you have a significant number of clinical trials sort of ongoing, have you thought at all about changing the clinical trial strategy, slowing some sound, emphasizing others is sort of question one and then related is just -- it benefits the incumbent for all the companies that are trying to get into this marketplace and they've lost basically 18 months and sort of competitively did that start becoming a bigger advantage to those that are already in the market, specifically in Structural Heart and TAVR, where the trial burden is very high. Thanks so much.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah, thanks David. You make a good point. The trial burden is high and so it is -- it is more difficult right now. I can tell you that our team and our researchers

are very committed. They're ready to get back at it. And so although there were delays, I don't know if it's fair to characterize it is an 18-month delay, David, I think that's probably overstating it to some extent. Yeah, I think we talked when we said what happened in 2020 for example in some of the TMTT trials, it's certainly cost us a couple of quarters and now, we're seeing it a little slow again. But our team really feels through conversation that researchers that it's going to come back. When you're trying to develop real new opportunities like TMTT or expand indications in TAVR like early TAVR and moderate AS, those are heavy lifts that take the long-term commitment and we're getting really nice

participation in cooperation with FDA. So it's going to get done. It just is a bit of a headwind right now.

Operator

Thank you. Our next question comes from Raj Denhoy with Jefferies. Please state your question.

Raj Denhoy -- *Jefferies -- Analyst*

Hi, good evening. I want to ask a little bit on the near-term as well. You mentioned that some of the larger centers were maybe seeing slow referrals, is there anything you can comment really on how that pipeline looks and how quickly, it can refill if things do start to open up and essential -- will there be a kind of continued lag effect on your recovery relative to what happens in the broader market because of that referral network.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. Thanks, Raj. So what we were referring to is just reflecting back on the fourth quarter, we had this observation that the larger centers saw less growth than the smaller centers. The exactly why that happened, we can -- we only kind of speculate Raj. So we obviously have conversations with them and we have anecdotal information that suggests, hey, you know those larger centers maybe used to pull from much broader geography and maybe there is less referrals during this time of COVID than you would expect in a normal environment. So having said that, when when these sort of slowdown down, yes, they also slowdown qualifying patients. So it takes a while for that pipeline to refill. So that is -- that's legitimate, but then again, when we gave our estimates, we've taken that into account. So when we say, hey, we think TAVR is going to grow 15% to 20% in 2021, we've taken into account that, yeah, there's this lag at the beginning of the year. So we're still camping on sites to engage with patients and feel very motivated to do that, but you know where we're headed.

Raj Denhoy -- *Jefferies -- Analyst*

Understood. Yeah. Maybe just one quick followup on that. So noticed on the market globally, have you seen much impact in the marketplace, did that impact some of that share. Any thoughts there on how that's going?

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. Thanks Raj. They didn't have a really large share position. And so, yeah, I'm sure we were the beneficiary to a small extent you know if I reflect all the way back to our Investor Conference in 2019, we estimated that we would probably

have some small share loss during 2020 and we don't -- it's kind of tough for us to find that at this point, we're not sure that that happened. That may have been part of a contributor.

Operator

Thank you. Our next question comes from Larry Biegelsen with Wells Fargo. Please state your question.

Larry Biegelsen -- *Wells Fargo -- Analyst*

Good afternoon and thanks for taking the question. One on PASCAL for me, one on different one separately. So Mike, you expect to launch PASCAL in the U.S. in late '22, does that assume completing enrollment in 2021 of Class 2-D and presenting the data in early '22 and PASCAL precision, Mike, what are the benefits of that and the timing and I have one follow-up.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. Thanks, Larry. So let me be a little bit more precise. So what we said is that we'll get approval by the end of '22, end of next year and we'll probably be launching in '23. So I wouldn't want to necessarily model sales in 2022, exactly what the run-up looks like before that we're not -- we haven't really talked about we haven't laid it up, obviously, you're right, there is multiple steps when do we complete enrollment, when do we complete the followup, when do the reports show up and I don't have clear estimates for you at this time of when that's going to happen. Is it relates to the PASCAL precision, we're really proud of that system, it's designed to deliver significant advancements to our stabilizer in our catheter in our handle. It's the precision one is not -- we haven't really laid out timing, I think that's going to sort of evolve over the course of 2021, but I can probably come back with more accurate timing at a later date.

Larry Biegelsen -- *Wells Fargo -- Analyst*

And Mike, thanks for that, and few years ago, you were developing a product for aortic insufficiency, what's the status and what are your thoughts on that market opportunity. Is it just too small, given all the bigger opportunities that you're pursuing now. Thank you.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. We really don't have there Larry to say that that is a pipeline item that's imminent. That goes back quite a way, the one product that we have that sort of helps that group of patients is really in the surgical side, this KONECT product that also replaces the aortic root that certainly helps those kind of patients, but

to suggest that we have a transcatheter one around the corner would be overstating it.

Operator

Thank you. Our next question comes from Robbie Marcus with JP Morgan. Please state your question.

Robbie Marcus -- *JP Morgan -- Analyst*

Great. Thanks for taking the question. So with a little slowdown here with COVID, what are you seeing in terms of trial enrollment, is that also getting delayed and is that -- is that assumed in the timelines that you gave us today.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. Thanks, Robbie. So yeah, we are feeling it in trial enrollment. This is not an easy time when we're going through what we just saw here at the end of the quarter and the start of this quarter, it is a tough time. It's kind of fun, I mean the hospitals, it's not like all hospitals have been impacted, but the ones that have been impacted are really full up, right. They really struggle to be able to handle new patients, which includes clinical trials. So, but having said that, all the dates that we gave you anticipated what's going on. We would give you new dates, if we didn't think that we could achieve those. So, yes, yes, it is a little tough time right now. Yes it is. But do we think that there is going to be a recovery. There is a lot of interest among the clinical researchers to get back at it and really they are enthusiastic about it, as we are and so, we think that we're going to get after a pretty hard when it opens back up again.

Robbie Marcus -- *JP Morgan -- Analyst*

Great. Still a lot of sick patients that need help.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yes, there are.

Robbie Marcus -- *JP Morgan -- Analyst*

Unfortunately. Maybe just a quick follow-up, you're still generating a very healthy amount of cash even in 2021 here, how should we think about the priorities for that use of cash and are there any areas to the business that might see some M&A potential? Thanks.

Scott B. Ullem -- *Corporate Vice President, Chief Financial Officer*

Robbie, it's Scott. Thanks for the question. So our focus and our priorities for use of cash haven't really changed. The first one, of course, is making sure that we've got sufficient cash to invest in internal growth opportunities and that includes building out our plant infrastructure. So we've got now multiple production facilities around the world. We've recently gotten a lot further along and are almost completed with Costa Rica, we've broken ground on new facility in Ireland, and as the company continues to grow, we'll continue to in a disciplined fashion invest capital to support that growth on the production side. As it relates to M&A, we're very active on the business development front. And we are continually looking for external growth opportunities. As you know, most of these are typically small. We usually by pre-revenue companies or technologies or we'll make investments in companies or buy options to acquire companies based upon how they perform and development efforts, and so those activities will continue. We've got this -- we've got a good problem to have, which is we continue to generate net cash and that's why we've got over $2 billion now on the balance sheet. So we think carefully about how to do that and we think carefully about how to manage the share count and for the time being and for the foreseeable future, our preferred means of returning capital to shareholders will be through continued share repurchase and we've got over $600 million of share repurchase authorization left. Thanks a lot.

Operator

Our next question comes from Josh Jennings with Cowen. Please state your question.

Joshua Jennings -- *Cowen -- Analyst*

Hi, good evening. Thanks for taking the questions. Just two on the $7 billion, reiteration $7 billion TAVR market by 2024, the first is you've had that target for a couple -- a little while now in front of the China approval, does that include an internal assumption for within the market for China TAVR and then the second

layer is just thinking about TAVR and TAVR and TAVR and SAVR, could those two indications represent 10% or more of that $7 billion dollar opportunity in 2024. Thanks for taking the questions guys.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. Thanks Josh. Yeah. So we feel pretty confident in that plus $7 billion TAVR market opportunity. It does include China, it also includes most of those indication expansions like you just mentioned like TAVR and TAVR and TAVR and SAVR. What's not in there really is early TAVR, so this asymptomatic patients if we got that it would be very late in the period, so probably hardly any impact and

we're not expecting to be moderate to read out and really impact that number as well. So maybe that -- is that sufficient to answer your question.

Joshua Jennings -- *Cowen -- Analyst*

Yeah. Thanks for the help, Mike. I appreciate it.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Sure.

Operator

Thank you. Our next question comes from Suraj Kalia with Oppenheimer. Please state your question.

Suraj Kalia -- *Oppenheimer -- Analyst*

Good afternoon everyone and thanks for taking my questions. Mike, couple of quick question, I just wanted to follow up on Raj's question on TAVR and then I have a TMTT question. Forgive me if I heard it wrong, why would referrals in the largest centers in the U.S. be different than the smaller centers and if I could throw in my TMTT question for PASCAL in Europe, Mike, for the centers that are early adopters, what is the -- if a patient comes in, what would be the key rationale for them choosing PASCAL versus let's say a G3 MitraClip. Thank you for taking my question.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Sure. So going back to the large centers versus small centers. First of all, this was simply an observation on our part. If we looked at our largest centers versus our smaller centers, the smaller centers grew faster in the fourth quarter than the larger centers. So, now why is that, now we start speculating to some extent because we really don't have that clearer picture, it's just a fact of how that happened, part of what we have heard anecdotally is that the large centers were

often improve a matter of fact attract patients, let's say, from a multi-state area, whereas a small center might only attract patients in their local area and given COVID being what it is, these elderly patients willing to travel long distances to a referral center, we wonder and we hear from others, they speculate that that's the reason. So again, you can take that for what it's worth, but that's probably the best answer that we have on that one. In terms of the centers that are adopters, how does it compare. We feel really good about the outcomes. We've been doing a lot of work in Europe and trying to help people have outstanding outcomes and so clinicians have experience with PASCAL and many of those experiences have -- many of those clinicians also have experience with MitraClip

system. We have both PASCAL and PASCAL Ace, so they have options in terms of what they might use. And I think it's a patient-specific decision that clinicians are making at this point of what they think might be best for their patients. It's still early, you know our data by comparison is still relatively light, although we're proud that we have 3,000 patients were treated last year and most of those are with PASCAL, so we're starting to get some pretty good experience, but it's still -- there is some time before this plays out.

Operator

Thank you. Our next question comes from Matt Miksic with Credit Suisse. Please state your question.

Matthew Miksic -- *Credit Suisse -- Analyst*

Thanks so much for squeezing us in. So I did want to have a followup on MitraClip. It's just -- and on the mitral repair, I should say and PASCAL in Europe. I'm wondering if you're seeing any difference in the sort of variability or referral of say mitral repair in the small, relatively smaller footprint that you have there versus TAVR, just to one of your competitors reported and those numbers were down a little harder maybe then sort of TAVR volumes are down and just trying to sort through what they could mean if anything and any color you have would be appreciated. I have one follow-up.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. Thanks, Matt. I think I understand your question. Are you saying, hey, it looks like the mitral numbers are down more than the aortic numbers. And is that the essence of the question?

Matthew Miksic -- *Credit Suisse -- Analyst*

That is right.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Okay. Yeah, in fact, that is our observation as well. It appears that that is indeed the case. Now, I'm going to speculate as to why, TAVR has been out there for quite a while. We have really compelling evidence, we have very mature systems, a very reproducible results, well-trained infrastructure. By comparison on the mitral side, it's still relatively young. The indications are nearly as clear. So it's -- it's a less mature market and not a surprise probably but that's taken place. But I think your observations are correct.

Matthew Miksic -- *Credit Suisse -- Analyst*

Great. And then just a follow-up, and I apologize if I -- it it's been asked, but just the sort of maybe confidence in these sort of call it acceleration maybe off of a slightly lower, more sluggish Q1 and then getting to your to your original range for full year, what gives you that sort of the confidence that you'll be able to kind of bounce back in Q2 and still wind up in roughly the same place.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. There was a version of that, Matt, but that's fine. Yeah, we really do have confidence that it's going to come back. We think it's going to be ramped during the course of the year. Q1, we're just based on what we're seeing so far, it's going to be a tough quarter and so we acknowledge that, but we always thought it would be tough, it might be a little tougher than we thought, but we really believe that there is a lot of pent-up demand of patients and they are very much going to seek treatment and once the fear of COVID and once hospitals get themselves squared away and we think they really will, they'll be in much better shape by the time we get into second half of the year, but we are going to realize those kind of growth rates.

Operator

Our next question comes from Danielle Antalffy with SVB Leerink. Please state your question.

Danielle Antalffy -- *SVB Leerink -- Analyst*

Hey, good afternoon guys. Thanks so much for taking my question. Mike, if I could just follow-up on the referral question and I'm not sure what level of visibility you guys do you have into the referral channel, but just curious what you saw in the sort of June, July, August timeframe as far as refilling the funnel and how quickly that happens and whether that could serve as a proxy to what we could see whenever we get past this most recent COVID resurge and then I don't know if the right way to think about it is diagnostic facilities were

operating at X percent of normal levels or what, but any color you could give there would be great.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. Danielle, your observation is a good one. I think we all remember the trauma that happened when sort of the bottom fell out in the middle of March last year and -- but we also remember that things recovered pretty quickly, right. There was a pretty sharp V that we felt, and so this question about how fast does the pipeline fill up and how fast the patients come back, if that's any indication, it didn't take -- it wasn't quarters, it was a matter of months when things really started bouncing back. So yeah, you're right, you could use that as some kind of a proxy to try and estimate what might happen now.

Danielle Antalffy -- *SVB Leerink -- Analyst*

That's it from me. Thanks.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Sure.

Operator

Our next question comes from Vijay Kumar with Evercore ISI. Please state your question.

Vijay Kumar -- *Evercore ISI -- Analyst*

Hey guys, thanks for taking my question. A couple of quick I guess guidance questions. Gross margins, I think I heard you, Scott, mention 150 basis points of headwind in Q4, given your comments on FX, any changes on how FX impacts gross margins for fiscal '21 or Q1 perhaps.

Scott B. Ullem -- *Corporate Vice President, Chief Financial Officer*

Sure. So in '21, we think FX probably hits us another 50 basis points negative on the gross margin line and so, we're coming off of. In the fourth quarter, we finished at 75.3%, but we're also expecting better mix as TAVR continues to grow. We've also got some operational efficiencies that are going to continue to benefit on the gross margin line. And so, we think we'll be able to largely offset that additional 50 basis points of FX pressure on gross margin. And end up in that 76% to 77% range that we guided to.

Vijay Kumar -- *Evercore ISI -- Analyst*

That's helpful. And then perhaps, Mike, you can chime in on this, but I'm curious,

the share count assumption here for Q1 assumes no buybacks, I'm just curious given the cash position. What would cause I guess for you guys to be a little bit more aggressive on the buybacks.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. I'll start and I encourage Scott to jump in, because he is very much the leader of this and a good partner. We have a long history of opportunistically buying shares, when we think that there is a disconnect, but what we do routinely is to try and offset the dilution that's associated with our -- with our equity programs. So we're going to expect to do that and I think that would be

something that's typical, in terms of doing something opportunistic, we basically just look for disconnects.

Scott B. Ullem -- *Corporate Vice President, Chief Financial Officer*

Yeah. So we don't match exactly period by period the offsetting of dilution from equity awards, but we do over time try to not only offset that dilution, but also by down the total net shares outstanding, you've seen us do that consistently over time. So last year, we bought back about $625 million for the stock, which was in excess of the dilution from employee option exercises and delivery of restricted stock and the like. And so you should expect that we're going to continue to be opportunistic, as Mike said and be active repurchasers over time.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah, I want to say those average shares last was around $68 a share. We consider that an opportunity.

Operator

Thank you. Our next question comes from Matt Taylor with UBS. Please state your question.

Matthew Taylor -- *UBS -- Analyst*

All right. Thank you for taking questions. So I had two related questions. So we've talked a lot about your clinical pipeline and new product flow. I was just hoping you could give us a couple of key guide post, what are you looking for this year in terms of data at PCR or other places, approval that we should be watching out for and then as we're talking about the clinical trial delays in terms of enrollment, has it gotten to a point where you feel like you need to adjust any of your timelines or is it just a little bit slower and we're not there yet.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. So I'll start with the second question. We really are not changing our timelines. If we were changing our timelines, we would certainly tell you and we believe that we're going to hit those and those are our best estimates, we're trying to do that as accurately as we can, in terms of what you're going to expect to see this year out of meetings like EuroPCR, I think what you're going to see for the most part is followup on the many many trials, everything from EFS to CE Mark trials and more. So it will be -- there'll be more patients, there'll be longer timeframes, where data will be shared and so you'll see that we've got quite an extensive portfolio in TMTT. So I think you're going to see a number of reports over the course of the year.

Matthew Taylor -- *UBS -- Analyst*

Okay.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Thanks, Matt. Diego, next question.

Operator

Thank you. And our last question comes from Pito -- I'm sorry, our next question comes from Pito Chickering with Deutsche Bank. Please state your question.

Pito Chickering -- *Deutsche Bank -- Analyst*

Good afternoon, guys. Thanks for fitting me in. Two quick ones here for the U.S. market, your largest competitor has been pretty aggressive trying to take back market share in the back half of 2020, I'm just curious if you -- if you can give any color on where the market share ended up during sort of the fourth quarter and how would you think about market share, changing one way or the other in 2021?

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. So yeah, I think what we've tried to do is provide a statement in our prepared remarks. That said that we felt like the market grew pretty much at the same pace that we did. So we didn't really see appreciable share change in the quarter. So again, having said that, it's pretty hard to determine what exact share positions are and it's even more difficult during a pandemic, so we're not suggesting that it's exact, but in our estimates, it was pretty flat.

Pito Chickering -- *Deutsche Bank -- Analyst*

Great. Then a quick follow-up for guidance. U.S. markets in Europe is obviously weaker than you expected in December, we talked about strength in Japan, Australia, and South Korea. Can you walk us through if those markets have

Australia, and South Korea. Can you walk us through if those markets have accelerated, which is the -- your guidance at the Analyst Day, can you give more color on these markets. Thanks so much.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

So we're not suggesting that those three countries, for example, are better since the Analyst Day. What we're saying is, those are examples of countries, where the penetration is low and the growth rate is high. So those were really healthy growth rates significantly above the rest of the portfolio that's pulling it up. Now some of those are pretty small base by comparison like Korea and Australia will be pretty small compared to what's going on in Europe, etc., but nonetheless as those treatment rates increase in those countries, it certainly helps the growth rate.

Operator

Thank you. And we have time for last question and that comes from Joanne Wuensch with Citi Bank. Please state your question.

Joanne Wuensch -- *Citi -- Analyst*

Thank you for fitting me in and good evening. I'll make it quick. Doubling TMTT revenues in 2021 is impressive. Do you think you've hit sort of a tipping point, can we think of this as an accelerant over the next couple of years or how do you think, broadly speaking, and I recognize COVID makes it more difficult, the TMT market in Europe. Thanks.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Yeah. I think maybe it's just fair to say, Joanne. This is a really big market opportunity, remember, when we talk about it, we talk about it in billions and when you look at where our sales are right now, they are really low. So our opportunity to grow at a pretty significant pace, I don't think it should be that surprising. The doubling is nice and we're pleased to do that, but we've got a long way to go. We really think it's important, it's a big opportunity for us. The big drivers are going to be our evidence. When we really put a strong clinical evidence up there that's compelling in significant clinical trials, those are the kind of things that are really going to drive even more significant inflection points, if you will, of course, we've got a great team, and a nice reputation and a nice really differentiated products, but the data is going to be the bigger issue and again it's -- it's got much more potential than this in the long run.

Operator

Thank you. And that's all the questions we have, I'll turn it back to Mr. Mussallem

for closing remarks.

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Okay. Well, thanks for all the continued interest in Edwards, and even though COVID is challenging right now, we do see better days ahead and we're very optimistic about the future of Edwards Lifesciences. So Mark, Scott, and I welcome any additional questions by telephone.

And with that, back to you, Mark.

Operator

I don't think Mark's mic is open now, sir. Thank you. And this concludes today's conference and you can access the replay by dialing 877-660-6853, please use conference ID 13710472. Once again, to access the replay, please dial 877-660-6853 and using conference ID 13710472. Have a good day. Thank you.

Duration: 60 minutes

Call participants:

Mark Wilterding -- *Vice President, Investor Relations*

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Scott B. Ullem -- *Corporate Vice President, Chief Financial Officer*

Bob Hopkins -- *Bank of America -- Analyst*

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Matthew Taylor -- *UBS -- Analyst*

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[illegible] -- *Citi -- Analyst*

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EXHIBIT 32

frontiers in Cardiovascular Medicine

ORIGINAL RESEARCH
published: 18 March 2021
doi: 10.3389/fcvm.2021.623146

Minimizing Paravalvular Regurgitation With the Novel SAPIEN 3 Ultra TAVR Prosthesis: A Real-World Comparison Study

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Objectives: We investigated performance and outcome of the latest-generation balloon-expandable SAPIEN 3 Ultra prosthesis (S3U) compared to the established SAPIEN 3 prosthesis (S3) in a real-world cohort, with focus on paravalvular regurgitation (PVR).

Background: PVR is an adverse prognostic indicator of short- and long-term survival after transcatheter aortic valve replacement (TAVR). The S3U has been designed to improve sealing.

Methods: We enrolled 343 consecutive patients presenting with severe native aortic valve stenosis eligible for a balloon-expandable prosthesis. The established S3 was implanted in the first 200 patients, the following 143 patients received the novel S3U after introduction in our institution. Primary endpoint was PVR after TAVR. Furthermore, we investigated procedural parameters and in-hospital and 30-day outcome.

Results: PVR was significantly lower in the S3U cohort compared to the S3 cohort. They differed in their rate of mild PVR (11.2 vs. 48.0%, $p < 0.001$), whereas at least moderate PVR was similarly low in both cohorts (0.7 vs. 0.5%, $p = 0.811$). A significant reduction of post-dilatation rate, fluoroscopy time, and amount of contrast was observed in patients treated with the novel S3U ($p < 0.001$). The rate of adverse events in the in-hospital course and at 30 days were similarly low. At 30 days more patients receiving S3U improved in NYHA class (improvement ≥2 grades 34.6 vs. 19.9%, $p = 0.003$).

Conclusion: The current study provides evidence that the novel S3U strongly minimizes PVR, thereby demonstrating the efficacy of improved sealing. Further studies will have to address if the observed reduction of PVR with S3U has prognostic significance.

Keywords: transcatheter aortic valve replacement, balloon expandable valve, paravalvular regurgitation, SAPIEN 3 ultra, aortic stenosis

OPEN ACCESS

Edited by:
Maximillian A. Rogers, Brigham and Women's Hospital and Harvard Medical School, United States

Reviewed by:
Shunsuke Katsuki, Kyushu University Hospital, Japan
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Specialty section:
This article was submitted to Heart Valve Disease, a section of the journal Frontiers in Cardiovascular Medicine

Received: *29 October 2020*
Accepted: *25 January 2021*
Published: *18 March 2021*

Citation:
Tamm AR, Hell MM, Geyer M, Kreidel F, da Rocha e Silva JG, Seidl M, Ruf TF, Kornberger A, Beiras-Fernandez A, Münzel T and von Bardeleben RS (2021) Minimizing Paravalvular Regurgitation With the Novel SAPIEN 3 Ultra TAVR Prosthesis: A Real-World Comparison Study. Front. Cardiovasc. Med. 8:623146. doi: 10.3389/fcvm.2021.623146

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has evolved into a standard treatment for patients with symptomatic severe aortic valve stenosis (AS) regardless of surgical risk (1, 2). With respect to the hemodynamic status, TAVR offers lower transvalvular aortic gradients, larger effective orifice area, and a lower rate of patient-prosthesis mismatch compared to a surgical prosthesis (3, 4). However, paravalvular regurgitation (PVR) occurs more often in TAVR procedure and has been associated with a worse short- and long-term survival (4–7). With the advancement in prosthetic valve technology, the incidence of at least moderate PVR has significantly declined. Nevertheless, several reports suggested that even mild PVR is an adverse prognostic indicator for mid- and long-term outcome (6–9).

Different balloon- and self-expandable prosthesis systems have been released and approved for clinical use. Due to their mechanical characteristics, balloon-expandable prostheses are less prone to PVR compared to self-expandable prostheses (10). Among the balloon-expandable devices, the SAPIEN series (Edwards Lifesciences Inc., Irvine, CA, USA) has been recently extended with the novel S3U. It features ∼40% taller, textured polyethylene terephthalate outer skirt compared to the third-generation S3, intended to improve sealing of the prosthesis and reduce the amount of PVR. First reports with the S3U system showed a good in-hospital and 30-day clinical outcome but the quality of comparison is limited (11–13).

The aim of this real-world, high-volume TAVR single-center observer study was to compare the procedural performance and 30-day outcome of the latest-generation balloon-expandable prosthesis—the S3U—with its preceding model, the S3. The particular focus and primary endpoint of the study was the rate of PVR.

METHODS

Patient Population and Pre-interventional Assessment

We screened all consecutive patients with high-grade symptomatic native AS scheduled for transfemoral TAVR and eligible for a balloon-expandable prosthesis between January 2019 and March 2020 for enrolment. Non-eligibility for a balloon-expandable but rather self-expanding prosthesis was the presence of moderate to severe annular or left ventricular outflow tract calcifications due to a higher risk for annulus rupture with balloon-expandable devices. Furthermore, patients with severely calcified and narrow femoral arteries were in favor for a self-expandable prosthesis (Evolut R, Medtronic Inc., Minneapolis, MN, USA) due to the smaller absolute required vessel diameter of the corresponding access sheath. Patients with a large annulus size suitable for the 29 mm SAPIEN prosthesis were not enrolled in the study, as the S3U is only available in sizes 20, 23, and 26 mm. Furthermore, since no 20 mm S3U has been implanted, the two patients receiving a 20 mm S3 were excluded in the comparison.

The S3 has been implanted at our institution in more than 1,000 patients since 2014. In September 2019, we switched to the latest-generation S3U. Therefore, in the first half of the enrolment period (January–August 2019), all patients received a S3 (200 patients). Starting from September 2019, all further patients were implanted the latest-generation S3U. Finally, 343 patients were included in the study (**Figure 1**). The study was approved by the Institutional Review Board (reference number: 2019-14692), all patients provided written consent. Covariates, including cardiac history and risk factors, were obtained by a structured interview. The "European System for Cardiac Operative Risk Evaluation II" (EuroSCORE II) and the "Society of Thoracic Surgeon" (STS) score were calculated in all patients. Indication for TAVR was confirmed by the interdisciplinary heart team.

In all patients, severe AS (aortic valve orifice area <1.0 cm^2) was diagnosed in our echocardiography lab. Pre-interventional CT imaging of the aortic annulus and the vascular access route was performed according to current recommendations and post-processed using a semi-automated software (3mensio Structural Heart, Pie Medical Imaging BV, Maastricht, The Netherlands) (14, 15). Aortic root dimensions, distance between annular plane and coronary artery ostia, an orthogonal fluoroscopic angulation plane for implantation and the vascular access route were assessed in all patients. Additionally, the distribution of annular/sub-annular and left ventricular outflow tract calcification was qualitatively graded (none, mild, moderate, and severe) (14).

S3U and Delivery System

The CE-mark approved S3U is available in three sizes: 20, 23, and 26 mm. The novel key feature of the S3U is a taller, textured polyethylene terephthalate outer skirt with ∼40% increase in height compared to the third-generation S3 which is supposed to improve the sealing of the prosthesis (**Figure 1**). Other components of the valve, including the cobalt-chromium alloy stent with a low delivery profile, open cell geometry and high radial strength, the bovine pericardial leaflets and the inner sealing skirt remain unchanged to the S3. According to manufacturer's recommendations, the Commander delivery system with the 14 French eSheath was applied.

Implantation Procedure

The TAVR procedure was performed under sedation or, if needed, in intubation anesthesia in a hybrid operating suite. The interdisciplinary established team of interventional cardiologists and cardiac surgeons has been trained and certified for the SAPIEN system and performed more than 1,000 previous joint TAVR procedures according to current recommendations. Apart from the prosthesis type, the technical aspects of the procedure did not differ between both cohorts and followed the recommended standards. Prosthesis sizing was based on pre-procedural CT analysis according to manufacturers' recommendations. A transvenous temporary pacemaker was

Abbreviations: AS, aortic stenosis; PPI, permanent pacemaker implantation; PVR, paravalvular regurgitation; RBBB, right bundle branch block; S3, SAPIEN 3 valve prosthesis; S3U, SAPIEN 3 Ultra valve prosthesis; TAVR, transcatheter aortic valve replacement; VARC-2, updated criteria of the Valve Academic Research Consortium.

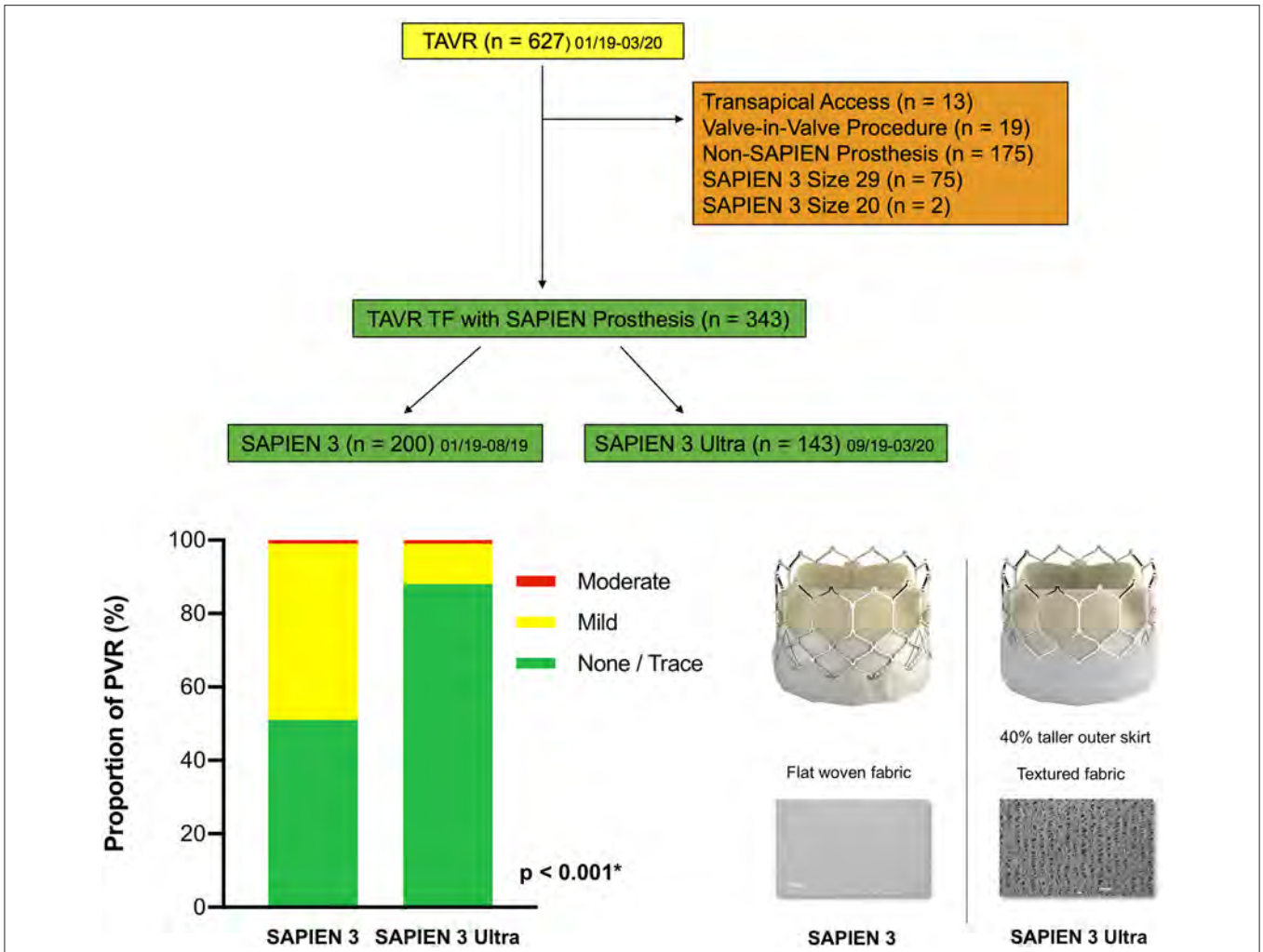


FIGURE 1 | Patient population. A total of 627 patients undergoing TAVR from January 2019 until March 2020 at the Heart Valve Center Mainz were screened. Reasons for exclusion are displayed on the right side. Finally, 200 patients with a SAPIEN 3 and 143 patients with a SAPIEN 3 Ultra were enrolled in the study. TAVR, transcatheter aortic valve replacement; TF, transfemoral access. Central illustration. Impact on paravalvular regurgitation: The SAPIEN 3 Ultra significantly lowers the rate of paravalvular regurgitation after TAVR compared to the SAPIEN 3. The SAPIEN 3 (left) and last-generation SAPIEN 3 Ultra prostheses (right). The novel SAPIEN 3 Ultra features a taller, textured polyethylene terephthalate outer skirt with ∼40% increase in height. All other prosthesis components remained unchanged from the SAPIEN 3. PVR, paravalvular regurgitation. *P*-value was calculated by Chi squared test. Data represented as percentage of total.

applied in all patients. Pre-dilatation was at discretion of the interventionalist and mainly due to severe commissural calcification or very high transvalvular gradients. Post-dilatation was performed in patients with at least moderate residual PVR evaluated by multi-modality assessment (angiography, transthoracic echocardiography, and invasive hemodynamic assessment with simultaneous determination of left ventricular and aortic pressures). The puncture site was sealed using dedicated closure systems. Procedural parameters including procedure time (duration from puncture to suture), need for post-dilatation, amount of contrast and fluoroscopy time were assessed. Prosthesis oversizing was calculated with the formula (S3U or S3 nominal area/MDCT systolic annular area−1) × 100 (16) and four categories were set stepwise from <0 to >10% (**Supplementary Table 2**) according to the literature (17, 18).

Post-procedural Course

Post-procedurally, the temporary pacemaker sheath remained for 24 h and patients were ECG-monitored through 72 h. Indications for a permanent pacemaker implantation (PPI) were a third-degree atrioventricular block or a symptomatic second-degree atrioventricular block Mobitz II.

A 3-month dual antiplatelet therapy followed by a lifelong single antiplatelet therapy was prescribed as antithrombotic treatment. Patients with the indication for oral anticoagulation received a 1-month single antiplatelet therapy in addition to their lifelong oral anticoagulation.

Pre-discharge transthoracic echocardiography was performed in all patients for semi-quantitative grading of final PVR, determination of the prosthesis gradient and cardiac function. According to current recommendations,

PVR was graded as none or trace, mild, moderate and severe (19).

Outcome

Study endpoints were established according to the Valve Academic Research Consortium-2 (VARC-2) definitions (20). For in-hospital outcome, we included device success, all-cause death, cardiac death, myocardial infarction, stroke, vascular complications, bleeding, new PPI, PVR grade at discharge and acute kidney injury in our analysis. Patients were followed up in an outpatient department at 30 days or by telephone contact for assessment of the early safety combined endpoint.

Statistics

Statistical analysis was performed using SPSS software (IBM® SPSS® statistics, version 24 for Mac). Continuous variables were expressed as mean ± SD when normally distributed, otherwise as median and interquartile ranges. Categorical variables were presented as frequencies and percentage, unless otherwise specified. Shapiro–Wilk test was used to assess normality for continuous data. Statistical significance was assessed using a *t*-test in normally distributed data or a Mann-Whitney-*U*-test in non-normally distributed data. Chi-square test was used to compare categorical variables. For multi-variate analysis, stepwise logistic regression models were used to examine independent relationships between patient and procedural parameters and PVR or PPI. All statistical tests were two-sided and $p < 0.05$ was considered to be statistically significant.

RESULTS

Baseline Characteristics

The total cohort included 343 patients (43.1% male) with a mean patient age of 80 ± 7 years and a mean EuroSCORE II of 5.2 ± 5.2% and STS Score 5.0 ± 4.1%, respectively. Except for a higher rate of prior myocardial infarction and less patients with NYHA class III in the S3 cohort, there were no significant differences in terms of age, cardiovascular risk factors or comorbidities between patients enclosed in the S3 (200 patients) and the S3U (143 patients) cohorts. Baseline characteristics are presented in **Table 1**.

Procedural Data

Device success by VARC2-criteria was achieved in 95.6% patients with no significant difference between the two cohorts ($p = 0.35$). There was no peri-procedural death or incorrect positioning of the prosthesis with the need for implantation of a second valve. The 15 cases not meeting the VARC2-criteria of device success had either a moderate PVR after initial valve deployment (2 patients, 0.5%) or a mean gradient ≥20 mmHg as assessed by echocardiography at discharge (13 patients, 3.8%).

Among the patients receiving the latest-generation S3U, a 23 mm prosthesis was implanted in 70 patients (49%) and a 26 mm prosthesis in 73 patients (51%). In the third-generation S3 cohort, 106 patients (53%) received a 23 mm prosthesis and 94 patients (47%) a 26 mm prosthesis. Pre-dilatation was performed in 36 patients (10.5%) with no significant difference between

TABLE 1 | Patient characteristics.

	All patients (*N* = 343)	S3 (*N* = 200)	S3U (*N* = 143)	*p*-value
Age (years)	80.2 ± 7.1	79.9 ± 7.3	80.7 ± 6.8	0.297
Male sex—*n* (%)	148 (43.1)	85 (42.5)	63 (44.1)	0.774
BMI(kg/m^2)	27.1 ± 4.9	27 ± 5.3	27.3 ± 4.3	0.561
EuroSCORE II	5.2 ± 5.2	5.4 ± 5.6	5 ± 4.4	0.493
STS score	5.0 ± 4.1	5.0 ± 4.1	5.1 ± 4.2	0.771
NYHA class				
I	15 (4.4)	10 (5.0)	5 (3.5)	0.502
II	77 (22.4)	51 (25.5)	26 (18.2)	0.109
III	229 (66.8)	123 (61.5)	106 (74.1)	0.014
IV	22 (6.4)	16 (8.0)	6 (4.2)	0.156
Coronary artery disease—*n* (%)	254 (60.3)	176 (63.3)	78 (54.5)	0.082
Previous myocardial infarction—*n* (%)	47 (13.7)	34 (17.0)	13 (9.1)	0.036
Previous PCI—*n* (%)	157 (45.8)	94 (47.0)	63 (44.1)	0.589
Previous open-heart surgery—*n* (%)	30 (8.7)	16 (8.0)	14 (9.8)	0.563
Previous stroke—*n* (%)	42 (12.2)	23 (11.5)	19 (13.3)	0.619
Peripheral artery disease ≥ grade II	33 (9.6)	21 (10.5)	12 (8.4)	0.514
Arterial hypertension—*n* (%)	309 (90.1)	176 (88.0)	133 (93.0)	0.126
Diabetes (%)	100 (29.2)	58 (29.0)	42 (29.4)	0.941
COPD ≥ grade II—*n* (%)	21 (6.1)	11 (5.5)	10 (7.0)	0.57
GFR (ml/min)	55.6 ± 23.8	55.7 ± 23.1	55.5 ± 24.8	0.932
Reduced GFR <30 ml/min	41 (12.0)	22 (11.0)	19 (13.3)	0.52
Congenital bicuspid valve	49 (14.3)	29 (14.5)	20 (14.0)	0.893
Atrial fibrillation—*n* (%)	84 (24.6)	47 (23.6)	37 (26.1)	0.606
Permanent pacemaker—*n* (%)	38 (11.1)	19 (9.5)	19 (13.3)	0.271
Preexisting RBBB	21 (6.1)	14 (7.0)	7 (4.9)	0.423
Pulmonary hypertension—*n* (%)	50 (14.6)	34 (17.0)	16 (11.2)	0.133
Left ventricular ejection fraction (%)	55.2 ± 10.3	55.5 ± 10.3	54.8 ± 10.2	0.522
Reduced Ejection Fraction <40%	34 (10.0)	19 (9.5)	15 (10.6)	0.758
Aortic valve area (cm^2)	0.76 ± 0.18	0.75 ± 0.18	0.77 ± 0.18	0.322
Aortic valve peak gradient (mmhg)	62.1 ± 26.5	63.8 ± 28.9	59.7 ± 22.6	0.155
Aortic valve mean gradient (mmhg)	37.1 ± 14.3	37.4 ± 14.1	36.8 ± 14.5	0.701
Severe commissural calcification—*n* (%)	139 (40.6)	79 (39.7)	60 (42.0)	0.675

BMI, Body Mass Index; EuroSCORE, European System for Cardiac Operative Risk Evaluation; STS Score, Society of Thoracic Surgeons Predicted Risk of Mortality; NYHA class, New York Heart Association Functional Classification of Heart Failure; PCI, Percutaneous Coronary Intervention; CABG, Coronary Artery Bypass Graft; TIA, Transient Ischemic Attack; COPD, Chronic Obstructive Pulmonary Disease; GFR, Glomerular filtration rate; ICD, Internal Cardioverter Defibrillator; RBBB, Right Bundle Branch Block, S3, SAPIEN 3, S3U, SAPIEN 3 Ultra.

P-value was calculated by Chi squared test and Student's t-test. Data represented as mean ± SD for metric variables and number and percentage of total in categorical variables.

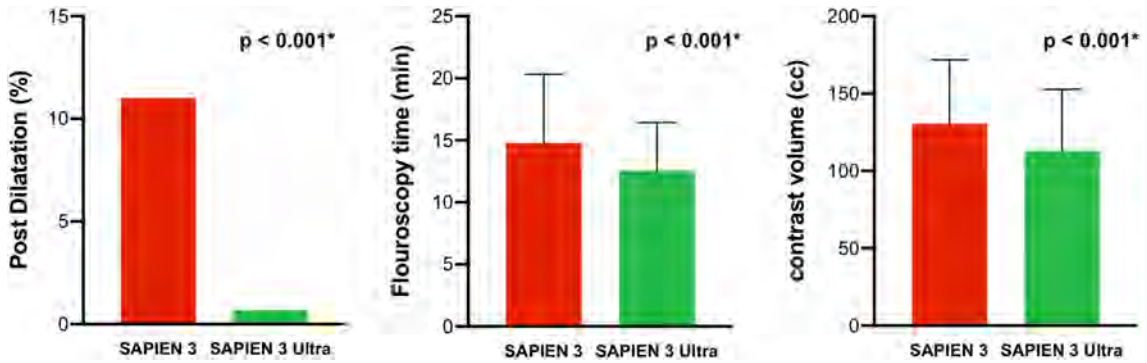


FIGURE 2 | Procedural performance. The SAPIEN 3 Ultra performed significantly better in terms of post dilatation rate, fluoroscopy time, and amount of contrast compared to the SAPIEN 3. *P*-value was calculated by Chi squared test and Student's *t*-test. Data represented as mean ± SD for metric variables and number and percentage of total in categorical variables.

both cohorts ($p = 0.998$). Likewise, procedural time was similar between both treatment groups ($p = 0.43$). However, post-dilatation due to an at least moderate post-implant PVR after valve deployment was significantly lower in the S3U cohort compared to the S3 cohort (1 vs. 22 patients, $p < 0.001$). Furthermore, fluoroscopy time and amount of contrast were significantly lower in the S3U cohort compared to the S3 cohort (12.6 ± 3.9 vs. 14.8 ± 5.5 min, $p < 0.001$, and 113.1 ± 39.6 vs. 130.4 ± 41.6 ml, $p < 0.001$, respectively, **Figure 2**). Major TAVR-related complications occurred in 3 patients (all cardiac tamponades due to wire related ventricular injury, one of them with need for median sternotomy in the S3U cohort, 2 with pericardiocentesis alone in the S3 cohort). There was no peri-procedural death. Procedural data are summarized in **Table 2**.

TABLE 2 | Procedural details.

	All patients (*N* = 343)	S3 (*N* = 200)	S3U (*N* = 143)	*p*-value
Prosthesis size—*n* (%)				
23 mm	176 (51.3)	106 (53.0)	70 (49.0)	0.459
26 mm	167 (48.7)	94 (47.0)	73 (51.0)	
Balloon pre-dilatation—*n* (%)	36 (10.5)	21 (10.5)	15 (10.5)	0.998
Balloon post-dilatation—*n* (%)	23 (6.7)	22 (11.0)	1 (0.7)	<0.001
General anesthesia—*n* (%)	45 (13.1)	32 (16.0)	13 (9.1)	0.062
Procedure time (min)	64.6 ± 33.9	65.8 ± 20.2	62.9 ± 46.9	0.431
Fluoroscopy time (min)	13.9 ± 5.0	14.8 ± 5.5	12.6 ± 3.9	<0.001
Contrast volume (cc)	123.3 ± 41.6	130.4 ± 41.6	113.1 ± 39.6	<0.001

S3, SAPIEN 3; S3U, SAPIEN 3 Ultra.
P-value was calculated by Chi squared test and Student's t-test. Data represented as mean ± SD for metric variables and number and percentage of total in categorical variables.

Outcome

The primary endpoint PVR was significantly lower in the S3U cohort compared to the S3 cohort (11.9 vs. 48.5%, $p < 0.001$, **Figure 1**). There was no patient with a severe PVR in both cohorts. The rate of moderate PVR was very low (0.6%) and was observed in 1 patient in the S3U and 1 in the S3 cohort, respectively. In contrast, the rate of mild PVR was significantly lower in patients receiving a S3U compared to patients receiving the third-generation prosthesis (11.2 vs. 48%, $p < 0.001$). In age- and sex-adjusted multi-variable analysis (**Supplementary Table 3**), prosthesis type and oversizing (odds ratio, OR 0.75, $p = 0.002$) remained the only two independent predictors for the presence of PVR with the S3U having a more than 7-fold reduced risk (OR 0.13, $p < 0.001$).

In-hospital outcome showed no significant difference in all cause death, stroke, acute myocardial infarction, vascular complication, bleeding complication, acute kidney injury, need for PPI, new onset of atrial fibrillation or mean prosthetic gradient as assessed by echocardiography.

For 30-day outcome assessment, 17 (4.9%) patients were lost to follow-up. Early safety end-point including, among other parameters, all cause death (1.8%) and stroke (1.9%), revealed no significant difference between the S3U and S3 cohort (3.9 vs. 4.6%, $p = 0.76$). Patients who were implanted a S3U were significantly more often free of symptoms (NYHA class I, 44.1 vs. 31.4%, $p = 0.02$) and improvement of two or more NYHA class grades was higher (34.6 vs. 19.9%, $p = 0.003$) compared to patients with a S3, while overall improvement (reduction of at least 1 NYHA class) did not show a significant difference (75.6 vs. 69.1%, $p = 0.21$) (**Figure 3**).

The rate of new PPI was low in our study (8.9% at in-hospital and 9.6% at 30-day assessment) with no significant difference at in-hospital or 30-day post-procedural course between the two cohorts ($p = 0.10$ and $p = 0.23$, respectively). Age- and sex-adjusted multivariate analysis (**Supplementary Table 4**) including prosthesis type, severe commissural calcification, bicuspid anatomy, post-dilatation, right bundle branch block (RBBB), 1st degree AV Block, left bundle branch block (LBBB) and prosthesis oversizing revealed only a pre-procedural RBBB as a significant independent predictor for new PPI after TAVR (OR 9.22, $p < 0.001$). Peri- and post-procedural outcomes are summarized in **Table 3**.

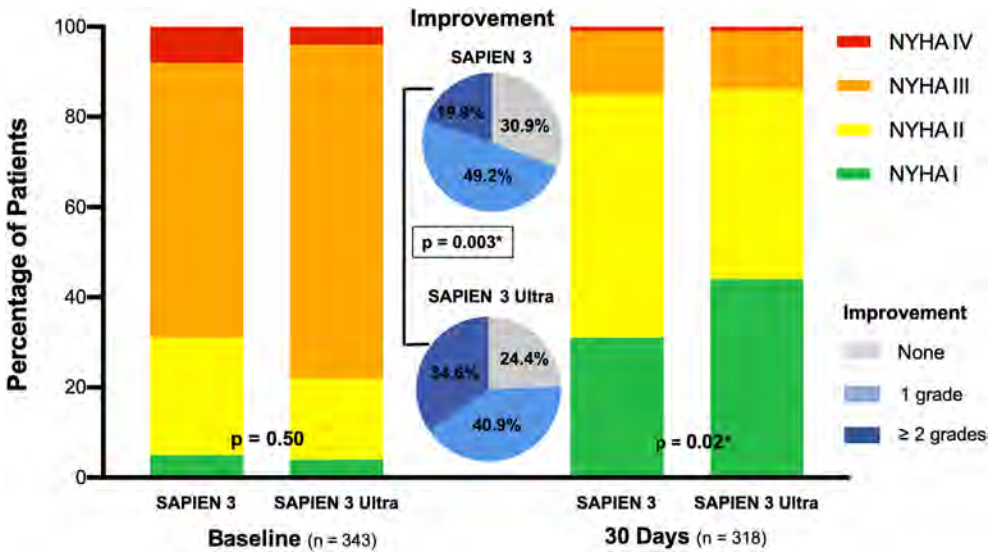


FIGURE 3 | NYHA functional class. NYHA (New York Heart Association) functional class at baseline and 30 days. Significantly more patients receiving the SAPIEN 3 Ultra were free of symptoms and improved in NYHA class at 30 days compared to patients with the SAPIEN 3. *P*-value was calculated by Chi squared test. Data represented as percentage of total.

DISCUSSION

The current study is, to our knowledge, the first to compare the performance and 30-day outcome of the latest-generation S3U with the third-generation, well-established S3 in a modern primary TAVR implantation approach in an equal device size distribution between the TAVR generations. This study is also the first to report a comparison using the same delivery system for both TAVR generations, thus excluding major bias to outcome and complications at 30 days.

The main finding and addressed primary endpoint of the study was a significantly lower incidence of paravalvular regurgitation after TAVR with the novel S3U. Furthermore, procedural performance in terms of fluoroscopy time, amount of contrast and rate of post-dilatation were superior compared to the third-generation valve model. Additionally, more patients receiving the S3U were free of symptoms at 30 days follow-up. Overall, the S3U was non-inferior in procedural safety compared to the third-generation prosthesis.

The S3U has been introduced in November 2018 in the available sizes 20, 23, and 26 mm. The novel prosthesis differs by ∼40% taller, textured polyethylene terephthalate outer skirt compared to the prior S3. The design changes have been influenced in observation of the very good PVR performance of the 29 mm S3 (21). Hence, the novel S3U prosthesis is only available for patients with an annulus diameter <26.5 mm. Recently, Saia et al. reported their first multicenter prospective registry experience with the novel S3U (11). Furthermore, Rheude et al. (13) and Moriyama et al. (12) presented a comparison of the novel Sapien 3 ultra prothesis with its previous model Sapien 3. Overall, these two least studies and our current work all show a low incidence rate of all major complications both in-hospital and at 30 days proving the safety of the novel device. Though, the patient collective and the procedural characteristics show substantial differences between our current work and the studies by Rheude et al. (13) and Moriyama et al. (12). Our procedural strategy included a modern implantation approach with attempted primary TAVR prosthesis implant leading to a large difference in the rate of predilatation between our study and the other two reports. Only 10.5% of patients were predilatated in this study. In contrast, this rate was as high as ∼60% in the study by Rheude et al. (13) and ∼34% by Moriyama et al. (12). Furthermore, our study design included only patients suitable for a prosthesis size of 20, 23, and 26 mm (available in both S3 und S3U) as there is no Ultra version available for the 29 mm prosthesis. In the reports by Rheude et al. (13) and Moriyama et al. (12), patients receiving a 29 mm S3 prosthesis accounted for up to a third of the cohort. As already shown in previous studies, the number of patients sized for a 20 mm valve is very low. In our real-world study, there was no S3U 20 mm and only two S3 20 mm prosthesis implantations which we decided to exclude from the study in the interest of comparability.

In our study there were also no differences in the applied delivery system excluding potential implant success bias between the generations evaluated. The other studies used at least in parts the novel Ultra delivery system with the 14 French seamless, expandable Axela® sheath, which was supposed to streamline the procedure, eliminate valve alignment and flex catheter retraction steps. However, in some instances potential issues with both devices were reported. Therefore, the manufacturer has now paired the S3U valve with the conventional Commander Delivery System and 14F eSheath (11). This system is well-established and has been applied routinely with the S3 since 2014. In the current study, we consequently applied the Commander delivery

TABLE 3 | Peri- and post-procedural outcomes.

	All patients (*N* = 343)	S3 (*N* = 200)	S3U (*N* = 143)	*p*-value
In hospital				
Device success—*n* (%)	328 (95.6)	193 (96.5)	135 (94.4)	0.350
All cause death—*n* (%)	2 (0.6)	1 (0.5)	1 (0.5)	0.846
Stroke—*n* (%)	4 (1.2)	2 (1.0)	2 (1.4)	0.735
Acute myocardial infarction—*n* (%)	1 (0.3)	1 (0.5)	0 (0.0)	0.397
Vascular complications—n (%)				
Minor	34 (9.9)	21 (10.5)	13 (9.1)	0.667
Major	5 (1.5)	2 (1.0)	3 (2.1)	0.403
Bleeding complications—n (%)				
Minor	12 (3.5)	5 (2.5)	7 (4.9)	0.234
Major	1 (0.3)	0 (0.0)	1 (0.7)	0.417
Life-threatening or disabling	1 (0.3)	0 (0.0)	1 (0.7)	0.469
Acute kidney injury ≥2—*n* (%)	7 (2.0)	5 (2.5)	2 (1.4)	0.477
New permanent pacemaker—*n* (%)	27/305 (8.9)	20/181 (11.0)	7/124 (5.6)	0.103
New atrial fibrillation—*n* (%)	4/239 (1.7)	2/140 (1.4)	2 / 99 (2.0)	0.826
Paravalvular regurgitation—n (%)				
None or trace	229 (66.8)	103 (51.5)	126 (88.1)	<0.001
Mild	112 (32.7)	96 (48.0)	16 (11.2)	<0.001
Moderate	2 (0.6)	1 (0.6)	1 (0.6)	0.811
Severe	0 (0.0)	0 (0.0)	0 (0.0)	1.000
Prosthetic mean gradient (mmHg)	11.6 ± 4.4	11.6 ± 4.7	11.7 ± 3.9	0.793
23 mm valve	12.4 ± 4.5	12.5 ± 4.8	12.2 ± 4.0	0.627
26 mm valve	10.6 ± 3.7	10.2 ± 3.7	11.1 ± 3.7	0.135
At 30 days				
All cause death—*n* (%)	6/326 (1.8)	3/197 (1.5)	3/129 (2.3)	0.598
Early safety—*n* (%)	14/326 (4.3)	9/197 (4.6)	5/129 (3.9)	0.763
Stroke—*n* (%)	6/326 (1.8)	4/197 (2.0)	2/129 (1.6)	0.752
New permanent pacemaker—*n* (%)	28/292 (9.6)	20/178 (11.2)	8/114 (7.0)	0.232
NYHA class—*n* (%)				
I	116/318 (36.5)	60/191 (31.4)	56/127 (44.1)	0.021
II	152/318 (49.1)	100/191 (53.4)	52/127 (42.5)	0.057
III	42/318 (13.5)	27/191 (14.1)	15/127 (12.6)	0.695
IV	3/318 (0.9)	2/191 (1.0)	1/127 (0.8)	0.814

NYHA class, New York Heart Association Functional Classification of Heart Failure; S3, SAPIEN 3; S3U, SAPIEN 3 Ultra.
P-value was calculated by Chi squared test and Student's t-test. Data represented as mean ± SD for metric variables and number and percentage of total in categorical variables.

system for both S3 and S3U. This allowed a true evaluation of the prosthesis performance, which was not further confounded by a novel delivery kit. As expected, we found no difference in bleeding rates and access site complications between the two study arms. Finally, we included patients with a mean age of 81.4 ± 8.3 years across all risk categories with a mean STS score of 5.0 ± 4.1 representing an intermediate risk, elderly real-world cohort. In contrast, the patients included by Rheude et al. (13) and Moriyama et al. (12) ranged with a similar mean age demonstrating a low risk group cohort (mean STS between 3 and 4%).

The primary endpoint of our comparison study was the occurrence of PVR after TAVR. Moderate or severe PVR was observed in 1–14% of patients after TAVR, whereas mild PVR ranges from 6 to 63% (5–8, 22). Moderate or severe PVR after TAVR has been consistently shown to increase mid- and long-term mortality (6–8, 21, 23). Several reports have also suggested a worse outcome for even mild PVR (7–9, 22). Numerous factors have been identified to favor the risk for PVR. Among the patient-related factors, aortic annulus and root calcification are the ones most predictive for later PVR (5, 24). Technical-related causes include undersizing of the prosthesis, malpositioning or incomplete apposition to the native annulus (5, 16, 21). Furthermore, balloon-expandable TAVR prostheses are less prone to cause PVR due to specific design and mechanical properties (10). The recent SOLVE trial reported an at least moderate paravalvular regurgitation of 3.4% for the new-generation self-expanding TAVR prosthesis and a 1.5% rate of at least moderate PVR for the third-generation balloon-expandable S3 (25). Pibarot et al. reported for the third-generation S3 a 3.5% rate of at least moderate PVR and a 32.6 and 8.2% rate of mild or mild-moderate PVR, respectively (21). For the latest generation S3U, Saia et al. showed a 10% rate of mild PVR and a 1.4% rate of moderate PVR (11). Rheude et al. (13) reported a significant decrease in the rate of mild PVR with the S3U (19%) compared to the S3 prosthesis (43%). Similarly, Moriyama et al. (12) showed significantly lower rates of mild PVR with the S3U (7%) compared to the S3 prosthesis (19%). In both studies, there was no significant difference in the rate of moderate PVR between the two prothesis. This is in line with our present results showing an 11% rate of mild PVR and a 0.7% rate of moderate PVR for the S3U leading to a significant risk-reduction for PVR compared to the previous S3 model (11.9 vs. 48.5%, $p < 0.001$) which already proved to exert a rather low risk for PVR among other prosthesis types (25, 26). Additionally, the rate of PVR directly after valve deployment was significantly lower in the S3U resulting in a significant lower rate of post-dilatation. Although we did not observe a difference in terms of safety outcome, post-dilatation should be reduced to a minimum to avoid the risk of annulus rupture, rhythm disturbances or valve dislocation. Among the analyzed parameters in the present study, prosthesis-type and prosthesis undersizing were the only two independent predictors for PVR after TAVR. Patients receiving a S3U reported more often relief of symptoms after 30 days which may be attributed to a lower rate of mild PVR. However, long-term outcome with this new S3U will have to be assessed in future studies.

In addition to the above-mentioned reduction in PVR, a superior performance of the new S3U was also observed by a reduced amount of required contrast and fluoroscopy time. We assume that this reduction might partially be a result of the lower rate of post-dilatation. Reduction in contrast to a required minimum is important to prevent peri-procedural renal failure.

Large trials have shown rates of 5–57% of patients who suffered from acute kidney injury after TAVR which significantly affects long-term outcome and mortality (27, 28). We observed in-hospital acute kidney failure of stage 2 or higher in 2.0% of patients. However, the rate did not significantly differ between the two cohorts. With the opening of TAVR indication for younger and low-risk patients, approaches to lower radiation exposure become increasingly important. Here, we found a 15% decrease of fluoroscopy time with the latest-generation S3U compared to its third-generation pre-model. Long-term effects will have to be evaluated in further studies.

Compared to other recent publications, we observed a relatively low rate of post-procedural PPI with a tendency to less PPI in the S3U cohort (5.6 vs. 11.0%, $p = 0.10$) at in-hospital assessment (1, 25, 26, 29, 30). Yet, multivariate analysis revealed only preexisting RBBB to be an independent predictor of PPI and thus, a further significant influence of the S3U could not be determined.

Several limitations have to be acknowledged. First, this study reflects "real world" patients across all risk-categories enrolled in a high-volume single-center observational study rather than a highly selected trial population. Although single-center studies represent an institutional performance, they also minimize cofounders. The study was not designed in randomized fashion, but patients were assigned to either the S3 or the S3U cohort depending on their time of treatment. The 143 S3U patients represented the first patients being treated with the new valve. Though there was no experience at the start of enrollment with this new prosthesis, we observed no inferiority in terms of safety but even a superior procedural performance in some aspects compared to the established S3. As we present a real-world study, we did not pre-determine a certain number for each prosthesis size to be implanted. Furthermore, the current study provides only 30-day follow-up data which limits to conclude on hard outcomes.

CONCLUSIONS

This present real-world study shows that the latest-generation balloon-expandable S3U reduces PVR to a minimum in comparison to the previous S3 model, thereby demonstrating the efficacy of improved sealing. A significant decrease of paravalvular regurgitation with this prosthesis provides a promising result given the steadily growing numbers of TAVR procedures. A superiority for the novel valve was also found in terms of post-dilatation rate, radiation time and the amount of contrast as well as relief of symptoms at 30 days. Further studies need to assess whether the reduction of PVR with S3U may have prognostic significance.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The study was approved by the Institutional Review Board (reference number: 2019-14692). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AT: conceptualization, project administration, formal analysis and writing—review and editing. MH: conceptualization, formal analysis, and writing—original draft. MG: investigation and formal analysis. FK: investigation and data curation. JR and MS: data curation and methodology. TR, AK, and AB-F: investigation. TM and RvB: supervision and writing—review and editing. All authors have participated in the work and have read and approved the manuscript.

ACKNOWLEDGMENTS

This work contains part of the doctoral thesis of MS.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fcvm.2021.623146/full#supplementary-material

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Conflict of Interest: AT reports having received lecture honoraria from Edwards Lifesciences and Medtronic. FK reports having received consultancy and lecture honoraria from Abbott Cardiovascular and Edwards Lifesciences. TR reports having received lecture honoraria from Abbott Cardiovascular. AB-F reports having received consultancy and lecture honoraria from Abbott Cardiovascular and Edwards Lifesciences. RvB reports having received consultancy and lecture honoraria from Abbott Cardiovascular and Edwards Lifesciences.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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EXHIBIT 33

Introducing the
SAPIEN 3
Ultra valve

The next generation
of TAVR



SAPIEN 3 Ultra valve:
The valve you know and trust continues to evolve

Built upon the proven SAPIEN platform, the **SAPIEN 3 Ultra** transcatheter heart valve is designed with your patient's future needs in mind.



Sealing skirt technology



Iconic geometric frame



Valve tissue



Sealing skirt technology
Now featuring a ~40% taller*, textured polyethylene terephthalate (PET) outer skirt.

*Compared to the Edwards SAPIEN 3 valve

Edwards Commander Delivery System:
For predictable, proven results

Features of the Edwards Commander Delivery System

- Stable, precise deployment delivering 99% first-time accuracy†
- Low delivery profile
- Dual articulation for coaxiality
- Optimal positioning control

†The PARTNER II Trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=1077).



Edwards eSheath Introducer Set:
For controlled deployment

Features of the Edwards eSheath

- 14F & 16F low-profile access leads to significant reduction in major vascular complications‡
- Dynamic Expansion Mechanism (DEM) for low-profile access
- Hydrophilic coating designed for ease of insertion

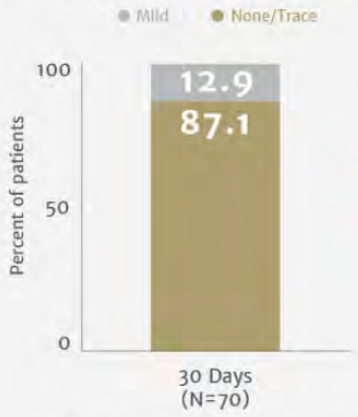
‡PARTNER II Trial intermediate-risk SAPIEN 3 valve cohort (VARC II) versus SAPIEN XT valve cohort (VARC I) 30-day results.





Edwards SAPIEN 3 Ultra valve is engineered for your patient's future

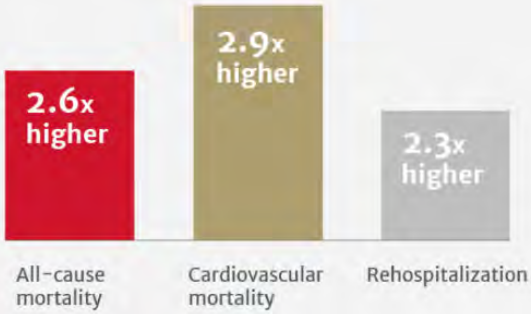
SAPIEN 3 Ultra Study paravalvular leak (PVL) at 30 days[1]



0%
≥ moderate PVL at 30 days

30-Day findings were Core Lab adjudicated.

In severe AS, ≥ moderate PVL is associated with increased mortality and rehospitalization[†]



The SAPIEN 3 valve is equivalent to surgery

0.6%
≥ moderate PVL at 1 year[2]

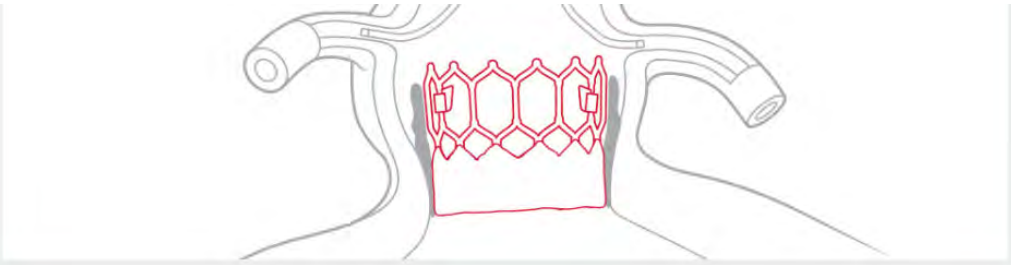
[†]Multivariable analysis of the association between at least moderate PVL and 1-year outcomes for the SAPIEN 3 PARTNER II Trial.

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Edwards SAPIEN 3 Ultra valve is designed with your patient's future needs in mind

The SAPIEN 3 Ultra features a low frame height and large cell design to easily **facilitate future coronary access** should your patient require a procedure post-TAVR.





SAPIEN 3 Ultra in action



TAVR Procedural Animation Using the SAPIEN 3 Ultra System

3:21

See how the SAPIEN 3 Ultra valve is delivered and implanted right into the heart.

Upcoming events

May 15

May 15–17
ACC—Atlanta, GA

ACC invites cardiovascular specialists to share up-to-date information on the latest clinical topics in heart disease. Presenters will describe current treatment approaches and analyze emerging trends across the cardiovascular continuum.
Visit conference website

Jul 20

July 20–22
TVT—Miami, FL

Experience the TVT Conference, which will offer a mix of world-renowned experts discussing educational live cases and exciting new ideas across the topics of transcatheter valve repair and replacement.
Visit conference website

Sep 1

September 1–4
PICS/AICS—Las Vegas, NV

PICS/AICS is a clinically focused conference with sessions on both congenital and structural heart disease, as well as live case demonstrations from around the globe.
Visit conference website

Nov 4

November 4–6
TCT—Orlando, FL

TCT offers insight on interventional topics with cutting-edge educational content, informative booths, a wide panel of speakers, and discussions on the latest therapies and clinical research.
Visit conference website

Important safety information

Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications: The valves and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper-evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or if the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets. Failure to use slow, controlled inflation and prescribed nominal inflation volumes may result in balloon rupture, and lead to patient death or serious injuries associated with difficulty retrieving the delivery system and surgical intervention.

Precautions: Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium or abnormalities in the atrial septum preventing safe transseptal access. Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; pre-existing prosthetic ring in any position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy; hypertrophic cardiomyopathy with or without obstruction (HOCM); echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. For Left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage. Ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor PA pressure in homolateral radial artery. Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthetic valve be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general

associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; thoracic bleeding; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury or brachial plexus injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; mechanical failure of delivery system and/or accessories; and non-emergent reoperation.

Edwards Axela Sheath

Indications: The Edwards Axela sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 Ultra delivery system.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm as it may preclude safe placement of the 14F Edwards Axela sheath. For subclavian/axillary vessels with the 29 mm Edwards SAPIEN 3 Ultra delivery system, caution should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath. Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath. Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed. When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position. When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

Potential Adverse Events: Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 Ultra transcatheter heart valve and the Edwards SAPIEN 3 transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices. There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.**

Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

Caution: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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Edwards

EXHIBIT 34

FDA U.S. FOOD & DRUG ADMINISTRATION

Premarket Approval (PMA)

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	SAPIEN 3 Ultra Transcatheter Heart Valve System
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered
Applicant	EDWARDS LIFESCIENCES, LLC. One Edwards Way Irvine, CA 92614
PMA Number	P140031
Supplement Number	S099
Date Received	10/21/2019
Decision Date	01/27/2021
Product Code	NPT[24]
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track No User Fee
Supplement Reason	Location Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval for the Edwards Costa Rica manufacturing site to manufacture the SAPIEN 3 Ultra transcatheter heart valve (Model 9750TFX, sizes 20mm, 23mm, and 26mm), located at:Zona Franca La Lima, De la entrada de Pequeno Mundo 100 mts oeste y 200 mts surFinca 31 y 32Guadalupe, CartagoCosta Rica 30106

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EXHIBIT 35

FDA U.S. FOOD & DRUG ADMINISTRATION

Premarket Approval (PMA)

New Search[22] Back to Search Results

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	Edwards SAPIEN 3, Ultra 3 Transcatheter Heart Valve
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered
Applicant	EDWARDS LIFESCIENCES, LLC. One Edwards Way Irvine, CA 92614
PMA Number	P140031
Supplement Number	S102
Date Received	11/18/2019
Decision Date	04/10/2020
Product Code	NPT[24]
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track No User Fee
Supplement Reason	Location Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval for a manufacturing site located at Edwards Lifesciences (Singapore) Pte. Ltd, 35 Changi North Crescent, Singapore 499641 SG, to receive and process bovine pericardial tissue sacs into treated tissue heart valve leaflets.

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EXHIBIT 36

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period From to
Commission File Number 1-15525

EDWARDS LIFESCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**36-4316614**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

One Edwards Way	**Irvine**	**California**	**92614**
(Address of Principal Executive Offices)			(Zip Code)

(949) 250-2500
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock, par value $1.00 per share	EW	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company
☒	☐	☐	☐	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☒.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2020 (the last trading day of the registrant's most recently completed second quarter): $42,640,586,293 based on the closing price of the registrant's common stock on the New York Stock Exchange. This calculation does not reflect a determination that persons are affiliates for any other purpose.

The number of shares outstanding of the registrant's common stock, $1.00 par value, as of January 31, 2021, was 624,518,873.

Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2021 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2020) are incorporated by reference into Part III, as indicated herein.

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EDWARDS LIFESCIENCES CORPORATION
Form 10-K Annual Report—2020
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PART I

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. Some statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, the expected impact of COVID-19 on our business, any predictions, opinions, expectations, plans, strategies, objectives and any statements of assumptions underlying any of the foregoing relating to the company's current and future business and operations, including, but not limited to, financial matters, development activities, clinical trials and regulatory matters, manufacturing and supply operations, and product sales and demand. These statements can sometimes be identified by the use of the forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "goal," "continue," "seek," "pro forma," "forecast," "intend," "guidance," "optimistic," "aspire," "confident," other forms of these words or similar words or expressions or the negative thereof. Statements of past performance, efforts, or results about which inferences or assumptions may be made can also be forward-looking statements and are not indicative of future performance or results; these statements can be identified by the use of words such as "preliminary," "initial," diligence," "industry-leading," "compliant," "indications," or "early feedback" or other forms of these words or similar words or expressions or the negative thereof. These forward-looking statements are subject to substantial risks and uncertainties that could cause our results or future business, financial condition, results of operations or performance to differ materially from our historical results or experiences or those expressed or implied in any forward-looking statements contained in this report. These risks and uncertainties include, but are not limited to: uncertainties regarding the severity and duration of the COVID-19 pandemic and its impact on our business and the economy generally, clinical trial or commercial results or new product approvals and therapy adoption; inability or failure to comply with regulations; unpredictability of product launches; competitive dynamics; changes to reimbursement for the company's products; the company's success in developing new products and avoiding manufacturing and quality issues; the impact of currency exchange rates; the timing or results of research and development and clinical trials; unanticipated actions by the U.S. Food and Drug Administration and other regulatory agencies; unexpected litigation impacts or expenses; and other risks detailed under "Risk Factors" in Part I, Item 1A below, as such risks and uncertainties may be amended, supplemented or superseded from time to time by our subsequent reports on Forms 10-Q and 8-K we file with the Securities and Exchange Commission. These forward-looking statements speak only as of the date on which they are made and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. If we do update or correct one or more of these statements, investors and others should not conclude that we will make additional updates or corrections.

Unless otherwise indicated or otherwise required by the context, the terms "we," "our," "it," "its," "Company," "Edwards," and "Edwards Lifesciences" refer to Edwards Lifesciences Corporation and its subsidiaries.

Item 1. Business

Overview

Edwards Lifesciences Corporation is the global leader in patient-focused medical innovations for structural heart disease and critical care monitoring. Driven by a passion to help patients, we partner with the world's leading clinicians and researchers and invest in research and development to transform care for those impacted by structural heart disease or who require hemodynamic monitoring during surgery or in intensive care. Edwards Lifesciences has been a leader in these areas for over six decades. Since our founder, Lowell Edwards, first dreamed of using engineering to address diseases of the human heart, we have steadily built a company on the premise of imagining, building, and realizing a better future for patients.

A pioneer in the development of heart valve therapies, we are the world's leading manufacturer of heart valve systems and repair products used to replace or repair a patient's diseased or defective heart valve. Our innovative work in heart valves encompasses both surgical and transcatheter therapies for heart valve replacement and repair. In addition, our robust pipeline of future technologies is focused on the less invasive repair or replacement of the mitral and tricuspid valves of the heart, which are more complex and more challenging to treat than the aortic valve that is currently the focus of many of our commercially approved valve technologies. We are also a global leader in hemodynamic and noninvasive brain and tissue oxygenation monitoring systems used to measure a patient's cardiovascular function in the hospital setting.

Cardiovascular disease is the number-one cause of death in the world, and is the top disease in terms of health care spending in nearly every country. Cardiovascular disease is progressive in that it tends to worsen over time and often affects the structure of an individual's heart.

Patients undergoing treatment for cardiovascular disease can be treated with a number of our medical technologies, which are designed to address individual patient needs with respect to disease process, comorbidities, and health status. For example, an individual with a heart valve disorder may have a faulty valve that is affecting the function of his or her heart or blood flow throughout his or her body. A clinician may elect to remove the valve and replace it with one of our bioprosthetic surgical tissue heart valves or surgically re-shape and repair the faulty valve with an Edwards Lifesciences annuloplasty ring. Alternatively, a clinician may implant an Edwards Lifesciences transcatheter valve or repair system via a catheter-based approach that does not require traditional open-heart surgery and can be done while the heart continues to beat. Patients in the hospital setting, including high-risk patients in the operating room or intensive care unit, are candidates for having their cardiac function or fluid levels monitored by our Critical Care products through multiple monitoring options, including noninvasive and minimally invasive technologies. These technologies enable proactive clinical decisions while also providing the opportunity for improving diagnoses and developing individualized therapeutic management plans for patients.

Corporate Background

Edwards Lifesciences Corporation was incorporated in Delaware on September 10, 1999.

Our principal executive offices are located at One Edwards Way, Irvine, California 92614. The telephone number at that address is (949) 250-2500. We make available, free of charge on our website located at www.edwards.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission ("SEC"). The contents of our website are not incorporated by reference into this report.

Edwards Lifesciences' Product and Technology Offerings

The following discussion summarizes the main areas of products and technologies we offer to treat advanced cardiovascular disease. Our products and technologies are categorized into four main areas: Transcatheter Aortic Valve Replacement, Transcatheter Mitral and Tricuspid Therapies, Surgical Structural Heart, and Critical Care. For more information on net sales from these four main areas, see *"Net Sales by Product Group*" in Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations*."

Transcatheter Aortic Valve Replacement

We are the global leader in transcatheter heart valve replacement technologies designed for the minimally invasive replacement of heart valves. The *Edwards SAPIEN* family of valves, including *Edwards SAPIEN XT,* the *Edwards SAPIEN 3,* and the *Edwards SAPIEN 3 Ultra* transcatheter aortic heart valves, and their respective delivery systems, are used to treat heart valve disease using catheter-based approaches for patients who have severe symptomatic aortic stenosis and certain patients

with congenital heart disease. Delivered while the heart is beating, these valves can enable patients to experience a better quality of life sooner than patients receiving traditional surgical therapies. We began offering our transcatheter heart valves to patients commercially in Europe in 2007, in the United States in 2011, and in Japan in 2013. Supported by extensive customer training and service, and a growing body of compelling clinical evidence, our *SAPIEN* family of transcatheter aortic heart valves are the most widely prescribed transcatheter heart valves in the world.

Sales of our transcatheter aortic valve replacement products represented 65%, 63%, and 61% of our net sales in 2020, 2019, and 2018, respectively.

Transcatheter Mitral and Tricuspid Therapies

We are making significant investments in the development of transcatheter heart valve repair and replacement technologies designed to treat mitral and tricuspid valve diseases. While many of these technologies are in early development and clinical phases, the *PASCAL* transcatheter valve repair system and the *Cardioband* systems for mitral and tricuspid valve repair are commercially available in Europe. The *PASCAL* system provides a differentiated, minimally-invasive therapy to address the needs of patients with mitral or tricuspid regurgitation through leaflet approximation, while the *Cardioband* system enables clinicians to restore a patient's mitral or tricuspid valve to a more functional state by reducing the annulus and lowering regurgitation. In addition to transcatheter repair, we believe transcatheter replacement is key to unlocking the full mitral and tricuspid opportunity, given the complex and diverse patient population. Our two-platform strategy positions us for leadership in the mid-to-long term. *SAPIEN M3* is based on the proven *SAPIEN* valve, paired with a novel docking system. We are also continuing to advance our *EVOQUE* platform for both mitral and tricuspid replacement. Both *SAPIEN M3* and *EVOQUE* transfemoral delivery systems are sub 30-French, which has benefits for femoral puncture and septal crossing, contributing to ease of use, and patient safety.

Surgical Structural Heart

The core of our surgical tissue heart valve product line is the *Carpentier-Edwards PERIMOUNT* pericardial valve platform, including the line of *PERIMOUNT Magna Ease* pericardial valves for aortic and mitral surgical valve replacement. With more long-term clinical publications on durability and performance than any other surgical valve, *PERIMOUNT* valves are the most widely implanted surgical tissue heart valves in the world. Our latest innovation, the *INSPIRIS RESILIA* aortic valve, is built on our *PERIMOUNT* platform and offers *RESILIA* tissue and *VFit* technology. *INSPIRIS* is now the leading aortic surgical valve in the world. In addition to our replacement valves, we are the worldwide leader in surgical heart valve repair therapies. In 2020, we launched the *HARPOON Beating Heart Mitral Valve Repair System*, which can help transform care for many patients with degenerative mitral regurgitation. We are also a global leader in cardiac cannula devices and offer a variety of procedure-enabling innovations that advance minimally invasive surgery. We believe the demand for surgical structural heart therapies is growing worldwide and that our innovation strategy will continue to extend our leadership and patient impact.

Sales of our surgical tissue heart valve products represented 16%, 17%, and 18% of our net sales in 2020, 2019, and 2018, respectively.

Critical Care

We are a world leader in hemodynamic monitoring systems used to measure a patient's heart function and fluid status in surgical and intensive care settings. Hemodynamic monitoring plays an important role in enhancing surgical recovery. Edwards' complete hemodynamic portfolio helps clinicians make proactive clinical decisions that can improve patient outcomes, and includes the minimally invasive *FloTrac* system, the noninvasive *ClearSight* system, and *ForeSight,* the noninvasive tissue oximetry system. We also support clinical needs with our well-established *Swan-Ganz* line of pulmonary artery catheters, arterial pressure monitoring products, and *Edwards Oximetry Central Venous Catheters*. In conjunction with our sensors, our *HemoSphere* monitoring platforms display valuable physiological information in an easy to understand and actionable manner. Amplifying our sensor and monitoring platform portfolio is the addition of our first predictive algorithm, *Acumen Hypotension Prediction Index,* which alerts clinicians in advance of a patient developing low blood pressure.

Sales of our core hemodynamic products represented 9%, 9%, and 10% of our net sales in 2020, 2019, and 2018, respectively.

Competition

The medical technology industry is highly competitive. We compete with many companies, including divisions of companies much larger than us and smaller companies that compete in specific product lines or certain geographies.

Furthermore, new product development and technological change characterize the areas in which we compete. Our present or future products could be rendered obsolete or uneconomical as a result of technological advances by one or more of our present or future competitors or by other therapies, including drug therapies. We must continue to develop and commercialize new products and technologies to remain competitive in the cardiovascular medical technology industry. We believe that we are competitive primarily because we deliver superior clinical outcomes that are supported by extensive data, and innovative features that enhance patient benefit, product performance, and reliability; these superior clinical outcomes are in part due to the level of customer and clinical support we provide.

The cardiovascular segment of the medical technology industry is dynamic and subject to significant change due to cost-of-care considerations, regulatory reform, industry and customer consolidation, and evolving patient needs. The ability to provide products and technologies that demonstrate value and improve clinical outcomes is becoming increasingly important for medical technology manufacturers.

We believe that we are a leading global competitor in each of our product lines. In Transcatheter Aortic Valve Replacement, our primary competitors include Medtronic PLC and Abbott Laboratories ("Abbott"). In Transcatheter Mitral and Tricuspid Therapies, our primary competitor is Abbott, and there are a considerable number of large and small companies with development efforts in these fields. In Surgical Structural Heart, our primary competitors include Medtronic PLC, Abbott, and CryoLife. In Critical Care, we compete primarily with a variety of companies in specific product lines including ICU Medical, Inc., PULSION Medical Systems SE, a subsidiary of Getinge AB, Cheetah Medical, Inc., a subsidiary of Baxter International, and LiDCO Group PLC, now part of Masimo.

Sales and Marketing

Our portfolio includes some of the most recognizable cardiovascular device product brands in treating structural heart disease today. We have a number of product lines that require sales and marketing strategies tailored to deliver high-quality, cost-effective products and technologies to customers worldwide. Because of the diverse global needs of the population that we serve, our distribution system consists of several direct sales forces as well as independent distributors. We are not dependent on any single customer and no single customer accounted for 10% or more of our net sales in 2020.

To ensure optimal outcomes for patients, we conduct educational symposia and best practices training for our physician, hospital executive, service line leadership, nursing, and clinical-based customers. We rely extensively on our sales and field clinical specialist personnel who work closely with our customers in hospitals. Field clinical specialists routinely attend procedures where Edwards' products are being used in order to provide guidance on the use of our devices, thereby enabling physicians and staff to reach expert proficiency and deliver positive patient outcomes. Our customers include physicians, nurses, and other clinical personnel, but can also include decision makers such as service line leaders, material managers, biomedical staff, hospital administrators and executives, purchasing managers, and ministries of health. Also, for certain of our product lines and where appropriate, our corporate sales team actively pursues approval of Edwards Lifesciences as a qualified supplier for hospital group purchasing organizations ("GPOs") that negotiate contracts with suppliers of medical products. Additionally, we have contracts with a number of United States and European national and regional buying groups, including healthcare systems and Integrated Delivery Networks. Where we choose to market our products is also influenced by the existence of, or potential for, adequate reimbursement to hospitals and other providers by national healthcare systems.

United States. In the United States, we sell substantially all of our products through our direct sales forces. In 2020, 57% of our net sales were derived from sales to customers in the United States.

International. In 2020, 43% of our net sales were derived internationally through our direct sales forces and independent distributors. Of the total international sales, 52% were in Europe, 25% were in Japan, and 23% were in Rest of World. We sell our products in approximately 100 countries, and our major international markets include Canada, China, France, Germany, Italy, Japan, and the United Kingdom. A majority of the sales and marketing approach outside the United States is direct sales, although it varies depending on each country's size and state of development.

Raw Materials and Manufacturing

We operate manufacturing facilities in various geographies around the world. We manufacture our Transcatheter Aortic Valve Replacement, Transcatheter Mitral and Tricuspid technologies, and Structural Surgical Heart products primarily in the United States (California and Utah), Singapore, Costa Rica, and Ireland. We manufacture our Critical Care products primarily in our facilities located in Puerto Rico and the Dominican Republic.

We use a diverse and broad range of raw and organic materials in the design, development, and manufacture of our products. We manufacture our non-implantable products from fabricated raw materials including resins, chemicals, electronics, and metals. Most of our replacement heart valves are manufactured from natural tissues harvested from animal tissue, as well as fabricated materials. We purchase certain materials and components used in manufacturing our products from external suppliers. In addition, we purchase certain supplies from single sources for reasons of sole source availability or constraints resulting from regulatory requirements.

We work with our suppliers to mitigate risk and seek continuity of supply while maintaining quality and reliability. Alternative supplier options are generally considered, identified, and approved for materials deemed critical to our products, although we do not typically pursue immediate regulatory qualification of alternative sources due to the strength of our existing supplier relationships and the time and expense associated with the regulatory validation process.

We comply with all current global guidelines regarding risks for products incorporating animal tissue intended to be implanted in humans. We follow rigorous sourcing and manufacturing procedures intended to safeguard humans from potential risks associated with diseases such as bovine spongiform encephalopathy ("BSE"). We obtain bovine tissue used in our pericardial tissue valve products only from sources within the United States and Australia, where strong control measures and surveillance programs exist. In addition, bovine tissue used in our pericardial tissue valve products is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility. Our manufacturing and sterilization processes are designed to render tissue biologically safe from all known infectious agents and viruses.

Quality Assurance

We are committed to providing to our patients quality products and have implemented modern quality systems and concepts throughout the organization. The quality system starts with the initial design concept, risk management, and product specification, and continues through the design of the product, packaging and labeling, and the manufacturing, sales, support, and servicing of the product. The quality system is intended to design quality into the products and utilizes continuous improvement concepts, including Lean/Six Sigma principles, throughout the product lifecycle.

Our operations are frequently inspected by the many regulators that oversee medical device manufacturing, including the United States Food and Drug Administration ("FDA"), European Notified Bodies, and other regulatory entities. The medical technology industry is highly regulated and our facilities and operations are designed to comply with all applicable quality systems standards, including the International Organization for Standardization ("ISO") 13485. These standards require, among other items, quality system controls that are applied to product design, component material, suppliers, and manufacturing operations. These regulatory approvals and ISO certifications can be obtained only after a successful audit of a company's quality system has been conducted by regulatory or independent outside auditors. Periodic reexamination by an independent outside auditor is required to maintain these certifications.

Environmental, Health, and Safety

We are committed to providing a safe and healthy workplace and complying with all relevant regulations and medical technology industry standards. Through our corporate and site level Environmental, Health, and Safety functions, we establish and monitor programs to reduce pollution, prevent injuries, and maintain compliance with applicable regulations. In order to measure performance, we monitor and report on a number of metrics, including regulated and non-regulated waste disposal, energy usage, water consumption, air toxic emissions, and injuries from our production activities. Each of our manufacturing sites is evaluated regularly with respect to a broad range of Environmental, Health, and Safety criteria.

Research and Development

In 2020, we made significant investments in research and development as we worked to develop therapies that we believe have the potential to change the practice of medicine. Research and development spending increased 1% year over year to 17% of 2020 sales. This increase was primarily the result of significant investments in our transcatheter structural heart programs, including an increase in clinical research for our mitral and tricuspid therapies business. We are engaged in ongoing research and development to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety, and reliability of our current leading products, and to expand the applications of our products as appropriate. We focus on opportunities within specific areas of structural heart disease and critical care monitoring.

A considerable portion of our research and development investment includes clinical trials and the collection of evidence that provide data for use in regulatory submissions, and required post-market approval studies involving applications of our

products. Our investment in clinical studies also includes outcomes and cost-effectiveness data for payers, clinicians, and healthcare systems.

In Transcatheter Aortic Valve Replacement, we are developing new products to further improve and streamline transcatheter aortic heart valve replacement procedures, and developing pulmonic platforms to expand therapies for congenital heart disease patients.

In Transcatheter Mitral and Tricuspid Therapies, we are making significant investments in innovation and clinical evidence to develop technologies designed to treat mitral and tricuspid valve diseases. In addition to our internally developed programs, we have made investments in several companies that are independently developing minimally-invasive technologies to treat structural heart diseases.

Our Surgical Structural Heart development programs include innovative platforms for patients who are best treated surgically, specifically active patients and patients with more complex combined procedures.

In our Critical Care product line, we are pursuing the development of a variety of decision support solutions for our clinicians. This includes next-generation noninvasive and minimally-invasive hemodynamic monitoring systems, and a next-generation monitor platform. We are also developing a decision support software suite with advanced algorithms for proactive hemodynamic management, including a semi-closed loop system for standardized management of patient fluid levels. Lastly, we are developing a connectivity platform that will offer clinicians additional clinical support, remote monitoring capability, analytics, and insights for their patients' hemodynamic status.

Our research and development activities are conducted primarily in facilities located in the United States and Israel. Our experienced research and development staff are focused on product design and development, quality, clinical research, and regulatory compliance. To pursue primary research efforts, we have developed alliances with several leading research institutions and universities, and also work with leading clinicians around the world in conducting scientific studies on our existing and developing products.

Proprietary Technology

Patents, trademarks, and other proprietary rights are important to the success of our business. We also rely upon trade secrets, know-how, continuing innovations, licensing opportunities, and non-disclosure agreements to develop and maintain our competitive position.

We own or have rights to a substantial number of patents and have patent applications pending both in the U.S. and in foreign countries. We continue to innovate and file new patent applications to protect the full range of our products and technologies.

Additionally, we are a party to numerous license agreements with various third parties pursuant to which we have obtained, for varying terms, the exclusive or non-exclusive rights to certain patents held by such third parties in consideration for cross-licensing rights and/or royalty payments. We have also licensed certain patent rights to others.

We undertake reasonable measures to protect our patent rights, including monitoring the products of our competitors for possible infringement of our owned and licensed patents. Litigation has been necessary to enforce certain patent rights held by us, and we plan to continue to defend and prosecute our rights with respect to such patents.

Moreover, we own certain U.S. registered trademarks used in our business. Many of our trademarks have also been registered for use in certain foreign countries where registration is available and where we have determined it is commercially advantageous to do so.

Government Regulation and Other Matters

Our products and facilities are subject to regulation by numerous government agencies, including the U.S. FDA, European Union Member States competent authorities, and the Japanese Pharmaceuticals and Medical Devices Agency, to confirm compliance with the various laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products. We are also governed by federal, state, local, and international laws of general applicability, such as those regulating employee health and safety, and the protection of the environment. Overall, the amount and scope of domestic and foreign laws and regulations applicable to our business has increased over time. Compliance with these regulations has not had a material effect on our capital expenditures, earnings, or competitive position to date, but new

regulations or amendments to existing regulations to make them more stringent could have such an effect in the future. We cannot estimate the expenses we may incur to comply with potential new laws or changes to existing laws, or the other potential effects these laws may have on our business.

United States Regulation. In the United States, the FDA has responsibility for regulating medical devices. The FDA regulates design, development, testing, clinical studies, manufacturing, labeling, promotion, and record keeping for medical devices, and reporting of adverse events, recalls, or other field actions by manufacturers and users to identify potential problems with marketed medical devices. Many of the devices that we develop and market are in a category for which the FDA has implemented stringent clinical investigation and pre-market clearance or approval requirements. The process of obtaining FDA clearance or approval to market a product is resource intensive, lengthy, and costly. FDA review may involve substantial delays that adversely affect the marketing and sale of our products. A number of our products are pending regulatory clearance or approval to begin commercial sales in various markets. Ultimately, the FDA may not authorize the commercial release of a medical device if it determines the device is not safe and effective or does not meet other regulatory standards. Additionally, even if a product is cleared or approved, the FDA may impose restrictions or require testing and surveillance programs to monitor the effects of these products once commercialized.

The FDA has the authority to halt the distribution of certain medical devices, detain or seize adulterated or misbranded medical devices, order the repair, replacement, or refund of the costs of such devices, or preclude the importation of devices that are or appear violative. The FDA also conducts inspections to determine compliance with the quality system regulations concerning the manufacturing and design of devices and current medical device reporting regulations, recall regulations, clinical testing regulations, and other requirements. The FDA may withdraw product clearances or approvals due to failure to comply with regulatory standards, or the occurrence of unforeseen problems following initial approval, and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. Additionally, the failure to comply with FDA or comparable regulatory standards or the discovery of previously unknown product problems could result in fines, delays, suspensions or withdrawals of regulatory clearances or approvals, seizures, injunctions, recalls, refunds, civil money penalties, or criminal prosecution. Our compliance with applicable regulatory requirements is subject to continual review. Moreover, the FDA and several other United States agencies administer controls over the export of medical devices from the United States and the import of medical devices into the United States, which could also subject us to sanctions for noncompliance.

We are also subject to additional laws and regulations that govern our business operations, products, and technologies, including:

- federal, state, and foreign anti-kickback laws and regulations, which generally prohibit payments to anyone, including physicians as an inducement to purchase or recommend a product;
- the Stark law, which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that provider;
- federal and state laws and regulations that protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of such information, in particular, the Health Insurance Portability and Accountability Act of 1996;
- the Physician Payments Sunshine Act, which requires public disclosure of the financial relationships of United States physicians and teaching hospitals with applicable manufacturers, including medical device, pharmaceutical, and biologics companies;
- the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally funded health care program, and health care fraud statutes that prohibit false statements and improper claims to any third-party payor; and
- the United States Foreign Corrupt Practices Act, which can be used to prosecute United States companies for arrangements with foreign government officials or other parties, or for not keeping accurate financial records or maintaining adequate internal controls to prevent and detect arrangements with foreign government officials or other parties.

Failure to comply with these laws and regulations could result in criminal liability, significant fines or penalties, negative publicity, and substantial costs and expenses associated with investigation and enforcement activities. To assist in our

compliance efforts, we work to adhere to many codes of ethics and conduct regarding our business activities in the United States and other countries in which we operate. In addition, we have in place a dedicated team to improve our internal business compliance programs and policies.

International Regulation. Internationally, the regulation of medical devices is complex. In Europe, our products are subject to extensive regulatory requirements. The regulatory regime in the European Union for medical devices became mandatory in June 1998. It requires that medical devices may only be placed on the market if they do not compromise safety and health when properly installed, maintained, and used in accordance with their intended purpose. National laws conforming to the European Union's legislation regulate our products under the medical devices regulatory system. Although the more variable national requirements under which medical devices were formerly regulated have been substantially replaced by the European Union Medical Devices Directive, individual nations can still impose unique requirements that may require supplemental submissions. The European Union medical device laws require manufacturers to declare that their products conform to the essential regulatory requirements after which the products may be placed on the market bearing the CE Mark. Manufacturers' quality systems for products in all but the lowest risk classification are also subject to certification and audit by an independent notified body. In Europe, particular emphasis is being placed on more sophisticated and faster procedures for the reporting of adverse events to the competent authorities.

In May 2017, the European Union (the "EU") implemented a new regulatory scheme for medical devices under the Medical Device Regulation ("MDR"). The MDR becomes fully effective in 2021 and will bring significant new requirements for many medical devices, including enhanced requirements for clinical evidence and documentation, increased focus on device identification and traceability, new definitions and registration of economic operators throughout the distribution chain, and additional post-market surveillance and vigilance. Compliance with the MDR requires re-certification of many of our products to the enhanced standards, and has resulted in and will continue to result in substantial additional expense. In addition, in the EU, we import some of our devices through our offices in Switzerland. Switzerland is not a member state of the EU, but is linked to the EU through bilateral treaties; therefore, the free movement of goods, including medical devices, between the EU and Switzerland after implementation of the MDR requires a revised Mutual Recognition Agreement ("MRA"), which continues to be under negotiation for the MDR. If an MRA covering the MDR is not put in place, then non-EU manufacturers may be required to make significant changes, including replacement of Swiss economic operators with operators based in EU Member States, and changes will need to be made to our device labeling and/or packaging to satisfy MDR requirements. If these measures are unable to be taken, it may no longer be possible to place such devices on the EU market.

In Japan, pre-market approval and clinical studies are required as is governmental pricing approval for medical devices. Clinical studies are subject to a stringent Japanese "Good Clinical Practices" standard. Approval time frames from the Japanese Ministry of Health, Labour and Welfare vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation of medical devices into Japan is subject to the "Good Import Practices" regulations. As with any highly regulated market, significant changes in the regulatory environment could adversely affect future sales.

In many of the other foreign countries in which we market our products, we may be subject to regulations affecting, among other things:

- product standards and specifications;
- packaging requirements;
- labeling requirements;
- product collection and disposal requirements;
- quality system requirements;
- import restrictions;
- tariffs;
- duties; and
- tax requirements.

Many of the regulations applicable to our devices and products in these countries are similar to those of the FDA. In some regions, the level of government regulation of medical devices is increasing, which can lengthen time to market and increase registration and approval costs. In many countries, the national health or social security organizations require our products to be qualified before they can be marketed and considered eligible for reimbursement.

Health Care Initiatives. Government and private sector initiatives to limit the growth of health care costs, including price regulation and competitive pricing, coverage and payment policies, comparative effectiveness reviews, technology assessments, increasing evidentiary demands, and managed-care arrangements, are continuing in many countries where we do business, including the United States, Europe, and Japan. As a result of these changes, the marketplace has placed increased emphasis on the delivery of more cost-effective medical therapies. For example, government programs, private health care insurance, and managed-care plans have attempted to control costs by restricting coverage and limiting the level of reimbursement for procedures or treatments, and some third-party payors require their pre-approval before new or innovative devices or therapies are utilized by patients. These various initiatives have created increased price sensitivity over medical products generally and may impact demand for our products and technologies.

The delivery of our products is subject to regulation by the United States Department of Health and Human Services ("HHS") and comparable state and foreign agencies responsible for reimbursement and regulation of health care items and services. Foreign governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services. Reimbursement schedules regulate the amount the United States government will reimburse hospitals and doctors for the inpatient care of persons covered by Medicare. HHS' Centers for Medicare & Medicaid Services ("CMS") may also review whether and/or under what circumstances a procedure or technology is reimbursable for Medicare beneficiaries. Changes in current coverage and reimbursement levels could have an adverse effect on market demand and our pricing flexibility. The CMS National Coverage Determination for Transcatheter Aortic Valve Replacement was issued in June 2019. The modernized requirements and more streamlined patient evaluation process are meaningful enhancements that may help ensure equitable access for more patients suffering from severe aortic stenosis.

Health care cost containment efforts have also prompted domestic hospitals and other customers of medical device manufacturers to consolidate into larger purchasing groups to enhance purchasing power. The medical technology industry has also experienced some consolidation, partly in order to offer a broader range of products to large purchasers. As a result, transactions with customers are larger, more complex, and tend to involve more long-term contracts than in the past. These larger customers, due to their enhanced purchasing power, may have a material impact on product pricing.

These laws or any future legislation, including deficit reduction legislation, could impact medical procedure volumes, reimbursement for our products, and demand for our products or the prices at which we sell our products.

Seasonality

Our quarterly net sales are influenced by many factors, including new product introductions, acquisitions, regulatory approvals, patient and physician holiday schedules, and other factors. Net sales in the third quarter are typically lower than other quarters of the year due to the seasonality of the United States and European markets, where summer vacation schedules normally result in fewer medical procedures.

Human Capital Management Strategy

Human Capital Management ("HCM") Governance

Attracting, developing, and retaining talent is fundamental to our success. The primary goals of our talent management strategy are to attract and maintain a motivated, professional workforce and to ensure alignment on our patient-focused innovation strategy.

Our Board of Directors has oversight over human capital management with time dedicated at each regularly scheduled meeting to discuss talent management, including, among other things, talent strategy, diversity, succession planning, employee development, employee health, safety, and welfare, results of employee surveys, and compensation. The Board of Directors also approves Key Operating Drivers, which are strategic milestones that include financial objectives and are tracked using a point system across our entire organization, that focus the Company and management toward short, medium, and long-term goals that align with our talent management strategy. In addition, the Chief Executive Officer ("CEO") has talent management related performance goals tied to his compensation; these Performance Management Objectives are tracked and, then, reported to and evaluated by our Board of Directors.

Our HCM governance includes a global talent development review ("TDR") process as well as an HCM dashboard. The purpose of our TDR process is to align our business strategy with talent strategies, assess talent against future organizational needs, evaluate critical talent populations, and enhance the strength of our succession planning. Our HCM dashboard is generated quarterly and provides insights on key metrics related to areas such as attraction and growth rates, retention trends, diversity, and employee sentiment.

Culture

Investing in our workforce means our employees can stay focused on our patient-focused innovation strategy and the development of life-saving therapies for the patients we serve. We are committed to maintaining a culture where we celebrate diversity, ensure that employees' voices are heard, and promote good health and safety. We strive to offer competitive employee benefits packages and are committed to fair and equitable pay practices. We track compensation patterns in all geographies where we operate, and we regularly look for ways to ensure fair and equitable pay.

We are committed to fostering an environment where all employees can grow and thrive. A diverse workforce results in a broader range of perspectives, helping drive our commitment to innovation.

We believe in empowering our employees and providing avenues that enable their voices to be heard. We conduct a multilingual global employee survey, called *my*Voice, to pulse our employees and gain their feedback in a confidential manner. We gain insights on various topics including patient focus, diversity, inclusion and belonging, quality, innovation, and engagement. Speak-Up is a resource available to all employees to bring forth compliance related concerns. In addition, during each quarterly townhall meeting, our CEO has an "Ask Mike" section in which he answers questions that have been submitted to him by employees. Answers to questions that are not covered in the townhall meeting are posted online internally.

We understand that good health leads to better performance. Edwards offers a competitive employee benefits package that includes, among other things, health and welfare insurance, health savings accounts, family support services, and a variety of site-specific programs. We regularly evaluate our benefits package to make modifications that are aligned with the competitive landscape, legislative changes, and the unique needs of our population. We also provide robust wellness programs that address prevention, nutrition, mental health, physical activity, education, financial fitness, and community service.

Talent Development

In addition to our robust TDR process and tuition reimbursement programs, we provide a variety of leadership, technical, and professional development programs around the globe.

Headcount and Labor Representation

As of December 31, 2020, we had approximately 14,900 employees worldwide, the majority of whom were located in the United States, Singapore, and the Dominican Republic. None of our North American employees are represented by a labor union. In various countries outside of North America, we interact with trade unions and work councils that represent employees.

Additional details regarding diversity, talent development, compensation, and employee health and safety can be found in our Sustainability Report posted on our website at www.edwards.com under "About Us — Corporate Responsibility."

References to our website in this Annual Report on Form 10-K are provided for convenience only and the content on our website does not constitute a part of this Report.

Item 1A. Risk Factors

Our business and assets are subject to varying degrees of risk and uncertainty. An investor should carefully consider the risks described below, as well as other information contained in this Annual Report on Form 10-K and in our other filings with the SEC. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business. If any of these events or circumstances occurs, our business, financial condition, results of operations, or prospects could be materially harmed. In that case, the value of our securities could decline and an investor could lose part or all of his or her investment. In addition, forward-looking statements within the meaning of the federal securities laws that are contained in this Annual Report on Form 10-K or in our other filings or statements may be subject to the risks described below as well as other risks and uncertainties. Please read the cautionary notice regarding forward-looking statements in Part I above.

Business and Operating Risks

We are subject to risks associated with public health threats and epidemics, including the novel coronavirus ("COVID-19").

We are subject to risks associated with public health threats and epidemics, including the global health concerns relating to the COVID-19 pandemic. The global pandemic has adversely impacted and is likely to further adversely impact nearly all aspects of our business and markets, including our workforce and operations and the operations of our customers, suppliers, and business partners. In particular, we may experience material financial or operational impacts, including:

- Significant volatility or reductions in demand for our products;
- Impacts and delays to clinical trials, our pipeline milestones, or regulatory clearances and approvals; or
- The inability to meet our customers' needs or other obligations due to disruptions to our operations or the operations of our third-party partners, suppliers, contractors, logistics partners, or customers including disruptions to production, development, manufacturing, administrative, and supply operations and arrangements.

The extent to which the COVID-19 global pandemic and measures taken in response thereto impact our business, results of operations, and financial condition will depend on future developments, which are highly uncertain and are difficult to predict. These developments include, but are not limited to, the duration and spread of the outbreak (including new variants of COVID-19), its severity, the actions to contain the virus or address its impact, the timing, distribution, and efficacy of vaccines and other treatments, U.S. and foreign government actions to respond to the reduction in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume.

Failure to successfully innovate and develop new and differentiated products in a timely manner and effectively market these products could have a material effect on our prospects.

Our continued growth and success depend on our ability to innovate and develop new and differentiated products in a timely manner and effectively market these products. Without the timely innovation and development of products, our products could be rendered obsolete or less competitive by changing customer preferences or because of the introduction of a competitor's newer technologies. Innovating products requires the devotion of significant financial and other resources to research and development activities; however, there is no certainty that the products we are currently developing will complete the development process, or that we will obtain the regulatory or other approvals required to market such products in a timely manner or at all. Even if we timely innovate and develop products, our ability to market them could be constrained by a number of different factors, including barriers in patients' treatment pathway (including disease awareness, detection, and diagnosis), the need for regulatory clearance, restrictions imposed on approved indications, and uncertainty over third-party reimbursement. Failure in any of these areas could have a material effect on our prospects.

Unsuccessful clinical trials or procedures relating to products could have a material adverse effect on our prospects.

The regulatory approval process for new products and new indications for existing products requires extensive clinical trials and procedures, including early clinical feasibility and regulatory studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary approvals and the market's view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these trials or procedures will be enrolled or completed in a timely or cost-effective manner or result in a commercially viable product or indication; failure to do so could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures may be contradicted by subsequent analyses. In addition, results from our clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be

supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be delayed, suspended, or terminated by us, the FDA, or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks or any other reasons.

We operate in highly competitive markets, and if we do not compete effectively, our business will be harmed.

We face substantial competition and compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, product performance, brand name recognition, breadth of product offerings, real or perceived product advantages, pricing and availability and rate of reimbursement. In addition, given the trend toward value-based healthcare, if we are not able to continue to demonstrate the full value of our differentiated products to healthcare providers and payors, our competitive position could be adversely affected. See "*Competition*" under "*Business*" in Part I, Item 1 included herein.

If we identify underperforming operations or products or if there are unforeseen operating difficulties and expenditures in connection with business acquisitions or strategic alliances, we may be required, from time to time, to recognize charges, which could be substantial and which could adversely affect our results of operations.

We actively manage a portfolio of research and development products, and we regularly explore potential acquisitions of complementary businesses, technologies, services, or products, as well as potential strategic alliances. From time to time, we identify operations and products that are underperforming, do not fit with our longer-term business strategy or there may be unforeseen operating difficulties and significant expenditures during the integration of an acquired business, technology, service, or product into our existing operations. We may seek to dispose of these underperforming operations or products, and we may also seek to dispose of other operations or products for strategic or other business reasons. If we cannot dispose of an operation or product on acceptable terms, we may voluntarily cease operations related to that product. In addition, we may be required to take charges or write-downs in connection with acquisitions and divestitures. In particular, acquisitions of businesses engaged in the development of new products may give rise to developed technology and/or in-process research and development assets. To the extent that the value of these assets decline, we may be required to write down the value of the assets. Also, in connection with certain asset acquisitions, we may be required to take an immediate charge related to acquired in-process research and development assets. Any of these events could result in charges, which could be substantial and which could adversely affect our results of operations.

The success of many of our products depends upon certain key physicians.

We maintain working relationships with physicians upon whom we rely to provide considerable knowledge and experience. These physicians may assist us as researchers, marketing consultants, product trainers and consultants, inventors, and as public speakers. If new laws, regulations, or other developments limit our ability to appropriately engage these professionals or to continue to receive their advice and input, the development, marketing, and successful use of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations.

If we or one of our suppliers or logistics partners encounters manufacturing, logistics, or quality problems, our business could be materially adversely affected.

The manufacture and sterilization of many of our products is highly complex due in part to rigorous regulatory requirements. Quality is extremely important due to the serious and costly consequences of a product failure. Problems can arise for a number of reasons, including disruption of facility utilities, equipment malfunction, failure to follow protocols and procedures, raw material problems, software problems, or human error. Disruptions can occur at any time, including during production line transfers and expansions. Disruptions can also occur if our manufacturing and warehousing facilities are damaged by earthquakes, hurricanes, volcanoes, fires, and other natural disasters or catastrophic circumstances. As we expand into new markets and scale new products for commercial production, we may face unanticipated delays or surges in demand which could strain our production capacity and lead to other types of disruption. If any of these manufacturing, logistics, or quality problems arise or if we or one of our suppliers or logistics partner otherwise fail to meet internal quality standards or those of the FDA or other applicable regulatory body, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product liability and other costs, product approvals and production could be delayed, and our business could otherwise be materially adversely affected.

We rely on third parties in the design, manufacture, and sterilization of our products. Any failure by or loss of a vendor could result in delays and increased costs, which may adversely affect our business.

We rely on third parties for a broad range of raw and organic materials and other items in the design, manufacture, and sterilization of our products, and we purchase certain supplies and services from single sources for reasons of quality assurance, cost-effectiveness, availability, constraints resulting from regulatory requirements, and other reasons. We may experience supply interruptions due to a variety of factors, including:

- General economic conditions that could adversely affect the financial viability of our vendors;
- Vendors' election to no longer service medical technology companies due to the burdens of applicable quality requirements and regulations;
- The limitation or ban of certain materials used in the manufacture of our products; and
- Delays or shortages due to trade or regulatory embargoes.

A change or addition to our vendors could require significant effort due to the rigorous regulations and requirements of the FDA and other regulatory authorities; it could be difficult to establish additional or replacement sources on a timely basis, which could have a material adverse effect on our business.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could materially disrupt our operations and adversely affect our business and operating results.

The operation of our business depends on our information technology systems. We rely on our information technology systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches, data corruption, and cyber-based attacks. Cyber-based attacks can include, but are not limited to, computer viruses, computer denial-of-service attacks, phishing attacks, ransomware attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities, or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. In addition, federal, state, and international laws and regulations, such as the General Data Protection Regulation adopted by the European Union and the California Consumer Privacy Act, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail. In addition, a variety of our software systems are cloud-based data management applications, hosted by third-party service providers whose security and information technology systems are subject to similar risks.

The failure of either our or our service providers' information technology could disrupt our operations or result in decreased sales, result in liability claims or regulatory penalties, or lead to increased overhead costs, product shortages, loss or misuse of proprietary or confidential information, intellectual property, or sensitive or personal information, all of which could have a material adverse effect on our reputation, business, financial condition, and operating results.

Our business and results of operations may be adversely affected if we are unable to recruit and retain qualified management and other personnel.

Our continued success depends, in large part, on our ability to hire and retain qualified people or otherwise have access to such qualified people globally and if we are unable to do so, our business and operations may be impaired or disrupted. See "*Human Capital Management Strategy*" under "*Business*" in Part I, Item 1 included herein. Competition for highly qualified people is intense, and there is no assurance that we will be successful in attracting or retaining replacements to fill vacant positions, successors to fill retirements or employees moving to new positions, or other highly qualified personnel.

Market and Other External Risks

Because we operate globally, our business is subject to a variety of risks associated with international sales and operations.

Our extensive global operations and business activity as well as the fact that many of our manufacturing facilities and suppliers are outside of the United States are accompanied by certain financial, economic, political, and other risks, including those listed below.

Domestic and Global Economic Conditions. We cannot predict to what extent general domestic and global economic conditions may negatively impact our business. These include, but are not limited to, credit and capital markets, interest rates, tax law, including tax rate and policy changes, factors affecting global economic stability, the political environment relating to health care, and the potential implications of the U.K. "Brexit" or the withdrawal from the European Union of other member

countries. These and other conditions could also adversely affect our customers, payers, vendors and other stakeholders and may impact their ability or decision to purchase our products or make payments on a timely basis.

Health Care Legislation and Other Regulations. We are subject to various federal and foreign laws that govern our domestic and international business practices. For example, in the U.S., the Affordable Care Act, the Medicare Access and CHIP Reauthorization Act of 2015, and the 21st Century Cures Act, or any future legislation, including deficit reduction legislation, could impact medical procedure volumes, reimbursement for our products, and demand for our products or the prices at which we sell our products. In addition, a Mutual Recognition Agreement still under negotiation for the Medical Device Regulation can result in a lack of free movement of medical devices between the European Union and Switzerland, can impact our access in the European Union and can, ultimately, have a material effect on our business, financial condition, and results of operations. For more information about these laws as they relate to our business, see the section entitled "*Health Care Legislation*" and "*Government Regulation and Other Matter*s" in Part I, Item 1, "*Business*."

In addition, the United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and similar laws in other jurisdictions contain prohibitions against bribery and other illegal payments, and make it an offense to fail to have procedures in place that prevent such payments. Penalties resulting from any violation of these laws could adversely affect us and our business.

Taxes. We are subject to income taxes in the United States as well as other jurisdictions.

- *Provision for Income Taxes.* Our provision for income taxes and our underlying effective tax rate could fluctuate due to changes in the mix of earnings and losses in countries with differing statutory tax rates. Our income tax provision could also be impacted by changes in excess tax benefits of stock-based compensation, federal and state tax credits, non-deductible expenses, changes in the valuation of deferred tax assets and liabilities and our ability to utilize them, the applicability and creditability of withholding taxes, and effects from acquisitions.

- *Tax Reform*. Our provision for income taxes could be materially impacted by changes in accounting principles or evolving tax laws, including, but not limited to, global corporate tax reform and base-erosion and tax transparency efforts. For example, many countries are aligning their international tax rules with the Organisation for Economic Co-operation and Development's Base Erosion and Profit Shifting recommendations and action plans that aim to standardize and modernize international corporate tax policy, including changes to cross-border taxes, transfer pricing documentation rules, nexus-based tax practices, and taxation of digital activities.

- *Tax Audits*. We are subject to ongoing tax audits in the various jurisdictions in which we operate. Tax authorities may disagree with certain positions we have taken and assess additional taxes. Although we regularly assess the likely outcomes of the audits and record reserves for potential tax payments, the calculation of tax liabilities involves the application of complex tax laws, and our estimates could be different than the amounts for which we are ultimately liable.

- *Tax Incentives*. We benefit from various global tax incentives extended to encourage investment or employment. Several foreign jurisdictions have granted us tax incentives which require renewal at various times in the future. If our incentives are not renewed or we cannot or do not wish to satisfy all or part of the tax incentive conditions, we may lose the tax incentives and could be required to refund tax incentives previously realized. As a result, our provision for income taxes could be higher than it would have been had we maintained the benefits of the tax incentives.

Other economic, political, and social risks. Our future results could be harmed by a variety of other factors associated with doing business internationally such as those enumerated in these risk factors as well as the following:

- trade protection measures, quotas, embargoes, import or export requirements, and duties, tariffs, or surcharges;

- cultural or other local factors affecting financial terms with customers;

- differing labor regulations; and

- currency exchange rate fluctuations; that is, decreases in the value of the United States dollar to the Euro or the Japanese yen, as well as other currencies, have the effect of increasing our reported revenues even when the volume of international sales has remained constant. Increases in the value of the United States dollar relative to the Euro or the Japanese yen, as well as other currencies, have the opposite effect. Significant increases or decreases in the value of the United States dollar could have a material adverse effect on our revenues, cost of sales, or results of operations.

If government and other third-party payors decline to reimburse our customers for our products or impose other cost containment measures to reduce reimbursement levels, our ability to profitably sell our products will be harmed.

We sell our products and technologies to hospitals and other health care providers, nearly all of which receive reimbursement for the health care services provided to patients from third-party payors, such as government programs (both domestic and international), private insurance plans, and managed care programs. The ability of customers to obtain appropriate reimbursement for their products from private and governmental third-party payors is critical to our success. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact acceptance of new products.

Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Reimbursement levels may be decreased in the future. Additionally, future legislation, regulation, or reimbursement policies of third-party payors may otherwise adversely affect the demand for and price levels of our products. The introduction of cost containment incentives, combined with closer scrutiny of health care expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to hospital charges for services performed. Hospitals or physicians may respond to such cost-containment pressures by substituting lower cost products or other therapies.

Third-party payors may deny reimbursement if they determine that a device used in a procedure was not used in accordance with cost-effective treatment methods as determined by such third-party payors or was used for an unapproved indication. Third-party payors may also deny reimbursement for experimental procedures and devices. We believe that many of our existing products are cost-effective, even though the one-time cost may be significant, because they are intended to improve quality of life and reduce overall health care costs over a long period of time. We cannot be certain that these third-party payors will recognize these cost savings and quality of life benefits instead of merely focusing on the lower initial costs associated with competing therapies. If our products are not considered cost-effective by third-party payors, our customers may not be reimbursed for them, resulting in lower sales of our products.

Continued consolidation in the health care industry could have an adverse effect on our sales and results of operations.

The health care industry has been consolidating, and organizations such as GPOs, independent delivery networks, and large single accounts, such as the United States Veterans Administration, continue to consolidate purchasing decisions for many of our health care provider customers. As a result, transactions with customers are larger and more complex, and tend to involve more long-term contracts. The purchasing power of these larger customers has increased, and may continue to increase, causing downward pressure on product pricing. If we are not one of the providers selected by one of these organizations, we may be precluded from making sales to its members or participants. Even if we are one of the selected providers, we may be at a disadvantage relative to other selected providers that are able to offer volume discounts based on purchases of a broader range of medical equipment and supplies. Further, we may be required to commit to pricing that has a material adverse effect on our revenues, profit margins, business, financial condition, and results of operations. We expect that market demand, governmental regulation, third-party reimbursement policies, and societal pressures will continue to drive consolidation and increase pricing pressure.

Legal, Compliance, and Regulatory Risks

Our inability to protect our intellectual property or failure to maintain the confidentiality and integrity of data or other sensitive company information, by cyber-attack or other event, could have a material adverse effect on our business.

Our success and competitive position are dependent in part upon our ability to protect our proprietary intellectual property through a combination of patents and trade secrets. We cannot guarantee that the protective steps we take are adequate to protect these rights:

- Patents issued to or licensed by us in the past or in the future may be challenged and held invalid.
- As our patents expire, we may be unsuccessful in extending their protection through patent term extensions.
- Confidentiality agreements with certain employees, consultants, and other third parties intended to protect, in part, trade secrets and other proprietary information could be breached, and we may not have adequate remedies.
- Others could independently develop substantially equivalent proprietary information or gain access to our trade secrets or proprietary information, design around our technology, or develop competing technologies.

- Our intellectual property, other proprietary technology, and other sensitive company information is dependent on sophisticated information technology systems and is potentially vulnerable to cyber-attacks, loss, theft, damage, destruction from system malfunction, computer viruses, loss of data privacy, or misappropriation or misuse of it by those with permitted access, and other events.

- We may not detect infringement.

- Intellectual property protection may also be unavailable or limited in some foreign countries.

We spend significant resources to protect and enforce our intellectual property rights, sometimes resulting in expensive and time-consuming litigation that is complex and may ultimately be unsuccessful. Our inability to protect our intellectual property could have a material adverse effect on our business or prospects.

Third parties may claim we are infringing their intellectual property, and we could suffer significant litigation or licensing expenses or be prevented from selling products.

During recent years, we and our competitors have been involved in substantial litigation regarding patent and other intellectual property rights which is typically costly and time-consuming. We may be forced to defend against claims and legal actions alleging infringement of the intellectual property rights of others, and, if our defense is unsuccessful, Edwards could have significant liabilities to third parties or face injunctions that bar the sale of our products, or could require us to seek licenses from third parties. Such licenses may not be available on commercially reasonable terms, may prevent us from manufacturing, selling, or using certain products, or may be non-exclusive, which could provide our competitors access to the same technologies.

In addition, third parties could also obtain patents that may require us to either redesign products, negotiate licenses from such third parties, which may be costly, unavailable or require us to exit a particular product offering.

We and our customers are subject to rigorous governmental regulations and we may incur significant expenses to comply with these regulations and develop products that are compatible with these regulations. In addition, failure to comply with these regulations could subject us to substantial sanctions which could adversely affect our business, results of operations, and financial condition.

The medical technologies we create, study, manufacture and market globally are subject to rigorous regulation and scrutiny by the FDA and various other federal, state, and foreign governmental authorities. Government regulation applies to nearly all aspects of our products' lifecycles, including testing, clinical study, manufacturing, transporting, sourcing, safety, labeling, storing, packaging, recordkeeping, reporting, advertising, promoting, distributing, marketing, and importing or exporting of medical devices and products. In general, unless an exemption applies, a medical device or product must receive regulatory approval or clearance before it can be marketed or sold. Modifications to existing products or the marketing of new uses for existing products also may require regulatory approvals, approval supplements, or clearances. If we are unable to obtain these required approvals, we may be required to cease manufacturing and sale, or recall or restrict the use of such modified device, pay fines, or take other action until such time as appropriate clearance or approval is obtained.

Regulatory agencies may refuse to grant approval or clearance, or review and disagree with our interpretation of approvals or clearances, or with our decision that regulatory approval is not required or has been maintained. Regulatory submissions may require the provision of additional data and may be time consuming and costly, and their outcome is uncertain. Regulatory agencies may also change policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay approval or clearance of devices, or could impact our ability to market a previously cleared, approved, or unregulated device. Our failure to comply with these regulatory requirements of the FDA or other applicable regulatory requirements in the United States or elsewhere might subject us to administratively or judicially imposed sanctions. These sanctions include, among others, warning letters, fines, civil penalties, criminal penalties, injunctions, debarment, product seizure or detention, product recalls and total or partial suspension of production, sale and/or promotion. Any of the foregoing actions could result in decreased sales including as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations, and prospects. In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection, or investigation could divert substantial management attention from the operation of our business and have an adverse effect on our business, results of operations, and financial condition.

Also, we are subject to various United States and international laws pertaining to health care pricing, anti-corruption, and fraud and abuse, including prohibitions on kickbacks and the submission of false claims laws and restrictions on relationships with physicians and other referral sources. These laws are broad in scope and are subject to evolving interpretation, which could require us to incur substantial costs to monitor compliance. If we are found not to be in compliance, we may be required to alter our practices or have sanctions imposed against us and our officers and employees, including substantial fines, imprisonment, and exclusion from participation in governmental health care programs.

We may incur losses from product liability or other claims that could adversely affect our operating results.

Our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical technologies. Our products are often used in surgical and intensive care settings with seriously ill patients. In addition, many of the devices we manufacture and sell are designed to be implanted in the human body for long periods of time. Component failures, manufacturing and assembly flaws, design defects, software defects, medical procedure errors, or inadequate disclosure of product-related risks or information could result in an unsafe condition, injury to, or death of, patients. Such problems could result in product liability, medical malpractice or other lawsuits and claims, safety alerts, or product recalls in the future. We establish reserves and may incur charges in excess of those reserves. Although we maintain product liability and other insurance with coverages we believe are adequate, product liability or other claims may exceed insurance coverage limits, fines, and penalties. In addition, regulatory sanctions may not be covered by insurance, or insurance may not continue to be available or available on commercially reasonable terms. These litigation matters and regulatory actions, recalls or other actions, regardless of outcome, could have a material adverse effect on our business, reputation, and ability to attract and retain customers.

Use of our products in unapproved circumstances could expose us to liabilities.

The marketing approval from the FDA and other regulators of certain of our products are, or are expected to be, limited to specific indications. We are prohibited from marketing or promoting any unapproved use of our products. Physicians, however, can use these products in ways or circumstances other than those strictly within the scope of the regulatory approval. Although the product training we provide to physicians and other health care professionals is conducted in compliance with applicable laws, and therefore, is mainly limited to approved uses or for clinical trials, no assurance can be given that claims might not be asserted against us if our products are used in ways or for procedures that are not approved.

Our operations are subject to environmental, health, and safety regulations that could result in substantial costs.

Our operations are subject to environmental, health, and safety laws, and regulations concerning, among other things, the generation, handling, transportation, and disposal of hazardous substances or wastes, the cleanup of hazardous substance releases, and emissions or discharges into the air or water. We have incurred and may incur in the future expenditures in connection with environmental, health and safety laws, and regulations. New laws and regulations, violations of these laws or regulations, stricter enforcement of existing requirements, or the discovery of previously unknown contamination could require us to incur costs or could become the basis for new or increased liabilities that could be material.

We are subject to risks arising from concerns and/or regulatory actions relating to animal borne illnesses, including "mad cow disease."

Certain of our products, including pericardial tissue valves, are manufactured using bovine tissue. Concerns relating to the potential transmission of animal borne illnesses, including BSE, commonly known as "mad cow disease," from cows to humans may result in reduced acceptance of products containing bovine materials. Certain medical device regulatory agencies have considered whether to continue to permit the sale of medical devices that incorporate bovine material. We obtain bovine tissue only from closely controlled sources within the United States and Australia. The bovine tissue used in our pericardial tissue valves is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility for the suspected BSE infectious agent. We have not experienced any significant adverse impact on our sales as a result of concerns regarding BSE, but no assurance can be given that such an impact may not occur in the future.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

The locations and uses of our major properties are as follows:

North America		
Irvine, California	(1)	Corporate Headquarters, Research and Development, Regulatory and Clinical Affairs, Manufacturing, Marketing, Administration
Draper, Utah	(1),(2)	Manufacturing, Administration
Haina, Dominican Republic	(1),(2)	Manufacturing
Añasco, Puerto Rico	(2)	Manufacturing
Central America		
Cartago, Costa Rica	(1),(2)	Manufacturing
Europe		
Nyon, Switzerland	(1)	Administration, Marketing
Prague, Czech Republic	(2)	Administration
Shannon, Limerick, Ireland	(1),(2)	Manufacturing (under construction)
Asia		
Singapore	(1),(2)	Manufacturing, Distribution, Administration
Tokyo, Japan	(2)	Administration, Marketing, Distribution
Shanghai, China	(2)	Administration, Marketing
Caesarea, Israel	(2)	Research and Development
Or Yehuda, Israel	(2)	Research and Development

(1) Owned property.

(2) Leased property.

The Dominican Republic lease expires in 2022; the Puerto Rico property has two leases that expire in 2023; the Costa Rica lease expires in 2021; the Prague, Czech Republic lease expires in 2026; the Shannon, Ireland lease expires in 2024; the Tokyo, Japan lease expires in 2021; the Shanghai, China lease expires in 2021; Singapore has one land lease that expires in 2036 and one that expires in 2041; Caesarea, Israel has one lease that expires in 2021 and one that expires in 2030; and the Or Yehuda, Israel lease expires in 2023. We believe our properties have been well maintained, are in good operating condition, and are adequate for current needs. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

Item 3. Legal Proceedings

For a description of our material pending legal proceedings, please see Note 18 to the "*Consolidated Financial Statements*" of this Annual Report on Form 10-K, which is incorporated by reference.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the New York Stock Exchange (the "NYSE") under the symbol "EW."

Number of Stockholders

On January 31, 2021, there were 8,876 stockholders of record of our common stock.

Dividends

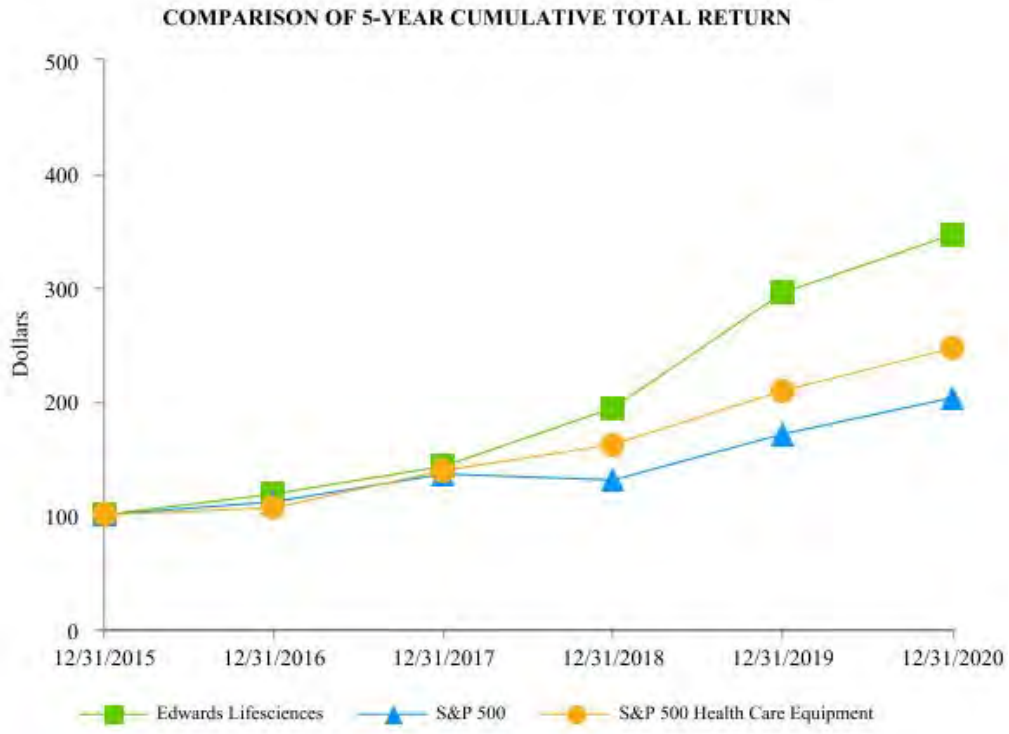
We have never paid any cash dividends on our capital stock and have no current plans to pay any cash dividends. Our current policy is to retain any future earnings for use in our business.

Issuer Purchases of Equity Securities

On May 8, 2019, the Board of Directors approved a stock repurchase program authorizing us to purchase on the open market, including pursuant to a Rule 10b5-1 plan and in privately negotiated transactions, up to $1.0 billion of our common stock. The repurchase program does not have an expiration date. We did not purchase any of our common stock during the fourth quarter of 2020 and, as of December 31, 2020, we had remaining authority to purchase $625.0 million of common stock.

Performance Graph

The following graph compares the performance of our common stock with that of the S&P 500 Index and the S&P 500 Health Care Equipment Index. The cumulative total return listed below assumes an initial investment of $100 at the market close on December 31, 2015 and reinvestment of dividends. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.



	Total Cumulative Return				
	2016	2017	2018	2019	2020
Edwards Lifesciences	**$ 118.64**	**$ 142.71**	**$ 193.94**	**$ 295.38**	**$ 346.53**
S&P 500	**111.96**	**136.40**	**130.42**	**171.49**	**203.04**
S&P 500 Health Care Equipment	**106.48**	**139.38**	**162.02**	**209.52**	**246.47**

Item 6. Selected Financial Data

		As of or for the Years Ended December 31,				
		2020	2019	2018	2017	2016
		(in millions, except per share data)				
OPERATING RESULTS	Net sales	$ 4,386.3	$ 4,348.0	$ 3,722.8	$ 3,435.3	$ 2,963.7
	Gross profit	3,305.7	3,233.6	2,783.4	2,560.0	2,166.3
	Operating income (a)	897.6	1,146.8	748.2	1,089.4	751.2
	Net income (a)	823.4	1,046.9	722.2	583.6	569.5
COMMON STOCK INFORMATION	Net income per common share (a) (c):					
	Basic	$ 1.32	$ 1.68	$ 1.15	$ 0.92	$ 0.89
	Diluted	1.30	1.64	1.13	0.90	0.87
	Cash dividends declared per common share	—	—	—	—	—
BALANCE SHEET DATA	Total assets	$ 7,237.1	$ 6,488.1	$ 5,323.7	$ 5,666.4	$ 4,518.5
	Long-term debt (b)	595.0	594.4	593.8	438.4	822.3

(a) The above results for 2020 include a $367.9 million pre-tax charge ($305.1 million, net of tax) related to a litigation settlement. The above results for 2019 include special charges of $64.6 million ($58.7 million, net of tax), primarily the impairment of certain assets and the acquisition of early-stage intellectual property. The above results for 2018 include special charges of $109.1 million ($103.0 million, net of tax), primarily the impairment of intangible assets and a $180.0 million ($137.5 million, net of tax) charge related to a litigation settlement. The above results for 2017 include a $112.5 million ($70.3 million, net of tax) gain for a litigation payment received in 2017 and a $262.0 million tax expense related to the implementation of U.S. tax law changes. See Part II, Item 7, *"Management's Discussion and Analysis of Financial Condition and Results of Operations*" and Note 3, Note 4, and Note 17 to the *"Consolidated Financial Statements"* for additional information.

(b) In October 2013, we issued $600.0 million of 2.875% fixed-rate unsecured senior notes due October 15, 2018 (the "2013 Notes"). At December 31, 2017, the 2013 Notes were classified as short-term obligations as these obligations were due within one year. These 2013 Notes were paid in October 2018. In June 2018, we issued $600.0 million of 4.3% fixed-rate unsecured senior notes due June 15, 2028, which were classified as long-term obligations as of December 31, 2020, 2019 and 2018. Amounts outstanding under our Five-Year Credit Agreement ("Credit Agreement") have been classified as long-term obligations in accordance with the terms of the Credit Agreement.

(c) The per share amounts for the prior periods presented have been retroactively adjusted to reflect the three-for-one stock split effected in the second quarter of 2020.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis presents the factors that had a material effect on our results of operations during the two years ended December 31, 2020. Also discussed is our financial position as of December 31, 2020. You should read this discussion in conjunction with the historical consolidated financial statements and related notes included elsewhere in this Form 10-K. For a discussion related to the results of operations for 2019 compared to 2018 and a discussion related to our consolidated cash flows for 2019 compared to 2018, refer to Part II, Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in our 2019 Annual Report on Form 10–K filed with the Securities and Exchange Commission on February 14, 2020.

Overview

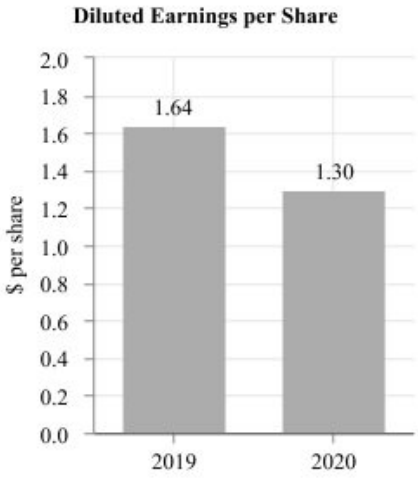
We are the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, we partner with the world's leading clinicians and researchers and invest in research and development to transform care for those impacted by structural heart disease or who require

hemodynamic monitoring during surgery or in intensive care. We conduct operations worldwide and are managed in the following geographical regions: United States, Europe, Japan, and Rest of World. Our products are categorized into the following main areas: Transcatheter Aortic Valve Replacement ("TAVR"), Transcatheter Mitral and Tricuspid Therapies ("TMTT"), Surgical Structural Heart ("Surgical"), and Critical Care.

On May 7, 2020, our Board of Directors declared a three-for-one stock split of our outstanding shares of common stock effected in the form of a stock dividend, distributed on May 29, 2020 to stockholders of record on May 18, 2020. We distributed two newly issued shares of common stock to holders of record of each share of common stock to effect the stock split. All applicable share and per-share amounts in this "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" have been retroactively adjusted to give effect to this stock split.

Financial Highlights and COVID-19





In March 2020, the World Health Organization categorized the Coronavirus disease 2019 ("COVID-19") as a pandemic. COVID-19 continues to spread throughout the United States and other countries across the world, and the duration and severity of its effects are currently unknown. The global pandemic has adversely impacted and is likely to further adversely impact nearly all aspects of our business and markets, including our workforce and the operations of our customers, suppliers, and business partners. Our priority has been to support our clinician partners, protect the well-being of our employees, and maintain continuous access to our life-saving technologies while offering front-line in-hospital support. Our manufacturing operations have continued to respond to impacts related to COVID-19, and we have been able to supply our technologies around the world. Across the organization, we are proactively managing inventory, assessing alternative logistics options, and closely monitoring the supply of components.

TAVR and Surgical procedure volumes varied greatly since the middle of March 2020 by geography, and even by hospital, as patients and their physicians analyzed the trade-off between aortic stenosis and their concern for COVID-19. In the last few weeks of the first quarter of 2020, procedure volumes related to our TAVR and Surgical products dropped significantly. Beginning in the second quarter of 2020, procedure volumes improved. In the second quarter of 2020, we also started to progressively resume patient enrollment in all clinical trials that were voluntarily paused or slowed at the end of the first quarter of 2020. While we saw improvements to pre-COVID levels when we resumed enrollment, procedure volumes and enrollment in our clinical trials have since been negatively impacted due to a resurgence of COVID-19 in late 2020. Even though health systems adapted to the challenge, the resurgence of COVID-19 late in 2020 continued to impact these patients who need care. In Critical Care, there was greater demand in Europe and the United States for our pressure monitoring products, but demand for other Critical Care products began to decrease at the end of the first quarter of 2020 due to COVID-19, and that trend continued through the fourth quarter of 2020.

Despite the challenges associated with COVID-19, our net sales for 2020 were $4.4 billion, representing an increase of $38.3 million over 2019, driven by sales growth of our TAVR products.

Our gross profit increase in 2020 was driven by a charge of $73.1 million recorded in 2019, primarily comprised of the write off of inventory related to strategic decisions regarding our TAVR portfolio, including the decision to discontinue our *CENTERA* program.

The decrease in our diluted earnings per share in 2020 was driven by an after-tax charge of $305.1 million to settle certain patent litigation related to transcatheter mitral and tricuspid repair products.

Healthcare Environment, Opportunities, and Challenges

The medical technology industry is highly competitive and continues to evolve. Our success is measured both by the development of innovative products and the value we bring to our stakeholders. We are committed to developing new technologies and providing innovative patient care, and we are committed to defending our intellectual property in support of those developments. While some evidence collection was slowed due to the COVID-19 pandemic, we and the clinical community are committed to continuing our trials and generating robust evidence. In 2020, we invested 17.3% of our net sales in research and development. The following is a summary of important developments during 2020:

- in response to the urgent COVID-19 response around the globe, we temporarily paused new enrollments in our active pivotal clinical trials of transcatheter mitral and tricuspid therapies, which began resuming in the second quarter of 2020;
- we received CE Mark for the *Edwards PASCAL* transcatheter valve repair system for the treatment of European patients with tricuspid regurgitation;
- we received Chinese regulatory approval for the *Edwards SAPIEN 3* transcatheter heart valve for the treatment of severe, symptomatic aortic stenosis patients at high risk for or unable to undergo open-heart surgery;
- we reached an agreement with Abbott to settle all outstanding patent disputes between the companies in cases related to transcatheter mitral and tricuspid repair products;
- we received FDA approval for the *KONECT RESILIA* aortic valved conduit, the first ready-to-implant solution for bio-Bentall procedures, a complex surgery that involves replacement of a patient's aortic valve, aortic root, and the ascending aorta.
- we treated our first patient in the RESTORE clinical trial, which will evaluate the safety and effectiveness of the investigational *HARPOON Beating Heart Mitral Valve Repair System* in the United States and Canada.

We are dedicated to generating robust clinical, economic, and quality of life evidence increasingly expected by patients, clinicians, and payors in the current healthcare environment, with the goal of encouraging the adoption of innovative new medical therapies that demonstrate superior outcomes.

Results of Operations

Net Sales by Major Regions
(dollars in millions)

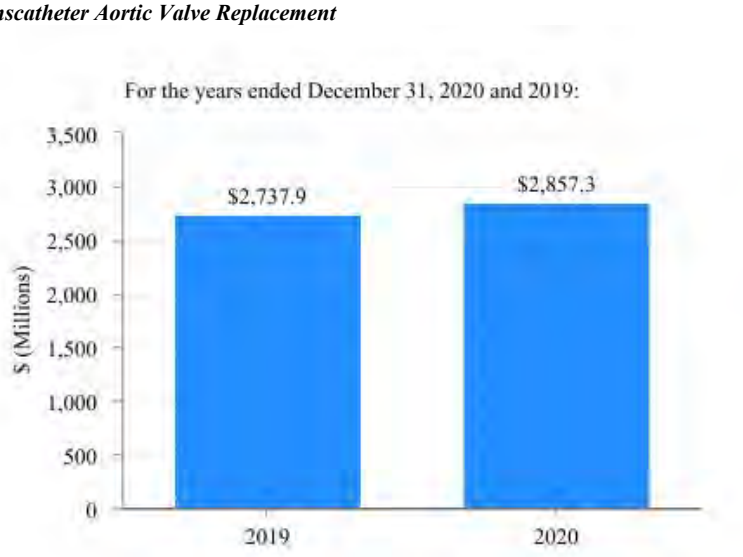
	Years Ended December 31,		Change	
	2020	2019	$	%
United States	$ 2,516.8	$ 2,532.7	$ (15.9)	(0.6)%
Europe	973.6	941.2	32.4	3.4 %
Japan	460.1	444.7	15.4	3.5 %
Rest of World	435.8	429.4	6.4	1.5 %
International	1,869.5	1,815.3	54.2	3.0 %
Total net sales	$ 4,386.3	$ 4,348.0	$ 38.3	0.9 %

International net sales include the impact of foreign currency exchange rate fluctuations. The impact of foreign currency exchange rate fluctuations on net sales is not necessarily indicative of the impact on net income due to the corresponding effect of foreign currency exchange rate fluctuations on international manufacturing and operating costs, and our hedging activities. For more information, see *"Quantitative and Qualitative Disclosures About Market Risk."*

Net Sales by Product Group
(dollars in millions)

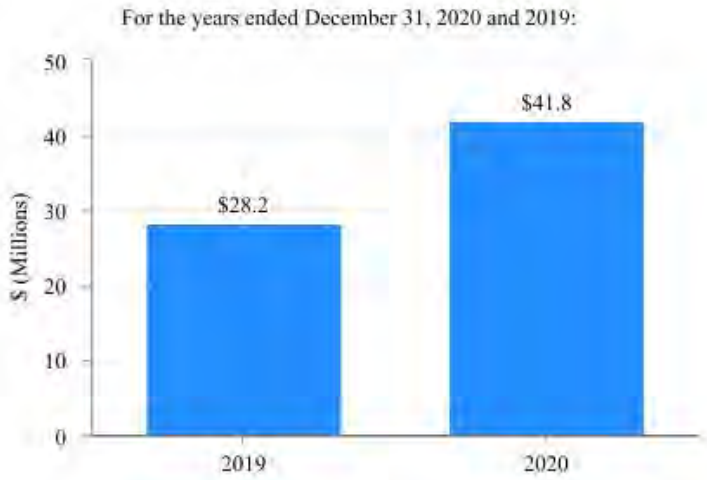
	Years Ended December 31,		Change	
	2020	2019	$	%
Transcatheter Aortic Valve Replacement	$ 2,857.3	$ 2,737.9	$ 119.4	4.4 %
Transcatheter Mitral and Tricuspid Therapies	41.8	28.2	13.6	48.5 %
Surgical Heart Valve Therapy	761.8	841.7	(79.9)	(9.5)%
Critical Care	725.4	740.2	(14.8)	(2.0)%
Total net sales	$ 4,386.3	$ 4,348.0	$ 38.3	0.9 %

Transcatheter Aortic Valve Replacement



The increase in net sales of TAVR products was due primarily to higher sales of the *Edwards SAPIEN 3 Ultra System* following its regulatory approval in the United States (December 2018) and in Europe (November 2018). The adoption of the *Edwards SAPIEN 3 Ultra System* continued to be very positive in 2020. However, our sales in 2020 were negatively impacted by the COVID-19 pandemic, and these challenges have continued in early 2021. Our procedure volumes dropped significantly beginning in March 2020 due to COVID-19, and began to steadily improve beginning in May 2020. In the first quarter of 2020, to ensure the safety of our employees and clinician partners from the threat of COVID-19, we decided to pause proctoring at centers that were not already trained on the *Edwards SAPIEN 3 Ultra System*. In the second quarter of 2020, we resumed proctoring.

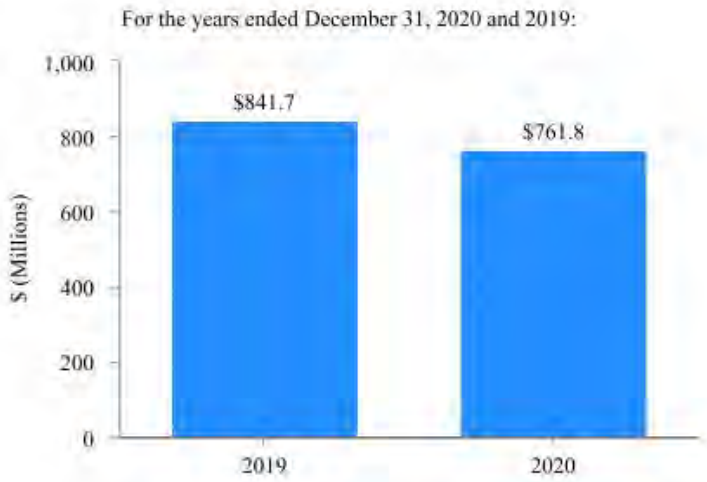
Transcatheter Mitral and Tricuspid Therapies



The increase in net sales of TMTT products was due primarily to sales in Europe of the *Edwards PASCAL* transcatheter valve repair system, which received CE Mark in February 2019. Our sales in 2020 were negatively impacted by the COVID-19 pandemic. Our procedure volumes for *PASCAL* dropped significantly in March 2020 due to COVID-19, and began to improve beginning in May 2020.

At the end of March 2020, we temporarily paused new enrollments in our active pivotal clinical trials of transcatheter mitral and tricuspid therapies in response to the COVID-19 response around the globe. In the second quarter of 2020, we began resuming enrollments. However, due to a resurgence of COVID-19 in late 2020, we are experiencing a negative impact to clinical trial enrollment. In May 2020, we received CE Mark for the *PASCAL Ace* implant system for mitral and tricuspid repair.

Surgical Structural Heart

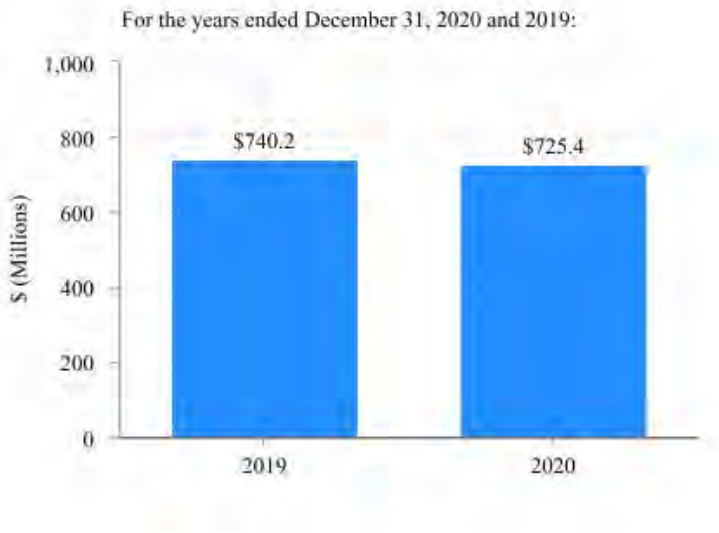


The decrease in net sales of Surgical products was due primarily to decreased sales of aortic tissue valves, primarily in the United States and Europe, due to the impact of COVID-19. The ongoing adoption of TAVR also contributed to the decrease in United States surgical aortic valve sales. These decreases were partially offset by increased sales of the *INSPIRIS RESILIA*

aortic valve and the *KONECT* aortic valved conduit, primarily in the United States. Increased and improved management of intensive care unit capacity, as well as prioritization of heart surgery in many hospitals, contributed to rebounding procedure volumes late in the second quarter of 2020. In the fourth quarter of 2020, hospitals experienced an influx of COVID-19 patients, limiting surgical valve procedures.

In Europe, our *HARPOON Beating Heart Mitral Valve Repair System* became available commercially at the end of 2019, and the first commercial case was successfully completed in Europe in the second quarter of 2020. In addition, we received FDA approval in April 2020 to begin our U.S. pivotal investigational device exemption study. *HARPOON* offers the potential for earlier treatment of degenerative mitral valve disease, with faster recovery and more consistent outcomes for surgical patients.

Critical Care



The decrease in net sales of Critical Care products was driven by a decline in sales of our enhanced surgical recovery products, primarily in the United States, as many surgical procedures were delayed due to COVID-19 beginning in March 2020. We also experienced a decline in orders of our *HemoSphere* advanced monitoring platform in the United States as hospitals limited their capital spending due to COVID-19.

These decreases in net sales were partially offset by increased demand for our pressure monitoring products, primarily in Europe and the United States, as COVID-19 hospitalizations increased. In addition, our sales in 2020 and 2019 included $22.6 million and $16.8 million, respectively, related to CAS Medical Systems, Inc. ("CASMED"), which we acquired on April 18, 2019. CASMED is a medical technology company dedicated to non-invasive monitoring of tissue oxygenation in the brain.

Gross Profit



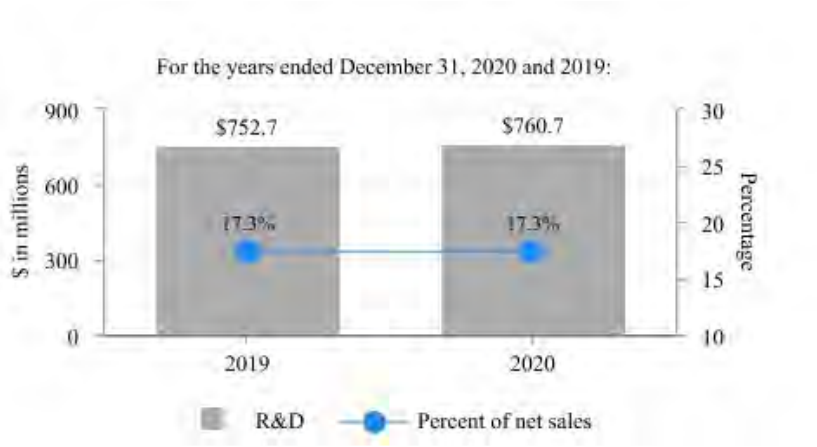
Our gross profit was higher as a percentage of net sales in 2020 compared to 2019. In 2019, our gross profit was reduced by $73.1 million due to the decision to discontinue our CENTERA program, resulting in a 1.7 percentage point increase in 2020 compared to 2019. This increase was partially offset by a) a 1.0 percentage point decrease in 2020 due to the impact of foreign currency exchange rate fluctuations, net of hedging, and b) incremental costs associated with COVID-19.

Selling, General, and Administrative ("SG&A") Expenses



The decrease in SG&A expenses in 2020 compared to 2019 was due primarily to a) decreased sales, marketing and travel-related expense associated with COVID-19 and b) lower performance-based compensation, partially offset by increased sales and marketing expenses related to transcatheter structural heart field personnel, primarily in the United States.

Research and Development ("R&D") Expenses



The increase in R&D expenses in 2020 compared to 2019 was due primarily to a) investments in our transcatheter mitral and tricuspid therapies and our aortic valve replacement programs and b) costs associated with discontinuing our *SUTRAFIX* program. These increases were partially offset by a) decreased spending on transcatheter aortic valve clinical trials and b) decreased performance-based compensation.

Intellectual Property Litigation Expenses, net

We incurred intellectual property litigation expenses, including settlements and external legal costs, of $405.4 million and $33.4 million during 2020 and 2019, respectively. On July 12, 2020, we reached an agreement with Abbott Laboratories and its direct and indirect subsidiaries ("Abbott") to, among other things, settle all outstanding patent disputes between the companies (the “Settlement Agreement”) in cases related to transcatheter mitral and tricuspid repair products. See Note 18 to the "*Consolidated Financial Statements*" for additional information. The Settlement Agreement resulted in us recording an estimated $367.9 million pre-tax charge and related liability in June 2020 related to past damages. In addition, we will incur royalty expenses through May 2024 totaling an estimated $100 million. We made a one-time $100.0 million payment to Abbott in July 2020, and will make quarterly payments in future years.

Change in Fair Value of Contingent Consideration Liabilities, net

The change in fair value of contingent consideration liabilities resulted in expense of $13.6 million in 2020 and income of $6.1 million in 2019. The expense in 2020 was primarily driven by the accretion of interest due to the passage of time and adjustments to discount rates, partially offset by changes in the projected probability and timing of milestone achievements, and the projected timing of cash inflows. The income in 2019 was due primarily to longer product development timelines, which reduced the probability of milestone achievements, partially offset by the accretion of interest due to the passage of time and discount rate adjustments.

Special Charges (Gain), net

For information on special charges and gains, see Note 4 to the "*Consolidated Financial Statements.*"

Interest Expense

Interest expense was $15.8 million and $20.7 million in 2020 and 2019, respectively. The decrease in interest expense resulted primarily from higher capitalized interest due to facilities construction.

Interest Income

Interest income was $23.4 million and $32.2 million in 2020 and 2019, respectively. The decrease in interest income resulted primarily from lower average interest rates, partially offset by a higher average investment balance.

Other Income, net
(in millions)

	Years Ended December 31,	
	2020	2019
Foreign exchange gains, net	$ (12.3)	$ (5.9)
Gain on investments	(0.6)	(0.5)
Non-service cost components of net periodic pension benefit cost	0.4	0.2
Other	1.0	(2.0)
Total other income, net	$ (11.5)	$ (8.2)

The net foreign exchange gains relate to the foreign currency fluctuations in our global trade and intercompany receivable and payable balances, offset by the gains and losses on derivative instruments intended as an economic hedge of those exposures.

The gain on investments represents our net share of gains and losses in investments accounted for under the equity method, and realized gains and losses on investments in equity securities.

The non-service cost components of net periodic pension benefit cost includes the costs of our defined benefit plans that are not attributed to services rendered by eligible employees during the year, such as interest costs, expected return on plan assets, and amortization of actuarial gains or losses.

Provision for Income Taxes

	Years Ended December 31,		Change	
	2020	2019	$	%
Provision for income taxes	93.3	119.6	(26.3)	(22.0)%
Effective tax rate	10.2 %	10.3 %		

Our effective income tax rate in 2020 and 2019 was 10.2% and 10.3%, respectively. Our effective tax rate for 2020 decreased slightly in comparison to 2019 primarily due to the tax benefit from the Settlement Agreement with Abbott (see Notes 3 and 18 to the "*Consolidated Financial Statements*"), partially offset by the increase in the U.S. tax on global intangible low-taxed income and the decrease in the tax benefit from employee share-based compensation.

In 2020, the difference between our 10.2% effective tax rate and the Federal statutory rate of 21% was primarily due to a) foreign earnings taxed at lower rates, b) Federal and California research and development credits, and c) the tax benefit from employee share-based compensation.

As of December 31, 2020, we have $145.1 million of California research expenditure tax credits that we expect to use in future periods. The credits may be carried forward indefinitely. Based upon anticipated future taxable income, we expect that it is more likely than not that all California research expenditure tax credits will be utilized, although the utilization of the full benefit is expected to occur over a number of years and into the distant future.

As of December 31, 2020, gross uncertain tax positions were $281.8 million. We estimate that these liabilities would be reduced by $95.1 million from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes, and timing adjustments. The net amount of $186.7 million, if not required, would favorably affect our effective tax rate.

We strive to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at any time. While we have accrued for matters we believe are more likely than not to require settlement, the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in the consolidated financial statements. Furthermore, we may later decide to challenge any assessments, if made, and may exercise our right to appeal. The

uncertain tax positions are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues, and issuance of new legislation, regulations, or case law. We believe that adequate amounts of tax and related penalty and interest have been provided in income tax expense for any adjustments that may result from our uncertain tax positions.

At December 31, 2020, all material state, local, and foreign income tax matters have been concluded for years through 2015. While not material, we continue to address matters in Wisconsin and India for years from 2010.

During 2018, we executed an Advance Pricing Agreement (“APA”) between the United States and Switzerland governments for tax years 2009 through 2020 covering various, but not all, transfer pricing matters. The unagreed transfer pricing matters, namely Surgical Structural Heart and Transcatheter Aortic Valve Replacement intercompany royalty transactions, then reverted to Internal Revenue Service ("IRS") Examination for further consideration as part of the respective years' regular tax audit. In addition, we signed agreements during 2018 with the IRS to settle open tax years 2009 through 2014, including all transfer pricing matters for those years and the tax treatment of a portion of a litigation settlement payment received in 2014.

The IRS began its examination of the 2015 and 2016 tax years during the fourth quarter of 2018 and later added the 2017 tax year to this audit cycle during the first quarter of 2019. The IRS audit field work for the 2015 through 2017 tax years was substantially completed during the fourth quarter of 2020, except for transfer pricing matters.

As a result, certain intercompany transactions covering tax years 2015 through 2020 that were not resolved under the APA program remain subject to IRS examination, and those transactions and related tax positions remain uncertain as of December 31, 2020. The IRS has signaled that it may be preparing proposed audit adjustments related to these intercompany transactions for the 2015 through 2017 tax years which, if issued, could be provided to us during 2021. We have considered this information in our evaluation of our reserves for uncertain tax positions.

These unresolved transfer pricing matters, net of any correlative repatriation tax adjustment, may be significant to our consolidated financial statements. Based on the information currently available and numerous possible outcomes, we cannot reasonably estimate what, if any, changes to our existing uncertain tax positions may occur in the next 12 months and, therefore, have continued to record the gross uncertain tax positions as a long-term liability.

We intend to file to renew the APA between the United States and Switzerland for the years 2021 and forward. In addition, we executed other APAs as follows: during 2017, an APA between the United States and Japan covering tax years 2015 through 2019; and during 2018, APAs between Japan and Singapore and between Switzerland and Japan covering tax years 2015 through 2019. We have filed to renew these APAs related to Japan for the years 2020 and forward. The execution of some or all of these APAs depends on a number of variables outside of our control.

We have received tax incentives in certain non-U.S. tax jurisdictions, the primary benefit for which will expire in 2029. The tax reductions as compared to the local statutory rates were $189.2 million ($0.30 per diluted share) and $157.6 million ($0.25 per diluted share) for the years ended December 31, 2020 and 2019, respectively.

Liquidity and Capital Resources

Our sources of cash liquidity include cash and cash equivalents, short-term investments, amounts available under credit facilities, and cash from operations. We believe that these sources are sufficient to fund the current requirements of working capital, capital expenditures, and other financial commitments for the next twelve months from the financial statement issuance date. However, we periodically consider various financing alternatives and may, from time to time, seek to take advantage of favorable interest rate environments or other market conditions.

The Tax Cuts and Jobs Act of 2017 (the "2017 Act"), which was signed into law on December 22, 2017, included extensive changes to the international tax regime. The 2017 Act required a deemed repatriation of post-1986 undistributed foreign earnings and profits. The one-time transition tax liability, as adjusted, is payable in five remaining annual installments, as outlined in the contractual obligations table below. As of December 31, 2020, we had a remaining tax obligation of $238.7 million related to the deemed repatriation. See Note 17 to the "*Consolidated Financial Statements*" for additional information about the one-time transition tax.

As of December 31, 2020, cash and cash equivalents and short-term investments held in the United States and outside the United States were $618.8 million and $783.8 million, respectively. During 2020, we repatriated cash of $600.0 million. We

assert that $1.1 billion of our foreign earnings continue to be permanently reinvested and our intent is to repatriate $599.8 million of our foreign earnings as of December 31, 2020.

On July 12, 2020, we reached the Settlement Agreement with Abbott to settle all outstanding patent disputes between the companies in cases related to transcatheter mitral and tricuspid repair products. The Settlement Agreement resulted in us recording an estimated $367.9 million pretax charge in June 2020 related to past damages. In addition, we will incur royalty expenses through May 2024 totaling an estimated $100 million. We made a one-time $100.0 million payment to Abbott in July 2020, and will make quarterly payments in future years. For further information, see Notes 3 and 18 to the "*Consolidated Financial Statements.*"

On April 18, 2019, we acquired CASMED for an aggregate cash purchase price of $2.45 per share of common stock, or $100.8 million. For more information, see Note 8 to the "*Consolidated Financial Statements.*"

Certain of our business acquisitions involve contingent consideration arrangements. Payment of additional consideration in the future may be required, contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. For further information, see Note 8 to the "*Consolidated Financial Statements.*"

We have a Five-Year Credit Agreement ("the Credit Agreement") which matures on April 28, 2023. The Credit Agreement provides up to an aggregate of $750.0 million in borrowings in multiple currencies. Subject to certain terms and conditions, we may increase the amount available under the Credit Agreement by up to an additional $250.0 million in the aggregate. As of December 31, 2020, there were no borrowings outstanding under the Credit Agreement. The Credit Agreement is unsecured and contains various financial and other covenants, including a maximum leverage ratio, as defined in the Credit Agreement. The Company was in compliance with all covenants at December 31, 2020.

In June 2018, we issued $600.0 million of 4.3% fixed-rate unsecured senior notes (the "2018 Notes") due June 15, 2028. We may redeem the 2018 Notes, in whole or in part, at any time and from time to time at specified redemption prices. As of December 31, 2020, we have not elected to redeem any of the 2018 Notes. As of December 31, 2020, the total carrying value of our 2018 Notes was $595.0 million. For further information on our debt, see Note 10 to the "*Consolidated Financial Statements*."

From time to time, we repurchase shares of our common stock under share repurchase programs authorized by the Board of Directors. We consider several factors in determining when to execute share repurchases, including, among other things, expected dilution from stock plans, cash capacity, and the market price of our common stock. During 2020, under the Board authorized repurchase programs, we repurchased a total of 3.0 million shares at an aggregate cost of $614.7 million, and as of December 31, 2020, we had remaining authority to purchase $625.0 million of our common stock. For further information, see Note 14 to the "*Consolidated Financial Statements*." In February 2021, we entered into an accelerated share repurchase agreement to repurchase $250.0 million of our common stock. For further information, see Note 22 to the "*Consolidated Financial Statements*."

Consolidated Cash Flows - For the twelve months ended December 31, 2020 and 2019



Net cash flows provided by **operating activities** of $1.1 billion for 2020 decreased $128.6 million from 2019 due primarily to lower operating profits in 2020 and a payment of $100.0 million for a litigation settlement, partially offset by a payment of $180.0 million in 2019 for a litigation settlement.

Net cash used in **investing activities** of $531.1 million in 2020 consisted primarily of capital expenditures of $407.0 million and net purchases of investments of $87.6 million.

Net cash used in investing activities of $595.8 million in 2019 consisted primarily of a) capital expenditures of $254.4 million, b) net purchases of investments of $174.9 million, c) a $100.2 million net cash payment associated with the acquisition of CASMED, d) a $35.0 million payment for an option to acquire a company, and e) a $24.0 million payment to acquire certain early-stage transcatheter intellectual property and associated clinical and regulatory experience.

We currently anticipate making capital expenditures of approximately $350 million in 2021 as we continue to invest in our operations.

Net cash used in **financing activities** of $486.9 million in 2020 consisted primarily of purchases of treasury stock of $625.4 million, partially offset by proceeds from stock plans of $140.5 million.

Net cash used in financing activities of $115.6 million in 2019 consisted primarily of purchases of treasury stock of $263.3 million, partially offset by proceeds from stock plans of $160.5 million.

Contractual Obligations

A summary of all of our contractual obligations and commercial commitments as of December 31, 2020 is as follows (in millions):

	Payments Due by Period				
Contractual Obligations	**Total**	**Year 1**	**Years 2-3**	**Years 4-5**	**After 5 Years**
Debt	$ 600.0	$ —	$ —	$ —	$ 600.0
Operating leases	108.1	30.0	35.1	14.9	28.1
Interest on debt	148.9	20.5	40.5	39.4	48.5
Transition tax on unremitted foreign earnings and profits (a)	238.7	25.1	72.2	141.4	—
Litigation settlement obligation (minimum payments)	250.0	50.0	100.0	100.0	—
Pension obligations (b)	2.5	2.5	—	—	—
Purchase and other commitments (c)	26.7	13.7	9.7	1.5	1.8
Total contractual cash obligations (d), (e)	$ 1,374.9	$ 141.8	$ 257.5	$ 297.2	$ 678.4

(a) As of December 31, 2020, we had recorded $238.7 million of income tax liabilities related to the one-time transition tax that resulted from the enactment of the 2017 Act. The transition tax is due in eight annual installments, with the first annual installment paid in 2018, the second annual installment paid in 2019 and the third annual installment paid in 2020. The remaining installment amounts will be equal to 8% of the total liability, payable in fiscal years 2021 through 2022, 15% in fiscal year 2023, 20% in fiscal year 2024, and 25% in fiscal year 2025. See Note 17 to the "*Consolidated Financial Statements*" for additional information about the one-time transition tax.

(b) The amount included in "Less Than 1 Year" reflects anticipated contributions to our various pension plans. Anticipated contributions beyond one year are not determinable. The total accrued benefit liability for our pension plans recognized as of December 31, 2020 was $52.9 million. This amount is impacted by, among other items, pension expense funding levels, changes in plan demographics and assumptions, and investment returns on plan assets. Therefore, we are unable to make a reasonably reliable estimate of the amount and period in which the liability might be paid, and did not include this amount in the contractual obligations table. See Note 13 to the "*Consolidated Financial Statements*" for further information.

(c) Purchase and other commitments consists primarily of open purchase orders for the acquisition of goods and services in the normal course of business. We have excluded open purchase orders with a remaining term of less than one year. For certain purchase and other commitments, such as commitments to fund equity method or other investments, the timing of the payment is not certain. In these cases, the maturity dates in the table reflect our best estimates.

(d) As of December 31, 2020, the gross liability for uncertain tax positions, including interest, was $301.2 million and relates primarily to transfer pricing matters. During 2018, we executed an APA between the United States and Switzerland governments for tax years 2009 through 2020 covering various but not all transfer pricing matters. As a result, certain

intercompany transactions covering tax years 2015 through 2020 that were not resolved under the APA program remain subject to IRS examination, and those transactions and related tax positions remain uncertain as of the balance sheet date. These unresolved transfer pricing matters may be significant to our consolidated financial statements, and the final outcome of the negotiations is uncertain. Management believes that adequate amounts of tax and related penalty and interest have been provided in income tax expense for any adjustments that may result for our uncertain tax positions. We are unable to make a reasonably reliable estimate of the amount and period in which the liability might be paid, and did not include this amount in the contractual obligations table.

(e) We acquire assets still in development, enter into research and development arrangements, acquire businesses, and sponsor certain clinical trials that often require milestone, royalty, or other future payments to third-parties, contingent upon the occurrence of certain future events. In situations where we have no ability to influence the achievement of the milestone or otherwise avoid the payment, we have included those payments in the table above. However, we have excluded from the table contingent milestone payments and other contingent liabilities for which we cannot reasonably predict future payments or for which we can avoid making payment by unilaterally deciding to stop development of a product or cease progress of a clinical trial. We estimate that these contingent payments could be up to $810.0 million if all milestones or other contingent obligations are met. This amount includes certain milestone-based contingent obligations that may be paid through a combination of cash and issuance of common stock, and certain sales-based royalties in excess of minimum payment thresholds related to litigation settlements.

Critical Accounting Policies and Estimates

Our results of operations and financial position are determined based upon the application of our accounting policies, as discussed in the notes to the "*Consolidated Financial Statements*." Certain of our accounting policies represent a selection among acceptable alternatives under GAAP. In evaluating our transactions, management assesses all relevant GAAP and chooses the accounting policy that most accurately reflects the nature of the transactions.

The application of accounting policies requires the use of judgment and estimates. These matters that are subject to judgments and estimation are inherently uncertain, and different amounts could be reported using different assumptions and estimates. Management uses its best estimates and judgments in determining the appropriate amount to reflect in the consolidated financial statements, using historical experience and all available information. We also use outside experts where appropriate. We apply estimation methodologies consistently from year to year.

We believe the following are the critical accounting policies which could have the most significant effect on our reported results and require subjective or complex judgments by management.

Revenue Recognition

When we recognize revenue from the sale of our products, the amount of consideration we ultimately receive varies depending upon the return terms, sales rebates, discounts, and other incentives that we may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The estimate of variable consideration requires significant judgment. We include estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely upon an assessment of historical payment experience, historical relationship to revenues, estimated customer inventory levels, and current contract sales terms with direct and indirect customers. Product returns are typically not significant because returns are generally not allowed unless the product is damaged at time of receipt. If the historical data and inventory estimates used to calculate the variable consideration do not approximate future activity, our financial position, results of operations, and cash flows could be impacted.

In addition, in limited circumstances, we may allow customers to return previously purchased products, such as for next-generation product offerings. For these transactions, we defer recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount of product to be returned when the next-generation products are shipped to the customer. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls, and variation in product utilization all affect the estimates related to sales returns and could cause actual returns to differ from these estimates.

Our sales adjustment related to distributor rebates given to our United States distributors represents the difference between our sales price to the distributor and the negotiated price to be paid by the end-customer. We validate the distributor rebate accrual quarterly through either a review of the inventory reports obtained from our distributors or an estimate of the

distributor's inventory. This distributor inventory information is used to verify the estimated liability for future distributor rebate claims based on historical rebates and contract rates. We periodically monitor current pricing trends and distributor inventory levels to ensure the credit for future distributor rebates is fairly stated.

Excess and Obsolete Inventory

The valuation of our inventory requires us to estimate excess, obsolete, and expired inventory. We base our provisions for excess, obsolete, and expired inventory on our estimates of forecasted net sales. A significant change in the timing or level of demand for our products as compared to forecasted amounts may result in recording additional allowances for excess, obsolete, and expired inventory in the future. In addition, our industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls, increasing levels of consigned inventory, and variation in product utilization all affect our estimates related to excess, obsolete, and expired inventory.

Intangible Assets and Long-lived Assets

We acquire intangible assets in connection with business combinations and asset purchases. The acquired intangible assets are recorded at fair value, which is determined based on a discounted cash flow analysis. The determination of fair value requires significant estimates, including, but not limited to, the amount and timing of projected future cash flows, the discount rate used to discount those cash flows, the assessment of the asset's life cycle, including the timing and expected costs to complete in-process projects, and the consideration of legal, technical, regulatory, economic, and competitive risks.

In-process research and development assets acquired in business combinations is reviewed for impairment annually, or whenever an event occurs or circumstances change that would indicate the carrying amount may be impaired. Additionally, management reviews the carrying amounts of other intangible and long-lived assets whenever events or circumstances indicate that the carrying amounts of an asset may not be recoverable. The impairment reviews require significant estimates about fair value, including estimation of future cash flows, selection of an appropriate discount rate, and estimates of long-term growth rates.

Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. We determine the fair value of the contingent consideration based primarily on the following factors:

- discount rates used to present value the projected cash flows;
- the probability of success of clinical events and regulatory approvals, and/or meeting commercial milestones;
- projected payment dates; and
- volatility of future revenue.

On a quarterly basis, we revalue these obligations and record changes in their fair value as an adjustment to earnings. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in our estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events, or changes in the assumed probability associated with regulatory approval.

The assumptions related to determining the value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration expense recorded in any given period.

Income Taxes

The determination of our provision for income taxes requires significant judgment, the use of estimates, and the interpretation and application of complex tax laws. Realization of certain deferred tax assets, primarily tax credits, net operating loss and other carryforwards, is dependent upon generating sufficient taxable income in the appropriate jurisdiction prior to the expiration of the carryforward periods. Failure to achieve forecasted taxable income in the applicable taxing jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in our effective tax rate on future earnings.

We have made an accounting policy election to recognize the U.S. tax effects of global intangible low-taxed income as a component of income tax expense in the period the tax arises.

We are subject to income taxes in the United States and numerous foreign jurisdictions. Our income tax returns are periodically audited by domestic and foreign tax authorities. These audits include questions regarding our tax filing positions, including the timing and amount of deductions and the allocation of income amongst various tax jurisdictions. We evaluate our tax positions and establish liabilities in accordance with the applicable accounting guidance on uncertainty in income taxes. Significant judgment is required in evaluating our uncertain tax positions, including estimating the ultimate resolution to intercompany pricing controversies between countries when there are numerous possible outcomes. We review these tax uncertainties quarterly and adjust the liability as events occur that affect potential liabilities for additional taxes, such as the progress of tax audits, lapsing of applicable statutes of limitations, negotiations between tax authorities, identification of new issues, and issuance of new legislation, regulations, or case law.

For additional details on our income taxes, see Note 2 and Note 17 to the "*Consolidated Financial Statements*."

Stock-based Compensation

We measure and recognize compensation expense for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options, service-based restricted stock units, market-based restricted stock units, performance-based restricted stock units, and employee stock purchase subscriptions. The fair value of each option award and employee stock purchase subscription is estimated on the date of grant using the Black-Scholes option valuation model. The fair value of market-based restricted stock units is determined using a Monte Carlo simulation model, which uses multiple input variables to determine the probability of satisfying the market condition requirements. The Black-Scholes and Monte Carlo models require various highly judgmental assumptions, including stock price volatility, risk-free interest rate, and expected option term. For performance-based restricted stock units, expense is recognized if and when we conclude that it is probable that the performance condition will be achieved, which requires judgment. Stock-based compensation expense is recorded net of estimated forfeitures. Judgment is required in estimating the stock awards that will ultimately be forfeited. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations would be impacted.

Legal Contingencies

We are or may be a party to, or may otherwise be responsible for, pending or threatened lawsuits including those related to products and services currently or formerly manufactured or performed, as applicable, by us, workplace and employment matters, matters involving real estate, our operations or health care regulations, or governmental investigations. We accrue for loss contingencies to the extent that we conclude that it is probable that a loss will be incurred and the amount of the loss can be reasonably estimated. These matters raise difficult and complex factual and legal issues and are subject to many uncertainties, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. As such, significant judgment is required in determining our legal accruals. We describe our legal proceedings in Note 18 to the "*Consolidated Financial Statements.*"

New Accounting Standards

Information regarding new accounting standards is included in Note 2 to the "*Consolidated Financial Statements."*

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our business and financial results are affected by fluctuations in world financial markets, including changes in currency exchange rates and interest rates. We manage these risks through a combination of normal operating and financing activities and derivative financial instruments. We do not use derivative financial instruments for trading or speculative purposes.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. Our investment strategy is focused on preserving capital and supporting our liquidity requirements, while earning a reasonable market return. We invest in a variety of debt securities, primarily time deposits, commercial paper, U.S. and foreign government and agency securities, asset-backed securities, corporate debt securities, and municipal debt securities. The market value of our investments may decline if current market interest rates rise. As of December 31, 2020, we had $985.9 million of investments in debt securities which had an average remaining term to maturity of approximately 1.56 years. Taking into consideration the average maturity of our debt securities, a hypothetical 0.5% to 1.0% absolute increase in interest rates at December 31, 2020 would have resulted in a $7.8 million to $15.6 million decrease in the fair value of these investments. Such a decrease would only result in a realized loss if we choose or are forced to sell the investments before the scheduled maturity, which we currently do not anticipate.

For more information related to investments, see Note 7 to the "*Consolidated Financial Statements.*"

We are also exposed to interest rate risk on our debt obligations. As of December 31, 2020, we had $600.0 million of Notes outstanding that carry a fixed rate, and also had available a $750.0 million Credit Agreement that carries a variable interest rate based on the London interbank offered rate ("LIBOR"). As of December 31, 2020, there were no borrowings outstanding under the Credit Agreement. Based on our December 31, 2020 variable debt levels, a hypothetical 1.0% absolute increase in floating market interest rates would not have impacted our interest expense since we had no variable debt outstanding during the year. As of December 31, 2020, a hypothetical 1.0% absolute increase in market interest rates would decrease the fair value of the fixed-rate debt by approximately $43.2 million. This hypothetical change in interest rates would not impact the interest expense on the fixed-rate debt.

For more information related to outstanding debt obligations, see Note 10 to the "*Consolidated Financial Statements.*"

Currency Risk

We are exposed to foreign currency risks that arise from normal business operations. These risks include the translation of local currency balances and results of our non-United States subsidiaries into United States dollars, currency gains and losses related to intercompany and third-party transactions denominated in currencies other than a subsidiary's functional currency, and currency gains and losses associated with intercompany loans. Our principal currency exposures relate to the Euro and the Japanese yen. Our objective is to minimize the volatility of our exposure to these risks through a combination of normal operating and financing activities and the use of derivative financial instruments in the form of foreign currency forward exchange contracts and cross currency swap contracts. The total notional amount of our derivative financial instruments entered into for foreign currency management purposes at December 31, 2020 was $1.8 billion. A hypothetical 10% increase/decrease in the value of the United States dollar against all hedged currencies would increase/decrease the fair value of these derivative contracts by $141.5 million. Any gains or losses on the fair value of derivative contracts would generally be offset by gains and losses on the underlying transactions, so the net impact would not be significant to our financial condition or results of operations.

For more information related to outstanding foreign exchange contracts, see Note 2 and Note 12 to the "*Consolidated Financial Statements.*"

Credit Risk

Derivative financial instruments involve credit risk in the event the financial institution counterparty should default. It is our policy to execute such instruments with major financial institutions that we believe to be creditworthy. At December 31, 2020, all derivative financial instruments were with bank counterparties assigned investment grade ratings by national rating agencies. We further diversify our derivative financial instruments among counterparties to minimize exposure to any one of these entities. We have not experienced a counterparty default and do not anticipate any non-performance by our current derivative counterparties.

Concentrations of Risk

We invest excess cash in a variety of debt securities, and diversify the investments between financial institutions. Our investment policy limits the amount of credit exposure to any one issuer.

In the normal course of business, we provide credit to customers in the health care industry, perform credit evaluations of these customers, and maintain allowances for potential credit losses, which have historically been adequate compared to actual losses. In 2020, we had no customers that represented 10% or more of our total net sales or accounts receivable, net.

Investment Risk

We are exposed to investment risks related to changes in the underlying financial condition and credit capacity of certain of our investments. As of December 31, 2020, we had $985.9 million of investments in debt securities of various companies, of which $766.5 million were long-term. In addition, we had $35.1 million of investments in equity instruments of public and private companies. Should these companies experience a decline in financial performance, financial condition or credit capacity, or fail to meet certain development milestones, including as a result of the impact from COVID-19 on their business or operations or otherwise, a decline in the investments' value may occur, resulting in unrealized or realized losses.

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All other schedules are omitted as they are not applicable or the required information is furnished in the Consolidated Financial Statements or notes thereto.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Edwards Lifesciences Corporation

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Edwards Lifesciences Corporation and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations, of comprehensive income, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019**,** and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the

company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Uncertain Tax Positions Related to Intercompany Transfer Pricing

As described in Notes 2 and 17 to the consolidated financial statements, the Company had a gross uncertain tax position liability balance of $281.8 million as of December 31, 2020, primarily related to transfer pricing. The Company is subject to income taxes in the United States and numerous foreign jurisdictions. As disclosed by management, the Company's income tax returns in these jurisdictions are periodically audited by domestic and foreign tax authorities. These audits include questions regarding the Company's tax filing positions, including the timing and amount of deductions and the allocation of income amongst various tax jurisdictions. Significant judgment is required by management in evaluating uncertain tax positions, including estimating the ultimate resolution to intercompany pricing controversies between countries when there are numerous possible outcomes.

The principal considerations for our determination that performing procedures relating to uncertain tax positions related to intercompany transfer pricing is a critical audit matter are the significant judgment by management when determining uncertain tax positions related to intercompany transfer pricing, including a high degree of estimation uncertainty in evaluating whether certain tax filing positions taken by management will be upheld by the related local tax authority. This in turn led to a high degree of auditor judgment, effort, and subjectivity in performing procedures to evaluate the accurate measurement of uncertain tax positions related to intercompany transfer pricing. Also, the evaluation of audit evidence available to support the tax liabilities for uncertain tax positions related to intercompany transfer pricing is complex and required significant auditor judgment as the nature of the evidence is highly subjective and the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to recognition of the liability for uncertain tax positions related to intercompany transfer pricing and controls over measurement of the liability. These procedures also included, among others, (i) testing the information used in the calculation of the liability for uncertain tax positions, including U.S. federal filing positions and the related final tax returns; (ii) testing the calculation of the liability for uncertain tax positions related to intercompany transfer pricing, by jurisdiction, including management's assessment of the technical merits of tax positions and estimates of the amount of tax benefit expected to be sustained; (iii) testing of management's assessment of possible outcomes of uncertain tax positions related to intercompany transfer pricing; and (iv) evaluating the status and results of income tax audits with the relevant tax authorities. Professionals with specialized skill and knowledge were used to assist in the evaluation of the completeness and measurement of the Company's uncertain tax positions related to intercompany transfer pricing, including evaluating the reasonableness of management's assessment of whether tax positions are more-likely-than-not to be sustained and the amount of potential benefit to be realized, and the application of relevant tax laws.

Fair Value of Contingent Consideration Liabilities
As described in Note 11 to the consolidated financial statements, certain of the Company's acquisitions involve contingent consideration arrangements. As of December 31, 2020, the Company had a contingent consideration liability of $186.1 million. As disclosed by management, payment of additional consideration is contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. These contingent consideration liabilities are measured by management at estimated fair value using either a probability weighted discounted cash flow analysis or a Monte Carlo simulation model, both of which consider significant unobservable inputs. These inputs

include (1) the discount rate used to present value the projected cash flows, (2) the probability of milestone achievement, (3) the projected payment dates, and (4) the volatility of future revenue.
The principal considerations for our determination that performing procedures relating to the fair value of contingent consideration liabilities is a critical audit matter are the significant judgment by management when estimating the fair value of these contingent consideration liabilities, including a high degree of estimation uncertainty in evaluating the discount rate, the probability of milestone achievement, the projected payment dates, and the volatility of future revenue. This in turn led to a high degree of auditor judgment, effort, and subjectivity in performing procedures to evaluate the fair value of contingent consideration liabilities. Also, the evaluation of audit evidence available to support the fair value of the contingent consideration liabilities is complex and resulted in significant auditor judgment as the nature of the evidence is highly subjective and the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's process for estimating the fair value of contingent consideration liabilities, including controls over the determination of the significant unobservable inputs selected by management. These procedures also included, among others, (i) testing management's process for estimating the fair value of contingent consideration liabilities and (ii) testing management's probability weighted discounted cash flow analysis or a Monte Carlo simulation used to estimate the fair value of the contingent consideration liabilities. Testing management's process included evaluating the appropriateness of the valuation methods used and the reasonableness of the significant assumptions related to the discount rate, the probability of milestone achievement, the projected payment dates, and the volatility of future revenue. Evaluating the reasonableness of the probability of milestone achievement and projected payment date of each milestone involved consideration of information obtained from the Company's product engineers, clinical trial data, and third-party industry data. The discount rate was evaluated by considering the cost of capital of comparable businesses and other industry factors. Professionals with specialized skill and knowledge were used to assist in the evaluation of certain significant assumptions, including the discount rate and volatility of future revenue.

/s/ PricewaterhouseCoopers LLP
Irvine, California
February 12, 2021

We have served as the Company's auditor since 1999

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED BALANCE SHEETS

(in millions, except par value)

	December 31,	
	2020	**2019**
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,183.2	$ 1,179.1
Short-term investments (Note 7)	219.4	337.8
Accounts receivable, net of allowances of $9.6 and $8.7, respectively	514.6	543.6
Other receivables	88.2	55.5
Inventories (Note 5)	802.3	640.9
Prepaid expenses	75.1	59.1
Other current assets	208.2	168.0
Total current assets	3,091.0	2,984.0
Long-term investments (Note 7)	801.6	585.5
Property, plant, and equipment, net (Note 5)	1,395.2	1,060.3
Operating lease right-of-use assets (Note 6)	94.2	80.1
Goodwill (Note 9)	1,173.2	1,167.7
Other intangible assets, net (Note 9)	331.4	336.5
Deferred income taxes	230.9	172.2
Other assets	119.6	101.8
Total assets	$ 7,237.1	$ 6,488.1
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 196.5	$ 180.4
Accrued and other liabilities (Note 5)	670.2	696.5
Operating lease liabilities (Note 6)	27.2	25.5
Total current liabilities	893.9	902.4
Long-term debt (Note 10)	595.0	594.4
Contingent consideration liabilities (Notes 8 and 11)	186.1	172.5
Taxes payable (Note 17)	215.3	236.6
Operating lease liabilities (Note 6)	72.7	58.9
Uncertain tax positions (Note 17)	214.4	171.7
Litigation settlement accrual (Notes 3 and 18)	233.0	—
Other long-term liabilities	252.4	203.3
Commitments and contingencies (Notes 6, 10 and 18)		
Stockholders' equity (Note 14)		
Preferred stock, $0.01 par value, authorized 50.0 shares, no shares outstanding	—	—
Common stock, $1.00 par value, 1,050.0 shares authorized, 636.4 and 218.1 shares issued, and 624.3 and 209.1 shares outstanding, respectively	636.4	218.1
Additional paid-in capital	1,438.1	1,623.3
Retained earnings	4,565.0	3,741.6
Accumulated other comprehensive loss	(161.1)	(156.0)
Treasury stock, at cost, 12.1 and 9.0 shares, respectively	(1,904.1)	(1,278.7)
Total stockholders' equity	4,574.3	4,148.3
Total liabilities and stockholders' equity	$ 7,237.1	$ 6,488.1

The accompanying notes are an integral part of these consolidated financial statements.

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share information)

	Years Ended December 31,		
	2020	**2019**	**2018**
Net sales	$ 4,386.3	$ 4,348.0	$ 3,722.8
Cost of sales	1,080.6	1,114.4	939.4
Gross profit	3,305.7	3,233.6	2,783.4
Selling, general, and administrative expenses	1,228.4	1,242.2	1,088.5
Research and development expenses	760.7	752.7	622.2
Intellectual property litigation expenses, net (Note 3)	405.4	33.4	214.0
Change in fair value of contingent consideration liabilities	13.6	(6.1)	(5.7)
Special charges (Note 4)	—	64.6	116.2
Operating income	897.6	1,146.8	748.2
Interest expense	15.8	20.7	29.9
Interest income	(23.4)	(32.2)	(32.0)
Special gain (Note 4)	—	—	(7.1)
Other income, net (Note 16)	(11.5)	(8.2)	(4.0)
Income before provision for income taxes	916.7	1,166.5	761.4
Provision for income taxes (Note 17)	93.3	119.6	39.2
Net income	$ 823.4	$ 1,046.9	$ 722.2
Share information (Note 2):			
Earnings per share:			
Basic	$ 1.32	$ 1.68	$ 1.15
Diluted	$ 1.30	$ 1.64	$ 1.13
Weighted-average number of common shares outstanding:			
Basic	622.6	624.8	627.6
Diluted	631.9	636.7	640.9

The accompanying notes are an integral part of these consolidated financial statements.

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in millions)

	Years Ended December 31,		
	2020	2019	2018
Net income	$ 823.4	$ 1,046.9	$ 722.2
Other comprehensive (loss) income, net of tax (Note 15):			
Foreign currency translation adjustments	32.4	(11.2)	(38.6)
Unrealized (loss) gain on hedges	(40.2)	(11.1)	40.4
Unrealized pension costs	(4.2)	(1.9)	0.6
Unrealized gain (loss) on available-for-sale investments	6.6	6.3	(3.3)
Reclassification of net realized investment loss to earnings	0.3	0.4	2.9
Other comprehensive (loss) income, net of tax	(5.1)	(17.5)	2.0
Comprehensive income	$ 818.3	$ 1,029.4	$ 724.2

The accompanying notes are an integral part of these consolidated financial statements.

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)

	Years Ended December 31,		
	2020	2019	2018
Cash flows from operating activities			
Net income	$ 823.4	$ 1,046.9	$ 722.2
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	107.2	89.3	77.4
Non-cash operating lease cost	28.2	25.3	—
Stock-based compensation (Notes 2 and 14)	92.6	81.3	71.0
Inventory write off	—	73.1	—
Impairment charges (Note 4)	—	40.6	118.8
Change in fair value of contingent consideration liabilities, net (Note 11)	13.6	(6.1)	(5.7)
Deferred income taxes	(49.4)	12.1	(27.3)
Purchased in-process research and development	—	24.0	—
Other	(3.5)	(2.8)	13.0
Changes in operating assets and liabilities:			
Accounts and other receivables, net	41.9	(88.0)	(28.7)
Inventories	(120.6)	(105.4)	(65.7)
Prepaid expenses and other current assets	(28.5)	(6.8)	15.6
Accounts payable and accrued liabilities	(84.5)	116.5	12.5
Litigation settlement accrual	270.5	(180.0)	180.0
Income taxes	(52.9)	43.2	(157.8)
Other	16.3	19.7	1.4
Net cash provided by operating activities	1,054.3	1,182.9	926.7
Cash flows from investing activities			
Capital expenditures	(407.0)	(254.4)	(238.7)
Purchases of held-to-maturity investments (Note 7)	(162.0)	(130.2)	(210.0)
Proceeds from sales and maturities of held-to-maturity investments (Note 7)	212.2	50.0	578.1
Purchases of available-for-sale investments (Note 7)	(689.7)	(437.9)	(249.3)
Proceeds from sales and maturities of available-for-sale investments (Note 7)	564.8	359.9	223.2
Acquisition (Notes 8 and 9)	—	(100.2)	—
Payment for acquisition option	(10.0)	(35.0)	—
Issuances of notes receivable	(27.0)	(12.9)	(0.6)
Investments in intangible assets and in-process research and development	(0.3)	(24.0)	(3.0)
Other	(12.1)	(11.1)	(23.0)
Net cash (used in) provided by investing activities	(531.1)	(595.8)	76.7
Cash flows from financing activities			
Proceeds from issuance of debt	16.2	18.9	688.0
Payments on debt and finance lease obligations	(17.0)	(28.9)	(1,125.3)
Purchases of treasury stock	(625.4)	(263.3)	(795.5)
Proceeds from stock plans	140.5	160.5	147.0
Payment of contingent consideration	—	—	(15.1)
Other	(1.2)	(2.8)	(0.3)
Net cash used in financing activities	(486.9)	(115.6)	(1,101.2)
Effect of currency exchange rate changes on cash, cash equivalents, and restricted cash	(20.5)	(3.0)	(6.5)
Net increase (decrease) in cash, cash equivalents, and restricted cash	15.8	468.5	(104.3)
Cash, cash equivalents, and restricted cash at beginning of year	1,184.4	715.9	820.2
Cash, cash equivalents, and restricted cash at end of year	$ 1,200.2	$ 1,184.4	$ 715.9

The accompanying notes are an integral part of these consolidated financial statements.

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in millions)

	Common Stock		Treasury Stock					
	Shares	Par Value	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
BALANCE AT DECEMBER 31, 2017	212.0	$ 212.0	2.3	$ (252.1)	$ 1,166.9	$ 1,962.1	$ (132.7)	$ 2,956.2
Impact to retained earnings from adoption of ASU 2016-16 and ASU 2018-02						10.4	(7.8)	2.6
BALANCE AT JANUARY 1, 2018	212.0	212.0	2.3	(252.1)	1,166.9	1,972.5	(140.5)	2,958.8
Net income						722.2		722.2
Other comprehensive income, net of tax							2.0	2.0
Common stock issued under equity plans	3.2	3.2			143.8			147.0
Stock-based compensation expense					71.0			71.0
Shares issued in payment for contingent consideration liabilities			(0.3)	32.2	2.7			34.9
Purchases of treasury stock			5.5	(795.5)				(795.5)
BALANCE AT DECEMBER 31, 2018	215.2	215.2	7.5	(1,015.4)	1,384.4	2,694.7	(138.5)	3,140.4
Net income						1,046.9		1,046.9
Other comprehensive loss, net of tax							(17.5)	(17.5)
Common stock issued under equity plans	2.9	2.9			157.6			160.5
Stock-based compensation expense					81.3			81.3
Purchases of treasury stock			1.5	(263.3)	—			(263.3)
BALANCE AT DECEMBER 31, 2019	218.1	218.1	9.0	(1,278.7)	1,623.3	3,741.6	(156.0)	4,148.3
Net income						823.4		823.4
Other comprehensive loss, net of tax							(5.1)	(5.1)
Common stock issued under equity plans	4.5	4.5			136.0			140.5
Stock-based compensation expense					92.6			92.6
Purchases of treasury stock			3.1	(625.4)				(625.4)
Stock issued to effect stock split	413.8	413.8			(413.8)			—
BALANCE AT DECEMBER 31, 2020	636.4	$ 636.4	12.1	$ (1,904.1)	$ 1,438.1	$ 4,565.0	$ (161.1)	$ 4,574.3

The accompanying notes are an integral part of these consolidated financial statements.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

Edwards Lifesciences Corporation ("Edwards Lifesciences" or the "Company") conducts operations worldwide and is managed in the following geographical regions: United States, Europe, Japan, and Rest of World. Edwards Lifesciences is focused on technologies that treat structural heart disease and critically ill patients. The products and technologies provided by Edwards Lifesciences are categorized into the following main areas: Transcatheter Aortic Valve Replacement, Transcatheter Mitral and Tricuspid Therapies, Surgical Structural Heart, and Critical Care.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Edwards Lifesciences and its majority-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company reviews its investments in other entities to determine whether the Company is the primary beneficiary of a variable interest entity ("VIE"). The Company would be the primary beneficiary of the VIE, and would be required to consolidate the VIE, if it has the power to direct the significant activities of the entity and the obligation to absorb losses or receive benefits from the entity that may be significant to the VIE. Based on the Company's analysis, it determined it is not the primary beneficiary of any VIEs; however, future events may require VIEs to be consolidated if the Company becomes the primary beneficiary.

Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

Stock Split

On May 7, 2020, the Company’s Board of Directors declared a three-for-one stock split of its outstanding shares of common stock effected in the form of a stock dividend, distributed on May 29, 2020 to stockholders of record on May 18, 2020. The Company distributed two newly issued shares of common stock to holders of record of each share of common stock to effect the stock split. All applicable share and per-share amounts in the consolidated financial statements and the notes to consolidated financial statements have been retroactively adjusted to reflect this stock split. The consolidated balance sheet as of December 31, 2019 and the consolidated statements of stockholders’ equity for the twelve months ended December 31, 2019 have not been retroactively adjusted to reflect the stock split.

Use of Estimates

The consolidated financial statements of Edwards Lifesciences have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") which have been applied consistently in all material respects. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates. In particular, the novel Coronavirus ("COVID-19") pandemic has adversely impacted and is likely to further adversely impact nearly all aspects of our business and markets, including our workforce and the operations of our customers, suppliers, and business partners. The full extent to which the pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including sales, expenses, manufacturing, clinical trials, research and development costs, reserves and allowances, fair value measurements, asset impairment charges, contingent consideration obligations, and the effectiveness of the Company's hedging instruments, will depend on future developments that are highly uncertain and difficult to predict. These developments include, but are not limited to, the duration and spread of the outbreak (including new variants of COVID-19), its severity, the actions to contain the virus or address its impact, the timing, distribution, and efficacy of vaccines and other treatments, U.S. and foreign government actions to respond to the reduction in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Foreign Currency Translation

When the local currency of the Company's foreign entities is the functional currency, all assets and liabilities are translated into United States dollars at the rate of exchange in effect at the balance sheet date. Income and expense items are translated at the weighted-average exchange rate prevailing during the period. The effects of foreign currency translation adjustments for these entities are deferred and reported in stockholders' equity as a component of "*Accumulated Other Comprehensive Loss*." The effects of foreign currency transactions denominated in a currency other than an entity's functional currency are included in "*Other Income, net.*"

Revenue Recognition

Revenue is recognized when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products or services.

The Company generates nearly all of its revenue from direct product sales and sales of products under consignment arrangements. Revenue from direct product sales is recognized at a point in time when the performance obligation is satisfied upon delivery of the product. Revenue from sales of consigned inventory is recognized at a point in time when the performance obligation is satisfied once the product has been implanted or used by the customer. The Company periodically reviews consignment inventories to confirm the accuracy of customer reporting. The Company also generates a small portion of its revenue from service contracts, and recognizes revenue from service contracts ratably over the term of the contracts. Sales taxes and other similar taxes that the Company collects concurrent with revenue-producing activities are excluded from revenue. The Company does not typically have any significant unusual payment terms beyond 90 days in its contracts with customers. In addition, the Company receives royalty payments for the licensing of certain intellectual property and recognizes the royalty when the subsequent sale of product using the intellectual property occurs.

The amount of consideration the Company ultimately receives varies depending upon the return terms, sales rebates, discounts, and other incentives that the Company may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The Company includes estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely upon an assessment of historical payment experience, historical relationship to revenues, estimated customer inventory levels, and current contract sales terms with direct and indirect customers.

The Company's sales adjustment related to distributor rebates given to the Company's United States distributors represents the difference between the Company's sales price to the distributor and the negotiated price to be paid by the end-customer. This distributor rebate is recorded as a reduction to sales and a reduction to the distributor's accounts receivable at the time of sale to a distributor. The Company periodically monitors current pricing trends and distributor inventory levels to ensure the credit for future distributor rebates is fairly stated.

The Company offers volume rebates to certain group purchasing organizations ("GPOs") and customers based upon targeted sales levels. Volume rebates offered to GPOs are recorded as a reduction to sales and an obligation to the GPOs, as the Company expects to pay in cash. Volume rebates offered to customers are recorded as a reduction to sales and either accounts receivable if the Company expects a net payment from the customer, or as an obligation to the customer if the Company expects to pay in cash. The provision for volume rebates is estimated based upon customers' contracted rebate programs, projected sales levels, and historical experience of rebates paid. The Company periodically monitors its customer rebate programs to ensure that the allowance and liability for accrued rebates is fairly stated.

Product returns are typically not significant because returns are generally not allowed unless the product is damaged at time of receipt. In limited circumstances, the Company may allow customers to return previously purchased products, such as for next-generation product offerings. For these transactions, the Company defers recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount of product to be returned when the next-generation products are shipped to the customer.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Company sells separately priced service contracts, which range from 12 to 36 months, to owners of its hemodynamic monitors. The Company invoices the customer the total amount of consideration at the inception of the contract and recognizes revenue ratably over the term of the contract. As of December 31, 2020 and December 31, 2019, $6.3 million and $8.4 million, respectively, of deferred revenue associated with outstanding service contracts was recorded in "*Accrued and Other Liabilities*" and "*Other Long-term Liabilities*." During 2020, the Company recognized as revenue $6.3 million that was included in the balance of deferred revenue as of December 31, 2019, and during 2019, the Company recognized as revenue $5.5 million that was included in the balance of deferred revenue as of December 31, 2018.

A limited number of the Company's contracts with customers contain multiple performance obligations. For these contracts, the transaction price is allocated to each performance obligation based on its relative standalone selling price charged to other customers.

The Company applies the optional exemption of not disclosing the amount of the transaction price allocated to unsatisfied performance obligations for contracts with an original expected duration of one year or less.

Shipping and Handling Costs

Shipping costs, which are costs incurred to physically move product from the Company's premises or third party distribution centers, including storage, to the customer's premises, are included in "*Selling, General, and Administrative Expenses*." Handling costs, which are costs incurred to store at the Company's premises, move, and prepare products for shipment, are included in "*Cost of Sales*." For the years ended December 31, 2020, 2019, and 2018, shipping costs of $74.0 million, $71.5 million, and $70.6 million, respectively, were included in "*Selling, General, and Administrative Expenses*."

Cash Equivalents

The Company considers highly liquid investments with original maturities of three months or less to be cash equivalents. These investments are valued at cost, which approximates fair value.

Investments

The Company invests its excess cash in debt securities, including time deposits, commercial paper, U.S. government and agency securities, asset-backed securities, corporate debt securities, and municipal debt securities. Investments with maturities of one year or less are classified as short-term, and investments with maturities greater than one year are classified as long-term. Investments that the Company has the ability and intent to hold until maturity are classified as held-to-maturity and carried at amortized cost. Investments in debt securities that are classified as available-for-sale are carried at fair value with unrealized gains and losses included in "*Accumulated Other Comprehensive Loss*." The Company determines the appropriate classification of its investments in debt securities at the time of purchase and reevaluates such designation at each balance sheet date.

The Company also has long-term equity investments in companies that are in various stages of development. These investments are reported at fair value or under the equity method of accounting, as appropriate. Equity investments that do not have readily determinable fair values are recorded at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. The Company accounts for investments in limited partnerships and limited liability corporations, whereby the Company owns a minimum of 5% of the investee's outstanding voting stock, under the equity method of accounting. These investments are recorded at the amount of the Company's investment and adjusted each period for the Company's share of the investee's income or loss, and dividends paid.

Realized gains and losses on investments that are sold are determined using the specific identification method, or the first-in, first-out method, depending on the investment type, and recorded to "*Other Income, net*." Income relating to investments in debt securities is recorded to "*Interest Income*."

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Equity investments without readily determinable fair value are considered impaired when there is an indication that the fair value of the Company's interest is less than the carrying amount. Equity method investments are considered impaired when there is an indication of an other-than-temporary decline in value below the carrying amount. Impairments of equity investments are recorded in "*Other Income, net.*"

Debt securities in an unrealized loss position are written down to fair value through "*Other Income, net*" if the Company intends to sell the security or it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. For debt securities in an unrealized loss position that do not meet the aforementioned criteria, the Company assesses whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, changes to the rating of the security by a rating agency, and any adverse conditions specifically related to the security, among other factors. When a credit loss exists, the Company compares the present value of cash flows expected to be collected from the debt security to the amortized cost basis of the security to determine the allowance amount that should be recorded, if any. For available-to-sale debt securities, any additional impairment not recorded through an allowance for credit losses is recognized in "*Accumulated Other Comprehensive Loss.*"

Accounts Receivable

The majority of the Company's accounts receivable arise from direct product sales and sales of products under consignment arrangements, and have payment terms that generally require payment within 30 to 90 days. The Company does not adjust its receivables for the effects of a significant financing component at contract exception if collection of the receivable is expected within one year or less from the time of sale. In countries where the Company has experienced a pattern of payments extending beyond the stated terms and collection of the receivable is expected beyond one year from the time of sale, the Company assesses whether the customer has a significant financing component and discounts the receivable and reduces the related revenues over the period of time that the Company estimates those amounts will be paid using the country's market-based borrowing rate for such period.

The Company provides reserves against accounts receivable for estimated losses that may result from a customer's inability to pay based on customer-specific analysis and general matters such as current assessments of past due balances, economic conditions and forecasts, and historical credit loss activity. Amounts determined to be uncollectible are charged or written-off against the reserve.

Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value. Market value for raw materials is based on replacement costs, and for other inventory classifications is based on net realizable value.

A write-down for excess or slow moving inventory is recorded for inventory which is obsolete, damaged, nearing its expiration date (generally triggered at six months prior to expiration), or slow moving (generally defined as quantities in excess of a two-year supply).

The Company allocates to inventory general and administrative costs that are related to the production process. These costs include insurance, manufacturing accounting personnel, human resources personnel, and information technology. During the years ended December 31, 2020, 2019, and 2018, the Company allocated $63.1 million, $56.6 million, and $45.0 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2020 and 2019 were $30.7 million and $22.8 million, respectively.

At December 31, 2020 and 2019, $130.0 million and $117.8 million, respectively, of the Company's finished goods inventories were held on consignment.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Property, Plant, and Equipment

Property, plant, and equipment are recorded at cost. Depreciation is principally calculated for financial reporting purposes on the straight-line method over the estimated useful lives of the related assets, which range from 10 to 40 years for buildings and improvements, from 3 to 15 years for machinery and equipment, and from 3 to 5 years for software. Leasehold improvements are amortized over the life of the related facility leases or the asset, whichever is shorter. Straight-line and accelerated methods of depreciation are used for income tax purposes. Construction in progress is not depreciated until the asset is ready for its intended use.

Depreciation expense for property, plant, and equipment was $101.8 million, $84.7 million, and $74.9 million for the years ended December 31, 2020, 2019, and 2018, respectively.

Leases

On January 1, 2019, the Company adopted an amendment to the guidance on leases using a modified retrospective transition approach. The Company determines whether a contract is, or contains, a lease at inception. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments. The Company's incremental borrowing rate is determined based on the estimated rate of interest for collateralized borrowing over a similar term as the associated lease. Right-of-use assets also include any lease payments made at or before lease commencement and any initial direct costs incurred, and exclude any lease incentives received.

The Company determines the lease term as the noncancellable period of the lease, and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the balance sheet. Certain of the Company's leases include variable lease payments that are based on costs incurred or actual usage, or adjusted periodically based on an index or a rate. The Company's leases do not contain any residual value guarantees.

The Company accounts for the lease and non-lease components as a single lease component for all of its leases except vehicle leases, for which the lease and non-lease components are accounted for separately.

Operating leases are included in "*Operating Lease Right-of-Use Assets*" and "*Operating Lease Liabilities*" on the Company's consolidated balance sheets. See Note 6 for further information.

Impairment of Goodwill and Long-lived Assets

Goodwill is reviewed for impairment annually in the fourth quarter of each fiscal year, or whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. Goodwill is tested for impairment at the reporting unit level by first performing a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying value. If the reporting unit does not pass the qualitative assessment, then the Company performs a quantitative impairment test. The Company determined, after performing a qualitative review of each reporting unit, that it is more likely than not that the fair value of each of its reporting units substantially exceeds the respective carrying amounts. Accordingly, in 2020, 2019, and 2018, the Company did not record any impairment loss.

Indefinite-lived intangible assets relate to in-process research and development acquired in business combinations. The estimated fair values of in-process research and development projects acquired in a business combination which have not reached technological feasibility are capitalized and accounted for as indefinite-lived intangible assets subject to impairment testing until completion or abandonment of the projects. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If the project is abandoned, all remaining capitalized amounts are written off immediately. Indefinite-lived intangible assets are reviewed for impairment annually in the fourth quarter of each fiscal year, or whenever an event occurs or circumstances change that would indicate the carrying amount may be impaired. An impairment

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

loss is recognized when the asset's carrying value exceeds its fair value. In-process research and development projects acquired in an asset acquisition are expensed unless the project has an alternative future use.

Management reviews the carrying amounts of other finite-lived intangible assets and long-lived tangible assets whenever events or circumstances indicate that the carrying amounts of an asset may not be recoverable. Impairment indicators include, among other conditions, cash flow deficits, historic or anticipated declines in revenue or operating profit, and adverse legal or regulatory developments. If it is determined that such indicators are present and the review indicates that the assets will not be fully recoverable, based on undiscounted estimated cash flows over the remaining amortization periods, their carrying values are reduced to estimated fair market value. Estimated fair market value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. For the purposes of identifying and measuring impairment, long-lived assets are grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities.

In 2020, the Company did not record any impairment loss related to its in-process research and development assets. In 2019, the Company recorded a $40.6 million charge related to the impairment of certain in-process research and development assets. In 2018, the Company recorded a $116.2 million charge related to the impairment of certain developed technology and in-process research and development assets. See Note 4 for further information.

Income Taxes

The Company is subject to income taxes in the United States and numerous foreign jurisdictions. Significant judgment is required in evaluating the Company's uncertain tax positions and determining its provision for income taxes. The Company recognizes the financial statement benefit of a tax position only after determining that a position would more likely than not be sustained based upon its technical merit if challenged by the relevant taxing authority and taken by management to the court of last resort. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon settlement with the relevant tax authority. The Company recognizes interest and penalties related to income tax matters in income tax expense. The Company has made an accounting policy election to recognize the U.S. tax effects of global intangible low-taxed income as a component of income tax expense in the period the tax arises.

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. The Company evaluates quarterly the realizability of its deferred tax assets by assessing its valuation allowance and adjusting the amount, if necessary. The factors used to assess the likelihood of realization are both historical experience and the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in the applicable taxing jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

Research and Development Costs

Research and development costs are charged to expense when incurred.

Earnings per Share

Basic earnings per share is computed by dividing net income by the weighted-average common shares outstanding during a period. Diluted earnings per share is computed based on the weighted-average common shares outstanding plus the effect of dilutive potential common shares outstanding during the period calculated using the treasury stock method. Dilutive potential common shares include employee equity share options, nonvested shares, and similar equity instruments granted by the Company. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The table below presents the computation of basic and diluted earnings per share (in millions, except for per share information):

	Years Ended December 31,		
	2020	2019	2018
Basic:			
Net income	$ 823.4	$ 1,046.9	$ 722.2
Weighted-average shares outstanding	622.6	624.8	627.6
Basic earnings per share	$ 1.32	$ 1.68	$ 1.15
Diluted:			
Net income	$ 823.4	$ 1,046.9	$ 722.2
Weighted-average shares outstanding	622.6	624.8	627.6
Dilutive effect of stock plans	9.3	11.9	13.3
Dilutive weighted-average shares outstanding	631.9	636.7	640.9
Diluted earnings per share	$ 1.30	$ 1.64	$ 1.13

Stock options, restricted stock units, and market-based restricted stock units to purchase approximately 2.0 million, 1.5 million, and 3.2 million shares were outstanding for the years ended December 31, 2020, 2019, and 2018, respectively, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive.

Stock-based Compensation

The Company measures and recognizes compensation expense for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options, restricted stock units (service-based, market-based, and performance-based), and employee stock purchase subscriptions. Stock-based compensation expense is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period (vesting period) on a straight-line basis. For performance-based restricted stock units, the Company recognizes stock-based compensation expense if and when the Company concludes that it is probable that the performance condition will be achieved, net of estimated forfeitures. The Company reassesses the probability of vesting at each quarter end and adjusts the stock-based compensation expense based on its probability assessment. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Upon exercise of stock options or vesting of restricted stock units, the Company issues common stock.

Total stock-based compensation expense was as follows (in millions):

	Years Ended December 31,		
	2020	2019	2018
Cost of sales	$ 17.2	$ 14.7	$ 11.4
Selling, general, and administrative expenses	56.6	51.2	46.3
Research and development expenses	18.8	15.4	13.3
Total stock-based compensation expense	92.6	81.3	71.0
Income tax benefit	(15.4)	(14.8)	(13.4)
Total stock-based compensation expense, net of tax	$ 77.2	$ 66.5	$ 57.6

Upon a participant's retirement, all unvested stock options and performance-based restricted stock units are immediately forfeited. In addition, upon retirement, a participant will immediately vest in 25% of service-based restricted stock units for each full year of employment with the Company measured from the grant date. All remaining unvested service-based restricted stock units are immediately forfeited. For market-based restricted stock units, upon retirement and in certain other specified cases, a participant will receive a pro-rated portion of the shares that would ultimately be issued based on attainment of the

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

performance goals as determined on the vesting date. The pro-rated portion is based on the participant's whole months of service with the Company during the performance period prior to the date of termination.

Derivatives

The Company uses derivative financial instruments to manage interest rate and foreign currency risks. It is the Company's policy not to enter into derivative financial instruments for speculative purposes.

Derivative financial instruments involve credit risk in the event the counterparty should default. It is the Company's policy to execute such instruments with global financial institutions that the Company believes to be creditworthy. The Company diversifies its derivative financial instruments among counterparties to minimize exposure to any one of these entities. The Company also uses International Swap Dealers Association master-netting agreements. The master-netting agreements provide for the net settlement of all contracts through a single payment in a single currency in the event of default, as defined by the agreements.

The Company uses foreign currency forward exchange contracts, cross currency swap contracts, and foreign currency denominated debt to manage its exposure to changes in currency exchange rates from (1) future cash flows associated with intercompany transactions and certain local currency expenses expected to occur within the next 13 months (designated as cash flow hedges), (2) its net investment in certain foreign subsidiaries (designated as net investment hedges) and (3) foreign currency denominated assets or liabilities (designated as fair value hedges). The Company also uses foreign currency forward exchange contracts that are not designated as hedging instruments to offset the transaction gains and losses associated with certain assets and liabilities denominated in currencies other than their functional currencies resulting principally from intercompany and local currency transactions.

All derivative financial instruments are recognized at fair value in the consolidated balance sheets. For each derivative instrument that is designated as a fair value hedge, the gain or loss on the derivative included in the assessment of hedge effectiveness is recognized immediately to earnings, and offsets the loss or gain on the underlying hedged item. The Company reports in "*Accumulated Other Comprehensive Loss*" the gain or loss on derivative financial instruments that are designated, and that qualify, as cash flow hedges. The Company reclassifies these gains and losses into earnings in the same line item and in the same period in which the underlying hedged transactions affect earnings. Changes in the fair value of net investment hedges are reported in "*Accumulated Other Comprehensive Loss*" as a part of the cumulative translation adjustment and would be reclassified into earnings if the underlying net investment is sold or substantially liquidated. The portion of the change in fair value related to components excluded from the hedge effectiveness assessment are amortized into earnings over the life of the derivative. The gains and losses on derivative financial instruments for which the Company does not elect hedge accounting treatment are recognized in the consolidated statements of operations in each period based upon the change in the fair value of the derivative financial instrument. Cash flows from net investment hedges are reported as investing activities in the consolidated statements of cash flows, and cash flows from all other derivative financial instruments are reported as operating activities.

Recently Adopted Accounting Standards

In August 2018, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting guidance on cloud computing service arrangements. The guidance aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance also requires an entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The guidance was effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The adoption of this guidance on January 1, 2020 did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued an amendment to the accounting guidance on fair value measurements. The guidance modifies the disclosure requirements on fair value measurements, including the removal of disclosures of the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation processes for Level 3 fair value measurements. The guidance also adds certain disclosure requirements related to Level 3 fair value measurements. The guidance was effective for fiscal years, and interim periods within those fiscal years,

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

beginning after December 15, 2019. The adoption of this guidance on January 1, 2020 did not have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued an amendment to the guidance on the measurement of credit losses on financial instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the “incurred loss” model with an “expected loss” model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The guidance was effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The adoption of this guidance on January 1, 2020 did not have a material impact on the Company's consolidated financial statements.

3. INTELLECTUAL PROPERTY LITIGATION EXPENSES, NET

The Company incurred intellectual property litigation expenses, including settlements and external legal costs, of $405.4 million, $33.4 million and $214.0 million during 2020, 2019 and 2018, respectively.

On July 12, 2020, the Company reached an agreement with Abbott Laboratories and its direct and indirect subsidiaries ("Abbott") to, among other things, settle all outstanding patent disputes between the companies (the “Settlement Agreement”) in cases related to transcatheter mitral and tricuspid repair products. See Note 18 for additional information. The Settlement Agreement resulted in the Company recording an estimated $367.9 million pre-tax charge and related liability in June 2020 related to past damages. In addition, the Company will incur royalty expenses through May 2024 totaling an estimated $100 million. The Company made a one-time $100.0 million payment to Abbott in July 2020, and will make quarterly payments in future years.

In January 2019, the Company reached an agreement with Boston Scientific Corporation ("Boston Scientific") to settle all outstanding patent disputes for a one-time payment to Boston Scientific of $180.0 million, which was included as an expense in 2018. The settlement covered alleged past damages and no further royalties will be owed by either party.

4. SPECIAL CHARGES (GAIN)

Impairment of Long-lived Assets

In December 2019, the Company recorded a charge of $40.6 million related to the impairment of certain in-process research and development assets, and in December 2018, the Company recorded a charge of $116.2 million related to the impairment of certain developed technology and in-process research and development assets. These assets were acquired as part of the acquisition of Valtech Cardio Ltd. ("Valtech"). The Company measured the amount of the impairments by calculating the amount by which the carrying values exceeded the estimated fair values, which were based on projected discounted future net cash flows. Based on market and clinical trial developments at the time of the impairments, the Company re-evaluated the clinical development plans for the technologies acquired from Valtech, which resulted in a reduction to the projected near-term discounted future net cash flows related to the acquired mitral technology for the 2018 charge, and related to the acquired mitral and tricuspid technology for the 2019 charge. The impairments were recorded to the Company’s Rest of World segment.

Acquisition of Intellectual Property

In March 2019, the Company recorded a $24.0 million charge related to the acquisition of early-stage transcatheter intellectual property and associated clinical and regulatory experience.

Pension Gain

In March 2018, the Company recorded a $7.1 million gain related to the curtailment of its defined benefit plan in Switzerland resulting from the closure of its manufacturing plant.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. OTHER CONSOLIDATED FINANCIAL STATEMENT DETAILS

Composition of Certain Financial Statement Captions

Components of selected captions in the consolidated balance sheets are as follows:

	As of December 31,	
	2020	2019
	(in millions)	
Inventories		
Raw materials	$ 136.7	$ 118.0
Work in process	140.0	121.7
Finished products	525.6	401.2
	$ 802.3	$ 640.9
Property, plant, and equipment, net		
Land	$ 97.6	$ 98.0
Buildings and leasehold improvements	881.5	619.8
Machinery and equipment	564.9	466.3
Equipment with customers	42.2	35.6
Software	94.2	87.9
Construction in progress	313.3	265.0
	1,993.7	1,572.6
Accumulated depreciation	(598.5)	(512.3)
	$ 1,395.2	$ 1,060.3
Accrued and other liabilities		
Employee compensation and withholdings	$ 236.7	$ 295.8
Accrued rebates	67.2	67.1
Property, payroll, and other taxes	49.7	51.4
Research and development accruals	52.3	51.4
Litigation settlement (Notes 3 and 18)	37.5	—
Litigation and insurance reserves (Note 18)	23.3	20.0
Taxes payable	18.6	52.9
Fair value of derivatives	39.3	6.4
Accrued marketing expenses	14.3	17.5
Accrued professional services	7.6	10.1
Accrued realignment reserves	14.5	16.7
Accrued relocation related costs	21.0	17.4
Other accrued liabilities	88.2	89.8
	$ 670.2	$ 696.5

In 2019, the Company recorded a $73.1 million charge to "*Cost of Sales*," primarily comprised of the write off of inventory related to strategic decisions regarding its transcatheter aortic valve portfolio, including the decision to discontinue its *CENTERA* program.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. OTHER CONSOLIDATED FINANCIAL STATEMENT DETAILS (Continued)

Supplemental Cash Flow Information
(in millions)

	Years Ended December 31,		
	2020	2019	2018
Cash paid during the year for:			
Interest	$ 19.9	$ 19.9	$ 30.1
Income taxes	$ 197.9	$ 61.5	$ 223.7
Amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 29.7	$ 28.6	$ —
Non-cash investing and financing transactions:			
Fair value of shares issued in payment for contingent consideration liabilities	$ —	$ —	$ 34.3
Right-of-use assets obtained in exchange for new lease liabilities	$ 39.7	$ 49.6	$ —
Capital expenditures accruals	$ 80.4	$ 50.8	$ 18.7

Cash, Cash Equivalents, and Restricted Cash
(in millions)

	Years Ended December 31,		
	2020	2019	2018
Cash and cash equivalents	$ 1,183.2	$ 1,179.1	$ 714.1
Restricted cash included in other current assets	16.6	1.6	1.5
Restricted cash included in other assets	0.4	3.7	0.3
Total cash, cash equivalents, and restricted cash	$ 1,200.2	$ 1,184.4	$ 715.9

Amounts included in restricted cash primarily represent funds placed in escrow related to litigation and real estate purchases, and funds restricted for construction.

6. LEASES

The Company leases certain office space, manufacturing facilities, land, apartments, warehouses, vehicles, and equipment with remaining lease terms ranging from less than 1 year to 20 years, some of which include options to extend or terminate the leases.

Operating lease costs for the years ended December 31, 2020, 2019, and 2018 were $30.5 million, $27.9 million, and $27.0 million, respectively. Short-term and variable lease costs were not material for the years ended December 31, 2020 and 2019.

Supplemental balance sheet information related to operating leases was as follows (in millions, except lease term and discount rate):

	As of December 31,	
	2020	2019
Operating lease right-of-use assets	$ 94.2	$ 80.1
Operating lease liabilities, current portion	$ 27.2	$ 25.5
Operating lease liabilities, long-term portion	72.7	58.9
Total operating lease liabilities	$ 99.9	$ 84.4

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. LEASES (Continued)

Maturities of operating lease liabilities at December 31, 2020 were as follows (in millions):

2021	$ 30.0
2022	20.7
2023	14.4
2024	8.8
2025	6.1
Thereafter	28.1
Total lease payments	108.1
Less: imputed interest	(8.2)
Total lease liabilities	$ 99.9

The following table provides information on the lease terms and discount rates:

	Years Ended December 31,	
	2020	2019
Weighted-average remaining lease term (in years)	6.6	5.3
Weighted-average discount rate	2.7 %	2.8 %

As of December 31, 2020, the Company had no additional operating lease commitments for office space that have not yet commenced.

7. INVESTMENTS

Debt Securities

Investments in debt securities at the end of each period were as follows (in millions):

	December 31, 2020				December 31, 2019			
Held-to-maturity	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Bank time deposits	$ 50.0	$ —	$ —	$ 50.0	$ 100.2	$ —	$ —	$ 100.2
Available-for-sale								
Bank time deposits	$ 24.1	$ —	$ —	$ 24.1	$ 13.1	$ —	$ —	$ 13.1
Commercial paper	—	—	—	—	34.3	—	—	34.3
U.S. government and agency securities	147.0	2.2	—	149.2	113.2	0.6	—	113.8
Foreign government bonds	—	—	—	—	1.7	—	—	1.7
Asset-backed securities	149.6	1.9	—	151.5	141.2	0.6	(0.1)	141.7
Corporate debt securities	600.8	7.5	—	608.3	487.0	2.3	(0.1)	489.2
Municipal securities	2.8	—	—	2.8	—	—	—	—
	$ 924.3	$ 11.6	$ —	$ 935.9	$ 790.5	$ 3.5	$ (0.2)	$ 793.8

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. INVESTMENTS (Continued)

The cost and fair value of investments in debt securities, by contractual maturity, as of December 31, 2020 were as follows:

	Held-to-Maturity		Available-for-Sale	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
	(in millions)			
Due in 1 year or less	$ 50.0	$ 50.0	$ 168.4	$ 169.4
Due after 1 year through 5 years	—	—	578.2	586.5
Instruments not due at a single maturity date	—	—	177.7	180.0
	$ 50.0	$ 50.0	$ 924.3	$ 935.9

Actual maturities may differ from the contractual maturities due to call or prepayment rights.

There were no investments that were in an unrealized loss position as of December 31, 2020. The following table presents gross unrealized losses and fair values for those investments that were in an unrealized loss position as of December 31, 2019, aggregated by investment category and the length of time that individual securities have been in a continuous loss position (in millions):

	December 31, 2019					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Lo
Asset-backed securities	$ 73.4	$ (0.1)	$ —	$ —	$ 73.4	$
Corporate debt securities	81.4	(0.1)	—	—	81.4	
	$ 154.8	$ (0.2)	$ —	$ —	$ 154.8	$

Investments in Unconsolidated Affiliates

The Company has a number of equity investments in privately and publicly held companies. Investments in these unconsolidated affiliates are recorded in "*Long-term Investments*" on the consolidated balance sheets, and are as follows:

	December 31,	
	2020	2019
	(in millions)	
Equity method investments		
Carrying value of equity method investments	$ 5.7	$ 6.2
Equity securities		
Carrying value of non-marketable equity securities	29.4	23.1
Total investments in unconsolidated affiliates	$ 35.1	$ 29.3

Non-marketable equity securities consist of investments in privately held companies without readily determinable fair values, and are reported at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. The Company recorded an upward adjustment of $1.8 million based on observable price changes and a downward adjustment of $0.7 million due to an impairment during 2020, and an upward adjustment of $0.3 million based on observable price changes during 2019. As of December 31, 2020 and 2019, the Company had recorded accumulated upward adjustments of $3.8 million and $2.0 million, respectively, based on observable price changes, and accumulated downward adjustments of $2.6 million and $1.9 million, respectively, due to impairment and observable price changes.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. INVESTMENTS (Continued)

During 2020, 2019, and 2018, the gross realized gains or losses from sales of available-for-sale investments were not material.

8. ACQUISITIONS

CAS Medical Systems, Inc.

On February 11, 2019, the Company entered into an agreement and plan of merger to acquire all the outstanding shares of CAS Medical Systems, Inc. ("CASMED") for an aggregate cash purchase price of $2.45 per share of common stock, or an equity value of approximately $100 million. The transaction closed on April 18, 2019, and the cash purchase price was $100.8 million. Acquisition-related costs of $2.0 million were recorded in "*Selling, General, and Administrative Expenses*" during the year ended December 31, 2019.

CASMED is a medical technology company dedicated to noninvasive monitoring of tissue oxygenation in the brain. The Company integrated the acquired technology platform into its hemodynamic monitoring platform. The acquisition was accounted for as a business combination. Tangible and intangible assets acquired were recorded based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair value of net assets acquired was recorded to goodwill. The following table summarizes the fair values of the assets acquired and liabilities assumed (in millions):

Current assets	$	6.1
Property and equipment, net		1.3
Goodwill		64.4
Developed technology		35.9
Customer relationships		8.8
Deferred tax assets		2.2
Liabilities assumed		(17.9)
Total purchase price		100.8
Less: cash acquired		(0.6)
Total purchase price, net of cash acquired	$	100.2

Goodwill includes expected synergies and other benefits the Company believes will result from the acquisition. Goodwill was assigned to the Company's United States segment and is not deductible for tax purposes. Developed technology assets are being amortized over a weighted-average useful life of 14 years. Customer relationships assets are being amortized over a weighted-average useful life of 10 years.

The results of operations for CASMED have been included in the accompanying consolidated financial statements from the date of acquisition. Pro forma results have not been presented as the results of CASMED are not material in relation to the consolidated financial statements of Edwards Lifesciences.

Harpoon Medical, Inc.

On December 1, 2017, the Company acquired all the outstanding shares of Harpoon Medical, Inc. for an aggregate cash purchase price of $119.5 million, which includes $16.0 million paid previously for a cost method investment and an exclusive option to acquire Harpoon Medical, Inc., and is net of $8.0 million received from the sale of the Company's previous ownership interest. In addition, the Company agreed to pay up to an additional $150.0 million in pre-specified milestone-driven payments over the next 10 years. The Company recognized in "*Contingent Consideration Liabilities*" a $59.7 million liability for the estimated fair value of the contingent milestone payments. The fair value of the contingent milestone payments are remeasured each quarter, with changes in the fair value recognized within operating expenses on the consolidated statements of operations. For further information on the fair value of the contingent milestone payments, see Note 11.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. ACQUISITIONS (Continued)

In-process research and development assets acquired as part of this transaction were capitalized at fair value, which was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. Completion of successful design developments, bench testing, pre-clinical studies and human clinical studies are required prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development, and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals. The valuation assumed $41.4 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, net cash inflows were modeled to commence in Europe in 2018, and in the United States and Japan in 2022. The Company does not currently anticipate significant changes to forecasted research and development expenditures, and net cash inflows commenced in Europe in 2020 and are now expected to commence in the United States and Japan in 2023. Upon completion of development, the underlying in-process research and development asset will be amortized over its estimated useful life.

Valtech Cardio Ltd.

On November 26, 2016, the Company entered into an agreement and plan of merger to acquire Valtech Cardio Ltd. ("Valtech") for approximately $340.0 million, subject to certain adjustments, with the potential for up to an additional $350.0 million in pre-specified milestone-driven payments over the next 10.0 years. The transaction closed on January 23, 2017, and the consideration paid included the issuance of approximately 2.8 million shares of the Company's common stock (fair value of $266.5 million) and cash of $86.2 million. The Company recognized in "*Contingent Consideration Liabilities*" a $162.9 million liability for the estimated fair value of the contingent milestone payments. For further information on the fair value of the contingent milestone payments, see Note 11.

Prior to the close of the transaction, Valtech spun off its early-stage transseptal mitral valve replacement technology program. Concurrent with the closing, the Company entered into an agreement for an exclusive option to acquire that program and its associated intellectual property for approximately $200.0 million, subject to certain adjustments, plus an additional $50.0 million if a certain European regulatory approval is obtained within 10 years of the acquisition closing date. The option expired in January 2020.

In-process research and development assets acquired as part of this transaction were capitalized at fair value, which was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. The valuation assumed $87.3 million of additional research and development expenditures would be incurred prior to the date of product introduction and that net cash inflows would commence in 2019. In December 2018, the Company recorded a $116.2 million impairment charge related to Valtech's intangible assets, and in December 2019, the Company recorded a $40.6 million impairment charge to write off the remaining in-process research and development assets. For further information, see Note 4.

CardiAQ Valve Technologies, Inc.

On July 3, 2015, the Company entered into an agreement and plan of merger to acquire CardiAQ Valve Technologies, Inc. ("CardiAQ") for an aggregate cash purchase price of $350.0 million, subject to certain adjustments. The transaction closed on August 26, 2015, and the cash purchase price after the adjustments was $348.0 million. In addition, the Company agreed to pay an additional $50.0 million if a certain European regulatory approval is obtained within 48 months of the acquisition closing date. The Company recognized in "*Contingent Consideration Liabilities*" a $30.3 million liability for the estimated fair value of this contingent milestone payment. The Company estimated this milestone would not be achieved and reversed the liability in 2018. For further information on the fair value of the contingent milestone payment, see Note 11.

In-process research and development assets acquired as part of this acquisition were capitalized at fair value, which was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. Completion of successful design developments, bench testing, pre-clinical studies and human clinical studies are required prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development, and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals. The valuation assumed $97.7 million of additional research and development expenditures would be incurred prior to the date of

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. ACQUISITIONS (Continued)

product introduction and that net cash inflows would commence in late 2018. As a result of certain design enhancements to increase the product's commercial life and applicability to a broader group of patients, the Company has incurred incremental research and development expenditures; however, the Company expects an increase in the net cash inflows, commencing in 2023. Upon completion of development, the underlying research and development intangible asset will be amortized over its estimated useful life.

9. GOODWILL AND OTHER INTANGIBLE ASSETS

Goodwill and in-process research and development assets resulting from purchase business combinations are not subject to amortization. Other acquired intangible assets with finite lives are amortized over their expected useful lives on a straight-line basis, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be used. The Company expenses costs incurred to renew or extend the term of acquired intangible assets.

In April 2019, the Company acquired CASMED. This transaction resulted in an increase to goodwill of $64.4 million and developed technology of $35.9 million. For further information, see Note 8.

The changes in the carrying amount of goodwill, by segment, during the years ended December 31, 2020 and 2019 were as follows:

	United States	Europe	Rest of World	Total
	(in millions)			
Goodwill at December 31, 2018	$ 709.3	$ 64.2	$ 338.7	$ 1,112.2
Goodwill acquired during the year	64.4	—	—	64.4
Currency translation adjustment	—	(1.4)	(7.5)	(8.9)
Goodwill at December 31, 2019	773.7	62.8	331.2	1,167.7
Currency translation adjustment	—	5.5	—	5.5
Goodwill at December 31, 2020	$ 773.7	$ 68.3	$ 331.2	$ 1,173.2

Other intangible assets consist of the following (in millions):

		December 31,					
		2020			2019		
	Weighted-Average Useful Life (in years)	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Finite-lived intangible assets							
Patents	7.4	$ 186.1	$ (183.6)	$ 2.5	$ 185.7	$ (182.1)	$ 3.6
Developed technology	13.1	155.2	(51.0)	104.2	153.5	(46.6)	106.9
Other	10.0	12.6	(6.0)	6.6	12.3	(4.4)	7.9
	12.6	353.9	(240.6)	113.3	351.5	(233.1)	118.4
Indefinite-lived intangible assets							
In-process research and development		218.1	—	218.1	218.1	—	218.1
		$ 572.0	$ (240.6)	$ 331.4	$ 569.6	$ (233.1)	$ 336.5

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)

Amortization expense related to other intangible assets for the years ended December 31, 2020, 2019, and 2018 was $5.4 million, $4.6 million, and $2.5 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2021	$ 5.2
2022	7.6
2023	10.1
2024	12.2
2025	14.8

10. DEBT AND CREDIT FACILITIES

In June 2018, the Company issued $600.0 million of fixed-rate unsecured senior notes (the "Notes") due June 15, 2028. Interest is payable semi-annually in arrears, with payments due in June and December of each year. The Company may redeem the Notes, in whole or in part, at any time and from time to time at specified redemption prices. In addition, upon the occurrence of certain change of control triggering events, the Company may be required to repurchase all or a portion of the Notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest. The Notes also include covenants that limit the Company's ability to incur secured indebtedness, enter into sale and leaseback transactions, and consolidate, merge, or transfer all or substantially all of its assets.

The following is a summary of the Notes as of December 31, 2020 and 2019:

	December 31,			
	2020		2019	
	Amount	Effective Interest Rate	Amount	Effective Interest Rate
	(in millions)		(in millions)	
Fixed-rate 4.300% 2018 Notes	$ 600.0	4.329 %	$ 600.0	4.329 %
Unamortized discount	(1.1)		(1.2)	
Unamortized debt issuance costs	(3.9)		(4.4)	
Total carrying amount	$ 595.0		$ 594.4	

As of December 31, 2020 and 2019, the fair value of the Notes was $711.2 million and $667.6 million, respectively, based on observable market prices in less active markets and categorized as Level 2 (Note 11). The debt issuance costs, as well as the discount, are being amortized to interest expense over the term of the notes.

The Company has a Five-Year Credit Agreement ("the Credit Agreement") which matures on April 28, 2023. The Credit Agreement provides up to an aggregate of $750.0 million in borrowings in multiple currencies. The Company may increase the amount available under the Credit Agreement, subject to agreement of the lenders, by up to an additional $250.0 million in the aggregate. Borrowings generally bear interest at the London interbank offered rate ("LIBOR"), or a comparable or successor rate, plus a spread ranging from 0.9% to 1.3%, depending on the leverage ratio, as defined in the Credit Agreement. The Company also pays a facility fee ranging from 0.1% to 0.2%, depending on the leverage ratio, on the entire credit commitment available, whether drawn or not. The facility fee is expensed as incurred. During 2020, the spread over LIBOR was 0.9% and the facility fee was 0.1%. Issuance costs of $2.4 million are being amortized to interest expense over the term of the Credit Agreement. As of December 31, 2020 and 2019, there were no borrowings outstanding under the Credit Agreement. Amounts outstanding under the Credit Agreement, if any from time to time, are classified as long-term obligations in accordance with the terms of the Credit Agreement. The Credit Agreement is unsecured and contains various financial and other covenants, including a maximum leverage ratio, as defined in the Credit Agreement. The Company was in compliance with all covenants at December 31, 2020.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. DEBT AND CREDIT FACILITIES (Continued)

The weighted-average interest rate under all debt obligations was 3.5% and 3.4% at December 31, 2020 and 2019, respectively.

11. FAIR VALUE MEASUREMENTS

The consolidated financial statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on a historical cost basis. Financial instruments of the Company consist of cash deposits, accounts and other receivables, investments, accounts payable, certain accrued liabilities, and borrowings under a revolving credit agreement. The carrying value of these financial instruments generally approximates fair value due to their short-term nature. Financial instruments also include notes payable. See Note 10 for further information on the fair value of the notes payable.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The Company prioritizes the inputs used to determine fair values in one of the following three categories:

Level 1—Quoted market prices in active markets for identical assets or liabilities.

Level 2—Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.

Level 3—Unobservable inputs that are not corroborated by market data.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table summarizes the Company's financial instruments which are measured at fair value on a recurring basis as of December 31, 2020 and 2019 (in millions):

December 31, 2020	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 16.2	$ —	$ —	$ 16.2
Available-for-sale investments:				
Bank time deposits	—	24.1	—	24.1
Corporate debt securities	—	608.3	—	608.3
Asset-backed securities	—	151.5	—	151.5
U.S. government and agency securities	56.9	92.2	—	149.1
Municipal securities	—	2.8	—	2.8
Investments held for deferred compensation plans	111.2	—	—	111.2
Derivatives	—	8.1	—	8.1
	$ 184.3	$ 887.0	$ —	$ 1,071.3
Liabilities				
Derivatives	$ —	$ 39.3	$ —	$ 39.3
Deferred compensation plans	111.6	—	—	111.6
Contingent consideration liabilities	—	—	186.1	186.1
	$ 111.6	$ 39.3	$ 186.1	$ 337.0
December 31, 2019				
Assets				
Cash equivalents	$ 0.7	$ 31.7	$ —	$ 32.4
Available-for-sale investments:				
Bank time deposits	—	13.1	—	13.1
Corporate debt securities	—	489.2	—	489.2
Asset-backed securities	—	141.7	—	141.7
U.S. government and agency securities	76.1	37.7	—	113.8
Foreign government bonds	—	1.7	—	1.7
Commercial paper	—	34.3	—	34.3
Investments held for deferred compensation plans	88.9	—	—	88.9
Derivatives	—	30.7	—	30.7
	$ 165.7	$ 780.1	$ —	$ 945.8
Liabilities				
Derivatives	$ —	$ 6.4	$ —	$ 6.4
Deferred compensation plans	88.7	—	—	88.7
Contingent consideration liabilities	—	—	172.5	172.5
	$ 88.7	$ 6.4	$ 172.5	$ 267.6

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

The following table summarizes the changes in fair value of the contingent consideration obligation for the years ended December 31, 2020 and 2019 (in millions):

	December 31,	
	2020	2019
Fair value, beginning of year	$ 172.5	$ 178.6
Changes in fair value	13.6	(6.1)
Fair value, end of year	$ 186.1	$ 172.5

The changes in 2020 in fair value of the contingent consideration obligation were primarily driven by the accretion of interest due to the passage of time and adjustments to discount rates, partially offset by a $12.7 million reduction to the liability due to changes in the projected probability and timing of milestone achievements, and the projected timing of cash inflows. During 2019, the contingent consideration liability was reduced by $24.1 million due to delays in product development, which reduced the probability of milestone achievement. This reduction was partially offset by changes in the fair value of the liabilities associated primarily with adjustments to discount rates and accretion of interest due to the passage of time.

Cash Equivalents and Available-for-sale Investments

The Company estimates the fair values of its money market funds based on quoted prices in active markets for identical assets. The Company estimates the fair values of its time deposits, commercial paper, U.S. and foreign government and agency securities, municipal securities, asset-backed securities, and corporate debt securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades and broker-dealer quotes on the same or similar securities, benchmark yields, credit spreads, prepayment and default projections based on historical data, and other observable inputs. The Company independently reviews and validates the pricing received from the third-party pricing service by comparing the prices to prices reported by a secondary pricing source. The Company’s validation procedures have not resulted in an adjustment to the pricing received from the pricing service.

Deferred Compensation Plans

The Company holds investments in trading securities related to its deferred compensation plans. The investments are in a variety of stock, bond, and money market mutual funds. The fair values of these investments and the corresponding liabilities are based on quoted market prices.

Derivative Instruments

The Company uses derivative financial instruments in the form of foreign currency forward exchange contracts and cross currency swap contracts to manage foreign currency exposures. All derivatives contracts are recognized on the balance sheet at their fair value. The fair value of foreign currency derivative financial instruments and the cross currency swap contracts was estimated based on quoted market foreign exchange rates, cross currency swap basis rates, and market discount rates. Judgment was employed in interpreting market data to develop estimates of fair value; accordingly, the estimates presented herein are not necessarily indicative of the amounts that the Company could realize in a current market exchange. The use of different market assumptions or valuation methodologies could have a material effect on the estimated fair value amounts.

Contingent Consideration Liabilities

Certain of the Company's acquisitions involve contingent consideration arrangements. Payment of additional consideration is contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. These contingent consideration liabilities are measured at estimated fair value using either a probability weighted discounted cash flow analysis or a Monte Carlo simulation model, both of which consider significant unobservable inputs. These inputs include (1) the discount rate used to present value the projected cash flows

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

(ranging from 0.08% to 8.53%; weighted average of 3.1%), (2) the probability of milestone achievement (ranging from 0.4% to 99.7%; weighted average of 70.7%), (3) the projected payment dates (ranging from 2023 to 2027; weighted average of 2026), and (4) the volatility of future revenue (ranging from 37.0% to 40.0%; weighted average of 38.8%). The weighted average of each of the above inputs was determined based on the relative fair value of each obligation. The use of different assumptions could have a material effect on the estimated fair value amounts.

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

The Company uses derivative financial instruments to manage its currency exchange rate risk and its interest rate risk as summarized below. Notional amounts are stated in United States dollar equivalents at spot exchange rates at the respective dates. The Company does not enter into these arrangements for trading or speculation purposes.

	Notional Amount	
	December 31, 2020	December 31, 2019
	(in millions)	
Foreign currency forward exchange contracts	$ 1,525.5	$ 1,336.5
Cross currency swap contracts	300.0	300.0

The following table presents the location and fair value amounts of derivative instruments reported in the consolidated balance sheets (in millions):

		Fair Value	
	Balance Sheet Location	December 31, 2020	December 31, 2019
Derivatives designated as hedging instruments			
Assets			
Foreign currency contracts	Other current assets	$ 7.3	$ 14.2
Foreign currency contracts	Other assets	$ —	$ 3.2
Cross currency swap contracts	Other assets	$ 0.8	$ 13.3
Liabilities			
Foreign currency contracts	Accrued and other liabilities	$ 39.3	$ 6.4

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

The following table presents the effect of master-netting agreements and rights of offset on the consolidated balance sheets (in millions):

December 31, 2020	Gross Amounts	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts Presented in the Consolidated Balance Sheet	Gross Amounts Not Offset in the Consolidated Balance Sheet		Net Amount
				Financial Instruments	Cash Collateral Received	
Derivative Assets						
Foreign currency contracts	$ 7.3	$ —	$ 7.3	$ (6.1)	$ —	$ 1.2
Cross currency swap contracts	$ 0.8	$ —	$ 0.8	$ —	$ —	$ 0.8
Derivative Liabilities						
Foreign currency contracts	$ 39.3	$ —	$ 39.3	$ (6.1)	$ —	$ 33.2
December 31, 2019						
Derivative Assets						
Foreign currency contracts	$ 17.4	$ —	$ 17.4	$ (5.7)	$ —	$ 11.7
Cross currency swap contracts	$ 13.3	$ —	$ 13.3	$ —	$ —	$ 13.3
Derivative Liabilities						
Foreign currency contracts	$ 6.4	$ —	$ 6.4	$ (5.7)	$ —	$ 0.7

The following tables present the effect of derivative and non-derivative hedging instruments on the consolidated statements of operations and consolidated statements of comprehensive income:

	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	2020	2019		2020	2019
	(in millions)			(in millions)	
Cash flow hedges					
Foreign currency contracts	$ (33.7)	$ 23.5	Cost of sales	$ 18.4	$ 40.9
			Selling, general, and administrative expenses	$ 2.2	$ 1.9

	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Recognized in Income on Derivative (Amount Excluded from Effectiveness Testing)	
	2020	2019		2020	2019
	(in millions)			(in millions)	
Net investment hedges					
Cross currency swap contracts	$ (12.6)	$ 12.5	Interest expense	$ 6.4	$ 6.6

The cross currency swaps have an expiration date of June 15, 2028. At maturity of the cross currency swap contracts, the Company will deliver the notional amount of €257.2 million and will receive $300.0 million from the counterparties. The Company will receive semi-annual interest payments from the counterparties based on a fixed interest rate until maturity of the agreements.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative		
		2020	2019	2018
			(in millions)	
Fair value hedges				
Foreign currency contracts	Other income, net	$ (1.4)	$ 1.4	$ 0.5

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative		
		2020	2019	2018
			(in millions)	
Derivatives not designated as hedging instruments				
Foreign currency contracts	Other income, net	$ (15.1)	$ 0.3	$ 9.7

The following table presents the effect of fair value and cash flow hedge accounting on the consolidated statements of operations:

	Location and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships		
	Twelve Months Ended December 31, 2020		
	Cost of sales	Selling, general, and administrative expenses	Other Income, net
Total amounts of income and expense line items shown in the consolidated statements of operations in which the effects of fair value or cash flow hedges are recorded	$ (1,080.6)	$ (1,228.4)	$ 11.5
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items	—	—	4.8
Derivatives designated as hedging instruments	—	—	(4.8)
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach	—	—	3.4
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income	18.4	2.2	—

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

	Location and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships		
	Twelve Months Ended December 31, 2019		
	Cost of sales	Selling, general, and administrative expenses	Other Income, net
Total amounts of income and expense line items shown in the consolidated statements of operations in which the effects of fair value or cash flow hedges are recorded	$ (1,114.4)	$ (1,242.2)	$ 8.2
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items	—	—	2.9
Derivatives designated as hedging instruments	—	—	(2.9)
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach	—	—	4.3
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income	40.9	1.9	—

The Company expects that during 2021 it will reclassify to earnings a $7.0 million loss currently recorded in "*Accumulated Other Comprehensive Loss*." For the years ended December 31, 2020, 2019, and 2018, the Company did not record any gains or losses due to hedge ineffectiveness.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS

Defined Benefit Plans

Edwards Lifesciences maintains defined benefit pension plans in Japan and certain European countries. In 2018, the Company curtailed its defined benefit plan in Horw, Switzerland (see Note 4).

	Years Ended December 31,	
	2020	2019
	(in millions)	
Change in projected benefit obligation:		
Beginning of year	$ 105.2	$ 97.4
Service cost	6.3	5.2
Interest cost	0.5	0.9
Participant contributions	1.5	1.3
Actuarial loss	2.9	8.2
Benefits paid	(0.6)	(4.2)
Plan amendment	—	(4.6)
Currency exchange rate changes and other	10.4	1.0
End of year	$ 126.2	$ 105.2
Change in fair value of plan assets:		
Beginning of year	$ 63.2	$ 60.4
Actual return on plan assets	0.4	2.0
Employer contributions	2.8	2.6
Participant contributions	1.5	1.3
Benefits paid	(0.6)	(4.2)
Currency exchange rate changes and other	6.0	1.1
End of year	$ 73.3	$ 63.2
Funded Status		
Projected benefit obligation	$ (126.2)	$ (105.2)
Plan assets at fair value	73.3	63.2
Underfunded status	$ (52.9)	$ (42.0)
Net amounts recognized on the consolidated balance sheet:		
Other long-term liabilities	$ 52.9	$ 42.0
Accumulated other comprehensive loss, net of tax:		
Net actuarial loss	$ (30.8)	$ (26.3)
Net prior service cost	6.6	6.7
Deferred income tax benefit	4.6	4.2
Total	$ (19.6)	$ (15.4)

The accumulated benefit obligation ("ABO") for all defined benefit pension plans was $120.9 million and $101.1 million as of December 31, 2020 and 2019, respectively. The projected benefit obligation and ABO were in excess of plan assets for all pension plans as of December 31, 2020 and 2019.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

The components of net periodic pension benefit cost (credit) are as follows (in millions):

	Years Ended December 31,		
	2020	2019	2018
Service cost, net	$ 6.3	$ 5.2	$ 6.0
Interest cost	0.5	0.9	0.8
Expected return on plan assets	(1.0)	(1.4)	(1.3)
Settlements and curtailment gain	—	—	(7.4)
Amortization of actuarial loss	1.6	0.9	0.8
Amortization of prior service credit	(0.7)	(0.2)	(0.1)
Net periodic pension benefit cost (credit)	$ 6.7	$ 5.4	$ (1.2)

Expected long-term returns for each of the plans' strategic asset classes were developed through consultation with investment advisors. Several factors were considered, including a survey of investment managers' expectations, current market data, minimum guaranteed returns in certain insurance contracts, and historical market returns over long periods. Using policy target allocation percentages and the asset class expected returns, a weighted-average expected return was calculated.

To select the discount rates for the defined benefit pension plans, the Company uses a modeling process that involves matching the expected duration of its benefit plans to a yield curve constructed from a portfolio of AA-rated fixed-income debt instruments, or their equivalent. For each country, the Company uses the implied yield of this hypothetical portfolio at the appropriate duration as a discount rate benchmark.

The weighted-average assumptions used to determine the benefit obligations are as follows:

	December 31,	
	2020	2019
Discount rate	0.3 %	0.5 %
Rate of compensation increase	2.6 %	2.7 %
Cash balance interest crediting rate	2.5 %	2.6 %
Social securities increase	1.6 %	1.6 %
Pension increase	1.8 %	1.8 %

The weighted-average assumptions used to determine the net periodic pension benefit cost are as follows:

	Years ended December 31,		
	2020	2019	2018
Discount rate	0.5 %	0.9 %	0.9 %
Expected return on plan assets	1.5 %	2.3 %	2.3 %
Rate of compensation increase	2.7 %	2.8 %	2.6 %
Cash balance interest crediting rate	1.5 %	1.5 %	1.5 %
Social securities increase	1.6 %	1.8 %	1.5 %
Pension increase	1.8 %	1.8 %	1.8 %

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

Plan Assets

The Company's investment strategy for plan assets is to seek a competitive rate of return relative to an appropriate level of risk and to earn performance rates of return in accordance with the benchmarks adopted for each asset class. Risk management practices include diversification across asset classes and investment styles, and periodic rebalancing toward asset allocation targets.

The Administrative and Investment Committee decides on the defined benefit plan provider in each location and that provider decides the target allocation for the Company's defined benefit plan at that location. The target asset allocation selected reflects a risk/return profile the Company feels is appropriate relative to the plans' liability structure and return goals. In certain plans, asset allocations may be governed by local requirements. Target weighted-average asset allocations at December 31, 2020, by asset category, are as follows:

Equity securities	25.3 %
Debt securities	47.5 %
Real estate	7.7 %
Other	19.5 %
Total	100.0 %

The fair values of the Company's defined benefit plan assets at December 31, 2020 and 2019, by asset category, are as follows (in millions):

December 31, 2020	Level 1	Level 2	Level 3	Total
Asset Category				
Cash	$ 3.0	$ —	$ —	$ 3.0
Equity securities:				
United States equities	3.3	—	—	3.3
International equities	16.1	—	—	16.1
Debt securities:				
United States government bonds	7.4	—	—	7.4
International government bonds	26.0	—	—	26.0
Real estate	—	5.6	—	5.6
Mortgages	—	3.1	—	3.1
Insurance contracts	—	—	1.0	1.0
Total plan assets measured at fair value	$ 55.8	$ 8.7	$ 1.0	$ 65.5
Alternative investments measured at net asset value (a)				7.8
Total plan assets				$ 73.3

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

December 31, 2019	Level 1	Level 2	Level 3	Total
Asset Category				
Cash	$ 3.8	$ —	$ —	$ 3.8
Equity securities:				
United States equities	3.0	—	—	3.0
International equities	11.2	—	—	11.2
Debt securities:				
United States government bonds	8.2	—	—	8.2
International government bonds	22.3	—	—	22.3
Real estate	—	4.4	—	4.4
Mortgages	—	2.3	—	2.3
Insurance contracts	—	—	0.9	0.9
Total plan assets	$ 48.5	$ 6.7	$ 0.9	$ 56.1
Alternative investments measured at net asset value (a)				7.1
Total plan assets				$ 63.2

(a) Certain investments that were measured at net asset value per share have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the total plan assets.

The following table summarizes the changes in fair value of the Company's defined benefit plan assets that have been classified as Level 3 for the years ended December 31, 2020 and 2019 (in millions):

	Insurance Contracts
Balance at December 31, 2018	$ 1.0
Purchases, sales and settlements	(0.1)
Balance at December 31, 2019	0.9
Currency exchange rate impact	0.1
Balance at December 31, 2020	$ 1.0

Equity and debt securities are valued at fair value based on quoted market prices reported on the active markets on which the individual securities are traded. Real estate investments are valued by discounting to present value the cash flows expected to be generated by the specific properties. Investments in mortgages are valued at cost, which is deemed to approximate its fair value. The insurance contracts are valued at the cash surrender value of the contracts, which is deemed to approximate its fair value. Alternative investments include hedge funds, private equity funds and other miscellaneous investments, and are valued using the net asset value provided by the fund administrator as a practical expedient. The net asset value is based on the fair value of the underlying assets owned by the fund divided by the number of shares outstanding.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

The following benefit payments, which reflect expected future service, as appropriate, at December 31, 2020, are expected to be paid (in millions):

2021	$ 4.6
2022	4.9
2023	6.7
2024	5.6
2025	5.3
2024-2026	36.7

As of December 31, 2020, expected employer contributions for 2021 are $2.5 million.

Defined Contribution Plans

The Company's employees in the United States and Puerto Rico are eligible to participate in a qualified defined contribution plan. In the United States, participants may contribute up to 25% of their eligible compensation (subject to tax code limitation) to the plan. Edwards Lifesciences matches the first 4% of the participant's annual eligible compensation contributed to the plan on a dollar-for-dollar basis. Edwards Lifesciences matches the next 2% of the participant's annual eligible compensation to the plan on a 50% basis. In Puerto Rico, participants may contribute up to 25% of their annual compensation (subject to tax code limitation) to the plan. Edwards Lifesciences matches the first 4% of participant's annual eligible compensation contributed to the plan on a 50% basis. The Company also provides a 2% profit sharing contribution calculated on eligible earnings for each employee. Matching contributions relating to Edwards Lifesciences employees were $36.6 million, $31.4 million, and $26.6 million in 2020, 2019, and 2018, respectively.

The Company also has nonqualified deferred compensation plans for a select group of employees. The plans provide eligible participants the opportunity to defer eligible compensation to future dates specified by the participant with a return based on investment alternatives selected by the participant. The amount accrued under these nonqualified plans was $111.6 million and $88.7 million at December 31, 2020 and 2019, respectively.

14. COMMON STOCK

Treasury Stock

In May 2019, the Board of Directors approved a stock repurchase program authorizing the Company to purchase up to $1.0 billion of the Company's common stock. The repurchase program does not have an expiration date. Stock repurchased under the program may be used to offset obligations under the Company's employee stock-based benefit programs and stock-based business acquisitions, and will reduce the total shares outstanding.

During 2020, 2019, and 2018, the Company repurchased 3.1 million, 1.5 million, and 5.5 million shares, respectively, at an aggregate cost of $625.4 million, $263.3 million, and $795.5 million, respectively, including shares purchased under the accelerated share repurchase ("ASR") agreements described below and shares acquired to satisfy tax withholding obligations in connection with the vesting of restricted stock units issued to employees. The timing and size of any future stock repurchases are subject to a variety of factors, including expected dilution from stock plans, cash capacity, and the market price of the Company's common stock.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. COMMON STOCK (Continued)

Accelerated Share Repurchase

During 2019 and 2018, the Company entered into ASR agreements providing for the repurchase of the Company's common stock based on the volume-weighted average price ("VWAP") of the Company's common stock during the term of the agreements, less a discount. The following table summarizes the terms of the ASR agreements (dollars and shares in millions, except per share data):

		Initial Delivery			Final Settlement		
Agreement Date	Amount Paid	Shares Received	Price per Share (a)	Value of Shares as % of Contract Value	Settlement Date	Total Shares Received	Average Price per Share (a)
April 2018	$ 400.0	2.5	$ 127.36	80 %	July 2018	2.8	$ 142.37
October 2018	$ 250.0	1.4	$ 139.22	80 %	November 2018	1.7	$ 150.54
May 2019	$ 150.0	0.7	$ 178.66	80 %	May 2019	0.8	$ 178.42
May 2019	$ 100.0	0.5	$ 170.02	80 %	June 2019	0.6	$ 178.46

(a) The three-for-one stock split distributed on May 29, 2020 excluded treasury shares. The shares and per share prices in the table are reflected at the pre-split amounts and prices at the time of the transaction.

The ASR agreements were accounted for as two separate transactions: (1) the value of the initial delivery of shares was recorded as shares of common stock acquired in a treasury stock transaction on the acquisition date and (2) the remaining amount of the purchase price paid was recorded as a forward contract indexed to the Company's own common stock and was recorded in "*Additional Paid-in Capital*" on the consolidated balance sheets. The initial delivery of shares resulted in an immediate reduction of the outstanding shares used to calculate the weighted-average common shares outstanding for basic and diluted earnings per share. The Company determined that the forward contract indexed to the Company's common stock met all the applicable criteria for equity classification and, therefore, was not accounted for as a derivative instrument.

Employee and Director Stock Plans

The Edwards Lifesciences Corporation Long-term Stock Incentive Compensation Program (the "Program") provides for the grant of incentive and non-qualified stock options, restricted stock, and restricted stock units for eligible employees of the Company. Under the Program, these grants are awarded at a price equal to the fair market value at the date of grant based upon the closing price on that date. Options to purchase shares of the Company's common stock granted under the Program generally vest over predetermined periods of between three to four years and expire seven years after the date of grant. Service-based restricted stock units of the Company's common stock granted under the Program generally vest over predetermined periods ranging from three to four years after the date of grant. Market-based restricted stock units of the Company's common stock granted under the Program vest over three years based on a combination of certain service and market conditions. The actual number of shares issued will be determined based on the Company's total stockholder return relative to a selected industry peer group. Performance-based restricted stock units vest based on a combination of certain service conditions and upon achievement of specified milestones. Under the Program, the number of shares of common stock available for issuance under the Program was 327.6 million shares. No more than 33.6 million shares reserved for issuance may be granted in the form of restricted stock or restricted stock units.

The Company also maintains the Nonemployee Directors Stock Incentive Compensation Program (the "Nonemployee Directors Program"). Under the Nonemployee Directors Program, annually each nonemployee director may receive up to 120,000 stock options or 48,000 restricted stock units of the Company's common stock, or a combination thereof, provided that in no event may the total value of the combined annual award exceed $0.2 million. These grants generally vest over one year from the date of grant. Under the Nonemployee Directors Program, an aggregate of 8.4 million shares of the Company's common stock has been authorized for issuance.

The Company has an employee stock purchase plan for United States employees and a plan for international employees (collectively "ESPP"). Under the ESPP, eligible employees may purchase shares of the Company's common stock at 85% of the lower of the fair market value of Edwards Lifesciences common stock on the effective date of subscription or the date of

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. COMMON STOCK (Continued)

purchase. Under the ESPP, employees can authorize the Company to withhold up to 12% (15% effective January 1, 2021) of their compensation for common stock purchases, subject to certain limitations. The ESPP is available to all active employees of the Company paid from the United States payroll and to eligible employees of the Company outside the United States, to the extent permitted by local law. The ESPP for United States employees is qualified under Section 423 of the Internal Revenue Code. The number of shares of common stock authorized for issuance under the ESPP was 45.9 million shares.

The fair value of each option award and employee stock purchase subscription is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following tables. The risk-free interest rate is estimated using the U.S. Treasury yield curve and is based on the expected term of the award. Expected volatility is estimated based on a blend of the weighted-average of the historical volatility of Edwards Lifesciences' stock and the implied volatility from traded options on Edwards Lifesciences' stock. The expected term of awards granted is estimated from the vesting period of the award, as well as historical exercise behavior, and represents the period of time that awards granted are expected to be outstanding. The Company uses historical data to estimate forfeitures and has estimated an annual forfeiture rate of 6.4%.

The Black-Scholes option pricing model was used with the following weighted-average assumptions for options granted during the following periods:

Option Awards

	2020	2019	2018
Average risk-free interest rate	0.3 %	2.3 %	2.9 %
Expected dividend yield	None	None	None
Expected volatility	33 %	30 %	29 %
Expected life (years)	5.0	5.1	5.0
Fair value, per share	$ 21.70	$ 18.17	$ 14.17

The Black-Scholes option pricing model was used with the following weighted-average assumptions for ESPP subscriptions granted during the following periods:

ESPP

	2020	2019	2018
Average risk-free interest rate	1.3 %	2.4 %	1.7 %
Expected dividend yield	None	None	None
Expected volatility	33 %	27 %	31 %
Expected life (years)	0.6	0.6	0.6
Fair value, per share	$ 16.61	$ 16.43	$ 12.18

The fair value of market-based restricted stock units was determined using a Monte Carlo simulation model, which uses multiple input variables to determine the probability of satisfying the market condition requirements. The weighted-average assumptions used to determine the fair value of the market-based restricted stock units during the years ended December 31, 2020, 2019, and 2018 included a risk-free interest rate of 0.2%, 2.2%, and 2.7%, respectively, and an expected volatility rate of 32.7%, 29.4%, and 29.7%, respectively.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. COMMON STOCK (Continued)

Stock option activity during the year ended December 31, 2020 under the Program and the Nonemployee Directors Program was as follows (in millions, except years and per-share amounts):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	17.1	$ 32.19		
Options granted	1.8	73.02		
Options exercised	(4.3)	18.16		
Options forfeited	(0.3)	49.74		
Outstanding as of December 31, 2020	14.3	41.27	3.4 years	$ 712.5
Exercisable as of December 31, 2020	9.5	32.32	2.5 years	558.1
Vested and expected to vest as of December 31, 2020	13.6	40.37	3.3 years	690.4

The following table summarizes nonvested restricted stock unit activity during the year ended December 31, 2020 under the Program and the Nonemployee Directors Program (in millions, except per-share amounts):

	Shares	Weighted-Average Grant-Date Fair Value
Nonvested as of December 31, 2019	2.7	$ 46.89
Granted (a)	0.9	71.31
Vested	(0.9)	40.03
Forfeited	(0.1)	49.90
Nonvested as of December 31, 2020	2.6	57.59

(a) The shares granted includes 0.1 million shares of market-based restricted stock units granted during 2020, which represents the target number of shares to be issued, and 0.1 million shares related to a previous year's grant of market-based restricted stock units since the payout percentage achieved at the end of the performance period was in excess of target. As described above, the actual number of shares ultimately issued is determined based on the Company's total stockholder return relative to a selected industry peer group.

The intrinsic value of stock options exercised and restricted stock units vested during the years ended December 31, 2020, 2019, and 2018 were $323.5 million, $382.1 million, and $281.1 million, respectively. The intrinsic value of stock options is calculated as the amount by which the market price of the Company's common stock exceeds the exercise price of the option. During the years ended December 31, 2020, 2019, and 2018, the Company received cash from exercises of stock options of $79.2 million, $110.4 million, and $103.7 million, respectively, and tax benefits from exercises of stock options and vesting of restricted stock units of $72.1 million, $85.1 million, and $62.5 million, respectively. The total grant-date fair value of stock options vested during the years ended December 31, 2020, 2019, and 2018 were $34.0 million, $31.2 million, and $29.0 million, respectively.

As of December 31, 2020, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units, and employee stock purchase subscriptions amounted to $140.9 million, which will be amortized over the weighted-average remaining requisite service period of 30 months.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. ACCUMULATED OTHER COMPREHENSIVE LOSS

Presented below is a summary of activity for each component of "*Accumulated Other Comprehensive Loss*" for the years ended December 31, 2020, 2019, and 2018.

	Foreign Currency Translation Adjustments	Unrealized (Loss) Gain on Hedges	Unrealized (Loss) Gain on Available-for-sale Investments	Unrealized Pension Costs (a)	Total Accumulated Other Comprehensive Loss
			(in millions)		
December 31, 2017	$ (100.1)	$ (13.9)	$ (4.6)	$ (14.1)	$ (132.7)
Impact from adoption of ASU 2016-16 and ASU 2018-02	(4.9)	(2.9)	—	—	(7.8)
January 1, 2018	(105.0)	(16.8)	(4.6)	(14.1)	(140.5)
Other comprehensive (loss) income before reclassifications	(36.7)	35.1	(3.1)	7.6	2.9
Amounts reclassified from accumulated other comprehensive loss	—	19.1	2.9	(6.7)	15.3
Deferred income tax expense	(1.9)	(13.8)	(0.2)	(0.3)	(16.2)
December 31, 2018	(143.6)	23.6	(5.0)	(13.5)	(138.5)
Other comprehensive (loss) income before reclassifications	(1.5)	27.9	7.9	(3.2)	31.1
Amounts reclassified from accumulated other comprehensive loss	(6.6)	(44.2)	0.4	0.7	(49.7)
Deferred income tax (expense) benefit	(3.1)	5.2	(1.6)	0.6	1.1
December 31, 2019	(154.8)	12.5	1.7	(15.4)	(156.0)
Other comprehensive income (loss) before reclassifications	35.7	(34.8)	8.0	(5.5)	3.4
Amounts reclassified from accumulated other comprehensive loss	(6.4)	(19.2)	0.3	0.9	(24.4)
Deferred income tax benefit (expense)	3.1	13.8	(1.4)	0.4	15.9
December 31, 2020	$ (122.4)	$ (27.7)	$ 8.6	$ (19.6)	$ (161.1)

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. ACCUMULATED OTHER COMPREHENSIVE LOSS (Continued)

(a) For the years ended December 31, 2020, 2019, and 2018, the change in unrealized pension costs consisted of the following (in millions):

	Pre-Tax Amount	Tax (Expense) Benefit	Net of Tax Amount
r service credit arising during period	$ 0.6	$ (0.2)	$ 0.4
ortization of prior service credit	(0.7)	0.1	(0.6)
prior service cost arising during period	(0.1)	(0.1)	(0.2)
actuarial loss arising during period	(4.5)	0.5	(4.0)
ealized pension costs, net	$ (4.6)	$ 0.4	$ (4.2)
r service credit arising during period	$ 4.6	$ (0.6)	$ 4.0
ortization of prior service credit	(0.2)	0.1	(0.1)
prior service credit arising during period	4.4	(0.5)	3.9
actuarial loss arising during period	(6.9)	1.1	(5.8)
ealized pension costs, net	$ (2.5)	$ 0.6	$ (1.9)
r service credit arising during period	$ 3.3	$ (0.9)	$ 2.4
ortization of prior service credit	(0.1)	—	(0.1)
prior service credit arising during period	3.2	(0.9)	2.3
actuarial loss arising during period	(2.3)	0.6	(1.7)
ealized pension credits, net	$ 0.9	$ (0.3)	$ 0.6

The following table provides information about amounts reclassified from "*Accumulated Other Comprehensive Loss*" (in millions):

Details about Accumulated Other Comprehensive Loss Components	Years Ended December 31, 2020	Years Ended December 31, 2019	Affected Line on Consolidated Statements of Operations
Foreign currency translation adjustments	$ 6.4	$ 6.6	Other income, net
	(1.6)	(1.6)	Provision for income taxes
	$ 4.8	$ 5.0	Net of tax
(Loss) gain on hedges	$ 18.4	$ 40.9	Cost of sales
	2.2	1.9	Selling, general, and administrative expenses
	(1.4)	1.4	Other income, net
	19.2	44.2	Total before tax
	(5.0)	(11.0)	Provision for income taxes
	$ 14.2	$ 33.2	Net of tax
(Loss) gain on available-for-sale investments	$ (0.3)	$ (0.4)	Other income, net
	(0.6)	(0.3)	Provision for income taxes
	$ (0.9)	$ (0.7)	Net of tax
Amortization of pension adjustments	$ (0.9)	$ (0.7)	Other income, net
	0.2	0.1	Provision for income taxes
	$ (0.7)	$ (0.6)	Net of tax

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. OTHER INCOME, NET

	Years Ended December 31,		
	2020	2019	2018
	(in millions)		
Foreign exchange gains, net	$ (12.3)	$ (5.9)	$ (6.7)
Gain on investments	(0.6)	(0.5)	1.7
Non-service cost components of net periodic pension benefit cost (credit)	0.4	0.2	(0.1)
Other	1.0	(2.0)	1.1
Total other income, net	$ (11.5)	$ (8.2)	$ (4.0)

17. INCOME TAXES

The Company's income before provision for income taxes was generated from United States and international operations as follows (in millions):

	Years Ended December 31,		
	2020	2019	2018
United States	$ 151.3	$ 383.4	$ 266.1
International, including Puerto Rico	765.4	783.1	495.3
	$ 916.7	$ 1,166.5	$ 761.4

The provision for income taxes consists of the following (in millions):

	Years Ended December 31,		
	2020	2019	2018
Current			
United States:			
Federal	$ 23.4	$ 31.3	$ 10.9
State and local	48.2	48.7	13.6
International, including Puerto Rico	73.9	29.1	35.9
Current income tax expense	$ 145.5	$ 109.1	$ 60.4
Deferred			
United States:			
Federal	$ 11.0	$ 28.3	$ (16.1)
State and local	(32.9)	(18.3)	(22.4)
International, including Puerto Rico	(30.3)	0.5	17.3
Deferred income tax (benefit) expense	(52.2)	10.5	(21.2)
Total income tax provision	$ 93.3	$ 119.6	$ 39.2

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

The components of deferred tax assets and liabilities are as follows (in millions):

	December 31,	
	2020	2019
Deferred tax assets		
Compensation and benefits	$ 88.6	$ 90.1
Benefits from uncertain tax positions	27.0	22.5
Net tax credit carryforwards	125.5	108.4
Net operating loss carryforwards	64.1	57.6
Accrued liabilities	105.0	41.3
Inventories	16.3	12.9
Cash flow and net investment hedges	3.3	—
State income taxes	0.5	0.5
Investments	1.8	1.5
Lease liability obligations	7.7	18.4
Other	3.6	3.4
Total deferred tax assets	443.4	356.6
Deferred tax liabilities		
Property, plant, and equipment	(53.4)	(22.6)
Cash flow and net investment hedges	—	(6.8)
Deferred tax on foreign earnings	(29.2)	(35.3)
Right-of-use assets	(7.0)	(17.5)
Other intangible assets	(76.3)	(71.0)
Other	(3.1)	(2.2)
Total deferred tax liabilities	(169.0)	(155.4)
Valuation allowance	(71.6)	(65.8)
Net deferred tax assets	$ 202.8	$ 135.4

During 2020, net deferred tax assets increased $67.4 million, including items that were recorded to stockholders' equity and which did not impact the Company's income tax provision.

The valuation allowance of $71.6 million as of December 31, 2020 reduces certain deferred tax assets to amounts that are more likely than not to be realized. This allowance primarily relates to the net operating loss carryforwards of certain non-United States subsidiaries and certain non-United States credit carryforwards.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

Net operating loss and capital loss carryforwards and the related carryforward periods at December 31, 2020 are summarized as follows (in millions):

	Carryforward Amount	Tax Benefit Amount	Valuation Allowance	Net Tax Benefit	Carryforward Period Ends
United States federal net operating losses	$ 26.6	$ 5.6	$ —	$ 5.6	2030-2037
United States federal net operating losses	11.3	2.4	—	2.4	Indefinite
United States state net operating losses	33.5	2.1	(2.1)	—	2026-2039
United States state net operating losses	1.0	0.1	(0.1)	—	Indefinite
Non-United States net operating losses	18.2	4.7	(3.6)	1.1	2020-2027
Non-United States net operating losses	295.1	49.2	(39.9)	9.3	Indefinite
United States capital losses	34.1	0.2	(0.2)	—	2024
Total	$ 419.8	$ 64.3	$ (45.9)	$ 18.4	

Certain tax attributes are subject to an annual limitation as a result of the acquisitions of Harpoon Medical, Inc. and CASMED (see Note 8), which constitute a change of ownership as defined under Internal Revenue Code Section 382.

The gross tax credit carryforwards and the related carryforward periods at December 31, 2020 are summarized as follows (in millions):

	Carryforward Amount	Valuation Allowance	Net Tax Benefit	Carryforward Period Ends
California research expenditure tax credits	$ 145.1	$ —	$ 145.1	Indefinite
Federal research expenditure tax credits	1.5	—	1.5	2026-2039
Puerto Rico purchases credit	23.4	(23.4)	—	Indefinite
Total	$ 170.0	$ (23.4)	$ 146.6	

The Company has $145.1 million of California research expenditure tax credits it expects to use in future periods. The credits may be carried forward indefinitely. Based upon anticipated future taxable income, the Company expects that it is more likely than not that all California research expenditure tax credits will be utilized, although the utilization of the full benefit is expected to occur over a number of years and into the distant future. Accordingly, no valuation allowance has been provided. The Company has $23.4 million of Puerto Rico purchases credit. Throughout its history and into the future, the Puerto Rico operations generate, or are expected to generate, credits each year in excess of its ability to utilize credits in those years. As a result, even though the credits have an indefinite life, the Company continues to record a valuation allowance on the credit carryforwards.

On December 22, 2017, Public Law 115-97, commonly referred to as the Tax Cuts and Jobs Act (the "2017 Act"), was signed into law. The 2017 Act a) reduced the U.S. federal corporate tax rate from 35 percent to 21 percent for tax years beginning after December 31, 2017, b) required companies to pay a one-time mandatory deemed repatriation tax on the cumulative earnings of certain foreign subsidiaries that were previously tax deferred, and c) created new taxes on certain foreign earnings in future years.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of generally accepted accounting principles in the United States of America in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Act. In accordance with SAB 118, as of December 31, 2017, the Company had estimated provisional amounts for a) $3.3 million of tax benefits in connection with the remeasurement of certain tax assets and liabilities, b) $297.4 million of net tax expense in connection with the one-time mandatory deemed repatriation tax on cumulative earnings of certain foreign subsidiaries, and c) $32.3 million of tax benefits associated with a tax reform related restructuring. In accordance with SAB 118, during 2018 the Company adjusted the provisional amounts as described below.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

As a result of Internal Revenue Service ("IRS") guidance issued subsequent to the 2017 Act, the $32.3 million of tax benefits associated with the tax reform related restructuring mentioned above were reversed in 2018. In addition, during 2018, the Company recorded a $12.8 million reduction in the repatriation tax and an additional benefit of $3.7 million in connection with the remeasurement of deferred tax assets. In accordance with SAB 118, the Company completed its accounting for the 2017 Act during the fourth quarter of 2018. In addition, the Company elected to pay the repatriation tax in installments over eight years.

The Company asserts that $1.1 billion of its foreign earnings continue to be indefinitely reinvested and it intends to repatriate $599.8 million of its foreign earnings as of December 31, 2020. The estimated net tax liability on the indefinitely reinvested earnings if repatriated is $21.1 million.

The Company has received tax incentives in certain non-U.S. tax jurisdictions, the primary benefit for which will expire in 2029. The tax reductions as compared to the local statutory rates were $189.2 million ($0.30 per diluted share), $157.6 million ($0.25 per diluted share), and $144.9 million ($0.23 per diluted share) for the years ended December 31, 2020, 2019, and 2018, respectively.

A reconciliation of the United States federal statutory income tax rate to the Company's effective income tax rate is as follows (in millions):

	Years Ended December 31,		
	2020	2019	2018
Income tax expense at U.S. federal statutory rate	$ 192.5	$ 245.0	$ 159.9
Foreign income taxed at different rates	(80.5)	(75.0)	(16.2)
State and local taxes, net of federal tax benefit	5.0	11.9	6.8
Tax credits, federal and state	(43.1)	(42.9)	(36.7)
Build (release) of reserve for prior years' uncertain tax positions	4.2	5.0	(35.5)
U.S. tax on foreign earnings, net of credits	1.5	(2.9)	(12.2)
Tax on global intangible low-taxed income	49.2	32.0	—
Foreign-derived intangible income deduction	(2.6)	(7.2)	(6.6)
U.S. federal deductible employee share-based compensation	(48.3)	(57.6)	(41.8)
Nondeductible employee share-based compensation	4.2	3.2	2.8
Impact related to 2017 U.S. Tax Reform	—	2.8	15.8
Other	11.2	5.3	2.9
Income tax provision	$ 93.3	$ 119.6	$ 39.2

The Company's effective tax rate for 2020 decreased slightly in comparison to 2019 primarily due to the tax benefit from the Settlement Agreement with Abbott (see Notes 3 and 18), partially offset by the increase in the U.S. tax on global intangible low-taxed income and the decrease in the tax benefit from employee share-based compensation. The Company's effective tax rate for 2019 increased in comparison to 2018 primarily because of the increase in the U.S. tax on global intangible low-taxed income and the tax benefit in 2018 from audit settlements.

Uncertain Tax Positions

As of December 31, 2020 and 2019, the gross uncertain tax positions were $281.8 million and $203.1 million, respectively. The Company estimates that these liabilities would be reduced by $95.1 million and $50.1 million, respectively, from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes, and timing adjustments. The net amounts of $186.7 million and $153.0 million, respectively, if not required, would favorably affect the Company's effective tax rate.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

A reconciliation of the beginning and ending amount of uncertain tax positions, excluding interest, penalties, and foreign exchange, is as follows (in millions):

	December 31,		
	2020	2019	2018
Uncertain gross tax positions, January 1	$ 203.1	$ 150.7	$ 225.6
Current year tax positions	86.4	55.4	37.8
Increase in prior year tax positions	6.0	0.8	13.9
Decrease in prior year tax positions	(10.0)	(3.8)	(78.8)
Settlements	(3.7)	—	(46.5)
Lapse of statutes of limitations	—	—	(1.3)
Uncertain gross tax positions, December 31	$ 281.8	$ 203.1	$ 150.7

The table above summarizes the gross amounts of uncertain tax positions without regard to reduction in tax liabilities or additions to deferred tax assets and liabilities if such uncertain tax positions were settled.

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2020, the Company had accrued $14.3 million (net of $5.1 million tax benefit) of interest related to uncertain tax positions, and as of December 31, 2019, the Company had accrued $9.3 million (net of $3.5 million tax benefit) of interest related to uncertain tax positions. During 2020, 2019, and 2018, the Company recognized interest expense (benefit), net of tax benefit, of $5.0 million, $4.7 million, and $(2.8) million, respectively, in "*Provision for Income Taxes*" on the consolidated statements of operations.

The Company strives to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at any time. While the Company has accrued for matters it believes are more likely than not to require settlement, the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in the consolidated financial statements. Furthermore, the Company may later decide to challenge any assessments, if made, and may exercise its right to appeal. The uncertain tax positions are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues, and issuance of new legislation, regulations, or case law. Management believes that adequate amounts of tax and related penalty and interest have been provided in income tax expense for any adjustments that may result from these uncertain tax positions.

At December 31, 2020, all material state, local, and foreign income tax matters have been concluded for years through 2015. While not material, the Company continues to address matters in Wisconsin and India for years from 2010.

During 2018, the Company executed an Advance Pricing Agreement (“APA”) between the United States and Switzerland governments for tax years 2009 through 2020 covering various, but not all, transfer pricing matters. The unagreed transfer pricing matters, namely Surgical Structural Heart and Transcatheter Aortic Valve Replacement intercompany royalty transactions, then reverted to IRS Examination for further consideration as part of the respective years' regular tax audit. In addition, the Company signed agreements during 2018 with the IRS to settle open tax years 2009 through 2014, including all transfer pricing matters for those years and the tax treatment of a portion of a litigation settlement payment received in 2014.

The IRS began its examination of the 2015 and 2016 tax years during the fourth quarter of 2018 and later added the 2017 tax year to this audit cycle during the first quarter of 2019. The IRS audit field work for the 2015-2017 tax years was substantially completed during the fourth quarter of 2020, except for transfer pricing matters.

As a result, certain intercompany transactions covering tax years 2015 through 2020 that were not resolved under the APA program remain subject to IRS examination, and those transactions and related tax positions remain uncertain as of December 31, 2020. The IRS has signaled that it may be preparing proposed audit adjustments related to these intercompany transactions for the 2015-2017 tax years which, if issued, could be provided to the Company during 2021. The Company has considered this information in its evaluation of its uncertain tax positions.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

These unresolved transfer pricing matters, net of any correlative repatriation tax adjustment, may be significant to the Company's consolidated financial statements. Based on the information currently available and numerous possible outcomes, the Company cannot reasonably estimate what, if any, changes to its existing uncertain tax positions may occur in the next 12 months and, therefore, has continued to record the gross uncertain tax positions as a long-term liability.

The Company intends to file to renew the APA between the United States and Switzerland for the years 2021 and forward. In addition, the Company executed other APAs as follows: during 2017, an APA between the United States and Japan covering tax years 2015 through 2019; and during 2018, APAs between Japan and Singapore and between Switzerland and Japan covering tax years 2015 through 2019. The Company has filed to renew these APAs related to Japan for the years 2020 and forward. The execution of some or all of these APAs depends on a number of variables outside of the Company's control.

18. LEGAL PROCEEDINGS

In January 2019, Abbott filed lawsuits against Edwards Lifesciences and its direct and indirect subsidiaries ("Edwards") in the Federal District Court in the District of Delaware, in the United Kingdom, Germany, Switzerland and Italy, and, in February 2020, in Ireland, alleging patent infringement involving Edwards' *PASCAL* heart valve repair system (collectively, the "*PASCAL* litigation"). In February 2019, Edwards filed a lawsuit against Abbott in the Federal District Court in the Central District of California alleging patent infringement involving Abbott's MITRACLIP device (with the *PASCAL* litigation, the "Abbott Matters"). On July 12, 2020, Edwards entered into the Settlement Agreement with Abbott to, among other things, settle all patent litigation between the parties related to alleged patent infringement involving Edwards' *PASCAL* heart valve repair system and Abbott's MITRACLIP device. Pursuant to the Settlement Agreement, all of the Abbott Matters and related appeals in courts worldwide were dismissed. The Settlement Agreement resulted in the Company recording an estimated $367.9 million pre-tax net charge in June 2020 related to past damages. See Note 3 for additional information.

In addition, the Company is or may be a party to, or may otherwise be responsible for, pending or threatened lawsuits including those related to products and services currently or formerly manufactured or performed, as applicable, by the Company, workplace and employment matters, matters involving real estate, Company operations or health care regulations, or governmental investigations (the "Other Lawsuits"). The Other Lawsuits raise difficult and complex factual and legal issues and are subject to many uncertainties, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Management does not believe that any loss relating to the Other Lawsuits would have a material adverse effect on the Company's overall financial condition, results of operations or cash flows. However, the resolution of one or more of the Other Lawsuits in any reporting period, could have a material adverse impact on the Company's financial results for that period. The Company is not able to estimate the amount or range of any loss for legal contingencies related to the Other Lawsuits for which there is no reserve or additional loss for matters already reserved.

The Company is subject to various environmental laws and regulations both within and outside of the United States. The Company's operations, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While it is difficult to quantify the potential impact of continuing compliance with environmental protection laws, management believes that such compliance will not have a material impact on the Company's financial results. The Company's threshold of disclosing material environmental legal proceedings involving a governmental authority where potential monetary exposure is involved is $1 million.

19. SEGMENT INFORMATION

The Company conducts operations worldwide and is managed in the following geographical regions: United States, Europe, Japan, and Rest of World. All regions sell products that are used to treat advanced cardiovascular disease.

The Company's geographic segments are reported based on the financial information provided to the Chief Operating Decision Maker (the Chief Executive Officer). The Company evaluates the performance of its geographic segments based on net sales and operating income. The accounting policies of the segments are substantially the same as those described in Note 2. Segment net sales and segment operating income are based on internally derived standard foreign exchange rates, which may differ from year to year, and do not include inter-segment profits. Because of the interdependence of the reportable segments,

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. SEGMENT INFORMATION (Continued)

the operating profit as presented may not be representative of the geographical distribution that would occur if the segments were not interdependent. Net sales by geographic area are based on the location of the customer.

Certain items are maintained at the corporate level and are not allocated to the segments. The non-allocated items include net interest expense, global marketing expenses, corporate research and development expenses, manufacturing variances, corporate headquarters costs, special gains and charges, stock-based compensation, foreign currency hedging activities, certain litigation costs, changes in the fair value of contingent consideration liabilities, and most of the Company's amortization expense. Although most of the Company's depreciation expense is included in segment operating income, due to the Company's methodology for cost build-up, it is impractical to determine the amount of depreciation expense included in each segment, and, therefore, a portion is maintained at the corporate level. The Company neither discretely allocates assets to its operating segments, nor evaluates the operating segments using discrete asset information.

The table below presents information about Edwards Lifesciences' reportable segments (in millions):

	Years Ended December 31,		
	2020	2019	2018
Segment Net Sales			
United States	$ 2,516.8	$ 2,532.7	$ 2,055.2
Europe	945.2	926.1	826.4
Japan	448.6	441.4	398.4
Rest of World	451.5	433.3	396.0
Total segment net sales	$ 4,362.1	$ 4,333.5	$ 3,676.0
Segment Operating Income			
United States	$ 1,727.3	$ 1,742.3	$ 1,368.1
Europe	479.3	472.0	394.8
Japan	286.4	272.3	237.0
Rest of World	150.1	127.9	115.6
Total segment operating income	$ 2,643.1	$ 2,614.5	$ 2,115.5

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. SEGMENT INFORMATION (Continued)

The table below presents reconciliations of segment net sales to consolidated net sales and segment operating income to consolidated income before provision for income taxes ("pre-tax income") (in millions):

	Years Ended December 31,		
	2020	2019	2018
Net Sales Reconciliation			
Segment net sales	$ 4,362.1	$ 4,333.5	$ 3,676.0
Foreign currency	24.2	14.5	46.8
Consolidated net sales	$ 4,386.3	$ 4,348.0	$ 3,722.8
Pre-tax Income Reconciliation			
Segment operating income	$ 2,643.1	$ 2,614.5	$ 2,115.5
Unallocated amounts:			
Corporate items	(1,358.0)	(1,439.7)	(1,058.1)
Special charges	—	(64.6)	(116.2)
Intellectual property litigation expenses, net	(405.4)	(33.4)	(214.0)
Change in fair value of contingent consideration liabilities, net	(13.6)	6.1	5.7
Foreign currency	31.5	63.9	15.3
Consolidated operating income	897.6	1,146.8	748.2
Non-operating income	19.1	19.7	13.2
Consolidated pre-tax income	$ 916.7	$ 1,166.5	$ 761.4

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. SEGMENT INFORMATION (Continued)

Enterprise-Wide Information

Enterprise-wide information is based on actual foreign exchange rates used in the Company's consolidated financial statements.

	As of or for the Years Ended December 31,		
	2020	2019	2018
	(in millions)		
Net Sales by Geographic Area			
United States	$ 2,516.8	$ 2,532.7	$ 2,055.3
Europe	973.6	941.2	885.1
Japan	460.1	444.7	396.8
Rest of World	435.8	429.4	385.6
	$ 4,386.3	$ 4,348.0	$ 3,722.8
Net Sales by Major Product Area			
Transcatheter Aortic Valve Replacement	$ 2,857.3	$ 2,737.9	$ 2,283.8
Transcatheter Mitral and Tricuspid Therapies	41.8	28.2	2.9
Surgical Structural Heart	761.8	841.7	761.6
Critical Care	725.4	740.2	674.5
	$ 4,386.3	$ 4,348.0	$ 3,722.8
Long-lived Tangible Assets by Geographic Area			
United States	$ 1,084.3	$ 849.1	$ 642.1
Europe	192.7	101.5	36.6
Japan	20.4	21.7	6.7
Rest of World	311.0	269.4	214.4
	$ 1,608.4	$ 1,241.7	$ 899.8

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

20. QUARTERLY FINANCIAL RESULTS AND MARKET FOR THE COMPANY'S STOCK (UNAUDITED)

Years Ended December 31,	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(in millions, except per share data)				
2020					
Net sales	$ 1,128.7	$ 925.0	$ 1,140.9	$ 1,191.7	$ 4,386.3
Gross profit	863.6	686.8	859.9	895.4	3,305.7
Net income (loss) (a)	310.6	(121.9)	325.2	309.5	823.4
Earnings (loss) per common share (a):					
Basic	0.50	(0.20)	0.52	0.50	1.32
Diluted	0.49	(0.20)	0.52	0.49	1.30
Market price:					
High	$ 81.90	$ 78.43	$ 87.79	$ 92.08	$ 92.08
Low	51.51	56.44	66.87	70.92	51.51
2019					
Net sales	$ 993.0	$ 1,086.9	$ 1,094.0	$ 1,174.1	$ 4,348.0
Gross profit	761.2	782.9	801.6	887.9	3,233.6
Net income (b)	249.7	242.3	274.7	280.2	1,046.9
Earnings per common share (b):					
Basic	0.40	0.39	0.44	0.45	1.68
Diluted	0.39	0.38	0.43	0.44	1.64
Market price:					
High	$ 65.95	$ 65.00	$ 76.06	$ 82.55	$ 82.55
Low	46.95	55.23	61.00	71.08	46.95

(a) The second quarter of 2020 includes a $367.9 million charge related to a litigation settlement.

(b) The first quarter of 2019 includes a $24.0 million charge related to the acquisition of early-stage transcatheter intellectual property and associated clinical and regulatory experience. The second and third quarters of 2019 include a $46.2 million and $26.9 million charge, respectively, related to the write off of inventory. The fourth quarter of 2019 includes a $40.6 million charge related to the impairment of certain in-process research and development assets.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

21. VALUATION AND QUALIFYING ACCOUNTS

	Balance at Beginning of Period	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Deductions	Balance at End of Period
			(in millions)		
Year ended December 31, 2020					
Allowance for doubtful accounts (a)	$ 14.7	$ 3.1	$ —	$ (1.4)	$ 16.4
Tax valuation allowance (b)	64.0	6.3	0.6	(1.1)	69.8
Year ended December 31, 2019					
Allowance for doubtful accounts (a)	$ 13.6	$ 4.7	$ 0.2	$ (3.8)	$ 14.7
Tax valuation allowance (b)	44.9	18.9	0.2	—	64.0
Year ended December 31, 2018					
Allowance for doubtful accounts (a)	$ 13.7	$ 2.2	$ 1.0	$ (3.3)	$ 13.6
Tax valuation allowance (b)	41.6	7.1	(1.8)	(2.0)	44.9

(a) The deductions related to allowances for doubtful accounts represent accounts receivable which are written off.

(b) The tax valuation allowances are provided for other-than-temporary impairments and unrealized losses related to certain investments that may not be recognized due to the uncertainty of the ready marketability of certain impaired investments, and net operating loss and credit carryforwards that may not be recognized due to insufficient taxable income.

22. SUBSEQUENT EVENT

In February 2021, Edwards entered into an ASR agreement to repurchase $250.0 million of the Company's common stock based on the volume-weighted average price ("VWAP") of the Company's common stock during the term of the agreements, less a discount. Upon entering into the agreement, Edwards received an initial delivery of 2.4 million shares, representing approximately 80% of the shares to be repurchased. At the termination of the ASR, Edwards may receive additional shares or may be required to pay additional cash or shares (at the Company's election). The final settlement is based on the VWAP over the term of the agreement, less a discount. The ASR agreement has a scheduled termination date of March 18, 2021.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. The Company's management, including the Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2020.

Based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded as of December 31, 2020 that the Company's disclosure controls and procedures are designed at a reasonable assurance level and are effective in providing reasonable assurance that the information required to be disclosed by the Company in the reports it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting. The Company's management, including the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, the Company's management concluded that its internal control over financial reporting was effective as of December 31, 2020. The effectiveness of the Company's internal control over financial reporting as of December 31, 2020 has been audited by PricewaterhouseCoopers LLP, the independent registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K, as stated in their report which appears herein.

Changes in Internal Control Over Financial Reporting. There have been no changes in the Company's internal control over financial reporting that occurred during the Company's fourth fiscal quarter of 2020 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. We have not experienced any material impact to our internal control over financial reporting despite the fact that many of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the potential impact of COVID-19 on our internal controls to minimize the impact on their design and operating effectiveness.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Certain information required by this Item will be set forth under the headings "Board of Directors Matters—Proposal 1 - Election of Directors—Board of Director Nominees," "Board of Directors Matters—Corporate Governance Policies and Practices," and "Executive Compensation and Other Information—Executive Officers" in the definitive proxy statement to be filed in connection with the Company's 2021 Annual Meeting of Stockholders (the "Proxy Statement") (which Proxy Statement will be filed with the SEC within 120 days of December 31, 2020). The information required by this Item to be contained in the Proxy Statement is incorporated herein by reference. The Company has adopted a code of ethics that applies to all directors and employees, including the Company's principal executive officer, principal financial officer, and principal accounting officer, or persons performing similar functions. The code of ethics (business practice standards) is posted on the Company's website, which is found at www.edwards.com under "Investors—Corporate governance—Corporate responsibility—Global Integrity Program." To the extent required by applicable rules of the SEC and the New York Stock Exchange, the Company intends to disclose on its website any amendments to, or waivers from, any provision of its code of ethics that apply to the Company's directors and executive officers, including the principal executive officer, principal financial officer or controller or persons performing similar functions.

Item 11. Executive Compensation

The information contained under the heading "Executive Compensation and Other Information" in the Proxy Statement is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information contained under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the Proxy Statement is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information contained under the heading "Other Matters and Business—Related Persons Transactions" and under the heading "Corporate Governance Policies and Practices—Director Independence" in the Proxy Statement is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information contained under the headings "Audit Matters—Fees Paid to Principal Accountants" and "Audit Matters—Pre-Approval of Services" in the Proxy Statement is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this report:

1. Consolidated Financial Statements. See “Index to Consolidated Financial Statements” in Part II, Item 8 herein.

2. Financial Statement Schedules. Other schedules are not applicable and have not been included herein.

3. Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Edwards Lifesciences Corporation, dated May 16, 2013 (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences' report on Form 8-K filed on May 17, 2013)
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Edwards Lifesciences Corporation, dated May 7, 2020 (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences’ report on Form 8-K filed on May 8, 2020)
3.3	Bylaws of Edwards Lifesciences Corporation, as amended and restated as of February 25, 2016 (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences' report on Form 8-K filed on March 2, 2016)
4.1	Specimen form of certificate representing Edwards Lifesciences Corporation common stock (incorporated by reference to Exhibit 4.1 in Edwards Lifesciences' Registration Statement on Form 10 (File No. 001-15525) filed on March 15, 2000)
+4.2	Description of Edwards Lifesciences Corporation's Capital Stock
4.3	Indenture, dated as of September 6, 2013, between Edwards Lifesciences Corporation and Wells Fargo Bank, National Association, as trustee (incorporated by reference to Exhibit 4.5 in Edwards Lifesciences' Registration Statement on Form S-3 (File No. 333-191022) filed on September 6, 2013) (the "Indenture")
4.4	First Supplemental Indenture, dated as of October 3, 2013, to the Indenture (incorporated by reference to Exhibit 4.1 in Edwards Lifesciences' report on Form 8-K filed on October 3, 2013)
4.5	Second Supplemental Indenture, dated as of June 15, 2018, to the Indenture (incorporated by reference to Exhibit 4.2 in Edwards Lifesciences' report on Form 8-K filed on June 15, 2018) ("Second Supplemental Indenture")
4.6	Form of Global Note for the 4.300% Senior Notes due 2028 (incorporated by reference to Exhibit A in the Second Supplemental Indenture filed as Exhibit 4.2 in Edwards Lifesciences' report on Form 8-K filed on June 15, 2018)
10.1	Five-Year Credit Agreement, dated as of April 30, 2018, among Edwards Lifesciences Corporation and certain of its subsidiaries, as Borrowers, the lenders signatory thereto, Bank of America, N.A., as Administrative Agent, JPMorgan Chase Bank, N.A., as Syndication Agent, and Morgan Stanley MUFG Loan Partners, LLC, Deutsche Bank Securities Inc., HSBC Bank USA, National Association, and Wells Fargo Bank, National Association, as Co-Documentation Agents (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 8-K filed on April 30, 2018)
#10.2	Settlement Agreement, dated May 19, 2014, between Edwards Lifesciences Corporation and Medtronic, Inc. (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2014)
*10.3	Edwards Lifesciences Corporation Form of Employment Agreement (incorporated by reference to Exhibit 10.8 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003)
*10.4	Edwards Lifesciences Corporation Amended and Restated Employment Agreement for Michael A. Mussallem, dated March 30, 2009 (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2009)
*10.5	Edwards Lifesciences Corporation Amended and Restated Chief Executive Officer Change-in-Control Severance Agreement, dated October 9, 2012 (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended September 30, 2012)
*10.6	Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended September 30, 2012)
*10.7	Edwards Lifesciences Corporation 2018 Edwards Incentive Plan (incorporated by reference to Exhibit 10.7 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2018)
*10.8	Edwards Lifesciences Corporation Long-Term Stock Incentive Compensation Program, as amended and restated as of May 7, 2020 (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2020)

Exhibit No.	Description
*10.9	Edwards Lifesciences Corporation Form of Participant Stock Option Statement and related Long-Term Stock Program Global Nonqualified Stock Option Award Agreement for awards granted prior to May 2015 (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2011)
*10.10	Edwards Lifesciences Corporation Form of Participant Restricted Stock Unit Statement and related Long-Term Stock Program Global Restricted Stock Unit Award Agreement for awards granted prior to May 2015 (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2011)
*10.11	Edwards Lifesciences Corporation Form of Long-Term Stock Incentive Compensation Program Global Nonqualified Stock Option Award Agreement for awards granted beginning May 2015 (incorporated by reference to Exhibit 10.3 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2015)
*10.12	Edwards Lifesciences Corporation Form of Long-Term Stock Incentive Compensation Program Global Restricted Stock Unit Award Agreement for awards granted beginning May 2015 (incorporated by reference to Exhibit 10.4 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2015)
*10.13	Edwards Lifesciences Corporation Form of Performance-Based Restricted Stock Unit Award Statement and related Long-Term Stock Program Global Performance-Based Restricted Stock Unit Award Agreement for awards granted beginning May 2015 (incorporated by reference to Exhibit 10.5 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2015)
*10.14	Edwards Lifesciences Corporation Nonemployee Directors Stock Incentive Program, as amended and restated as of February 25, 2016 (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2016)
*10.15	Edwards Lifesciences Corporation 2020 Nonemployee Directors Stock Incentive Program (incorporated by reference to Appendix B in Edwards Lifesciences' Definitive Proxy Statement filed on March 25, 2020)
+*10.16	Edwards Lifesciences Corporation Form of Participant Stock Option Statement and related Nonemployee Directors Stock Incentive Program Nonqualified Stock Option Award Agreement
+*10.17	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Units Agreement
+*10.18	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Agreement
*10.19	Edwards Lifesciences Corporation Executive Deferred Compensation Plan, as amended and restated effective as of November 9, 2011 (incorporated by reference to Exhibit 10.7 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2011)
*10.20	Edwards Lifesciences Corporation Officer Perquisite Program Guidelines, as of February 20, 2013 (incorporated by reference to Exhibit 10.25 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2012)
*10.21	Edwards Lifesciences Corporation Form of Indemnification Agreement (incorporated by reference to Exhibit 10.20 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2011)
21.1	Subsidiaries of Edwards Lifesciences Corporation
23	Consent of Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
+32	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

Pursuant to a request for confidential treatment, confidential portions of this exhibit have been redacted and have been filed separately with the Securities and Exchange Commission
* Represents management contract or compensatory plan
+ Furnished herewith

Table of Contents

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EDWARDS LIFESCIENCES CORPORATION

February 12, 2021 By: /s/ MICHAEL A. MUSSALLEM

Michael A. Mussallem
Chairman of the Board and
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ MICHAEL A. MUSSALLEM Michael A. Mussallem	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	February 12, 2021
/s/ SCOTT B. ULLEM Scott B. Ullem	Corporate Vice President, Chief Financial Officer (Principal Financial Officer)	February 12, 2021
/s/ ROBERT W.A. SELLERS Robert W.A. Sellers	Vice President, Corporate Controller (Principal Accounting Officer)	February 12, 2021
/s/ KIERAN T. GALLAHUE Kieran T. Gallahue	Director	February 12, 2021
/s/ LESLIE S. HEISZ Leslie S. Heisz	Director	February 12, 2021
/s/ PAUL A. LAVIOLETTE Paul A. LaViolette	Director	February 12, 2021
/s/ WILLIAM J. LINK, PH.D. William J. Link, Ph.D.	Director	February 12, 2021
/s/ STEVEN R. LORANGER Steven R. Loranger	Director	February 12, 2021
/s/ MARTHA H. MARSH Martha H. Marsh	Director	February 12, 2021
/s/ RAMONA SEQUEIRA Ramona Sequeira	Director	February 12, 2021
/s/ NICHOLAS J. VALERIANI Nicholas J. Valeriani	Director	February 12, 2021

Exhibit 4.2

DESCRIPTION OF CAPITAL STOCK

References to "we," "us" and "our" refer to Edwards Lifesciences Corporation.

General

This section summarizes the rights of our capital stock, certain provisions of our amended and restated certificate of incorporation, as amended (our "certificate of incorporation"), and our bylaws, as amended and restated (our "bylaws"), and certain provisions of applicable law. The following description is only a summary and is qualified by reference to our certificate of incorporation and our bylaws, each of which is incorporated by reference as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission.

Authorized Capitalization

Our authorized capital stock consists of:

- 1,050,000,000 shares of common stock, with a par value of $1.00 per share; and
- 50,000,000 shares of preferred stock, with a par value of $0.01 per share, of which 3,500,000 shares have been designated as "Series A Junior Participating Preferred Stock."

As of December 31, 2020, 636.4 million shares of our common stock were issued and 624.3 million shares of our common stock were outstanding, and no shares of our preferred stock were issued and outstanding. As of December 31, 2020, we also had approximately 336 million shares of our common stock reserved to be issued upon exercise of outstanding stock options and restricted stock units granted to employees and directors.

Common Stock

The holders of our common stock are entitled to one vote for each share on all matters submitted to a vote of stockholders and do not have cumulative voting rights with respect to the election of directors. Holders of our common stock are entitled to receive ratably such dividends as may be declared from time to time by our board of directors out of legally available assets. In the event of our liquidation, dissolution or winding up, holders of common stock are entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any amounts due to any holders of preferred stock. Holders of our common stock have no preemptive or conversion rights. No redemption or sinking fund provisions apply to our common stock. The rights, preferences and privileges of holders of our common stock are subject to the rights of the holders of shares of any series of preferred stock which we may issue. All of our outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our board of directors has the authority, without stockholder approval, to issue up to 50,000,000 shares of our preferred stock in one or more series and to determine, with respect to any such series, the powers, preferences and rights of the shares of such series, and the qualifications, limitations and restrictions thereof, including, without limitation, voting rights, dividend rights, conversion rights, terms of redemption, liquidation preference, sinking fund terms and the number of shares constituting any series and the designation thereof.

Our board of directors can issue, without stockholder approval, preferred stock with voting and conversion rights that could adversely affect the voting power of the holders of common stock and reduce the likelihood that such holders will receive dividend payments or payments upon liquidation. Such issuance could have the effect of decreasing the market price of the common stock. The issuance of preferred stock or even the ability to issue preferred stock could also have the effect of delaying, deterring or preventing a change of control or other corporate action.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaw Provisions

Our certificate of incorporation and bylaws contain certain provisions that may make it more difficult to acquire control of us by means of a tender offer, open market purchase, proxy fight or otherwise. These provisions and certain provisions of Delaware law are expected to discourage coercive takeover practices and inadequate takeover bids.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, could deprive stockholders of opportunities to realize takeover premiums for their shares.

Set forth below is a summary of the relevant provisions of our certificate of incorporation and bylaws and certain applicable sections of the General Corporation Law of the State of Delaware. For additional information we refer you to the provisions of our certificate of incorporation, our bylaws and those sections of the General Corporation Law of the State of Delaware.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware regulating corporate takeovers. In general, Section 203, subject to certain exceptions, prohibits a publicly-held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that such person or entity became an interested stockholder, unless:

- prior to that date, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding specified shares; or
- at or subsequent to that date of the transaction that resulted in a person or entity becoming an interested stockholder, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 662⁄3% of the outstanding voting stock that is not owned by the interested stockholder.

The application of Section 203 may limit the ability of stockholders to approve a transaction that they may deem to be in their best interests. In addition, Section 203 makes it more difficult for an interested stockholder to effect various business combinations with a corporation for a three-year period, although the stockholders may, by adopting an amendment to our certificate of incorporation or bylaws, elect not to be governed by this section, effective 12 months after adoption.

In general, Section 203 defines “business combination” as:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation to or with the interested stockholder;
- subject to certain exceptions, any transaction which results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any person that is:

- the owner of 15% or more of the outstanding voting stock of the corporation;
- an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of the corporation at any time within three years immediately prior to the relevant date; or
- an affiliate or associate of the above.

Our certificate of incorporation and bylaws do not exclude us from the restrictions imposed under Section 203. We anticipate that the provisions of Section 203 may encourage companies interested in acquiring us to negotiate in advance with our board of directors because the stockholder approval requirement would be avoided if a majority of the directors then in office approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder.

Our Board of Directors

Our certificate of incorporation provides that the number of directors may be fixed from time to time by the board of directors, subject to the rights of holders of shares of any series of preferred stock to elect additional directors under specific circumstances. The size of our board of directors is currently fixed at eight directors. Each elected director holds office until his or her successor is duly elected and qualified, or until his or her earlier death, resignation, disqualification or removal.

Our certificate of incorporation and bylaws do not authorize cumulative voting with regard to the election of directors.

Board Vacancies

Our certificate of incorporation and bylaws provide that any vacancy in our board of directors may be filled only by a majority of the directors then in office, though less than a quorum, or by our sole remaining director. Each director so elected shall hold office until his or her successor is duly elected and qualified, or until his or her earlier death, resignation, disqualification or removal.

Advance Notice Requirements for Stockholder Proposals and Director Nominees

Our bylaws provide that stockholders seeking to make nominations of candidates for election as directors, or to bring other business before an annual or special meeting of the stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice must be delivered to and received at our principal executive offices not less than 90 days nor more than 120 days prior to the meeting. However, in the event that the date of the annual meeting is more than 25 days before or more than 25 days after the first anniversary date of the preceding year's annual meeting, or in the event of a special meeting of stockholders called for the purpose of electing directors, a stockholder's notice must be delivered to our principal executive offices not later than the close of business on the 10th day following the earlier of the date on which such notice of the date of the meeting was mailed or such public disclosure of the date of the meeting was made. Our bylaws also specify certain requirements as to the form and content of a stockholder's notice. These provisions may restrict the ability of our stockholders to bring business before our annual meeting of stockholders or to make nominations for directors at our annual meeting or any special meeting of stockholders.

Proxy Access

Our bylaws permit an eligible stockholder or group of stockholders to include up to a specified number of director nominees in our proxy materials for an annual meeting of stockholders. To qualify, the stockholders (or group of up to thirty stockholders) must have continuously owned for at least three years 3% or more of our

outstanding shares of capital stock. The maximum number of stockholder nominees permitted under the proxy access provisions of our bylaws is generally the greater of (i) two or (ii) 20% of the total number of our directors in office as of the last day on which notice of a nomination may be delivered.

Notice of a nomination under our proxy access bylaw provisions must generally be submitted to our principal executive offices not less than 120 days nor more than 150 days prior to the first anniversary of the date that we first mailed our proxy statement to stockholders for the immediately preceding annual meeting of stockholders. The notice must contain certain information specified in our bylaws.

Blank Check Preferred Stock

Our certificate of incorporation provides that our board of directors can issue, without stockholder approval, up to 50,000,000 shares of our preferred stock in one or more series and to determine, with respect to any such series, the powers, preferences and rights of the shares of such series, and the qualifications, limitations and restrictions thereof, including, without limitation, voting rights, dividend rights, conversion rights, terms of redemption, liquidation preference, sinking fund terms and the number of shares constituting any series and the designation thereof.

Stockholder Action by Written Consent

Our certificate of incorporation provides that all actions requiring the vote or consent of stockholders must be taken at a regular or special meeting of stockholders and cannot be taken by written consent without a meeting.

Choice of Forum

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be, to the fullest extent permitted by law, the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision is intended to apply to claims arising under Delaware state law and would not apply to claims brought pursuant to the Securities Exchange Act of 1934 or Securities Act of 1933, or any other claim for which the federal courts have exclusive jurisdiction.

Transfer Agent and Registrar

Computershare is the transfer agent and registrar for our common stock.

Listing

Our common stock is listed on the NYSE under the symbol “EW.”

Exhibit 10.16

Participant Stock Option Statement

Name:

Date of Grant:	**Option Price:**
Date of Expiration:	**Number of Shares Covered:**

Vesting Schedule

This certifies that on _____, Edwards Lifesciences Corporation granted to the Participant shown above a Nonqualified Stock Option to purchase shares of its common stock as indicated above upon the terms and conditions of the Nonemployee Directors Stock Incentive Program and the attached Nonqualified Stock Option Award Agreement (the "Award Agreement"). The Award Agreement imposes additional limitations on the Participant's rights under the Option and provides for early termination of the Option (before the Expiration Date set forth above) in the event of termination of the Participant's Directorship.

Edwards Lifesciences Corporation

By



Michael A. Mussallem
Chairman and Chief Executive Officer

Edwards Lifesciences Corporation
Nonemployee Directors Stock Incentive Program
Nonqualified Stock Option Award Agreement

THIS AGREEMENT, in conjunction with the Participant Stock Option Statement attached to the front of this agreement (the "Statement") effective as of the Date of Grant set forth on the Statement, represents the grant of a nonqualified stock option (the "Option") by Edwards Lifesciences Corporation, a Delaware corporation (the "Company"), to the Participant named on the Statement, pursuant to the provisions of the Nonemployee Directors Stock Incentive Program (the "Program"). This agreement and the Statement shall be considered one agreement and are referred to herein as the "Agreement."

The Program provides additional terms and conditions governing the Option. If there is any inconsistency between the terms of this Agreement and the terms of the Program, the Program's terms shall completely supersede and replace the conflicting terms of this Agreement. All capitalized terms shall have the meanings ascribed to them in the Program, unless specifically set forth otherwise herein. The parties hereto agree as follows:

1. Grant of Stock Option. The Company hereby grants to the Participant an Option to purchase the number of Shares set forth on the Statement, at the stated Option Price set forth on the Statement, which is one hundred percent (100%) of the Fair Market Value of a Share on the Date of Grant, in the manner and subject to the terms and conditions of the Program and this Agreement.

The grant of this Option to the Participant shall not confer any right to such Participant (or any other Participant) to be granted any Option or other Awards in the future under the Program.

2. Exercise of Stock Option. Except as may otherwise be provided in Sections 3 and 4 below, the Participant may only exercise this Option according to the vesting schedule set forth on the Statement, provided that no exercise may occur subsequent to the close of business on the Date of Expiration (as set forth on the Statement).

The number of Shares for which this Option becomes vested and exercisable pursuant to this Section 2 shall be rounded up to the next whole number in the event that the use of the percentages set forth on the Statement results in the Option being exercisable with respect to a fractional Share. In addition, the Option may be exercised in whole or in part, but not for less than fifty (50) Shares at any one time, unless fewer than fifty (50) Shares then remain subject to the Option, and the Option is then being exercised as to all such remaining Shares.

3. Termination of Directorship:

(a) ***By Death or Disability***: All unvested Shares under this Option shall immediately vest and become exercisable as of the Participant's date of termination of service by death or Disability. Shares under this Option that vest and become exercisable in accordance with this Section 3(a) or that are already vested and exercisable as of the Participant's date of termination by reason of death or Disability, may be purchased only until the earlier of: (i) the Date of Expiration of this Option; or (ii) the third (3rd) anniversary of the Participant's date of termination by reason of death or Disability.

(b) For Other Reasons: Unless determined otherwise by the Committee or its designee in their sole discretion, all unvested Shares under this Option shall immediately terminate and be forfeited to the Company as of the date of the Participant's termination of service for any reason other than the reasons set forth in Section 3(a) above. Shares under this Option that are vested and exercisable as of the date of a termination of service for any reason other than those reasons set forth in Section 3(a) above may be purchased until the earlier of: (i) the Date of Expiration of this Option; or (ii) the third (3rd) anniversary of the Participant's date termination of service.

4. Change in Control. Notwithstanding anything to the contrary in this Agreement, in the event of a Change in Control of the Company prior to the Participant's termination of service for any reason, all Shares under this Option shall immediately vest and become exercisable in full.

5. Restrictions on Transfer. This Option may not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated, other than by will or by the laws of descent and distribution. Further, this Option shall be exercisable during the Participant's lifetime only by the Participant or the Participant's legal representative.

6. Recapitalization. In the event there is any change in the Company's Shares through the declaration of stock dividends or through recapitalization resulting in stock split-ups or through merger, consolidation, exchange of Shares, or otherwise, the number and class of Shares subject to this Option, as well as the Option Price, shall be equitably adjusted by the Committee, in the manner determined in its sole discretion, to prevent dilution or enlargement of rights.

7. Procedure for Exercise of Option. This Option may be exercised by delivery of written notice (or such other form of notice as the Company may specify) to the Company at its executive offices, addressed to the attention of its Secretary or the Company's designee. Such notice: (a) shall be signed by the Participant or his or her legal representative (or assented to in a form other than written signature if and to the extent that the Company specifies); (b) shall specify the number of full Shares then elected to be purchased with respect to the Option; (c) if a Registration Statement under the Securities Act of 1933 is not in effect with respect to the Shares to be purchased, shall contain a representation of the Participant that the Shares are being acquired by him or her for investment and with no present intention of selling or transferring them, and that he or she will not sell or otherwise transfer the Shares except in compliance with all applicable securities laws and requirements of any stock exchange upon which the Shares may then be listed; and (d) shall be accompanied by payment in full of the Option Price of the Shares to be purchased (or a satisfactory "cashless exercise" notice).

The Option Price upon exercise of this Option shall be payable to the Company in full either: (a) in cash or its equivalent (acceptable cash equivalents shall be determined at the sole discretion of the Committee); (b) by tendering previously acquired Shares (by either actual delivery or attestation) having an aggregate Fair Market Value at the time of exercise equal to the total Option Price; (c) by a "cashless exercise" to the extent permitted under Federal Reserve Board's Regulation T and other applicable law, and subject to such procedures and limitations as the Company may specify from time to time; (d) by any other means which the Committee determines to be consistent with the Program's purpose and applicable law; or (e) by a combination of two or more of (a) through (d).

As promptly as practicable after receipt of notice and payment upon exercise (or satisfactory "cashless exercise" notice) and subject to any Company "cashless exercise" procedures, the Company shall cause to be issued and delivered to the Participant in certificate form or otherwise, evidence of the Shares so purchased, which may, if appropriate, be endorsed with or otherwise include appropriate restrictive legends. The Company shall maintain a record of all information pertaining to the Participant's rights under this Agreement, including the number of Shares for which the Option is exercisable. If the Option shall have been exercised in full, this Agreement shall be returned to the Company and canceled.

8. Beneficiary Designation. The Participant may, from time to time, name any beneficiary or beneficiaries (who may be named contingently or successively) to whom any benefit under this Agreement is to be paid in case of his or her death before he or she receives any or all of such benefit. Each such designation shall revoke all prior designations by the Participant, shall be in a form prescribed by the Company, and will be effective only when filed by the Participant in writing with the Secretary of the Company during the Participant's lifetime. In the absence of any such designation, benefits remaining unpaid at the Participant's death shall be paid to the Participant's estate.

9. Rights as a Stockholder. The Participant shall have no rights as a stockholder of the Company with respect to the Shares subject to this Agreement until such time as the purchase price has been paid, and the Shares have been issued and delivered to him or her.

10. Continuation of Service. This Agreement shall not confer upon the Participant any right to continue providing services to the Company or to be nominated to the Board, nor shall this Agreement interfere in any way with the Company's right to terminate the Participant's service at any time.

11. Miscellaneous.

(a) This Agreement and the rights of the Participant hereunder are subject to all the terms and conditions of the Program, as the same may be amended from time to time, as well as to such rules and regulations as the Committee may adopt for administration of the Program. The Committee shall have the right to impose such restrictions on any Shares acquired pursuant to the exercise of this Option, as it may deem advisable for regulatory compliance, including, without limitation, restrictions under applicable federal securities laws, under the requirements of any stock exchange or market upon which such Shares are then listed and/or traded, and under any blue sky or state securities laws applicable to such Shares. It is expressly understood that the Committee is authorized to administer, construe, and make all determinations necessary or appropriate to the administration of the Program and this Agreement, all of which shall be binding upon the Participant.

(b) The Board may terminate, amend, or modify the Program and the Committee may amend or modify this Option at any time; provided, however, that except for the Company's right to cash out this Option under certain circumstances pursuant to Section 6.10 of the Program, no such termination, amendment, or modification of the Program or amendment of this Option may in any material way adversely affect the Participant's rights under this Agreement, without the express consent of the Participant.

(c) The Company shall have the power and the right to deduct or withhold, or require the Participant to remit to the Company, an amount sufficient to satisfy all federal, state, local and foreign taxes required by law or regulations to be withheld with respect to any exercise of the Participant's rights under this Agreement.

The Participant may elect, subject to any procedural rules adopted by the Committee, to satisfy the minimum withholding requirement, in whole or in part, by having the Company withhold Shares having an aggregate Fair Market Value on the date the tax is to be determined, equal to or less than the minimum amount required to be withheld.

(d) The Participant agrees to take all steps necessary to comply with all applicable provisions of federal, state and foreign securities law in exercising his or her rights under this Agreement.

(e) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(f) All obligations of the Company under the Program and this Agreement, with respect to this Option, shall, to the extent legally permissible, be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

(g) To the extent not preempted by federal law, this Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware.

Accepted and agreed:

Company: Director:
Edwards Lifesciences Corporation

By: _____ _____

Exhibit 10.17

Edwards Lifesciences Corporation
Nonemployee Directors Stock Incentive Program
Restricted Stock Units Agreement

You have been selected to be a Participant in the Edwards Lifesciences Corporation Nonemployee Directors Stock Incentive Program (the "Program"), as specified below:

Participant:

Date of Grant:

Number of Restricted Stock Units Granted:

Vesting Date: The Restricted Stock Units shall vest on the date and in the amount listed below:

Vesting Date	Number of Units Which Vest

THIS AGREEMENT, effective as of the Date of Grant set forth above, represents the grant of Restricted Stock Units by Edwards Lifesciences Corporation, a Delaware corporation (the "Company"), to the Participant named above, pursuant to the provisions of the Program.

The Program provides additional terms and conditions governing the Restricted Stock Units. If there is any inconsistency between the terms of this Agreement and the terms of the Program, the Program's terms shall completely supersede and replace the conflicting terms of this Agreement. All capitalized terms shall have the meanings ascribed to them in the Program, unless specifically set forth otherwise herein. The parties hereto agree as follows:

1. Restricted Stock Units. The Participant is entitled to receive one Share for each Restricted Stock Unit, provided the Restricted Stock Units have not terminated.

2. Service to the Company. Except as may otherwise be provided in Sections 5 or 6, the Restricted Stock Units granted hereunder shall vest in full on the Vesting Date (as set forth above) provided the Participant remains a Nonemployee Director of the Company from the Date of Grant through (and including) such date.

This grant of Restricted Stock Units shall not confer any right to the Participant (or any other Participant) to be granted Restricted Stock Units or other Awards in the future under the Program.

3. Issuance of Shares. Except as may otherwise be provided herein and in the Program, the Shares issuable with respect to any Restricted Stock Units that have vested shall be issued as soon as administratively feasible following the Vesting Date applicable to such units. Any such issuance of Shares shall be subject to applicable Federal and state securities laws.

4. Shareholder Rights. The Participant shall not have any shareholder rights hereunder with respect to any Shares issuable until the Shares have been issued.

5. Termination of Directorship.

a) By Death or Disability: In the event the service of the Participant is terminated due to death or Disability, then the Restricted Stock Units held by the Participant at the time of his or her death or Disability shall immediately become fully vested.

b) Termination for Other Reasons: In the event of the Participant's termination of service with the Company for any reason other than death or Disability, all Restricted Stock Units held by the Participant at the time of service termination and still subject to vesting shall be forfeited by the Participant to the Company.

6. Change in Control. Notwithstanding anything to the contrary in this Agreement, in the event of a Change in Control of the Company prior to the Participant's termination of service, the Restricted Stock Units shall immediately become fully vested.

7. Nontransferability. Restricted Stock Units granted pursuant to this Agreement may not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated, other than by will or by the laws of descent and distribution, except as provided in the Program.

8. Restriction on Sale of Shares. Notwithstanding any other provision of the Program or this Agreement to the contrary, the Shares acquired upon vesting of the Restricted Stock Units (net of any Shares sold to cover applicable taxes due in connection with the settlement of the Restricted Stock Units) may not be sold, transferred or otherwise disposed of prior to the Participant's cessation of service as a Nonemployee Director of the Company.

9. Recapitalization. In the event there is any change in the Company's Shares through the declaration of stock dividends or through recapitalization resulting in stock split-ups or through merger, consolidation, exchange of Shares, or otherwise, the number and class of Restricted Stock Units subject to this Agreement shall be equitably adjusted by the Committee, in the manner determined in its sole discretion, to prevent dilution or enlargement of rights.

10. Tax Withholding. The Company shall have the power and the right to deduct or withhold, or require the Participant or beneficiary to remit to the Company, an amount sufficient to satisfy federal, state, and local taxes (including the Participant's FICA obligation), domestic or foreign, required by law or regulation to be withheld with respect to any taxable event arising as a result of this Agreement. The Participant may elect, subject to any procedural rules adopted by the Committee, to satisfy the minimum withholding tax requirement, in whole or in part, by having the Company withhold Shares having an aggregate Fair Market Value on the date the tax is to be determined, equal to or less than such minimum withholding tax.

11. Beneficiary Designation. The Participant may, from time to time, name any beneficiary or beneficiaries (who may be named contingently or successively) to whom any benefit under this Agreement is to be paid in case of his or her death before he or she receives any or all of such benefit. Each such designation shall revoke all prior designations by the Participant, shall be in a form prescribed by the Company, and will be effective only when filed by the Participant in writing with the Secretary of the Company during the Participant's lifetime. In the absence of any such designation, benefits remaining unpaid at the Participant's death shall be paid to the Participant's estate.

12. Continuation of Service. This Agreement shall not confer upon the Participant any right to continue providing services to the Company or to be nominated to the Board, nor shall this Agreement interfere in any way with the Company's right to terminate the Participant's service at any time.

13. Miscellaneous.

a) This Agreement and the rights of the Participant hereunder are subject to all the terms and conditions of the Program, as the same may be amended from time to time, as well as to such rules and regulations as the Committee may adopt for administration of the Program. The Committee shall have the right to impose such restrictions on any Shares acquired pursuant to this Agreement, as it may deem advisable for regulatory compliance, including, without limitation, restrictions under applicable Federal securities laws, under the requirements of any stock exchange or market upon which such Shares are then listed and/or

traded, and under any blue sky or state securities laws applicable to such Shares. It is expressly understood that the Committee is authorized to administer, construe, and make all determinations necessary or appropriate to the administration of the Program and this Agreement, all of which shall be binding upon the Participant.

b) The Board may terminate, amend or modify the Program and, the Committee may amend this Agreement; provided, however, that no such termination, amendment, or modification of the Program may in any material way adversely affect the Participant's rights under this Agreement, without the express consent of the Participant.

c) The Participant agrees to take all steps necessary to comply with all applicable provisions of federal, state and foreign securities law in exercising his or her rights under this Agreement.

d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

e) All obligations of the Company under the Program and this Agreement, with respect to the Restricted Stock Units, shall to the extent legally permissible, be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

f) To the extent not preempted by federal law, this Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware.

Accepted and agreed:

Company: Director:
Edwards Lifesciences Corporation

By: _____ _____

Exhibit 10.18

Edwards Lifesciences Corporation
Nonemployee Directors Stock Incentive Program
Restricted Stock Agreement

You have been selected to be a Participant in the Edwards Lifesciences Corporation Nonemployee Directors Stock Incentive Program (the "Program"), as specified below:

Participant:

Date of Grant:

Number of Shares of Restricted Stock Granted:

Lapse of Restrictions Dates: Restrictions placed on the Shares of Restricted Stock shall lapse on the date and in the amount listed below:

Date on Which Restrictions Lapse	Number of Shares for Which Restrictions Lapse	Cumulative Number of Shares for Which Restrictions Lapse

THIS AGREEMENT, effective as of the Date of Grant set forth above, represents the grant of Shares of Restricted Stock by Edwards Lifesciences Corporation, a Delaware corporation (the "Company"), to the Participant named above, pursuant to the provisions of the Program.

The Program provides additional terms and conditions governing the Restricted Stock. If there is any inconsistency between the terms of this Agreement and the terms of the Program, the Program's terms shall completely supersede and replace the conflicting terms of this Agreement. All capitalized terms shall have the meanings ascribed to them in the Program, unless specifically set forth otherwise herein. The parties hereto agree as follows:

1. Service to the Company. Except as may otherwise be provided in Sections 5 or 6, the Restricted Stock granted hereunder is granted on the condition that the Participant remains a Nonemployee Director of the Company from the Date of Grant through (and including) each of the separate Lapse of Restrictions Dates, as set forth above (each such time period is referred to herein as a "Period of Restriction").

This grant of Restricted Stock shall not confer any right to the Participant (or any other Participant) to be granted Restricted Stock or other Awards in the future under the Program.

2. Certificate Legend. Shares of Restricted Stock granted hereunder shall be registered in the name of the Participant and the Company shall cause to be issued and delivered to the Participant, in certificate form or otherwise, evidence of the purchased Shares of Restricted Stock. If such Shares are certificated, in the sole discretion of the Committee, such certificate may be deposited in a bank or with the Company. Each certificate representing Shares of Restricted Stock granted pursuant to the Program shall bear the following legend:

> "The sale or other transfer of the shares of stock represented by this certificate, whether voluntary, involuntary, or by operation of law is subject to certain restrictions on transfer set forth in the Edwards Lifesciences Corporation Nonemployee Directors Stock Incentive Program, rules of administration adopted pursuant to such Program, and a Restricted Stock Agreement dated May 8, 2020. A copy of the Edwards Lifesciences Corporation Nonemployee Directors Stock Incentive Program, such rules, and

such Restricted Stock Agreement may be obtained from the Secretary of Edwards Lifesciences Corporation."

3. Removal of Restrictions. Except as may otherwise be provided herein and in the Program, the Shares of Restricted Stock granted pursuant to this Agreement shall become freely transferable by the Participant on the day following the date and in the amount set forth under the Lapse of Restrictions Dates above, subject to applicable Federal and state securities laws. Once Shares of Restricted Stock are no longer subject to any Period of Restriction, the Participant shall be entitled to have the legend required by Section 2 of this Agreement removed from the applicable stock certificates; provided, however, one or more other legends may continue to apply, such as a legend pertaining to transfer restrictions imposed pursuant to Rule 144 of the Securities Act of 1933, as amended.

4. Voting Rights and Dividends. During the Period of Restriction, the Participant may exercise full voting rights and shall accrue all dividends and other distributions paid with respect to the Shares of Restricted Stock while they are held. If any such dividends or distributions are paid in Shares, such Shares shall be subject to the same restrictions on transferability as are the Shares of Restricted Stock with respect to which they were paid.

5. Termination of Directorship.

a) By Death or Disability: In the event the service of the Participant is terminated due to death or Disability during the Periods of Restriction, the Periods of Restriction and the restrictions imposed on the Shares of Restricted Stock held by the Participant at the time of his or her death or Disability shall immediately lapse with all such Shares becoming immediately transferable by the Participant or his or her estate, subject to applicable Federal and state securities laws.

b) Termination for Other Reasons: In the event of the Participant's termination of service with the Company for any reason other than death or Disability during the Periods of Restriction, all Shares of Restricted Stock held by the Participant at the time of service termination and still subject to a Period of Restriction and other restrictions shall be forfeited by the Participant to the Company.

6. Change in Control. Notwithstanding anything to the contrary in this Agreement, in the event of a Change in Control of the Company during the Periods of Restriction and prior to the Participant's termination of service, the Periods of Restriction and restrictions imposed on the Shares shall immediately lapse with all such Shares of Restricted Stock vesting and becoming freely transferable by the Participant, subject to applicable Federal and state securities laws.

7. Nontransferability. During the Periods of Restriction, Shares of Restricted Stock granted pursuant to this Agreement may not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated (a "Transfer"), other than by will or by the laws of descent and distribution, except as provided in the Program. If any Transfer, whether voluntary or involuntary, of unvested Shares of Restricted Stock is made, or if any attachment, execution, garnishment, or lien shall be issued against or placed upon the Shares of Restricted Stock, the Participant's right to such Shares of Restricted Stock shall be immediately forfeited by the Participant to the Company, and this Agreement shall lapse.

8. Recapitalization. In the event there is any change in the Company's Shares through the declaration of stock dividends or through recapitalization resulting in stock split-ups or through merger, consolidation, exchange of Shares, or otherwise, the number and class of Shares of Restricted Stock subject to this Agreement shall be equitably adjusted by the Committee, in the manner determined in its sole discretion, to prevent dilution or enlargement of rights.

9. Tax Withholding. The Company shall have the power and the right to deduct or withhold, or require the Participant or beneficiary to remit to the Company, an amount sufficient to satisfy federal, state, and local taxes (including the Participant's FICA obligation), domestic or foreign, required by law or regulation to be withheld with respect to any taxable event arising as a result of this Agreement. The Participant may elect, subject to any procedural rules adopted by the Committee, to satisfy the minimum withholding tax requirement, in whole or in part,

by having the Company withhold Shares having an aggregate Fair Market Value on the date the tax is to be determined, equal to such minimum withholding tax.

10. Beneficiary Designation. The Participant may, from time to time, name any beneficiary or beneficiaries (who may be named contingently or successively) to whom any benefit under this Agreement is to be paid in case of his or her death before he or she receives any or all of such benefit. Each such designation shall revoke all prior designations by the Participant, shall be in a form prescribed by the Company, and will be effective only when filed by the Participant in writing with the Secretary of the Company during the Participant's lifetime. In the absence of any such designation, benefits remaining unpaid at the Participant's death shall be paid to the Participant's estate.

11. Continuation of Service. This Agreement shall not confer upon the Participant any right to continue providing services to the Company or to be nominated to the Board, nor shall this Agreement interfere in any way with the Company's right to terminate the Participant's service at any time.

12. Special Tax Election.

a) Section 83(b) Election. Under Code Section 83, the excess of the Fair Market Value of the Shares of Restricted Stock on the date any forfeiture restrictions applicable to such Shares lapse over the price paid for those shares, if any, will be reportable as ordinary income on the lapse date. Participant may elect under Code Section 83(b) to be taxed at the time the Shares of Restricted Stock are acquired, rather than on the Lapse of Restrictions Dates. If Participant chooses to make an election under Code Section 83(b), such election must be filed with the Internal Revenue Service within thirty (30) days after the date of this Agreement.

b) Filing Responsibility**.** Participant acknowledges that, if Participant, chooses to file an election under Section 83(b), it is the Participant's sole responsibility, and not the Company's to file a timely election under Code Section 83(b), even if Participant requests the Company or its representatives to make this filing on his or her behalf.

13. Miscellaneous.

a) This Agreement and the rights of the Participant hereunder are subject to all the terms and conditions of the Program, as the same may be amended from time to time, as well as to such rules and regulations as the Committee may adopt for administration of the Program. The Committee shall have the right to impose such restrictions on any Shares acquired pursuant to this Agreement, as it may deem advisable for regulatory compliance, including, without limitation, restrictions under applicable Federal securities laws, under the requirements of any stock exchange or market upon which such Shares are then listed and/or traded, and under any blue sky or state securities laws applicable to such Shares. It is expressly understood that the Committee is authorized to administer, construe, and make all determinations necessary or appropriate to the administration of the Program and this Agreement, all of which shall be binding upon the Participant.

b) The Board may terminate, amend or modify the Program and, the Committee may amend this Agreement; provided, however, that no such termination, amendment, or modification of the Program may in any material way adversely affect the Participant's rights under this Agreement, without the express consent of the Participant.

c) The Participant agrees to take all steps necessary to comply with all applicable provisions of federal, state and foreign securities law in exercising his or her rights under this Agreement.

d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

e) All obligations of the Company under the Program and this Agreement, with respect to the Restricted Stock, shall to the extent legally permissible, be binding on any successor to the Company, whether the

existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

f) To the extent not preempted by federal law, this Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware.

Accepted and agreed:

Company: Director:
Edwards Lifesciences Corporation

By: _____ _____

Exhibit 21.1

The following is a list of subsidiaries of Edwards Lifesciences Corporation, omitting subsidiaries which, considered in the aggregate as a single subsidiary, would not constitute a significant subsidiary as of December 31, 2020:

Legal Entity		State of Incorporation/ Formation		Country of Incorporation/ Formation
Edwards Lifesciences LLC		Delaware		U.S.
Edwards Lifesciences SAS				France
Edwards Lifesciences Services GmbH				Germany
Edwards Lifesciences (Japan) Limited				Japan
Edwards Lifesciences Holding B.V.				The Netherlands
Edwards Lifesciences (Singapore) Pte Ltd				Singapore
Edwards Lifesciences AG				Switzerland

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-33054, 333-33056, 333-40434, 333-52334, 333-52346, 333-60670, 333-98219, 333-105961, 333-127260, 333-150810, 333-154242, 333-168462, 333-183106, 333-192229, 333-195853, 333-204180, 333-211333, and 333-217909) and Form S-3 (No. 333-232866) of Edwards Lifesciences Corporation of our report dated February 12, 2021 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Irvine, California
February 12, 2021

Exhibit 31.1

EDWARDS LIFESCIENCES CORPORATION
CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002
CERTIFICATION

I, Michael A. Mussallem, certify that:

1. I have reviewed this annual report on Form 10-K of Edwards Lifesciences Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ MICHAEL A. MUSSALLEM
Michael A. Mussallem
Chairman of the Board and Chief Executive Officer

February 12, 2021

Exhibit 31.2

EDWARDS LIFESCIENCES CORPORATION
CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002
CERTIFICATION

I, Scott B. Ullem, certify that:

1. I have reviewed this annual report on Form 10-K of Edwards Lifesciences Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ SCOTT B. ULLEM
Scott B. Ullem
Corporate Vice President,
Chief Financial Officer

February 12, 2021

Exhibit 32

EDWARDS LIFESCIENCES CORPORATION
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Edwards Lifesciences Corporation (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Michael A. Mussallem, Chairman of the Board and Chief Executive Officer of the Company, and Scott B. Ullem, Corporate Vice President, Chief Financial Officer, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

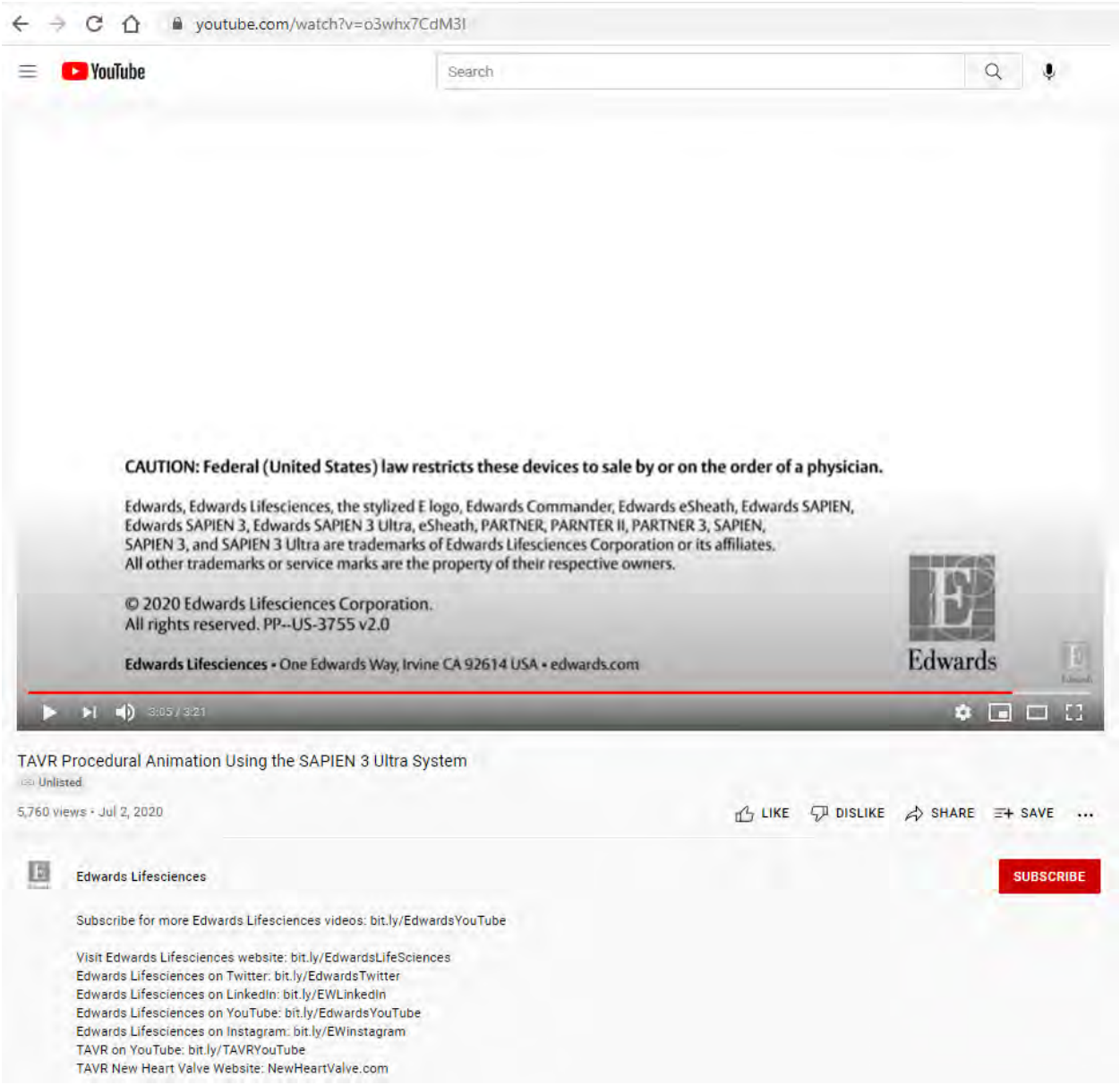
/s/ MICHAEL A. MUSSALLEM
Michael A. Mussallem
Chairman of the Board and Chief Executive Officer

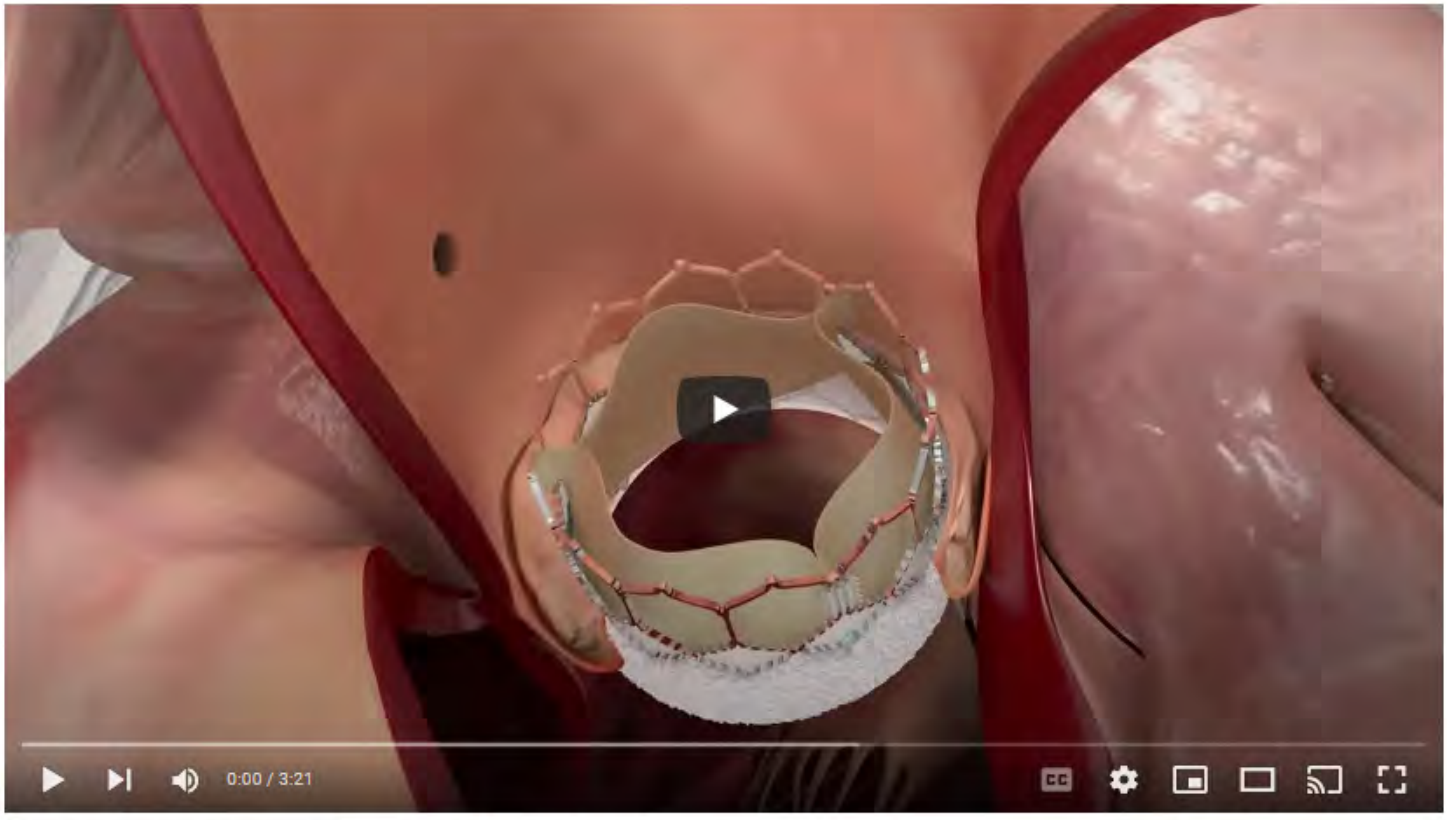
February 12, 2021

/s/ SCOTT B. ULLEM
Scott B. Ullem
Corporate Vice President,
Chief Financial Officer

February 12, 2021

EXHIBIT 37


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TAVR Procedural Animation Using the SAPIEN 3 Ultra System

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EXHIBIT 38

February 22 is Heart Valve Disease Awareness Day. To learn more about severe aortic stenosis, the most common type of HVD, order your Free TAVR Info Kit.

NewHeartValve.com
by Edwards Lifesciences

Find a TAVR Hospital Free Info Kit

Stop? I'm just getting started.

Transcatheter aortic valve replacement (TAVR)

Learn more



Important Risk Information

What are you waiting for?

Get back to life with TAVR, the less invasive aortic heart valve replacement option for severe aortic stenosis

Ask your doctor for a TAVR evaluation today.

Find out if TAVR is right for you

Aortic stenosis is a progressive disease that affects up to



2.5 Million
people over the age of 75 in the United States.

Once it advances to the severe stage, the deadly disease won't wait for you to delay treatment.[1,2]

Learn what causes aortic stenosis

After the onset of symptoms, patients with severe aortic stenosis have a survival rate



as low as 50%

Important Risk Information

Learn why treatment can't wait



that can treat your severe aortic stenosis, with next day discharge for most patients. This allows you to get back to your life quicker.

Learn about less invasive TAVR

Can a heart valve be replaced without open heart surgery?

Yes. In fact, TAVR should be considered for all patients suffering from severe aortic stenosis and who are experiencing symptoms. With transcatheter aortic valve replacement, you don't need to have your chest opened. This less invasive option is available to patients living with severe aortic stenosis. With TAVR, patients have a shorter recovery time and most patients return home the next day. It is time to talk to your doctor about a TAVR evaluation. Take back your future by treating your severe aortic stenosis.

Explore how TAVR works

Important Risk Information



Video: Watch Mario's story >



Want more information delivered directly to you

Get a free information kit by email or mail to learn about severe aortic stenosis and the TAVR procedure.

Important Risk Information

What you'll receive in your kit:

- Education on severe aortic stenosis and symptoms checklist once it becomes severe
- Information on TAVR as a treatment option
- Videos of patients sharing their experiences with TAVR
- Discussion guide for talking with your doctor
- List of hospitals in your area that perform TAVR

Get your free info kit

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2. Osnabrugge RLJ, Mylotte D, Head SJ, et al. Aortic Stenosis in the elderly: disease prevalence and number of candidates for transcatheter aortic valve replacement: a meta-analysis and modeling study. J Am Coll Cardiol. 2013;62(11):1002-1012.
3. Otto C. Timing of aortic valve surgery [Valve Disease]. Heart. 2000;84(2):211-218.

Important Risk Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications:

The Edwards SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter [illegible] Valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic

Important Risk Information

ring who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications (Who should not use):

The Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System should not be used in patients who:

- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.
- Have a mitral ring that is damaged and can no longer support the valve.

Warnings:

The Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System should not be used in patients who:

- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, compared to other standard treatments for aortic stenosis in the high or greater risk population.
- If an incorrect valve size for your anatomy is used, it may lead to heart injury, valve leakage, movement, or dislodgement.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are sensitive to anesthesia, contrast media, cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or plastics.
- The Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves may not last as long in younger patients, or patients with a disease that results in more calcium in their blood.
- During the procedure, your doctors should monitor the dye used in the body; [illegible] in excess it could lead to kidney damage. X-ray guidance used during the procedu[illegible]may cause injury to the skin, which may be painful, damaging, and long-lasting.

- Patients who have already had a valve replaced should be carefully assessed by their physician prior to receiving a new valve to ensure proper placement of the new valve.
- Injury can occur if the delivery system is not used properly.
- Transcatheter heart valve patients should talk to their physicians about the potential need for medications that thin the blood or prevent blood clots from forming. Patients who do not may be at increased risk of a stroke. Blood-thinning medication may increase the risk of bleeding in the brain (stroke).
- Transcatheter valve replacement is not recommended in previous mitral valve rings that are damaged or have become too rigid.

Precautions:

The long-term durability of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 transcatheter heart valves are not known at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing. Limited clinical data are available for transcatheter aortic valve replacement in patients who are born with an aortic heart valve that has only two leaflets and who are determined to be at low risk for open heart surgery. A patient's anatomical characteristics should be considered by their physicians when using the valve in this patient population. In addition, patient age should be considered as long-term durability of the valve has not been established. Patients who need a dental procedure should talk to their doctor about risk of infection and needing antibiotics. Patients should be treated post-procedure for heart infection as a precaution.

The safety and effectiveness of the transcatheter heart valves are also not known for patients who have:

- An aortic heart valve that is not calcified, contains only one leaflet, has leaflets with large pieces of calcium that may block the vessels that supply blood to the heart or in which the main problem is that the valve leaks.
- Who have a prosthetic ring in the tricuspid position.
- A heart that does not pump well, has thickening of the heart muscle, with or without blockage, unusual ultrasound images of the heart that could represent irregularities

syndrome, a condition that affects many areas of the body and increases the risk of developing various cancers and tumors.

- Low white, red or platelet blood cell counts, or history of bleeding because the blood does not clot properly.
- Diseased, abnormal, or irregularly shaped vessels leading to the heart. Vessels which are heavily diseased or too small for the delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- Whose previously implanted artificial valve or ring is not securely in place or is damaged that could cause it to leak.
- Whose previously implanted valve or ring could block a blood vessel caused from the leaflet partially detaching.

Potential risks associated with the procedure include:

- Death, stroke, paralysis (loss of muscle function), permanent disability, or severe bleeding.
- Risks to the heart, including heart attack or heart failure, sudden loss of heart function, a heart that does not pump well, irregular heartbeat that may result in a need for a permanent pacemaker, chest pain, heart murmur, false aneurysm, recurring aortic stenosis (narrowing), too much fluid around the heart, injury to the structure of the heart.
- Risks to your lungs or breathing, including difficulty breathing, fainting, dizziness, buildup of fluid in or around the lungs, weakness, or inability to exercise.
- Risks involving bleeding or your blood supply, including formation of a blood clot, high or low blood pressure, limited blood supply, a decrease in red blood cells, or abnormal lab values, bleeding in the abdominal cavity, collection of blood under the skin, serious damage to the arteries, severe bleeding in the heart or in the body that could require a transfusion or surgery.

- Additional risks, including life-threatening infection, dislodgement of calcified material, air embolism (air bubbles in the blood vessels), poor kidney function or failure, nerve injury, fever, allergic reaction to anesthesia or dye, reoperation, pain, infection, or bleeding at incision sites, or swelling.

Additional potential risks specifically associated with the use of the heart valves include:

- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery or emergency heart surgery and possible removal of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), valve issues not related to structure (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage) or mechanical failure of the delivery system and/or accessories.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

Stay Informed

Stay informed about severe aortic stenosis and its treatment options, including transcatheter aortic valve replacement (TAVR).

Join now

Contact Us

Call:

1 (949) 250-2012

Important Risk Information

Edwards Lifesciences Corporation
Attn: Patient Education Center
One Edwards Way
Irvine, CA 92614

Email

NewHeartValve – US

Important Risk Information

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Site Map

Privacy Policy

Legal Terms

Healthcare Professional Website

COOKIE PREFERENCES

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EXHIBIT 39

February 22 is Heart Valve Disease Awareness Day. Take control of your severe aortic stenosis, the most common type of HVD, by using this Informed Discussion Guide.

Find a TAVR Hospital

For Healthcare Professionals

Talking With Your Doctor

Edwards

Edwards TAVR

I'm Just Getting Started. Nothing Will

We know you want to be informed, empowered, and in control when making important decisions about treating your severe aortic stenosis. When it comes to choosing transcatheter aortic valve replacement (TAVR), or other treatment options, that means knowing which treatment option is best for you.

Put yourself in the driver's seat of your health. Talk to your doctor about your valve options today.



Don't Settle for Just Any Valve. Know the Differences

TAVR is available to more people than ever before. Learn about the features unique to Edwards TAVR and why having an Edwards valve matters.[1]

Explore Edwards Valves



Your Second Act Is Waiting. Edwards TAVR Can Help You Get There

Without aortic valve replacement, severe aortic stenosis is fatal. Luckily, you can experience a quicker recovery, a shorter hospital stay, and a faster return to activities with an Edwards TAVR valve, when compared to open heart surgery. Freedom from severe aortic stenosis means freedom to do more of what you love. Find out how an Edwards TAVR valve can help you get back to life quicker than open heart surgery.[2]

> Understand the Edwards Clinical Difference



Get Support and Resources to Live Your Best Life

From an interactive discussion guide and helpful websites to TAVR brochures and procedure videos—there are many resources available to help you throughout your TAVR treatment journey. Discover the many resources available to you as you embrace the next act in life.

View Edwards Resources

Next Page: Explore Edwards TAVR Valves

Explore Edwards TAVR valves and learn why they lead to better outcomes for patients.

Go to the Explore Edwards TAVR Valves page

References

1. The SAPIEN 3 and SAPIEN 3 Ultra valve are both commercially available in the United States. Your doctor will tell you which valve you will receive.

2. PARTNER 3 trial, low-risk cohort unadjusted clinical event rates, AT population.

COOKIE PREFERENCES

Important Risk Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications:
The Edwards SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve, a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications (Who should not use):
The Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System should not be used in patients who:

- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.
- Have a mitral ring that is damaged and can no longer support the valve.

Warnings:

- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, compared to other standard treatments for aortic stenosis in the high or greater risk population.
- If an incorrect valve size for your anatomy is used, it may lead to heart injury, valve leakage, movement, or dislodgement.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are sensitive to anesthesia, contrast media, cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or plastics.
- The Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves may not last as long in younger patients, or patients with a disease that results in more calcium in their blood.
- During the procedure, your doctors should monitor the dye used in the body; if used in excess it could lead to kidney damage. X-ray guidance used during the procedure may cause injury to the skin, which may be painful, damaging, and long-lasting.
- Patient's creatinine level should be measured prior to the procedure.
- Patients who have already had a valve replaced should be carefully assessed by their physician prior to receiving a new valve to ensure proper placement of the new valve.
- Injury can occur if the delivery system is not used properly.
- Transcatheter heart valve patients should talk to their physicians about the potential need for medications that thin the blood or prevent blood clots from forming. Patients who do not may be at increased risk of a stroke. Blood-thinning medication may increase the risk of bleeding in the brain (stroke).
- Transcatheter valve replacement is not recommended in previous mitral valve rings that are damaged or have become too rigid.

Precautions:
The long-term durability of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 transcatheter heart valves are not known at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing. Limited clinical data are available for transcatheter aortic valve replacement in patients who are born with an aortic heart valve that has only two leaflets and who are determined to be at low risk for open heart surgery. A patient's anatomical characteristics should be considered by their physicians when using the valve in this patient population. In addition, patient age should be considered as long-term durability of the valve has not been established. Patients who need a dental procedure should talk to their doctor about risk of infection and needing antibiotics. Patients should be treated post-procedure for heart infection as a precaution.

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- An aortic heart valve that is not calcified, contains only one leaflet, has leaflets with large pieces of calcium that may block the vessels that supply blood to the heart or in which the main problem is that the valve leaks.

- Who have a prosthetic ring in the tricuspid position.
- A heart that does not pump well, has thickening of the heart muscle, with or without blockage, unusual ultrasound images of the heart that could represent irregularities such as a blood clot, a diseased mitral valve that is calcified or leaking, or Gorlin syndrome, a condition that affects many areas of the body and increases the risk of developing various cancers and tumors.
- Low white, red or platelet blood cell counts, or history of bleeding because the blood does not clot properly.
- Diseased, abnormal, or irregularly shaped vessels leading to the heart. Vessels which are heavily diseased or too small for the delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- Whose previously implanted artificial valve or ring is not securely in place or is damaged that could cause it to leak.
- Whose previously implanted valve or ring could block a blood vessel caused from the leaflet partially detaching.

Potential risks associated with the procedure include:

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- Additional risks, including life-threatening infection, dislodgement of calcified material, air embolism (air bubbles in the blood vessels), poor kidney function or failure, nerve injury, fever, allergic reaction to anesthesia or dye, reoperation, pain, infection, or bleeding at incision sites, or swelling.

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Edwards

EXHIBIT 40

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Fiscal Year Ended December 31, 2019
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period From to
Commission File Number 1-15525

EDWARDS LIFESCIENCES CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**36-4316614**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

One Edwards Way	**Irvine**	**California**	**92614**
(Address of Principal Executive Offices)			(Zip Code)

(949) 250-2500
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock, par value $1.00 per share	EW	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐	Smaller reporting company	☐	Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates as of June 28, 2019 (the last trading day of the registrant's most recently completed second quarter): $34,109,197,847 based on the closing price of the registrant's common stock on the New York Stock Exchange. This calculation does not reflect a determination that persons are affiliates for any other purpose.

The number of shares outstanding of the registrant's common stock, $1.00 par value, as of January 31, 2020, was 209,122,578.

Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2020 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2019) are incorporated by reference into Part III, as indicated herein.

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EDWARDS LIFESCIENCES CORPORATION
Form 10-K Annual Report—2019
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PART I

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items, plans or expectations with respect to development activities, clinical trials or regulatory approvals, any statements of plans, strategies and objectives of management for future operations, any statements concerning our future operations, financial conditions and prospects, and any statements of assumptions underlying any of the foregoing. These statements can sometimes be identified by the use of the forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "goal," "continue," "seek," "pro forma," "forecast," "intend," "guidance," "optimistic," "aspire," "confident," other forms of these words or similar words or expressions or the negative thereof. Statements of past performance, efforts, or results about which inferences or assumptions may be made can also be forward-looking statements and are not indicative of future performance or results; these statements can be identified by the use of words such as "preliminary," "initial," diligence," "industry-leading," "compliant," "indications," or "early feedback" or other forms of these words or similar words or expressions or the negative thereof. Investors are cautioned not to unduly rely on such forward-looking statements. These forward-looking statements are subject to substantial risks and uncertainties that could cause our results or future business, financial condition, results of operations or performance to differ materially from our historical results or experiences or those expressed or implied in any forward-looking statements contained in this report. See "Risk Factors" in Part I, Item 1A below for a discussion of these risks, as such risks may be amended, supplemented or superseded from time to time by our subsequent reports on Forms 10-Q and 8-K. These forward-looking statements speak only as of the date on which they are made and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. If we do update or correct one or more of these statements, investors and others should not conclude that we will make additional updates or corrections.

Unless otherwise indicated or otherwise required by the context, the terms "we," "our," "it," "its," "Company," "Edwards," and "Edwards Lifesciences" refer to Edwards Lifesciences Corporation and its subsidiaries.

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Item 1. Business

Overview

Edwards Lifesciences Corporation is the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, we partner with the world's leading clinicians and researchers and invest in research and development to transform care for those impacted by structural heart disease or who require hemodynamic monitoring during surgery or in intensive care. Edwards Lifesciences has been a leader in these areas for over six decades. Since our founder, Lowell Edwards, first dreamed of using engineering to address diseases of the human heart, we have steadily built a company on the premise of imagining, building, and realizing a better future for patients.

A pioneer in the development of heart valve therapies, we are the world's leading manufacturer of heart valve systems and repair products used to replace or repair a patient's diseased or defective heart valve. Our innovative work in heart valves encompasses both surgical and transcatheter therapies for heart valve replacement and repair. In addition, our robust pipeline of future technologies is focused on the less invasive repair or replacement of the mitral and tricuspid valves of the heart, which are more complex and more challenging to treat than the aortic valve that is currently the focus of many of our commercially approved valve technologies. We are also a global leader in hemodynamic and noninvasive brain and tissue oxygenation monitoring systems used to measure a patient's cardiovascular function in the hospital setting.

Cardiovascular disease is the number-one cause of death in the world, and is the top disease in terms of health care spending in nearly every country. Cardiovascular disease is progressive in that it tends to worsen over time and often affects the structure of an individual's heart.

Patients undergoing treatment for cardiovascular disease can be treated with a number of our medical technologies, which are designed to address individual patient needs with respect to disease process, comorbidities, and health status. For example, an individual with a heart valve disorder may have a faulty valve that is affecting the function of his or her heart or blood flow throughout his or her body. A clinician may elect to remove the valve and replace it with one of our bioprosthetic surgical tissue heart valves or surgically re-shape and repair the faulty valve with an Edwards Lifesciences annuloplasty ring. Alternatively, a clinician may implant an Edwards Lifesciences transcatheter valve or repair system via a catheter-based approach that does not require traditional open-heart surgery and can be done while the heart continues to beat. Patients in the hospital setting, including high-risk patients in the operating room or intensive care unit, are candidates for having their cardiac function or fluid levels monitored by our Critical Care products through multiple monitoring options, including noninvasive and minimally invasive technologies. These technologies enable proactive clinical decisions while also providing the opportunity for improving diagnoses and developing individualized therapeutic management plans for patients.

Corporate Background

Edwards Lifesciences Corporation was incorporated in Delaware on September 10, 1999.

Our principal executive offices are located at One Edwards Way, Irvine, California 92614. The telephone number at that address is (949) 250-2500. We make available, free of charge on our website located at www.edwards.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission ("SEC"). The contents of our website are not incorporated by reference into this report.

Edwards Lifesciences' Product and Technology Offerings

The following discussion summarizes the main areas of products and technologies we offer to treat advanced cardiovascular disease. Our products and technologies are categorized into four main areas: Transcatheter Aortic Valve Replacement, Transcatheter Mitral and Tricuspid Therapies, Surgical Structural Heart, and Critical Care. For more information on net sales from these four main areas, see *"Net Sales by Product Group*" in Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations*."

Transcatheter Aortic Valve Replacement

We are the global leader in transcatheter heart valve replacement technologies designed for the minimally invasive replacement of heart valves. The *Edwards SAPIEN* family of valves, including *Edwards SAPIEN XT,* the *Edwards SAPIEN 3,* and the *Edwards SAPIEN 3 Ultra* transcatheter aortic heart valves, and their respective delivery systems, are used to treat heart

valve disease using catheter-based approaches for patients who have severe symptomatic aortic stenosis and certain patients with congenital heart disease. Delivered while the heart is beating, these valves can enable patients to experience a better quality of life sooner than patients receiving traditional surgical therapies. We began offering our transcatheter heart valves to patients commercially in Europe in 2007, in the United States in 2011, and in Japan in 2013. Supported by extensive customer training and service, and a growing body of compelling clinical evidence, our *SAPIEN* family of transcatheter aortic heart valves are the most widely prescribed transcatheter heart valves in the world.

Sales of our transcatheter aortic valve replacement products represented 63%, 61%, and 59% of our net sales in 2019, 2018, and 2017, respectively.

Transcatheter Mitral and Tricuspid Therapies

We are making significant investments in the development of transcatheter heart valve repair and replacement technologies designed to treat mitral and tricuspid valve diseases. While many of these technologies are in early development and clinical phases, the *PASCAL* transcatheter valve repair system and the *Cardioband* systems for mitral and tricuspid valve repair are commercially available in Europe. The *PASCAL* system provides a differentiated, minimally-invasive therapy to address the needs of patients with mitral regurgitation through leaflet approximation, while the *Cardioband* system enables clinicians to restore a patient's mitral or tricuspid valve to a more functional state by reducing the annulus and lowering regurgitation.

Surgical Structural Heart

The core of our surgical tissue heart valve product line is the *Carpentier-Edwards PERIMOUNT* pericardial valve platform, including the line of *PERIMOUNT Magna Ease* pericardial valves for aortic and mitral surgical valve replacement. With more long-term clinical publications on durability and performance than any other surgical valve, *PERIMOUNT* valves are the most widely implanted surgical tissue heart valves in the world. Our latest innovation, the *INSPIRIS RESILIA* aortic valve, is built on our *PERIMOUNT* platform and offers *RESILIA* tissue and *VFit* technology. *INSPIRIS* is now a leading aortic valve in the U.S. and in Japan. In addition to our replacement valves, we are the worldwide leader in surgical heart valve repair therapies, which include annuloplasty rings. We are also a global leader in cardiac cannula devices and offer a variety of procedure-enabling innovations that advance minimally invasive surgery. At the end of 2019, we received European regulatory approval for the *HARPOON Beating Heart Mitral Valve Repair System*, which can help transform care for many patients with degenerative mitral regurgitation.

Sales of our surgical tissue heart valve products represented 17%, 18%, and 21% of our net sales in 2019, 2018, and 2017, respectively.

Critical Care

We are a world leader in hemodynamic monitoring systems used to measure a patient's heart function and fluid status in surgical and intensive care settings. Hemodynamic monitoring plays an important role in enhancing surgical recovery. Edwards' complete hemodynamic portfolio helps clinicians make proactive clinical decisions that can improve patient outcomes, and includes the minimally invasive *FloTrac* system, the noninvasive *ClearSight* system, and recently added *ForeSight,* the noninvasive tissue oximetry system. We also support clinical needs with our well-established *Swan-Ganz* line of pulmonary artery catheters, arterial pressure monitoring products, and *Edwards Oximetry Central Venous Catheters*. In conjunction with our sensors, our *HemoSphere* monitoring platforms display valuable physiological information in an easy to understand and actionable manner. Amplifying our sensor and monitoring platform portfolio is the addition of our first predictive algorithm, *Acumen Hypotension Prediction Index,* which alerts clinicians in advance of a patient developing low blood pressure.

Sales of our core hemodynamic products represented 9%, 10%, and 10% of our net sales in 2019, 2018, and 2017, respectively.

Competition

The medical technology industry is highly competitive. We compete with many companies, including divisions of companies much larger than us and smaller companies that compete in specific product lines or certain geographies. Furthermore, new product development and technological change characterize the areas in which we compete. Our present or future products could be rendered obsolete or uneconomical as a result of technological advances by one or more of our present or future competitors or by other therapies, including drug therapies. We must continue to develop and commercialize new products and technologies to remain competitive in the cardiovascular medical technology industry. We believe that we

compete primarily on the basis of clinical superiority supported by extensive data, and innovative features that enhance patient benefit, product performance, and reliability. Customer and clinical support, and data that demonstrate both improvement in a patient's quality of life and a product's cost-effectiveness, are additional aspects of competition.

The cardiovascular segment of the medical technology industry is dynamic and subject to significant change due to cost-of-care considerations, regulatory reform, industry and customer consolidation, and evolving patient needs. The ability to provide products and technologies that demonstrate value and improve clinical outcomes is becoming increasingly important for medical technology manufacturers.

We believe that we are a leading global competitor in each of our product lines. In Transcatheter Aortic Valve Replacement, our primary competitors include Medtronic PLC and Boston Scientific Corporation. In Transcatheter Mitral and Tricuspid Therapies, our primary competitor is Abbott Laboratories, and there are a considerable number of large and small companies with development efforts in these fields. In Surgical Structural Heart, our primary competitors include Medtronic PLC, Abbott Laboratories, LivaNova, and CryoLife. In Critical Care, we compete primarily with a variety of companies in specific product lines including ICU Medical, Inc., PULSION Medical Systems SE, a subsidiary of Getinge AB, Cheetah Medical, Inc., a subsidiary of Baxter International, and LiDCO Group PLC.

Sales and Marketing

Our portfolio includes some of the most recognizable cardiovascular device product brands in treating structural heart disease today. We have a number of product lines that require sales and marketing strategies tailored to deliver high-quality, cost-effective products and technologies to customers worldwide. Because of the diverse global needs of the population that we serve, our distribution system consists of several direct sales forces as well as independent distributors. We are not dependent on any single customer and no single customer accounted for 10% or more of our net sales in 2019.

To help provide awareness of our products and technologies, we conduct educational symposia and best practices training for our physician, hospital executive, service line leadership, nursing, and clinical-based customers. We rely extensively on our sales and field clinical specialist personnel who work closely with our customers in hospitals. Field clinical specialists routinely attend procedures where Edwards' products are being used in order to provide guidance on the use of our devices, thereby enabling physicians and staff to reach expert proficiency and deliver positive patient outcomes. Our customers include physicians, nurses, and other clinical personnel, but can also include decision makers such as service line leaders, material managers, biomedical staff, hospital administrators and executives, purchasing managers, and ministries of health. Also, for certain of our product lines and where appropriate, our corporate sales team actively pursues approval of Edwards Lifesciences as a qualified supplier for hospital group purchasing organizations ("GPOs") that negotiate contracts with suppliers of medical products. Additionally, we have contracts with a number of United States and European national and regional buying groups, including healthcare systems and Integrated Delivery Networks. Where we choose to market our products is also influenced by the existence of, or potential for, adequate reimbursement to hospitals and other providers by national healthcare systems.

United States. In the United States, we sell substantially all of our products through our direct sales forces. In 2019, 58% of our net sales were derived from sales to customers in the United States.

International. In 2019, 42% of our net sales were derived internationally through our direct sales forces and independent distributors. Of the total international sales, 52% were in Europe, 24% were in Japan, and 24% were in Rest of World. We sell our products in approximately 100 countries, and our major international markets include Canada, China, France, Germany, Italy, Japan, and the United Kingdom. A majority of the sales and marketing approach outside the United States is direct sales, although it varies depending on each country's size and state of development.

Raw Materials and Manufacturing

We operate manufacturing facilities in various geographies around the world. We manufacture our Transcatheter Aortic Valve Replacement, Transcatheter Mitral and Tricuspid technologies, and Structural Surgical Heart products primarily in the United States (California and Utah), Singapore, Costa Rica, and Ireland. We manufacture our Critical Care products primarily in our facilities located in Puerto Rico and the Dominican Republic.

We use a diverse and broad range of raw and organic materials in the design, development, and manufacture of our products. We manufacture our non-implantable products from fabricated raw materials including resins, chemicals, electronics, and metals. Most of our replacement heart valves are manufactured from natural tissues harvested from animal tissue, as well as fabricated materials. We purchase certain materials and components used in manufacturing our products from external

suppliers. In addition, we purchase certain supplies from single sources for reasons of sole source availability or constraints resulting from regulatory requirements.

We work with our suppliers to mitigate risk and seek continuity of supply while maintaining quality and reliability. Alternative supplier options are generally considered, identified, and approved for materials deemed critical to our products, although we do not typically pursue immediate regulatory qualification of alternative sources due to the strength of our existing supplier relationships and the time and expense associated with the regulatory validation process.

We comply with all current global guidelines regarding risks for products incorporating animal tissue intended to be implanted in humans. We follow rigorous sourcing and manufacturing procedures intended to safeguard humans from potential risks associated with diseases such as bovine spongiform encephalopathy ("BSE"). We obtain bovine tissue used in our pericardial tissue valve products only from sources within the United States and Australia, where strong control measures and surveillance programs exist. In addition, bovine tissue used in our pericardial tissue valve products is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility. Our manufacturing and sterilization processes are designed to render tissue biologically safe from all known infectious agents and viruses.

Quality Assurance

We are committed to providing to our patients quality products and have implemented modern quality systems and concepts throughout the organization. The quality system starts with the initial design concept, risk management, and product specification, and continues through the design of the product, packaging and labeling, and the manufacturing, sales, support, and servicing of the product. The quality system is intended to design quality into the products and utilizes continuous improvement concepts, including Lean/Six Sigma principles, throughout the product lifecycle.

Our operations are frequently inspected by the many regulators that oversee medical device manufacturing, including the United States Food and Drug Administration ("FDA"), our European Notified Bodies, and other regulatory entities. The medical technology industry is highly regulated and our facilities and operations are designed to comply with all applicable quality systems standards, including the International Organization for Standardization ("ISO") 13485. These standards require, among other items, quality system controls that are applied to product design, component material, suppliers, and manufacturing operations. These regulatory approvals and ISO certifications can be obtained only after a successful audit of a company's quality system has been conducted by regulatory or independent outside auditors. Periodic reexamination by an independent outside auditor is required to maintain these certifications.

Environmental, Health, and Safety

We are committed to providing a safe and healthy workplace and complying with all relevant regulations and medical technology industry standards. Through our corporate and site level Environmental, Health, and Safety functions, we establish and monitor programs to reduce pollution, prevent injuries, and maintain compliance with applicable regulations. In order to measure performance, we monitor and report on a number of metrics, including regulated and non-regulated waste disposal, energy usage, water consumption, air toxic emissions, and injuries from our production activities. Each of our manufacturing sites is evaluated regularly with respect to a broad range of Environmental, Health, and Safety criteria.

Research and Development

In 2019, we made significant investments in research and development as we worked to develop therapies that we believe have the potential to change the practice of medicine. Research and development spending increased 21% year over year to 17% of 2019 sales. This increase was primarily the result of significant investments in our transcatheter structural heart programs, including an increase in clinical research for our mitral and tricuspid therapies business. We are engaged in ongoing research and development to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety, and reliability of our current leading products, and to expand the applications of our products as appropriate. We focus on opportunities within specific areas of structural heart disease and critical care monitoring.

A considerable portion of our research and development investment includes clinical trials and the collection of evidence that provide data for use in regulatory submissions, and required post-market approval studies involving applications of our products. Our investment in clinical studies also includes outcomes and cost-effectiveness data for payers, clinicians, and healthcare systems.

In Transcatheter Aortic Valve Replacement, we are developing new products to further improve and streamline transcatheter aortic heart valve replacement procedures, and developing pulmonic platforms to expand therapies for congenital heart disease patients.

In Transcatheter Mitral and Tricuspid Therapies, we are making significant investments in innovation and clinical evidence to develop technologies designed to treat mitral and tricuspid valve diseases and other structural heart conditions. In addition to our internally developed programs, we have made investments in several companies that are independently developing minimally-invasive technologies to treat structural heart diseases.

Our Surgical Structural Heart development programs include innovative platforms for patients who are best treated surgically, specifically active patients and patients with more complex combined procedures.

In our Critical Care product line, we are pursuing the development of a variety of decision support solutions for our clinicians. This includes next-generation noninvasive and minimally-invasive hemodynamic monitoring systems, and a next-generation monitor platform. We are also developing a decision support software suite with advanced algorithms for proactive hemodynamic management, including a semi-closed loop system for standardized management of patient fluid levels.

Our research and development activities are conducted primarily in facilities located in the United States and Israel. Our experienced research and development staff are focused on product design and development, quality, clinical research, and regulatory compliance. To pursue primary research efforts, we have developed alliances with several leading research institutions and universities, and also work with leading clinicians around the world in conducting scientific studies on our existing and developing products.

Proprietary Technology

Patents, trademarks, and other proprietary rights are important to the success of our business. We also rely upon trade secrets, know-how, continuing innovations, and licensing opportunities to develop and maintain our competitive position.

We own more than 4,700 issued United States patents, pending United States patent applications, issued foreign patents, and pending foreign patent applications. We also have licensed various United States and foreign patents and patent applications that relate to aspects of the technology incorporated in certain of our products, including our heart valves and annuloplasty rings. We also own or have rights in United States and foreign patents and patent applications in the field of transcatheter heart valve repair and replacement. In addition, we own or have rights in United States and foreign patents and patent applications that cover catheters, systems and methods for hemodynamic monitoring, and vascular access products, among others.

We are a party to several license agreements with unrelated third parties pursuant to which we have obtained, for varying terms, the exclusive or non-exclusive rights to certain patents held by such third parties in consideration for cross-licensing rights and/or royalty payments. We have also licensed certain patent rights to others.

We monitor the products of our competitors for possible infringement of our owned and licensed patents. Litigation has been necessary to enforce certain patent rights held by us, and we plan to continue to defend and prosecute our rights with respect to such patents.

We own certain United States registered trademarks used in our business. Many of our trademarks have also been registered for use in certain foreign countries where registration is available and where we have determined it is commercially advantageous to do so.

Government Regulation and Other Matters

Our products and facilities are subject to regulation by numerous government agencies, including the FDA, European Community Notified Bodies, and the Japanese Pharmaceuticals and Medical Devices Agency, to confirm compliance with the various laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products. We are also governed by federal, state, local, and international laws of general applicability, such as those regulating employee health and safety, and the protection of the environment. Overall, the amount and scope of domestic and foreign laws and regulations applicable to our business has increased over time.

United States Regulation. In the United States, the FDA has responsibility for regulating medical devices. The FDA regulates design, development, testing, clinical studies, manufacturing, labeling, promotion, and record keeping for medical

devices, and reporting of adverse events, recalls, or other field actions by manufacturers and users to identify potential problems with marketed medical devices. Many of the devices that we develop and market are in a category for which the FDA has implemented stringent clinical investigation and pre-market clearance or approval requirements. The process of obtaining FDA clearance or approval to market a product is resource intensive, lengthy, and costly. FDA review may involve substantial delays that adversely affect the marketing and sale of our products. A number of our products are pending regulatory clearance or approval to begin commercial sales in various markets. Ultimately, the FDA may not authorize the commercial release of a medical device if it determines the device is not safe and effective or does not meet other standards for clearance. Additionally, even if a product is cleared or approved, the FDA may impose restrictions or require testing and surveillance programs to monitor the effects of these products once commercialized.

The FDA has the authority to halt the distribution of certain medical devices, detain or seize adulterated or misbranded medical devices, order the repair, replacement, or refund of the costs of such devices, or preclude the importation of devices that are or appear violative. The FDA also conducts inspections to determine compliance with the quality system regulations concerning the manufacturing and design of devices and current medical device reporting regulations, recall regulations, clinical testing regulations, and other requirements. The FDA may withdraw product clearances or approvals due to failure to comply with regulatory standards, or the occurrence of unforeseen problems following initial approval, and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. Additionally, the failure to comply with FDA or comparable regulatory standards or the discovery of previously unknown product problems could result in fines, delays, or suspensions of regulatory clearances or approvals, seizures, injunctions, recalls, refunds, civil money penalties, or criminal prosecution. Our compliance with applicable regulatory requirements is subject to continual review. Moreover, the FDA and several other United States agencies administer controls over the export of medical devices from the United States and the import of devices into the United States, which could also subject us to sanctions for noncompliance.

We are also subject to additional laws and regulations that govern our business operations, products, and technologies, including:

- federal, state, and foreign anti-kickback laws and regulations, which generally prohibit payments to physicians or other purchasers of medical products as an inducement to purchase a product;
- the Stark law, which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that provider;
- federal and state laws and regulations that protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of such information, in particular, the Health Insurance Portability and Accountability Act of 1996;
- the Physician Payments Sunshine Act, which requires public disclosure of the financial relationships of United States physicians and teaching hospitals with applicable manufacturers, including medical device, pharmaceutical, and biologics companies;
- the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally funded health care program, and health care fraud statutes that prohibit false statements and improper claims to any third-party payor; and
- the United States Foreign Corrupt Practices Act, which can be used to prosecute companies in the United States for arrangements with foreign government officials or other parties outside the United States.

Failure to comply with these laws and regulations could result in criminal liability, significant fines or penalties, negative publicity, and substantial costs and expenses associated with investigation and enforcement activities. To assist in our compliance efforts, we adhere to many codes of ethics and conduct regarding our sales and marketing activities in the United States and other countries in which we operate. In addition, we have in place a dedicated team to improve our internal business compliance programs and policies.

International Regulation. Internationally, the regulation of medical devices is complex. In Europe, our products are subject to extensive regulatory requirements. The regulatory regime in the European Union for medical devices became mandatory in June 1998. It requires that medical devices may only be placed on the market if they do not compromise safety and health when properly installed, maintained, and used in accordance with their intended purpose. National laws conforming

to the European Union's legislation regulate our products under the medical devices regulatory system. Although the more variable national requirements under which medical devices were formerly regulated have been substantially replaced by the European Union Medical Devices Directive, individual nations can still impose unique requirements that may require supplemental submissions. The European Union medical device laws require manufacturers to declare that their products conform to the essential regulatory requirements after which the products may be placed on the market bearing the CE Mark. Manufacturers' quality systems for products in all but the lowest risk classification are also subject to certification and audit by an independent notified body. In Europe, particular emphasis is being placed on more sophisticated and faster procedures for the reporting of adverse events to the competent authorities.

In May 2017, the European Union (the "EU") implemented a new regulatory scheme for medical devices under the Medical Device Regulation ("MDR"). The MDR becomes fully effective in 2020 and will bring significant new requirements for many medical devices, including enhanced requirements for clinical evidence and documentation, increased focus on device identification and traceability, new definitions and registration of economic operators throughout the distribution chain, and additional postmarket surveillance and vigilance. Compliance with the MDR will require re-certification of many of our products to the enhanced standards, and will result in substantial additional expense. In addition, in the EU, we import some of our devices through our offices in Switzerland. Switzerland is not a member state of the EU, but is linked to the EU through bilateral treaties; therefore, the free movement of goods, including medical devices, between the EU and Switzerland after implementation of the MDR requires a revised Mutual Recognition Agreement ("MRA"), which continues to be under negotiation for the MDR. If an MRA covering the MDR is not put in place, then non-EU manufacturers may be required to make significant changes, including replacement of Swiss economic operators with operators based in EU Member States, and changes will need to be made to our device labeling and/or packaging to satisfy MDR requirements. If these measures are unable to be taken, it may no longer be possible to place such devices on the EU market.

In Japan, pre-market approval and clinical studies are required as is governmental pricing approval for medical devices. Clinical studies are subject to a stringent "Good Clinical Practices" standard. Approval time frames from the Japanese Ministry of Health, Labour and Welfare vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation of medical devices into Japan is subject to the "Good Import Practices" regulations. As with any highly regulated market, significant changes in the regulatory environment could adversely affect future sales.

In many of the other foreign countries in which we market our products, we may be subject to regulations affecting, among other things:

- product standards and specifications;
- packaging requirements;
- labeling requirements;
- product collection and disposal requirements;
- quality system requirements;
- import restrictions;
- tariffs;
- duties; and
- tax requirements.

Many of the regulations applicable to our devices and products in these countries are similar to those of the FDA. In some regions, the level of government regulation of medical devices is increasing, which can lengthen time to market and increase registration and approval costs. In many countries, the national health or social security organizations require our products to be qualified before they can be marketed and considered eligible for reimbursement.

Health Care Initiatives. Government and private sector initiatives to limit the growth of health care costs, including price regulation and competitive pricing, coverage and payment policies, comparative effectiveness reviews, technology assessments, increasing evidentiary demands, and managed-care arrangements, are continuing in many countries where we do

business, including the United States, Europe, and Japan. As a result of these changes, the marketplace has placed increased emphasis on the delivery of more cost-effective medical therapies. For example, government programs, private health care insurance, and managed-care plans have attempted to control costs by restricting coverage and limiting the level of reimbursement for procedures or treatments, and some third-party payors require their pre-approval before new or innovative devices or therapies are utilized by patients. These various initiatives have created increased price sensitivity over medical products generally and may impact demand for our products and technologies.

The delivery of our products is subject to regulation by the Department of Health and Human Services ("HHS") in the United States and comparable state and foreign agencies responsible for reimbursement and regulation of health care items and services. Foreign governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services. Reimbursement schedules regulate the amount the United States government will reimburse hospitals and doctors for the inpatient care of persons covered by Medicare. HHS' Centers for Medicare & Medicaid Services ("CMS") may also review whether and/or under what circumstances a procedure or technology is reimbursable for Medicare beneficiaries. Changes in current coverage and reimbursement levels could have an adverse effect on market demand and our pricing flexibility. The CMS National Coverage Determination for Transcatheter Aortic Valve Replacement was issued in June 2019. The modernized requirements and more streamlined patient evaluation process are meaningful enhancements that may help ensure equitable access for more patients suffering from severe aortic stenosis.

Health care cost containment efforts have also prompted domestic hospitals and other customers of medical device manufacturers to consolidate into larger purchasing groups to enhance purchasing power. The medical technology industry has also experienced some consolidation, partly in order to offer a broader range of products to large purchasers. As a result, transactions with customers are larger, more complex, and tend to involve more long-term contracts than in the past. These larger customers, due to their enhanced purchasing power, may attempt to increase the pressure on product pricing.

Health Care Legislation. In 2010, significant reforms to the health care system were adopted as law in the United States as part of the Affordable Care Act. The law included provisions that, among other things, created programs to encourage a shift to value-based care, required all individuals to have health insurance (with limited exceptions), and imposed increased taxes. The law required the medical technology industry to pay a 2.3% excise tax on United States sales of most medical devices. The excise tax, which increased our operating expenses, was suspended for calendar years 2016 through 2019. In December 2019, this legislation was repealed.

These laws or any future legislation, including deficit reduction legislation, could impact medical procedure volumes, reimbursement for our products, and demand for our products or the prices at which we sell our products.

Seasonality

Our quarterly net sales are influenced by many factors, including new product introductions, acquisitions, regulatory approvals, patient and physician holiday schedules, and other factors. Net sales in the third quarter are typically lower than other quarters of the year due to the seasonality of the United States and European markets, where summer vacation schedules normally result in fewer medical procedures.

Employees

As of December 31, 2019, we had approximately 13,900 employees worldwide, the majority of whom were located in the United States, Singapore, the Dominican Republic, and Puerto Rico. We emphasize competitive compensation, benefits, equity participation, and a positive and attractive work environment in our efforts to attract and retain qualified personnel, and employ a rigorous talent management system. None of our North American employees are represented by a labor union. In various countries outside of North America, we interact with trade unions and work councils that represent a limited number of employees.

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Item 1A. Risk Factors

Our business and assets are subject to varying degrees of risk and uncertainty. An investor should carefully consider the risks described below, as well as other information contained in this Annual Report on Form 10-K and in our other filings with the SEC. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business. If any of these events or circumstances occurs, our business, financial condition, results of operations, or prospects could be materially harmed. In that case, the value of our securities could decline and an investor could lose part or all of his or her investment. In addition, forward-looking statements within the meaning of the federal securities laws that are contained in this Annual Report on Form 10-K or in our other filings or statements may be subject to the risks described below as well as other risks and uncertainties. Please read the cautionary notice regarding forward-looking statements in Part I above.

Business and Operating Risks

If we do not introduce new and differentiated products in a timely manner, our products may become more susceptible to competition or technologically obsolete and our operating results may suffer.

The cardiovascular products industry is characterized by technological changes, frequent new product introductions, and evolving industry standards. Without the timely introduction of new and differentiated products, our products could become more susceptible to competition or technologically obsolete and our revenue and operating results would suffer. Even if we are able to develop new or differentiated products, our ability to market them could be limited by the need for regulatory clearance, restrictions imposed on approved indications, entrenched patterns of clinical practice, barriers in the patients' path to treatment, uncertainty over third-party reimbursement, or other factors.

We devote significant financial and other resources to our research and development activities; however, the research and development process is prolonged and entails considerable uncertainty. Accordingly, products we are currently developing may not complete the development process or obtain the regulatory or other approvals required to market such products in a timely manner or at all.

In addition, even if we are able to successfully develop new or differentiated products, they may not produce revenue in excess of the costs of development, and they may be rendered obsolete or less competitive by changing customer preferences or the introduction by our competitors of products with newer technologies or features or other factors.

We may experience supply interruptions that could harm our ability to manufacture products.

We use a broad range of raw and organic materials and other items from third party vendors in the design, manufacture and sterilization of our products. Our Transcatheter Aortic Valve Replacement, Transcatheter Mitral and Tricuspid Therapies, and Surgical Structural Heart products are manufactured from treated natural animal tissue and man-made materials. Our non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics, and metals. We purchase certain of the materials and components used in the manufacture of our products from external suppliers, and we purchase certain supplies from single sources for reasons of quality assurance, cost-effectiveness, availability, constraints resulting from regulatory requirements and other reasons. We also contract with third parties for important services related to infrastructure and information technology. General economic conditions could adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products. While we work closely with suppliers to monitor their financial viability, assure continuity of supply, and maintain high quality and reliability, these efforts may not be successful. In addition, due to the rigorous regulations and requirements of the FDA and foreign regulatory authorities regarding the manufacture of our products (including the need for approval of any change in supply arrangements), we may have difficulty establishing additional or replacement sources on a timely basis or at all if the need arises. Certain suppliers may also elect to no longer service medical technology companies due to the burdens of applicable quality requirements and regulation. Although alternative supplier options are often considered and identified, we typically do not pursue regulatory qualification of alternative sources due to the strength of our existing supplier relationships and the time and expense associated with the regulatory validation process. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology, and the loss of any existing supply contract could have a material adverse effect on us.

Regulatory agencies in the United States or other international geographies from time to time have limited or banned the use of certain materials used in the manufacture of our products. In these circumstances, transition periods typically provide time to arrange for alternative materials. If we are unable to identify alternative materials or suppliers and secure approval for their use in a timely manner, our business could be harmed.

In addition, for our suppliers located outside the United States, trade or regulatory embargoes imposed by foreign countries or the United States could result in delays or shortages that could harm our business.

The manufacture of many of our products is highly complex and subject to strict quality controls. If we or one of our suppliers or logistics partners encounters manufacturing, logistics, or quality problems, our business could suffer.

The manufacture and sterilization of many of our products is highly complex due in part to rigorous regulatory requirements. In addition, quality is extremely important due to the serious and costly consequences of a product failure. Problems can arise for a number of reasons, including disruption of facility utilities, equipment malfunction, failure to follow protocols and procedures, raw material problems, software problems, or human error. Disruptions can occur at any time, including during implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions. As we expand into new markets, we may face unanticipated surges in demand which could strain our production capacity and lead to other types of disruption. Also, as we expand our manufacturing footprint, significant delays in construction and process validation could impact our production capacity. Further, scaling a new product for commercial production can sometimes be delayed. If these problems arise or if we otherwise fail to meet our internal quality standards or those of the FDA or other applicable regulatory body, which include detailed record-keeping requirements, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product liability and other costs, product approvals could be delayed, and our business could otherwise be adversely affected.

In addition, our manufacturing and warehousing facilities, as well as those of our suppliers and logistics partners, could be materially damaged by earthquakes, hurricanes, volcanoes, fires, and other natural disasters or catastrophic circumstances. While we believe that our exposure to significant losses from a catastrophic disaster could be partially mitigated by our ability to manufacture, store, and distribute some of our products at other facilities, the losses could have a material adverse effect on our business for an indeterminate period of time before this transition is complete and operates without significant disruption.

We may be required, from time to time, to recognize charges in connection with the write-down of our assets or dispositions of business operations or for other reasons.

We manage a portfolio of research and development products. From time to time, we identify operations and products that are underperforming or not a fit with our longer term business strategy. We may seek to dispose of these underperforming operations or products. We may also seek to dispose of other operations or products for strategic or other business reasons. If we cannot dispose of an operation or product on acceptable terms, we may voluntarily cease operations related to that product. Any of these events could result in charges, which could be substantial and which could adversely affect our results of operations.

We may not successfully identify and complete acquisitions or strategic alliances on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances, and such acquisitions could result in unforeseen operating difficulties and expenditures, require significant management resources, and require significant charges or write-downs.

We regularly explore potential acquisitions of complementary businesses, technologies, services, or products, as well as potential strategic alliances. We may be unable to find suitable acquisition candidates or appropriate partners with which to form alliances. Even if we identify appropriate acquisition or alliance candidates, we may be unable to complete the acquisitions or alliances on favorable terms, if at all. In addition, the process of integrating an acquired business, technology, service, or product into our existing operations could result in unforeseen difficulties and expenditures. Integration of an acquired company often requires significant expenditures as well as significant management resources that otherwise would be available for ongoing development of our other businesses. Moreover, we may not realize the anticipated financial or other benefits of an acquisition or alliance.

We may be required to take charges or write-downs in connection with acquisitions. In particular, acquisitions of businesses engaged in the development of new products may give rise to developed technology and/or in-process research and development assets. To the extent that the value of these assets declines, we may be required to write down the value of the assets. Also, in connection with certain asset acquisitions, we may be required to take an immediate charge related to acquired in-process research and development assets. Either of these situations could result in substantial charges, which could adversely affect our results of operations.

Acquisitions could also involve the issuance of equity securities, the incurrence of debt, contingent liabilities, or amortization of expenses related to other intangible assets, any of which could adversely impact our financial condition or results of operations. In addition, equity or debt financing required for such acquisitions may not be available.

We face intense competition, and if we do not compete effectively, our business will be harmed.

The cardiovascular medical technology industry is highly competitive. We compete with many companies, some of which are larger, with better brand or name recognition, and broader product offerings. Our customers consider many factors when selecting a product, including product reliability, breadth of product line, clinical outcomes, product availability, price, availability and rate of reimbursement, and services provided by the manufacturer. In addition, our ability to compete will depend in large part on our ability to develop and acquire new or differentiated products and technologies, anticipate technology advances, and keep pace with other developers of cardiovascular therapies, including drug therapies, and technologies. Our sales, technical, and other key personnel play an integral role in the development, marketing, and selling of new and existing products. If we are unable to recruit, hire, develop, and retain a talented, competitive workforce, our ability to compete may be adversely affected. Our competitive position can also be adversely affected by product problems, physician advisories, and safety alerts, reflecting the importance of quality in the medical technology industry. Our position can shift as a result of any of these factors. In addition, given the trend toward value-based healthcare, if we are not able to continue to demonstrate the full value of our differentiated products to healthcare providers and payors, our competitive position could be adversely affected. See "*Competition*" under "*Business*" included herein.

Unsuccessful clinical trials or procedures relating to products under development could have a material adverse effect on our prospects.

The regulatory approval process for new products and new indications for existing products requires extensive clinical trials and procedures, including early clinical feasibility and regulatory studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary approvals and the market's view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these trials or procedures will be enrolled or completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication; failure to do so could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures may be contradicted by subsequent clinical analysis. In addition, results from our clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be delayed, suspended, or terminated by us, the FDA, or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks or any other reasons.

The success of many of our products depends upon strong relationships with certain key physicians.

The development, marketing, and sale of many of our products requires us to maintain working relationships with physicians upon whom we rely to provide considerable knowledge and experience. These physicians may assist us as researchers, marketing consultants, product trainers and consultants, inventors, and as public speakers. If new laws, regulations, or other developments limit our ability to maintain strong relationships with these professionals or to continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions or data corruption could materially disrupt our operations and adversely affect our business and operating results.

The operation of our business depends on our information technology systems. We rely on our information technology systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches, data corruption, and cyber-based attacks. Cyber-based attacks can include computer viruses, computer denial-of-service attacks, phishing attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities, or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. In addition, federal, state, and international laws and regulations, such as the General Data Protection Regulation adopted by the European Union and the California Consumer Privacy Act, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail. In addition, a variety of our software systems are cloud-based data management applications, hosted by third-party service providers whose security and information technology systems are subject to similar risks.

The failure of either our or our service providers' information technology could disrupt our entire operation or result in decreased sales, result in liability claims or regulatory penalties, or lead to increased overhead costs, product shortages, loss or misuse of proprietary or confidential information, intellectual property, or sensitive or personal information, all of which could have a material adverse effect on our reputation, business, financial condition, and operating results.

Market and Other External Risks

General economic and political conditions could have a material adverse effect on our business.

External factors can affect our profitability and financial condition. Such external factors include general domestic and global economic conditions, such as interest rates, tax law including tax rate changes, and factors affecting global economic stability, and the political environment regarding health care in general. We cannot predict to what extent the global economic conditions may negatively impact our business. For example, negative conditions in the credit and capital markets could impair our ability to access the financial markets for working capital or other funds and could negatively impact our ability to borrow. An increase in interest rates could result in an increase in our borrowing costs and could otherwise restrict our ability to access the capital markets. Such conditions could result in decreased liquidity and impairments in the carrying value of our investments, and could adversely affect our results of operations and financial condition. These and other conditions could also adversely affect our customers and may impact their ability or decision to purchase our products or make payments on a timely basis.

Various laws, including the Affordable Care Act, the Medicare Access and CHIP Reauthorization Act of 2015, and the 21st Century Cures Act, or any future legislation, including deficit reduction legislation, could impact medical procedure volumes, reimbursement for our products, and demand for our products or the prices at which we sell our products. For more information about these laws as they relate to our business, see the section entitled "*Health Care Legislation*" in Part I, Item 1, "*Business.*"

We operate globally and changes in tax laws could adversely affect our results.

We are subject to income taxes in the United States as well as other jurisdictions. Our effective tax rate could fluctuate due to changes in the mix of earnings and losses in countries with differing statutory tax rates. Our tax expense could be impacted by changes in excess tax benefits of stock-based compensation, federal and state tax credits, non-deductible expenses, changes in the valuation of deferred tax assets and liabilities and our ability to utilize them, the applicability and creditability of withholding taxes, and effects from acquisitions.

Our tax provision could be impacted by changes in accounting principles and tax legislation. Corporate tax reform, base-erosion efforts, and tax transparency continue to be high priorities in many tax jurisdictions where we have business operations. In addition, many countries are beginning to align their international tax rules with the Organisation for Economic Co-operation and Development's Base Erosion and Profit Shifting recommendations and action plan that aim to standardize and modernize global corporate tax policy, including changes to cross-border tax, transfer pricing documentation rules, and nexus-based tax incentive practices. These changing tax laws could have a material adverse effect on our business.

We are subject to ongoing tax audits in the various jurisdictions in which we operate. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision. However, there can be no assurance that we will accurately predict the outcomes of these audits. We have recorded reserves for potential payments of tax to various tax authorities related to uncertain tax positions. However, the calculation of such tax liabilities involves the application of complex tax laws and regulations in many jurisdictions. If our estimate of tax liabilities proves to be less than the amount for which we are ultimately liable, we would incur additional charges, and such charges could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

If the tax incentives or tax holiday arrangements we have negotiated change or cease to be in effect or applicable, our income taxes could increase significantly.

We benefit from tax incentives extended to our foreign subsidiaries to encourage investment or employment. Several jurisdictions have granted us tax incentives which require renewal at various times in the future. The incentives are conditioned on achieving various thresholds of investments and employment, or specific types of income. Our taxes could increase if the incentives are not renewed upon expiration. If we cannot or do not wish to satisfy all or parts of the tax incentive conditions, we

may lose the related tax incentive and could be required to refund tax incentives previously realized. As a result, our effective tax rate could be higher than it would have been had we maintained the benefits of the tax incentives.

Our business is subject to economic, political, and other risks associated with international sales and operations.

Because we sell our products in a number of countries, our business is subject to the risks of doing business internationally, including risks associated with anti-corruption and anti-bribery laws. Our net sales originating outside the United States, as a percentage of total net sales, were 42% in 2019. We anticipate that sales from international operations will continue to represent a substantial portion of our total sales. In addition, many of our manufacturing facilities and suppliers are located outside of the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- changes in local medical reimbursement policies and programs;
- changes in foreign regulatory requirements;
- changes in a specific country's or region's political or economic conditions, including changing circumstances in emerging regions, that may reduce the number of procedures that use our products;
- trade protection measures, quotas, embargoes, import or export licensing requirements, and duties, tariffs, or surcharges;
- potentially negative impact of tax laws, including transfer pricing liabilities and tax costs associated with the repatriation of cash;
- difficulty in staffing and managing global operations;
- currency exchange rate fluctuations;
- cultural or other local factors affecting financial terms with customers;
- local economic and financial conditions, including sovereign defaults and decline in sovereign credit ratings, affecting the collectability of receivables, including receivables from sovereign entities;
- an outbreak of any life-threatening communicable disease;
- economic and political instability and local economic and political conditions;
- differing labor regulations; and
- differing protection of intellectual property.

In addition, a Mutual Recognition Agreement still under negotiation for the Medical Device Regulation can result in a lack of free movement of medical devices between the European Union and Switzerland, can impact our access in the European Union and can, ultimately, have a material effect on our business, financial condition, and results of operations. See "*Government Regulation and Other Matters*" under Item 1 "*Business*."

Substantially all of our sales outside of the United States are denominated in local currencies, principally in Europe (and primarily denominated in the Euro) and in Japan. The United States dollar value of our international sales varies with currency exchange rate fluctuations. Decreases in the value of the United States dollar to the Euro or the Japanese yen, as well as other currencies, have the effect of increasing our reported revenues even when the volume of international sales has remained constant. Increases in the value of the United States dollar relative to the Euro or the Japanese yen, as well as other currencies, have the opposite effect. Significant increases or decreases in the value of the United States dollar could have a material effect on our revenues, cost of sales, and results of operations. We have a hedging program for certain currencies that attempts to manage currency exchange rate risks to an acceptable level based on management's judgment of the appropriate trade-off between risk, opportunity, and cost; however, this hedging program does not completely eliminate the effects of currency exchange rate fluctuations.

The United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and similar laws in other jurisdictions contain prohibitions against bribery and other illegal payments, and make it an offense to fail to have procedures in place that

prevent such payments. Recent years have seen an increasing number of investigations and other enforcement activities under these laws. Although we have compliance programs in place with respect to these laws, which may be used as a defense to prove we had adequate procedures, no assurance can be given that a violation will not be found, and if found, the resulting penalties could adversely affect us and our business.

The stock market can be volatile and fluctuations in our quarterly sales and operating results as well as other factors could cause our financial guidance to vary from actual results and our stock price to decline.

From time to time, the stock market experiences extreme price and volume fluctuations. This volatility can have a significant effect on the market prices of securities for reasons unrelated to underlying performance. These broad market fluctuations may materially adversely affect our stock price, regardless of our operating results. In addition, the market price of our common stock could fluctuate substantially in response to any of the other risk factors set out above and below, as well as a number of other factors, including the performance of comparable companies or the medical technology industry, or changes in financial estimates and recommendations of securities analysts.

Our sales and operating results may vary significantly from quarter to quarter. A high proportion of our costs are fixed, due in part to significant selling, research and development, and manufacturing costs. Thus, small declines in revenue could disproportionately affect our operating results in a quarter, and the price of our common stock could fall. Other factors that could affect our quarterly sales and operating results include:

- announcements of innovations, new products, strategic developments, or business combinations by us or our competitors;
- demand for and clinical acceptance of products;
- the timing and execution of customer contracts, particularly large contracts that would materially affect our operating results in a given quarter;
- the timing and effectiveness of the introduction of new products;
- the timing of marketing, training, and other expenses related to the introduction of new products;
- the timing and substance of regulatory approvals;
- changes in foreign currency exchange rates;
- delays or problems in introducing new products, such as slower than anticipated adoption of transcatheter heart valves;
- changes in our pricing policies or the pricing policies of our competitors;
- governmental reimbursement rates, including the timing of approvals of governmental reimbursement rates or changes in reimbursement rates for our products;
- increased expenses, whether related to sales and marketing, raw materials or supplies, product development, or administration;
- changes in the level of economic activity in the United States or other regions in which we do business;
- changes to accounting standards;
- costs related to acquisitions of technologies or businesses; and
- our ability to expand our operations and the amount and timing of expansion-related expenditures.

The quarterly and full-year financial guidance we provide to investors and analysts with insight to our view of our future performance is based on assumptions about our sales and operating results. Due to the nature of our business and the numerous factors that can impact our sales and operating performance, including those described above, our financial guidance may vary

from actual results. If we fail to meet any financial guidance that we provide, or if we find it necessary to revise such guidance during the year, the price of our common stock could decline.

Continued consolidation in the health care industry could have an adverse effect on our sales and results of operations.

The health care industry has been consolidating, and organizations such as GPOs, independent delivery networks, and large single accounts, such as the United States Veterans Administration, continue to consolidate purchasing decisions for many of our health care provider customers. As a result, transactions with customers are larger and more complex, and tend to involve more long-term contracts. The purchasing power of these larger customers has increased, and may continue to increase, causing downward pressure on product pricing. If we are not one of the providers selected by one of these organizations, we may be precluded from making sales to its members or participants. Even if we are one of the selected providers, we may be at a disadvantage relative to other selected providers that are able to offer volume discounts based on purchases of a broader range of medical equipment and supplies. Further, we may be required to commit to pricing that has a material adverse effect on our revenues, profit margins, business, financial condition, and results of operations. We expect that market demand, governmental regulation, third-party reimbursement policies, and societal pressures will continue to change the worldwide health care industry, resulting in further business consolidations and alliances, which may exert further downward pressure on the prices of our products and could adversely impact our business, financial condition, and results of operations.

If government and other third-party payors decline to reimburse our customers for our products or impose other cost containment measures to reduce reimbursement levels, our ability to profitably sell our products will be harmed.

We sell our products and technologies to hospitals and other health care providers, all of which receive reimbursement for the health care services provided to patients from third-party payors, such as government programs (both domestic and international), private insurance plans, and managed care programs. The ability of customers to obtain appropriate reimbursement for their products from private and governmental third-party payors is critical to the success of medical technology companies. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact acceptance of new products.

Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. There can be no assurance that levels of reimbursement, if any, will not be decreased in the future, or that future legislation, regulation, or reimbursement policies of third-party payors will not otherwise adversely affect the demand for and price levels of our products. The introduction of cost containment incentives, combined with closer scrutiny of health care expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to hospital charges for services performed. Hospitals or physicians may respond to such cost-containment pressures by substituting lower cost products or other therapies.

Initiatives to limit the growth of health care costs, including price regulation, are underway in countries around the world. In many countries, customers are reimbursed for our products under a government operated insurance system. Under such a system, the government periodically reviews reimbursement levels and may limit patient access. If a government were to decide to reduce reimbursement levels, our product pricing could be adversely affected.

Third-party payors may deny reimbursement if they determine that a device used in a procedure was not used in accordance with cost-effective treatment methods as determined by such third-party payors or was used for an unapproved indication. Third-party payors may also deny reimbursement for experimental procedures and devices. We believe that many of our existing products are cost-effective, even though the one-time cost may be significant, because they are intended to improve quality of life and reduce overall health care costs over a long period of time. We cannot be certain that these third-party payors will recognize these cost savings and quality of life benefits instead of merely focusing on the lower initial costs associated with competing therapies. If our products are not considered cost-effective by third-party payors, our customers may not be reimbursed for them, resulting in lower sales of our products.

Legal, Compliance, and Regulatory Risks

We may incur losses from product liability or other claims that could adversely affect our operating results.

Our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical technologies. Our products are often used in surgical and intensive care settings with seriously ill patients. In addition, many of the devices we manufacture and sell are designed to be implanted in the human body for long periods of time. Component failures, manufacturing and assembly flaws, design defects, software defects, medical procedure errors, or inadequate disclosure of product-related risks or product-related information could result in an unsafe condition or injury to, or

death of, patients. Such problems could result in product liability, medical malpractice or other lawsuits and claims, safety alerts, or product recalls in the future, which, regardless of their ultimate outcome, could have a material adverse effect on our business, reputation, and ability to attract and retain customers. Product liability claims may be brought from time to time either by individuals or by groups seeking to represent a class. We may incur charges related to such matters in excess of any established reserves and such charges, including the establishment of any such reserves, could have a material adverse impact on our net income and net cash flows.

Our inability to protect our intellectual property or failure to maintain the confidentiality and integrity of data or other sensitive company information, by cyber-attack or other event, could have a material adverse effect on our business.

Our success and competitive position are dependent in part upon our proprietary intellectual property. We rely on a combination of patents and trade secrets to protect our proprietary intellectual property, and we expect to continue to do so. Although we seek to protect our proprietary rights through a variety of means, we cannot guarantee that the protective steps we have taken are adequate to protect these rights. Patents issued to or licensed by us in the past or in the future may be challenged and held invalid. In addition, as our patents expire, we may be unsuccessful in extending their protection through patent term extensions. The expiration of, or the failure to maintain or extend our patents, could have a material adverse effect on us.

We also rely on confidentiality agreements with certain employees, consultants, and other third parties to protect, in part, trade secrets and other proprietary information. These agreements could be breached, and we may not have adequate remedies for such a breach. In addition, others could independently develop substantially equivalent proprietary information or gain access to our trade secrets or proprietary information.

Our intellectual property, other proprietary technology, and other sensitive company information is dependent on sophisticated information technology systems and is potentially vulnerable to cyber-attacks, loss, damage, destruction from system malfunction, computer viruses, loss of data privacy, or misappropriation or misuse of it by those with permitted access, and other events. While we have invested to protect our intellectual property and other information, and continue to upgrade and enhance our systems to keep pace with continuing changes in information processing technology, there can be no assurance that our precautionary measures will prevent breakdowns, breaches, cyber-attacks, or other events. Such events could have a material adverse effect on our reputation, financial condition, or results of operations.

We spend significant resources to enforce our intellectual property rights, sometimes resulting in litigation. Intellectual property litigation is complex and can be expensive and time-consuming. However, our efforts in this regard may not be successful. We may not be able to detect infringement. In addition, competitors may design around our technology or develop competing technologies. Patent litigation can result in substantial cost and diversion of effort. Intellectual property protection may also be unavailable or limited in some foreign countries, enabling our competitors to capture increased market position. The invalidation of key intellectual property rights or an unsuccessful outcome in lawsuits filed to protect our intellectual property could have a material adverse effect on our financial condition, results of operations, or prospects.

Third parties may claim we are infringing their intellectual property, and we could suffer significant litigation or licensing expenses or be prevented from selling products.

During recent years, we and our competitors have been involved in substantial litigation regarding patent and other intellectual property rights in the medical technology industry. From time to time, we have been and may in the future be forced to defend against claims and legal actions alleging infringement of the intellectual property rights of others, and such intellectual property litigation is typically costly and time-consuming. Adverse determinations in any such litigation could result in significant liabilities to third parties or injunctions that bar the sale of our products, or could require us to seek licenses from third parties and, if such licenses are not available on commercially reasonable terms, prevent us from manufacturing, selling, or using certain products, any one of which could have a material adverse effect on us. In addition, some licenses may be non-exclusive, which could provide our competitors access to the same technologies.

Third parties could also obtain patents that may require us to either redesign products or, if possible, negotiate licenses from such third parties. Such licenses may materially increase our expenses. If we are unable to redesign products or obtain a license, we might have to exit a particular product offering.

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We and our customers are subject to rigorous governmental regulations and we may incur significant expenses to comply with these regulations and develop products that are compatible with these regulations. In addition, failure to comply with these regulations could subject us to substantial sanctions which could adversely affect our business, results of operations, and financial condition.

The medical technologies we manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state, and foreign governmental authorities, including regulations that cover the composition, labeling, testing, clinical study, design, sourcing, manufacturing, packaging, marketing, advertising, promotion, and distribution of our products.

We are required to register with the FDA as a device manufacturer. As a result, we are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation ("QSR") requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, design, quality control, and documentation procedures. The FDA may also inspect our compliance with requirements related to adverse event reporting, recalls or corrections (field actions), the conduct of clinical studies, and other requirements. In the European Union, we are required to maintain certain CE Mark and ISO certifications in order to sell our products, and are subject to periodic inspections by notified bodies to obtain and maintain these certifications. If we or our suppliers fail to adhere to QSR, CE Mark, ISO, or similar requirements, this could delay or interrupt product production or sales and/or lead to fines, difficulties in obtaining regulatory clearances, recalls, or other consequences, which in turn could have a material adverse effect on our financial condition and results of operations or prospects.

Medical devices must receive FDA clearance or approval before they can be commercially marketed in the United States. In addition, the FDA may require testing and surveillance programs to monitor the effects of approved products that have been commercialized, and can prevent or limit further marketing of a product based upon the results of post-marketing programs. Further, the federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, would be likely to cause or contribute to a death or serious injury. Federal regulations also require us to report certain recalls or corrective actions to the FDA. Furthermore, most major markets for medical devices outside the United States require clearance, approval, or compliance with certain standards before a product can be commercially marketed. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time-consuming, and clearances or approvals may not be granted for products or product improvements on a timely basis, if at all. Delays in receipt of, or failure to obtain, clearances or approvals for products or product improvements could result in delayed realization of product revenues or in substantial additional costs, which could have a material adverse effect on our business or results of operations or prospects. At any time after approval of a product for commercial sale, the FDA may conduct periodic inspections to determine compliance with QSR requirements, and/or current Medical Device Reporting regulations, or other regulatory requirements. Noncompliance with applicable requirements may subject us or responsible individuals to sanctions including civil money penalties, product seizure, injunction, or criminal prosecution. In addition, the FDA may withhold or delay pre-market approval of our products until the noncompliance is resolved. Product approvals by the FDA can also be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval.

The United States Physician Payment Sunshine Act, and similar laws in other jurisdictions, also impose reporting and disclosure requirements on device, pharmaceutical, and biologics companies for certain financial relationships with United States health care providers and teaching hospitals. Failure to submit required information or submitting incorrect information may result in significant civil monetary penalties.

We are also subject to various United States and international laws pertaining to health care pricing, anti-corruption, and fraud and abuse, including prohibitions on kickbacks and the submission of false claims laws and restrictions on relationships with physicians and other referral sources. These laws are broad in scope and are subject to evolving interpretation, which could require us to incur substantial costs to monitor compliance or to alter our practices if we are found not to be in compliance. Violations of these laws may be punishable by criminal or civil sanctions against us and our officers and employees, including substantial fines, imprisonment, and exclusion from participation in governmental health care programs.

Despite our implementation of compliance processes, we may be subject, from time to time, to inspections, investigations, and other enforcement actions by governmental authorities. If we are found not to be in compliance with applicable laws or regulations, the applicable governmental authority can impose fines, delay, suspend, or revoke regulatory clearances or approvals, institute proceedings to detain or seize our products, issue a recall, impose marketing or operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees, and institute criminal prosecution. Moreover, governmental authorities can ban or request the recall, repair, replacement, or refund of the cost of any device or product we manufacture or distribute. Any of the foregoing actions could result in decreased sales including as a

result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations, and prospects. In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection, or investigation could divert substantial management attention from the operation of our business and have an adverse effect on our business, results of operations, and financial condition.

Our industry is experiencing greater scrutiny and regulation by governmental authorities, which may lead to greater governmental regulation and scrutiny in the future.

In recent years, the medical technology industry has been subject to increased regulatory scrutiny, including by the FDA, numerous other federal, state, and foreign governmental authorities, as well as members of Congress. This has included increased regulation, enforcement, inspections, and governmental investigations of the medical technology industry and disclosure of financial relationships with health care professionals. We anticipate that the government will continue to scrutinize our industry closely, and that additional regulation by governmental authorities, both foreign and domestic, may increase compliance costs, exposure to litigation, and other adverse effects to our operations.

We are subject to risks arising from concerns and/or regulatory actions relating to animal borne illnesses, including "mad cow disease."

Certain of our products, including pericardial tissue valves, are manufactured using bovine tissue. Concerns relating to the potential transmission of animal borne illnesses, including BSE, commonly known as "mad cow disease," from cows to humans may result in reduced acceptance of products containing bovine materials. Certain medical device regulatory agencies have considered whether to continue to permit the sale of medical devices that incorporate bovine material. We obtain bovine tissue only from closely controlled sources within the United States and Australia. The bovine tissue used in our pericardial tissue valves is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility for the suspected BSE infectious agent. We have not experienced any significant adverse impact on our sales as a result of concerns regarding BSE, but no assurance can be given that such an impact may not occur in the future.

Use of our products in unapproved circumstances could expose us to liabilities.

The marketing approval from the FDA and other regulators of certain of our products are, or are expected to be, limited to specific indications. We are prohibited from marketing or promoting any unapproved use of our products. Physicians, however, can use these products in ways or circumstances other than those strictly within the scope of the regulatory approval. Although the product training we provide to physicians and other health care professionals is limited to approved uses or for clinical trials, no assurance can be given that claims might not be asserted against us if our products are used in ways or for procedures that are not approved.

Our operations are subject to environmental, health, and safety regulations that could result in substantial costs.

Our operations are subject to environmental, health, and safety laws, and regulations concerning, among other things, the generation, handling, transportation, and disposal of hazardous substances or wastes, the cleanup of hazardous substance releases, and emissions or discharges into the air or water. We have incurred and may incur in the future expenditures in connection with environmental, health and safety laws, and regulations. New laws and regulations, violations of these laws or regulations, stricter enforcement of existing requirements, or the discovery of previously unknown contamination could require us to incur costs or could become the basis for new or increased liabilities that could be material.

Item 1B. Unresolved Staff Comments

None.

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Item 2. Properties

The locations and uses of our major properties are as follows:

North America		
Irvine, California	(1)	Corporate Headquarters, Research and Development, Regulatory and Clinical Affairs, Manufacturing, Marketing, Administration
Draper, Utah	(1)	Manufacturing, Administration
Haina, Dominican Republic	(2)	Manufacturing
Añasco, Puerto Rico	(2)	Manufacturing
Central America		
Cartago, Costa Rica	(1),(2)	Manufacturing
Europe		
Nyon, Switzerland	(1)	Administration, Marketing
Prague, Czech Republic	(2)	Administration
Shannon, Limerick, Ireland	(1),(2)	Manufacturing (under construction)
Asia		
Tokyo, Japan	(2)	Administration, Marketing, Distribution
Shanghai, China	(2)	Administration, Marketing
Singapore	(1),(2)	Manufacturing, Distribution, Administration

(1) Owned property.

(2) Leased property.

The Dominican Republic lease expires in 2022; the Puerto Rico property has two leases that expire in 2023; the Costa Rica lease expires in 2021; the Prague, Czech Republic lease expires in 2026; the Shannon, Ireland lease expires in 2024; the Tokyo, Japan lease expires in 2021; the Shanghai, China lease expires in 2021; and Singapore has one land lease that expires in 2036 and one that expires in 2041. We believe our properties have been well maintained, are in good operating condition, and are adequate for current needs.

Item 3. Legal Proceedings

For a description of our material pending legal proceedings, please see Note 18 to the "*Consolidated Financial Statements*" of this Annual Report on Form 10-K, which is incorporated by reference.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the New York Stock Exchange (the "NYSE") under the symbol "EW."

Number of Stockholders

On January 31, 2020, there were 9,357 stockholders of record of our common stock.

Dividends

We have never paid any cash dividends on our capital stock and have no current plans to pay any cash dividends. Our current policy is to retain any future earnings for use in our business.

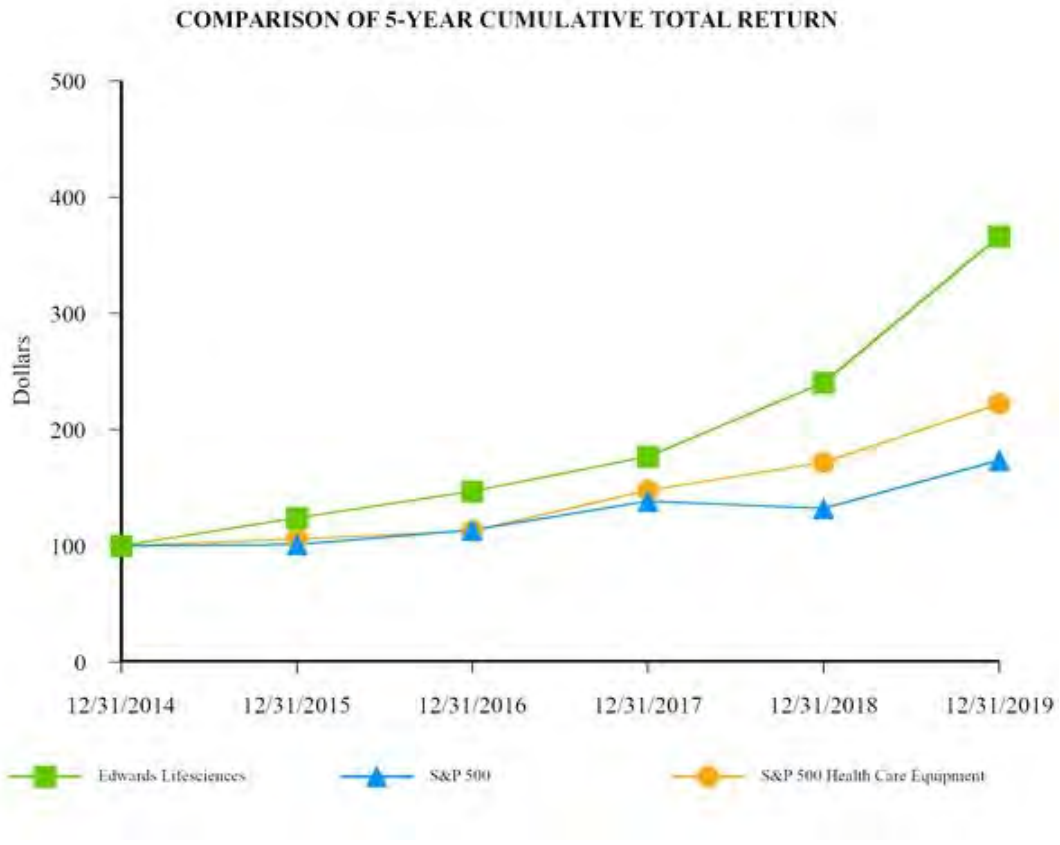
Issuer Purchases of Equity Securities

On November 15, 2017, the Board of Directors approved a stock repurchase program authorizing us to purchase on the open market, including pursuant to a Rule 10b5-1 plan, or in privately negotiated transactions, up to $1.0 billion of our common stock. On May 8, 2019, the Board of Directors approved a new stock repurchase program providing for an additional $1.0 billion of repurchases of our common stock. The repurchase programs do not have an expiration date. We did not purchase any of our common stock during the fourth quarter of 2019 and, as of December 31, 2019, we had remaining authority to purchase $1.2 billion of common stock.

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Performance Graph

The following graph compares the performance of our common stock with that of the S&P 500 Index and the S&P 500 Health Care Equipment Index. The cumulative total return listed below assumes an initial investment of $100 at the market close on December 31, 2014 and reinvestment of dividends. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.



	Total Cumulative Return				
	2015	2016	2017	2018	2019
Edwards Lifesciences	**$ 124.01**	**$ 147.12**	**$ 176.97**	**$ 240.49**	**$ 366.29**
S&P 500	**101.38**	**113.51**	**138.29**	**132.23**	**173.86**
S&P 500 Health Care Equipment	**105.97**	**112.85**	**147.71**	**171.70**	**222.04**

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Item 6. Selected Financial Data

		As of or for the Years Ended December 31,				
		2019	2018	2017	2016	2015
		(in millions, except per share data)				
OPERATING RESULTS	Net sales	$ 4,348.0	$ 3,722.8	$ 3,435.3	$ 2,963.7	$ 2,493.7
	Gross profit	3,233.6	2,783.4	2,560.0	2,166.3	1,876.5
	Operating income (a)	1,146.8	748.2	1,089.4	751.2	636.1
	Net income (a)	1,046.9	722.2	583.6	569.5	494.9
COMMON STOCK INFORMATION	Net income per common share (a):					
	Basic	$ 5.03	$ 3.45	$ 2.77	$ 2.67	$ 2.30
	Diluted	4.93	3.38	2.70	2.61	2.25
	Cash dividends declared per common share	—	—	—	—	—
BALANCE SHEET DATA	Total assets	$ 6,488.1	$ 5,323.7	$ 5,666.4	$ 4,518.5	$ 4,056.3
	Long-term debt (b)	594.4	593.8	438.4	822.3	596.9

(a) The above results for 2019 include special charges of $64.6 million. The above results for 2018 include special charges of $109.1 million (primarily the impairment of intangible assets) and a $180.0 million ($137.5 million, net of tax) charge in 2018 related to a litigation settlement. The above results for 2017 include a $112.5 million ($70.3 million, net of tax) gain for a litigation payment received in 2017 and a $262.0 million tax expense related to the implementation of U.S. tax law changes. See Part II, Item 7, *"Management's Discussion and Analysis of Financial Condition and Results of Operations*" and Note 3, Note 4 and Note 17 to the *"Consolidated Financial Statements"* for additional information.

(b) In October 2013, we issued $600.0 million of 2.875% fixed-rate unsecured senior notes due October 15, 2018 (the "2013 Notes"). At December 31, 2017, the 2013 Notes were classified as short-term obligations as these obligations were due within one year. These 2013 Notes were paid in October 2018. In June 2018, we issued $600.0 million of 4.3% fixed-rate unsecured senior notes due June 15, 2028, which were classified as long-term obligations as of December 31, 2019 and 2018. Amounts outstanding under our Five-Year Credit Agreement ("Credit Agreement") have been classified as long-term obligations in accordance with the terms of the Credit Agreement.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

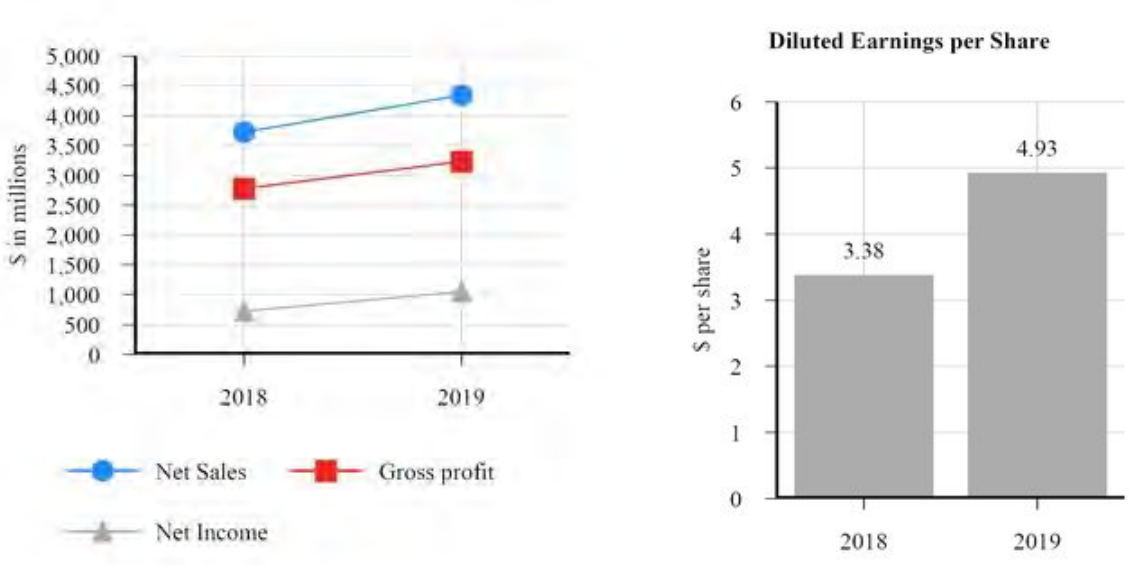
The following discussion and analysis presents the factors that had a material effect on our results of operations during the two years ended December 31, 2019. Also discussed is our financial position as of December 31, 2019. You should read this discussion in conjunction with the historical consolidated financial statements and related notes included elsewhere in this Form 10-K. For a discussion related to the results of operations for 2018 compared to 2017, refer to Part II, Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in our 2018 Annual Report on Form 10–K filed with the Securities and Exchange Commission on February 15, 2019.

Overview

We are the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, we partner with the world's leading clinicians and researchers and invest in research and development to transform care for those impacted by structural heart disease or who require hemodynamic monitoring during surgery or in intensive care. We conduct operations worldwide and are managed in the following geographical regions: United States, Europe, Japan, and Rest of World. Our products are categorized into the following main areas: Transcatheter Aortic Valve Replacement ("TAVR"), Transcatheter Mitral and Tricuspid Therapies ("TMTT"), Surgical Structural Heart ("Surgical"), and Critical Care. Prior to 2019, TMTT and TAVR had been reported together. Therefore, prior periods have been presented to conform with the updated product categories.

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Financial Highlights



Our sales growth was driven by our TAVR products, primarily the *Edwards SAPIEN 3* transcatheter heart valve and the *Edwards SAPIEN 3 Ultra System*. Our 2018 Surgical sales in the United States were reduced by a $82.5 million sales return reserve related to our conversion to a consignment inventory model.

Our gross profit increase was driven by our sales performance noted above and was positively impacted by an improved product mix, led by TAVR products. Partially offsetting this increase was a charge of $73.1 million recorded in 2019, primarily comprised of the write off of inventory related to strategic decisions regarding our TAVR portfolio, including the decision to discontinue our *CENTERA* program.

The increase in our net income and diluted earnings per share in 2019 was primarily driven by the aforementioned sales growth, partially offset by a 2018 tax benefit and the charge in 2019 related to strategic decisions regarding our TAVR portfolio.

Healthcare Environment, Opportunities, and Challenges

The medical technology industry is highly competitive and continues to evolve. Our success is measured both by the development of innovative products and the value we bring to our stakeholders. We are committed to developing new technologies and providing innovative patient care, and we are committed to defending our intellectual property in support of those developments. In 2019, we invested 17.3% of our net sales in research and development. The following is a summary of important developments during 2019:

- we reached an agreement with Boston Scientific Corporation ("Boston Scientific") in January 2019 to settle all outstanding patent disputes for a one-time payment to Boston Scientific of $180.0 million;
- we completed the acquisition of CAS Medical Systems, Inc. ("CASMED"). CASMED is a medical technology company dedicated to noninvasive monitoring of tissue oxygenation in the brain;
- we received CE Mark for the *Edwards PASCAL* transcatheter valve repair system;
- we received FDA approval to expand use of the *Edwards SAPIEN* and *SAPIEN 3 Ultra* transcatheter heart valve systems to the treatment of severe, symptomatic aortic stenosis patients who are determined to be at low risk of open-heart surgery;
- we received CE Mark to expand use of the *Edwards SAPIEN 3* transcatheter heart valve for the treatment of patients diagnosed with aortic stenosis who are at low risk for open-heart surgery; and

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- we received FDA approval for an Early Feasibility Study to evaluate the safety and function of the *Edwards EVOQUE* tricuspid valve replacement system.

We are dedicated to generating robust clinical, economic, and quality of life evidence increasingly expected by patients, clinicians, and payors in the current healthcare environment, with the goal of encouraging the adoption of innovative new medical therapies that demonstrate superior outcomes.

Results of Operations

Net Sales by Major Regions
(dollars in millions)

	Year Ended December 31,		Change	
	2019	2018	$	%
United States	$ 2,532.7	$ 2,055.3	$ 477.4	23.2%
Europe	941.2	885.1	56.1	6.4%
Japan	444.7	396.8	47.9	12.1%
Rest of World	429.4	385.6	43.8	11.3%
International	1,815.3	1,667.5	147.8	8.9%
Total net sales	$ 4,348.0	$ 3,722.8	$ 625.2	16.8%

International net sales include the impact of foreign currency exchange rate fluctuations. The impact of foreign currency exchange rate fluctuations on net sales is not necessarily indicative of the impact on net income due to the corresponding effect of foreign currency exchange rate fluctuations on international manufacturing and operating costs, and our hedging activities. For more information, see *"Quantitative and Qualitative Disclosures About Market Risk."*

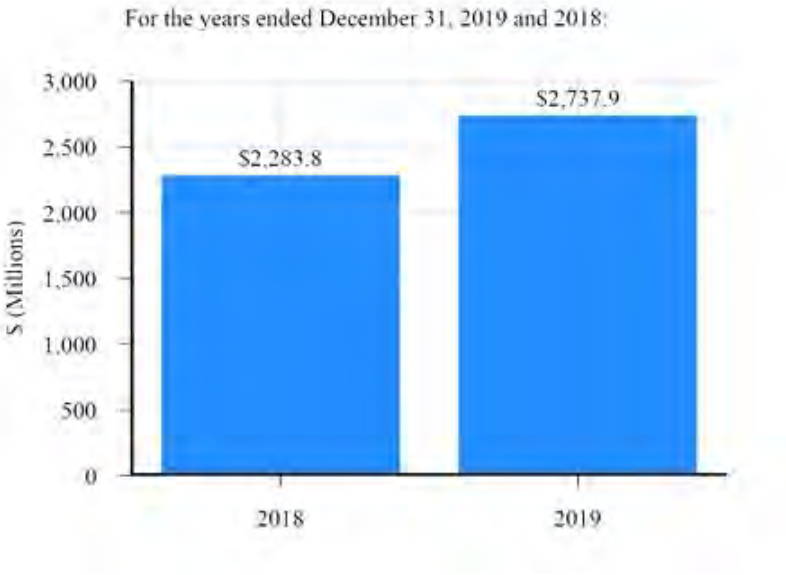
Net Sales by Product Group
(dollars in millions)

	Year Ended December 31,		Change	
	2019	2018	$	%
Transcatheter Aortic Valve Replacement	$ 2,737.9	$ 2,283.8	$ 454.1	19.9%
Transcatheter Mitral and Tricuspid Therapies	28.2	2.9	25.3	NM
Surgical Heart Valve Therapy	841.7	761.6	80.1	10.5%
Critical Care	740.2	674.5	65.7	9.7%
Total net sales	$ 4,348.0	$ 3,722.8	$ 625.2	16.8%

NM - Not meaningful

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Transcatheter Aortic Valve Replacement



The increase in net sales of TAVR products was due primarily to:

- higher sales of the *Edwards SAPIEN 3* valve, particularly in the United States, driven by strong therapy adoption; and
- higher sales of the *Edwards SAPIEN 3 Ultra System* following its regulatory approval in Europe (November 2018) and the United States (December 2018);

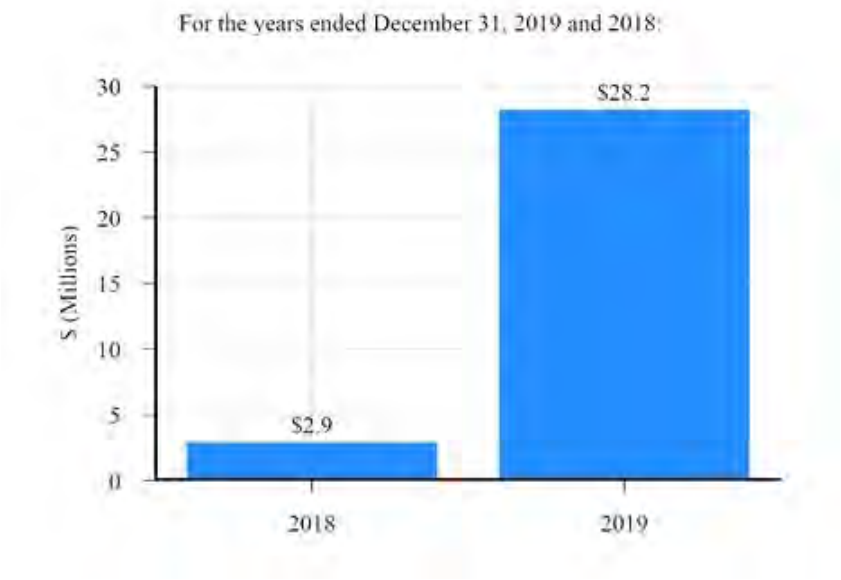
partially offset by:

- foreign currency exchange rate fluctuations, which decreased net sales by $32.7 million, due primarily to the weakening of the Euro against the United States dollar.

The March 2019 results of the PARTNER 3 Trial demonstrated superiority of *SAPIEN 3* TAVR over surgery in the low risk patient population. In August 2019, we received FDA approval to expand use of the *Edwards SAPIEN 3* and *SAPIEN 3 Ultra* transcatheter heart valve systems to the treatment of severe, symptomatic aortic stenosis patients who are determined to be at low risk of open-heart surgery. Given the approval for patients at low surgical risk and the continued excellence and versatility of our balloon expandable platform, we decided to discontinue the *CENTERA* program. While the *CENTERA* valve has demonstrated excellent clinical outcomes and is performing well for patients, the time and resources required to optimize deliverability and expand the indications to match the *SAPIEN 3* valve are significant. In November 2019, we received CE Mark to expand use of the *Edwards SAPIEN 3* transcatheter heart valve for the treatment of patients diagnosed with aortic stenosis who are at low risk for open-heart surgery.

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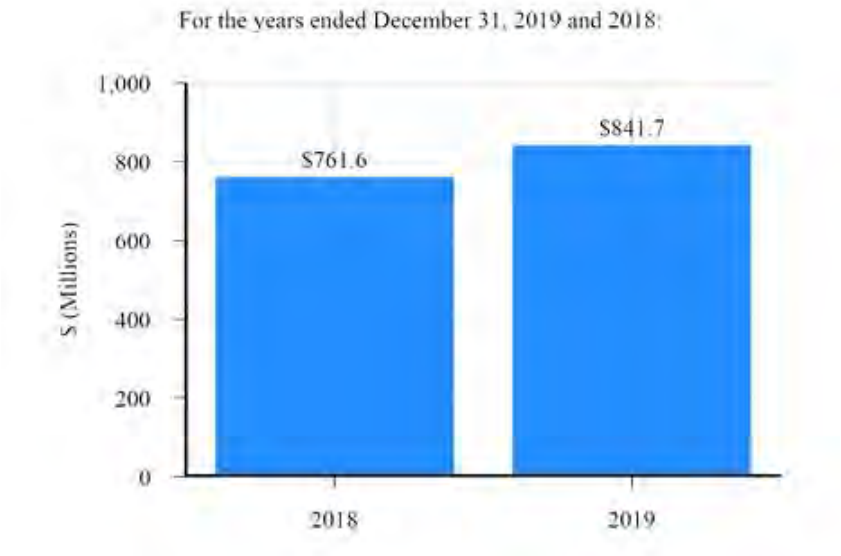
Transcatheter Mitral and Tricuspid Therapies



The increase in net sales of TMTT products was due primarily to sales of the *Edwards PASCAL* transcatheter valve repair system in Europe, which received CE Mark in February 2019.

In mitral repair, we continue to enroll our CLASP IID U.S. pivotal trial to study *PASCAL* in primary, or degenerative, mitral valve disease. We also have initiated enrollment in our CLASP IIF pivotal trial for patients with secondary, or functional, mitral valve disease. In September 2019, we received FDA approval for our CLASP IITR pivotal trial to study *PASCAL* in patients with symptomatic severe tricuspid regurgitation. In the fourth quarter of 2019, we received FDA approval for an Early Feasibility Study to evaluate the safety and function of the *Edwards EVOQUE* tricuspid valve replacement system.

Surgical Structural Heart



The increase in net sales of Surgical products was due primarily to:

- sales return reserves in 2018 of $82.5 million in the United States related to our conversion to a consignment inventory model; and

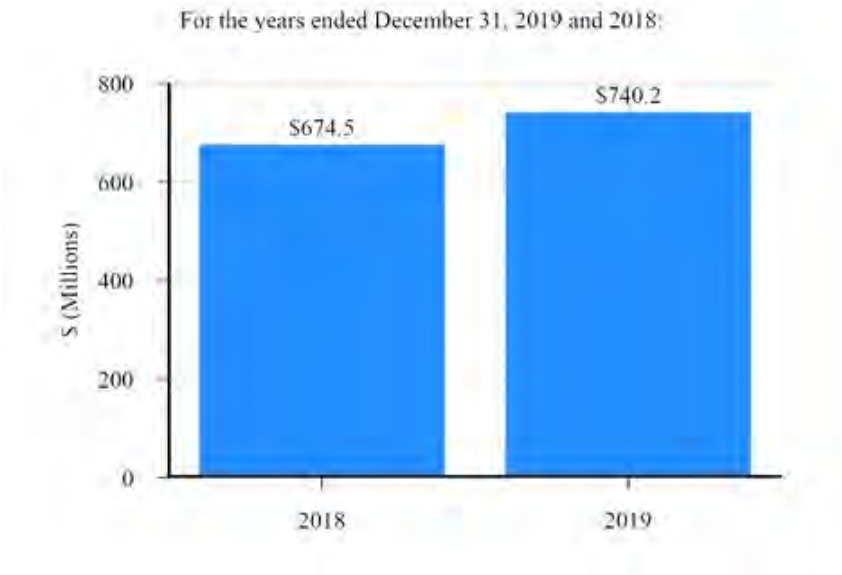
- increased sales of aortic tissue valves in Japan, Europe and the United States, primarily the *INSPIRIS RESILIA* aortic valve;

partially offset by:

- foreign currency exchange rate fluctuations, which decreased net sales by $14.5 million, due primarily to the weakening of the Euro against the United States dollar.

At the end of 2019, we received European regulatory approval for *HARPOON Beating Heart Mitral Valve Repair System*, and are in the process of beginning our commercial launch. *HARPOON* offers the potential for earlier treatment of degenerative mitral valve disease, with faster recovery and more consistent outcomes for surgical patients.

Critical Care



2019 Compared with 2018

The increase in net sales of Critical Care products was driven by our *HemoSphere* advanced monitoring platform, primarily in the United States, partially offset by foreign currency exchange rate fluctuations, which decreased net sales by $9.1 million, due primarily to the weakening of the Euro and various other currencies against the United States dollar.

On April 18, 2019, we completed the acquisition of CASMED, a medical technology company dedicated to noninvasive monitoring of tissue oxygenation in the brain. Our Critical Care sales for 2019 included $16.8 million related to CASMED.

We received FDA clearance in the third quarter of 2019 to use *FORE-SIGHT*, our cerebral oximetry technology, on our *Hemosphere* platform, and have initiated the commercial launch.

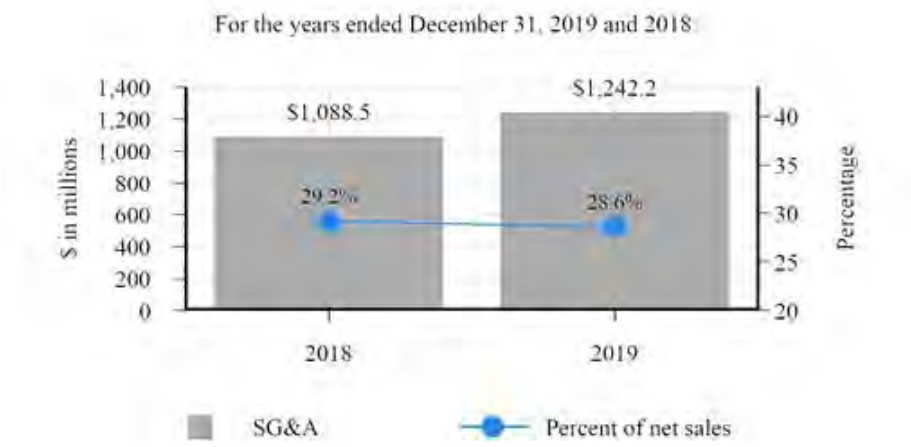
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Gross Profit



The decrease in gross profit as a percentage of net sales in 2019 compared to 2018 was driven by (1) a charge of $73.1 million related to strategic decisions regarding our transcatheter aortic valve portfolio, including the decision to discontinue our *CENTERA* program (for further information see the "*Financial Highlights*" section above), (2) the impact of multiple investments in our operations, including an increase in costs to improve our manufacturing processes and (3) spending in support of the new European device regulations. This decrease was partially offset by a 1.5 percentage point increase due to the impact of foreign currency exchange rate fluctuations, including the settlement of foreign currency hedging contracts.

Selling, General, and Administrative ("SG&A") Expenses



The increase in SG&A expenses in 2019 compared to 2018 was due primarily to higher transcatheter structural heart field personnel-related costs, primarily in the United States and Europe. These increases were partially offset by the impact of foreign currency, which decreased expenses by $16.7 million primarily due to the weakening of the Euro against the United States dollar. The decrease in SG&A expenses as a percentage of net sales was primarily due to leverage from our higher sales performance.

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Research and Development ("R&D") Expenses



The increase in R&D expenses in 2019 compared to 2018 was due primarily to investments in our transcatheter structural heart programs, including generating clinical evidence.

Intellectual Property Litigation Expenses (Income), net

We incurred intellectual property litigation expenses, including settlements and external legal costs, of $33.4 million and $214.0 million during 2019 and 2018, respectively. In January 2019, we reached an agreement with Boston Scientific to settle all outstanding patent disputes for a one-time payment to Boston Scientific of $180.0 million, which was included as an expense in 2018. The settlement covers alleged past damages and no further royalties will be owed by either party.

Change in Fair Value of Contingent Consideration Liabilities, net

The change in fair value of contingent consideration liabilities resulted in income of $6.1 million and $5.7 million for the years ended December 31, 2019 and 2018, respectively. The income was due primarily to longer product development timelines, which reduced the probability of milestone achievements. The income was net of expenses associated with changes in the fair value of the liabilities associated with adjustments to discount rates, accretion of interest due to the passage of time, and the 2018 achievement by Valtech Cardio Ltd. of a regulatory milestone. For further information, see Note 11 to the "*Consolidated Financial Statements*."

Special Charges, net

For information on special charges, see Note 4 to the "*Consolidated Financial Statements*."

Interest Expense

Interest expense was $20.7 million and $29.9 million in 2019 and 2018, respectively. The decrease in interest expense resulted primarily from a lower average debt balance.

Interest Income

Interest income was $32.2 million and $32.0 million in 2019 and 2018, respectively. The increase in interest income resulted primarily from higher average interest rates, partially offset by a lower average investment balance.

Other (Income) Expense, net
(in millions)

	Years Ended December 31,	
	2019	2018
Foreign exchange gains, net	$ (5.9)	$ (6.7)
(Gain) loss on investments	(0.5)	1.7
Non-service cost components of net periodic pension benefit cost (credit)	0.2	(0.1)
Other	(2.0)	1.1
Total other (income) expense, net	$ (8.2)	$ (4.0)

The net foreign exchange gains relate to the foreign currency fluctuations in our global trade and intercompany receivable and payable balances, offset by the gains and losses on derivative instruments intended as an economic hedge of those exposures.

The (gain) loss on investments represents our net share of gains and losses in investments accounted for under the equity method, and realized gains and losses on investments in equity securities.

The non-service cost components of net periodic pension benefit cost (credit) includes the costs of our defined benefit plans that are not attributed to services rendered by eligible employees during the year, such as interest costs, expected return on plan assets, and amortization of actuarial gains or losses. Certain costs associated with realignments, including settlements and curtailments, have been included as a component of "*Special (Gains) Charges, net.*" For further information, see Notes 4 and 13 to the "*Consolidated Financial Statements*."

Provision for Income Taxes

	Year Ended December 31,		Change	
	2019	2018	$	%
Provision for income taxes	119.6	39.2	80.4	205.1%
Effective tax rate	10.3%	5.1%		

Our effective income tax rate in 2019 and 2018 was 10.3% and 5.1%, respectively. Our effective tax rate for 2019 increased in comparison to 2018 primarily because of the increase in the U.S. tax on global intangible low-taxed income that became effective with the Tax Cuts and Jobs Act of 2017 (the "2017 Act"), and the tax benefit in 2018 from audit settlements.

In 2019, the difference between our 10.3% effective tax rate and the Federal statutory rate of 21% was primarily due to the foreign tax rate differential on foreign operations, the recognition of excess tax benefits on stock-based compensation, and Federal and California research and development credits.

As of December 31, 2019, gross uncertain tax positions were $203.1 million. We estimate that these liabilities would be reduced by $50.1 million from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes, and timing adjustments. The net amount of $153.0 million, if not required, would favorably affect our effective tax rate.

We strive to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at any time. While we have accrued for matters we believe are more likely than not to require settlement, the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in the consolidated financial statements. Furthermore, we may later decide to challenge any assessments, if made, and may exercise our right to appeal. The uncertain tax positions are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues, and issuance of new legislation, regulations, or case law. We believe that adequate amounts of tax and related penalty and interest have been provided in income tax expense for any adjustments that may result from our uncertain tax positions.

At December 31, 2019, all material state, local, and foreign income tax matters have been concluded for years through 2008. During 2018, we signed agreements with the Internal Revenue Service ("IRS") to settle tax years 2009 through 2014,

including transfer pricing matters and the tax treatment of a portion of a litigation settlement payment received in 2014. The IRS began its examination of the 2015 and 2016 tax years during the fourth quarter of 2018 and its examination of the 2017 tax year during the first quarter of 2019.

During 2018, we executed an Advance Pricing Agreement ("APA") between the United States and Switzerland governments for tax years 2009 through 2020 covering various transfer pricing matters and we have updated our transfer pricing policies accordingly. Certain intercompany transactions covering tax years 2015 through 2019 were not resolved and those related tax positions remain uncertain. These transfer pricing matters may be significant to our consolidated financial statements. Based upon the information currently available and numerous possible outcomes, we cannot reasonably estimate what, if any, changes in our existing uncertain tax positions may occur in the next 12 months and, therefore, have recorded the gross uncertain tax positions as a long-term liability.

In addition, we executed other APAs as follows: during 2017, an APA between the United States and Japan covering tax years 2015 through 2019; and during 2018, APAs between Japan and Singapore and between Switzerland and Japan covering tax years 2015 through 2019. We are evaluating filing to renew some or all of these APAs for the years 2020 and forward. The execution of some or all of these APAs depends on a number of variables outside of our control.

We have received tax incentives in certain non-U.S. tax jurisdictions, the primary benefit for which will expire in 2029. The tax reductions as compared to the local statutory rates were $157.6 million ($0.75 per diluted share) and $144.9 million ($0.70 per diluted share) for the years ended December 31, 2019 and 2018, respectively.

Liquidity and Capital Resources

Our sources of cash liquidity include cash and cash equivalents, short-term investments, amounts available under credit facilities, and cash from operations. We believe that these sources are sufficient to fund the current requirements of working capital, capital expenditures, and other financial commitments for the next twelve months from the financial statement issuance date. However, we periodically consider various financing alternatives and may, from time to time, seek to take advantage of favorable interest rate environments or other market conditions.

The 2017 Act, which was signed into law on December 22, 2017, included extensive changes to the international tax regime. The 2017 Act required a deemed repatriation of post-1986 undistributed foreign earnings and profits. The deemed repatriation resulted in a $263.9 million tax obligation as of December 31, 2019. The one-time transition tax liability, as adjusted, is payable in six remaining annual installments, as outlined in the contractual obligations table below. See Note 17 to the "*Consolidated Financial Statements*" for additional information about the one-time transition tax.

As of December 31, 2019, cash and cash equivalents and short-term investments held in the United States and outside the United States were $909.8 million and $607.1 million, respectively. During 2019, we repatriated cash and notes receivable of $1.2 billion. We assert that $1.1 billion of our foreign earnings continue to be permanently reinvested and our intent is to repatriate $140.7 million of our foreign earnings as of December 31, 2019.

On April 18, 2019, we acquired CASMED for an aggregate cash purchase price of $2.45 per share of common stock, or $100.8 million. For more information, see Note 8 to the "*Consolidated Financial Statements*."

Certain of our business acquisitions involve contingent consideration arrangements. Payment of additional consideration in the future may be required, contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels, or obtaining regulatory approvals. For further information, see Note 8 to the "*Consolidated Financial Statements*."

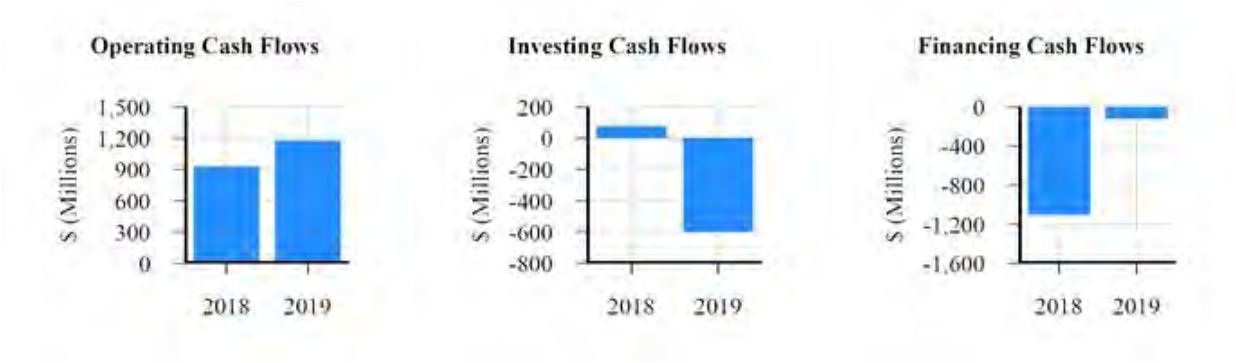
We have a Five-Year Credit Agreement ("the Credit Agreement") which matures on April 28, 2023. The Credit Agreement provides up to an aggregate of $750.0 million in borrowings in multiple currencies. Subject to certain terms and conditions, we may increase the amount available under the Credit Agreement by up to an additional $250.0 million in the aggregate. As of December 31, 2019, there were no borrowings outstanding under the Credit Agreement. The Credit Agreement is unsecured and contains various financial and other covenants, including a maximum leverage ratio, as defined in the Credit Agreement. The Company was in compliance with all covenants at December 31, 2019.

In June 2018, we issued $600.0 million of 4.3% fixed-rate unsecured senior notes (the "2018 Notes") due June 15, 2028. As of December 31, 2019, the total carrying value of our 2018 Notes was $594.4 million. For further information on our debt, see Note 10 to the "*Consolidated Financial Statements*."

We reached an agreement with Boston Scientific to settle all outstanding patent disputes for a one-time payment to Boston Scientific of $180.0 million, which was paid in January 2019.

From time to time, we repurchase shares of our common stock under share repurchase programs authorized by the Board of Directors. We consider several factors in determining when to execute share repurchases, including, among other things, expected dilution from stock plans, cash capacity, and the market price of our common stock. During 2019, under the Board authorized repurchase programs, we repurchased a total of 1.4 million shares at an aggregate cost of $255.0 million, and as of December 31, 2019, we had remaining authority to purchase $1.2 billion of our common stock. For further information, see Note 14 to the "*Consolidated Financial Statements*."

Consolidated Cash Flows - For the twelve months ended December 31, 2019 and 2018



Net cash flows provided by **operating activities** of $1.2 billion for 2019 increased $252.6 million from 2018 due primarily to (1) improved operating performance in 2019, (2) higher tax payments in 2018 related to an audit settlement, and (3) a higher bonus payout in 2018 associated with 2017 performance, partially offset by (1) a payment of $180.0 million in 2019 for a litigation settlement and (2) higher working capital needs in 2019.

Net cash used in **investing activities** of $595.8 million in 2019 consisted primarily of (1) capital expenditures of $254.4 million, (2) net purchases of investments of $158.2 million, (3) a $100.2 million net cash payment associated with the acquisition of CASMED, (4) a $35.0 million payment for an option to acquire a company, and (5) a $24.0 million payment to acquire certain early-stage transcatheter intellectual property and associated clinical and regulatory experience.

Net cash provided by investing activities of $76.7 million in 2018 consisted primarily of net proceeds from investments of $342.0 million, partially offset by capital expenditures of $238.7 million.

We currently anticipate making capital expenditures of approximately $400 million in 2020 as we continue to invest in our operations.

Net cash used in **financing activities** of $115.6 million in 2019 consisted primarily of purchases of treasury stock of $263.3 million, partially offset by proceeds from stock plans of $160.5 million.

Net cash used in financing activities of $1.1 billion in 2018 consisted primarily of purchases of treasury stock of $795.5 million and net debt repayments of $437.3 million, partially offset by proceeds from stock plans of $147.0 million.

Consolidated Cash Flows - For the twelve months ended December 31, 2018 and 2017

For a discussion related to our consolidated cash flows for 2018 compared to 2017, refer to Part II, Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in our 2018 Annual Report on Form 10–K filed with the Securities and Exchange Commission on February 15, 2019.

Contractual Obligations

A summary of all of our contractual obligations and commercial commitments as of December 31, 2019 is as follows (in millions):

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Debt	$ 600.0	$ —	$ —	$ —	$ 600.0
Operating leases	91.8	27.4	34.2	15.7	14.5
Interest on debt	164.3	19.9	39.8	38.5	66.1
Transition tax on unremitted foreign earnings and profits (a)	263.9	25.1	50.3	110.0	78.5
Pension obligations (b)	1.9	1.9	—	—	—
Purchase and other commitments (c)	43.6	28.0	12.1	1.3	2.2
Total contractual cash obligations (d), (e)	$ 1,165.5	$ 102.3	$ 136.4	$ 165.5	$ 761.3

(a) As of December 31, 2019, we had recorded $263.9 million of income tax liabilities related to the one-time transition tax that resulted from the enactment of the 2017 Act. The transition tax is due in eight annual installments, with the first annual installment paid in 2018 and the second annual installment paid in 2019. The remaining installment amounts will be equal to 8% of the total liability, payable in fiscal years 2020 through 2022, 15% in fiscal year 2023, 20% in fiscal year 2024, and 25% in fiscal year 2025. See Note 17 to the "*Consolidated Financial Statements*" for additional information about the one-time transition tax.

(b) The amount included in "Less Than 1 Year" reflects anticipated contributions to our various pension plans. Anticipated contributions beyond one year are not determinable. The total accrued benefit liability for our pension plans recognized as of December 31, 2019 was $42.0 million. This amount is impacted by, among other items, pension expense funding levels, changes in plan demographics and assumptions, and investment returns on plan assets. Therefore, we are unable to make a reasonably reliable estimate of the amount and period in which the liability might be paid, and did not include this amount in the contractual obligations table. See Note 13 to the "*Consolidated Financial Statements*" for further information.

(c) For certain purchase and other commitments, such as commitments to fund equity method or other investments, the timing of the payment may not be certain. In these cases, the maturity dates in the table reflect our best estimates.

(d) As of December 31, 2019, the gross liability for uncertain tax positions, including interest, was $215.9 million and relates primarily to transfer pricing matters. During 2018, we executed an APA between the United States and Switzerland governments for tax years 2009 through 2020 covering various transfer pricing matters and we have updated our transfer pricing policies accordingly. Certain intercompany transactions covering tax years 2015 through 2019 were not resolved and those related tax positions remain uncertain. These transfer pricing matters may be significant to our consolidated financial statements, and the final outcome of the negotiations is uncertain. Management believes that adequate amounts of tax and related penalty and interest have been provided in income tax expense for any adjustments that may result for our uncertain tax positions. We are unable to make a reasonably reliable estimate of the amount and period in which the liability might be paid, and did not include this amount in the contractual obligations table.

(e) We acquire assets still in development, enter into research and development arrangements, acquire businesses, and sponsor certain clinical trials that often require milestone, royalty, or other future payments to third-parties, contingent upon the occurrence of certain future events. In situations where we have no ability to influence the achievement of the milestone or otherwise avoid the payment, we have included those payments in the table above. However, we have excluded from the table contingent milestone payments and other contingent liabilities for which we cannot reasonably predict future payments or for which we can avoid making payment by unilaterally deciding to stop development of a product or cease progress of a clinical trial. We estimate that these contingent payments could be up to $565.0 million if all milestones or other contingent obligations are met. This amount includes certain milestone-based contingent obligations that may be paid through a combination of cash and issuance of common stock.

Critical Accounting Policies and Estimates

Our results of operations and financial position are determined based upon the application of our accounting policies, as discussed in the notes to the "*Consolidated Financial Statements*." Certain of our accounting policies represent a selection

among acceptable alternatives under GAAP. In evaluating our transactions, management assesses all relevant GAAP and chooses the accounting policy that most accurately reflects the nature of the transactions.

The application of accounting policies requires the use of judgment and estimates. These matters that are subject to judgments and estimation are inherently uncertain, and different amounts could be reported using different assumptions and estimates. Management uses its best estimates and judgments in determining the appropriate amount to reflect in the consolidated financial statements, using historical experience and all available information. We also use outside experts where appropriate. We apply estimation methodologies consistently from year to year.

We believe the following are the critical accounting policies which could have the most significant effect on our reported results and require subjective or complex judgments by management.

Revenue Recognition

When we recognize revenue from the sale of our products, the amount of consideration we ultimately receive varies depending upon the return terms, sales rebates, discounts, and other incentives that we may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The estimate of variable consideration requires significant judgment. We include estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely upon an assessment of historical payment experience, historical relationship to revenues, estimated customer inventory levels, and current contract sales terms with direct and indirect customers. Product returns are typically not significant because returns are generally not allowed unless the product is damaged at time of receipt. If the historical data and inventory estimates used to calculate the variable consideration do not approximate future activity, our financial position, results of operations, and cash flows could be impacted.

In addition, in limited circumstances, we may allow customers to return previously purchased products, such as for next-generation product offerings. For these transactions, we defer recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount of product to be returned when the next-generation products are shipped to the customer. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls, and variation in product utilization all affect the estimates related to sales returns and could cause actual returns to differ from these estimates.

Our sales adjustment related to distributor rebates given to our United States distributors represents the difference between our sales price to the distributor and the negotiated price to be paid by the end-customer. We validate the distributor rebate accrual quarterly through either a review of the inventory reports obtained from our distributors or an estimate of the distributor's inventory. This distributor inventory information is used to verify the estimated liability for future distributor rebate claims based on historical rebates and contract rates. We periodically monitor current pricing trends and distributor inventory levels to ensure the credit for future distributor rebates is fairly stated.

Excess and Obsolete Inventory

The valuation of our inventory requires us to estimate excess, obsolete, and expired inventory. We base our provisions for excess, obsolete, and expired inventory on our estimates of forecasted net sales. A significant change in the timing or level of demand for our products as compared to forecasted amounts may result in recording additional allowances for excess, obsolete, and expired inventory in the future. In addition, our industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls, increasing levels of consigned inventory, and variation in product utilization all affect our estimates related to excess, obsolete, and expired inventory.

Intangible Assets and Long-lived Assets

We acquire intangible assets in connection with business combinations and asset purchases. The acquired intangible assets are recorded at fair value, which is determined based on a discounted cash flow analysis. The determination of fair value requires significant estimates, including, but not limited to, the amount and timing of projected future cash flows, the discount rate used to discount those cash flows, the assessment of the asset's life cycle, including the timing and expected costs to complete in-process projects, and the consideration of legal, technical, regulatory, economic, and competitive risks.

In-process research and development assets acquired in business combinations is reviewed for impairment annually, or whenever an event occurs or circumstances change that would indicate the carrying amount may be impaired. Additionally, management reviews the carrying amounts of other intangible and long-lived assets whenever events or circumstances indicate that the carrying amounts of an asset may not be recoverable. The impairment reviews require significant estimates about fair value, including estimation of future cash flows, selection of an appropriate discount rate, and estimates of long-term growth rates.

Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. We determine the fair value of the contingent consideration based primarily on the following factors:

- discount rates used to present value the projected cash flows;
- the probability of success of clinical events and regulatory approvals, and/or meeting commercial milestones;
- projected payment dates; and
- volatility of future revenue.

On a quarterly basis, we revalue these obligations and record changes in their fair value as an adjustment to earnings. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in our estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events, or changes in the assumed probability associated with regulatory approval.

The assumptions related to determining the value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration expense recorded in any given period.

Income Taxes

The determination of our provision for income taxes requires significant judgment, the use of estimates, and the interpretation and application of complex tax laws. Realization of certain deferred tax assets, primarily tax credits, net operating loss and other carryforwards, is dependent upon generating sufficient taxable income in the appropriate jurisdiction prior to the expiration of the carryforward periods. Failure to achieve forecasted taxable income in the applicable taxing jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in our effective tax rate on future earnings.

We have made an accounting policy election to recognize the U.S. tax effects of global intangible low-taxed income as a component of income tax expense in the period the tax arises.

We are subject to income taxes in the United States and numerous foreign jurisdictions. Our income tax returns are periodically audited by domestic and foreign tax authorities. These audits include questions regarding our tax filing positions, including the timing and amount of deductions and the allocation of income amongst various tax jurisdictions. We evaluate our tax positions and establish liabilities in accordance with the applicable accounting guidance on uncertainty in income taxes. Significant judgment is required in evaluating our uncertain tax positions, including estimating the ultimate resolution to intercompany pricing controversies between countries when there are numerous possible outcomes. We review these tax uncertainties quarterly and adjust the liability as events occur that affect potential liabilities for additional taxes, such as the progress of tax audits, lapsing of applicable statutes of limitations, negotiations between tax authorities, identification of new issues, and issuance of new legislation, regulations, or case law.

For additional details on our income taxes, see Note 2 and Note 17 to the "*Consolidated Financial Statements*."

Stock-based Compensation

We measure and recognize compensation expense for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options, service-based restricted stock units, market-based restricted stock units, performance-based restricted stock units, and employee stock purchase subscriptions. The fair value of each option award and employee stock

purchase subscription is estimated on the date of grant using the Black-Scholes option valuation model. The fair value of market-based restricted stock units is determined using a Monte Carlo simulation model, which uses multiple input variables to determine the probability of satisfying the market condition requirements. The Black-Scholes and Monte Carlo models require various highly judgmental assumptions, including stock price volatility, risk-free interest rate, and expected option term. For performance-based restricted stock units, expense is recognized if and when we conclude that it is probable that the performance condition will be achieved, which requires judgment. Stock-based compensation expense is recorded net of estimated forfeitures. Judgment is required in estimating the stock awards that will ultimately be forfeited. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations would be impacted.

New Accounting Standards

Information regarding new accounting standards is included in Note 2 to the "*Consolidated Financial Statements."*

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our business and financial results are affected by fluctuations in world financial markets, including changes in currency exchange rates and interest rates. We manage these risks through a combination of normal operating and financing activities and derivative financial instruments. We do not use derivative financial instruments for trading or speculative purposes.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. Our investment strategy is focused on preserving capital and supporting our liquidity requirements, while earning a reasonable market return. We invest in a variety of fixed-rate debt securities, primarily time deposits, commercial paper, U.S. and foreign government and agency securities, asset-backed securities, corporate debt securities, and municipal debt securities. The market value of our investments may decline if current market interest rates rise. As of December 31, 2019, we had $894.0 million of investments in fixed-rate debt securities which had an average remaining term to maturity of approximately 1.0 years. Taking into consideration the average maturity of our fixed-rate debt securities, a hypothetical 0.5% to 1.0% absolute increase in interest rates at December 31, 2019 would have resulted in a $4.6 million to $9.2 million decrease in the fair value of these investments. Such a decrease would only result in a realized loss if we choose or are forced to sell the investments before the scheduled maturity, which we currently do not anticipate.

For more information related to investments, see Note 7 to the "*Consolidated Financial Statements.*"

We are also exposed to interest rate risk on our debt obligations. As of December 31, 2019, we had $600.0 million of Notes outstanding that carry a fixed rate, and also had available a $750.0 million Credit Agreement that carries a variable interest rate based on the London interbank offered rate ("LIBOR"). As of December 31, 2019, there were no borrowings outstanding under the Credit Agreement. Based on our December 31, 2019 variable debt levels, a hypothetical 1.0% absolute increase in our floating market interest rates would not have impacted our interest expense since we had no variable debt outstanding during the year. As of December 31, 2019, a hypothetical 1.0% absolute increase in market interest rates would decrease the fair value of the fixed-rate debt by approximately $44.7 million. This hypothetical change in interest rates would not impact the interest expense on the fixed-rate debt.

For more information related to outstanding debt obligations, see Note 10 to the "*Consolidated Financial Statements.*"

Currency Risk

We are exposed to foreign currency risks that arise from normal business operations. These risks include the translation of local currency balances and results of our non-United States subsidiaries into United States dollars, currency gains and losses related to intercompany and third-party transactions denominated in currencies other than a location's functional currency, and currency gains and losses associated with intercompany loans. Our principal currency exposures relate to the Euro and the Japanese yen. Our objective is to minimize the volatility of our exposure to these risks through a combination of normal operating and financing activities and the use of derivative financial instruments in the form of foreign currency forward exchange contracts and cross currency swap contracts. The total notional amount of our derivative financial instruments entered into for foreign currency management purposes at December 31, 2019 was $1.6 billion. A hypothetical 10% increase/decrease in the value of the United States dollar against all hedged currencies would increase/decrease the fair value of these derivative contracts by $117.0 million. Any gains or losses on the fair value of derivative contracts would generally be offset by gains and losses on the underlying transactions, so the net impact would not be significant to our financial condition or results of operations.

For more information related to outstanding foreign exchange contracts, see Note 2 and Note 12 to the "*Consolidated Financial Statements.*"

Credit Risk

Derivative financial instruments involve credit risk in the event the financial institution counterparty should default. It is our policy to execute such instruments with major financial institutions that we believe to be creditworthy. At December 31, 2019, all derivative financial instruments were with bank counterparties assigned investment grade ratings by national rating agencies. We further diversify our derivative financial instruments among counterparties to minimize exposure to any one of these entities. We have not experienced a counterparty default and do not anticipate any non-performance by our current derivative counterparties.

Concentrations of Risk

We invest excess cash in a variety of fixed-rate debt securities, and diversify the investments between financial institutions. Our investment policy limits the amount of credit exposure to any one issuer.

In the normal course of business, we provide credit to customers in the health care industry, perform credit evaluations of these customers, and maintain allowances for potential credit losses, which have historically been adequate compared to actual losses. In 2019, we had no customers that represented 10% or more of our total net sales or accounts receivable, net.

Investment Risk

We are exposed to investment risks related to changes in the underlying financial condition and credit capacity of certain of our investments. As of December 31, 2019, we had $894.0 million of investments in fixed-rate debt securities of various companies, of which $556.2 million were long-term. In addition, we had $29.3 million of investments in equity instruments of public and private companies. Should these companies experience a decline in financial condition or credit capacity, or fail to meet certain development milestones, a decline in the investments' values may occur, resulting in unrealized or realized losses.

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Item 8. Financial Statements and Supplementary Data

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DECEMBER 31, 2019

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Other schedules are not applicable and have not been submitted.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Edwards Lifesciences Corporation

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Edwards Lifesciences Corporation and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, of comprehensive income, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018**,** and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the

company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Uncertain Tax Positions Related to Intercompany Transfer Pricing

As described in Notes 2 and 17 to the consolidated financial statements, the Company had a gross uncertain tax position liability balance of $203.1 million as of December 31, 2019, primarily related to transfer pricing. The Company is subject to income taxes in the United States and numerous foreign jurisdictions. As disclosed by management, the Company's income tax returns in these jurisdictions are periodically audited by domestic and foreign tax authorities. These audits include questions regarding the Company's tax filing positions, including the timing and amount of deductions and the allocation of income amongst various tax jurisdictions. Significant judgment is required by management in evaluating uncertain tax positions, including estimating the ultimate resolution to intercompany pricing controversies between countries when there are numerous possible outcomes.

The principal considerations for our determination that performing procedures relating to uncertain tax positions related to intercompany transfer pricing is a critical audit matter are there was significant judgment by management when determining uncertain tax positions related to intercompany transfer pricing, including a high degree of estimation uncertainty in evaluating whether certain tax filing positions taken by management will be upheld by the related local tax authority. This in turn led to a high degree of auditor judgment, effort, and subjectivity in performing procedures to evaluate the timely identification and accurate measurement of uncertain tax positions related to intercompany transfer pricing. Also, the evaluation of audit evidence available to support the tax liabilities for uncertain tax positions related to intercompany transfer pricing is complex and required significant auditor judgment as the nature of the evidence is highly subjective and the audit effort involved the use of professionals with specialized skill and knowledge to assist in evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to identification and recognition of the liability for uncertain tax positions related to intercompany transfer pricing, and controls addressing completeness of the uncertain tax positions, as well as controls over measurement of the liability. These procedures also included, among others, (i) testing the information used in the calculation of the liability for uncertain tax positions, including intercompany agreements, international, federal, and state filing positions, and the related final tax returns; (ii) testing the calculation of the liability for uncertain tax positions related to intercompany transfer pricing, by jurisdiction, including management's assessment of the technical merits of tax positions and estimates of the amount of tax benefit expected to be sustained; (iii) testing the completeness of management's assessment of both the identification of uncertain tax positions related to intercompany transfer pricing and possible outcomes of each uncertain tax position; and (iv) evaluating the status and results of income tax audits with the relevant tax authorities. Professionals with specialized skill and knowledge were used to assist in the evaluation of the completeness and measurement of the Company's uncertain tax positions related to intercompany transfer pricing, including evaluating the reasonableness of management's assessment of whether tax positions are more-likely-than-not of being sustained and the amount of potential benefit to be realized, the application of relevant tax laws, and estimated interest and penalties.

Fair Value of Contingent Consideration Liabilities

As described in Note 11 to the consolidated financial statements, certain of the Company's acquisitions involve contingent consideration arrangements. As of December 31, 2019, the Company had a contingent consideration liability of $172.5 million. As disclosed by management, payment of additional consideration is contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. These contingent

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consideration liabilities are measured by management at estimated fair value using either a probability weighted discounted cash flow analysis or a Monte Carlo simulation model, both of which consider significant unobservable inputs. These inputs include (1) the discount rate used to present value the projected cash flows, (2) the probability of milestone achievement, (3) the projected payment dates, and (4) the volatility of future revenue.

The principal considerations for our determination that performing procedures relating to the fair value of contingent consideration liabilities is a critical audit matter are there was significant judgment by management when estimating the fair value of these contingent obligations, including a high degree of estimation uncertainty in evaluating the discount rate, the probability of milestone achievement, the projected payment dates, and the volatility of future revenue. This in turn led to a high degree of auditor judgment, effort, and subjectivity in performing procedures to evaluate the fair value of contingent consideration liabilities. Also, the evaluation of audit evidence available to support the fair value of the contingent consideration liabilities is complex and required significant auditor judgment as the nature of the evidence is highly subjective and the audit effort involved the use of professionals with specialized skill and knowledge to assist in evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's process for estimating the fair value of contingent consideration liabilities, including controls over the determination of the significant unobservable inputs selected by management. These procedures also included, among others, (i) testing management's process for estimating the fair value of contingent consideration liabilities and (ii) testing management's probability weighted discounted cash flow analysis or Monte Carlo simulation used to estimate the fair value of the contingent consideration liabilities. Testing management's process included evaluating the appropriateness of the valuation methods used and the reasonableness of the significant assumptions, including the discount rate, the probability of milestone achievement, the projected payment dates, and the volatility of future revenue. Evaluating the reasonableness of the probability of milestone achievement and projected payment date of each milestone involved consideration of information obtained from the Company's product engineers, clinical trial data, and third-party industry data. The discount rate was evaluated by considering the cost of capital of comparable businesses and other industry factors. Professionals with specialized skill and knowledge were used to assist in the evaluation of certain significant assumptions, including the discount rate and volatility of future revenue.

/s/ PricewaterhouseCoopers LLP
Irvine, California
February 14, 2020

We have served as the Company's auditor since 1999.

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EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED BALANCE SHEETS

(in millions, except par value)

	December 31,	
	2019	**2018**
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,179.1	$ 714.1
Short-term investments (Note 7)	337.8	242.4
Accounts receivable, net (Note 5)	543.6	456.9
Other receivables	55.5	80.4
Inventories (Note 5)	640.9	607.0
Prepaid expenses	59.1	54.3
Other current assets	168.0	131.8
Total current assets	2,984.0	2,286.9
Long-term investments (Note 7)	585.5	506.3
Property, plant, and equipment, net (Note 5)	1,060.3	867.5
Operating lease right-of-use assets (Note 6)	80.1	—
Goodwill (Note 9)	1,167.7	1,112.2
Other intangible assets, net (Note 9)	336.5	343.2
Deferred income taxes	172.2	174.0
Other assets	101.8	33.6
Total assets	$ 6,488.1	$ 5,323.7
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 180.4	$ 134.0
Accrued and other liabilities (Note 5)	696.5	742.6
Operating lease liabilities (Note 6)	25.5	—
Total current liabilities	902.4	876.6
Long-term debt (Note 10)	594.4	593.8
Contingent consideration liabilities (Notes 8 and 11)	172.5	178.6
Taxes payable (Note 17)	236.6	259.4
Operating lease liabilities (Note 6)	58.9	—
Uncertain tax positions (Note 17)	171.7	124.9
Other long-term liabilities	203.3	150.0
Commitments and contingencies (Notes 6, 10 and 18)		
Stockholders' equity (Note 14)		
Preferred stock, $.01 par value, authorized 50.0 shares, no shares outstanding	—	—
Common stock, $1.00 par value, 350.0 shares authorized, 218.1 and 215.2 shares issued, and 209.1 and 207.7 shares outstanding, respectively	218.1	215.2
Additional paid-in capital	1,623.3	1,384.4
Retained earnings	3,741.6	2,694.7
Accumulated other comprehensive loss	(156.0)	(138.5)
Treasury stock, at cost, 9.0 and 7.5 shares, respectively	(1,278.7)	(1,015.4)
Total stockholders' equity	4,148.3	3,140.4
Total liabilities and stockholders' equity	$ 6,488.1	$ 5,323.7

The accompanying notes are an integral part of these consolidated financial statements.

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EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share information)

	Years Ended December 31,		
	2019	**2018**	**2017**
Net sales	$ 4,348.0	$ 3,722.8	$ 3,435.3
Cost of sales	1,114.4	939.4	875.3
Gross profit	3,233.6	2,783.4	2,560.0
Selling, general, and administrative expenses	1,242.2	1,088.5	990.8
Research and development expenses	752.7	622.2	552.6
Intellectual property litigation expenses (income), net (Note 3)	33.4	214.0	(73.3)
Change in fair value of contingent consideration liabilities	(6.1)	(5.7)	(9.9)
Special charges, net (Note 4)	64.6	116.2	9.7
Other operating expenses	—	—	0.7
Operating income	1,146.8	748.2	1,089.4
Interest expense	20.7	29.9	23.2
Interest income	(32.2)	(32.0)	(20.3)
Special (gains) charges, net (Note 4)	—	(7.1)	50.2
Other (income) expense, net (Note 16)	(8.2)	(4.0)	1.4
Income before provision for income taxes	1,166.5	761.4	1,034.9
Provision for income taxes (Note 17)	119.6	39.2	451.3
Net income	$ 1,046.9	$ 722.2	$ 583.6
Share information (Note 2):			
Earnings per share:			
Basic	$ 5.03	$ 3.45	$ 2.77
Diluted	$ 4.93	$ 3.38	$ 2.70
Weighted-average number of common shares outstanding:			
Basic	208.3	209.2	210.9
Diluted	212.2	213.6	215.9

The accompanying notes are an integral part of these consolidated financial statements.

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EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in millions)

	Years Ended December 31,		
	2019	**2018**	**2017**
Net income	$ 1,046.9	$ 722.2	$ 583.6
Other comprehensive (loss) income, net of tax (Note 15):			
Foreign currency translation adjustments	(11.2)	(38.6)	97.5
Unrealized (loss) gain on cash flow hedges	(11.1)	40.4	(30.6)
Defined benefit pension plans	(1.9)	0.6	3.5
Unrealized gain (loss) on available-for-sale investments	6.3	(3.3)	(7.8)
Reclassification of net realized investment loss to earnings	0.4	2.9	3.1
Other comprehensive (loss) income, net of tax	(17.5)	2.0	65.7
Comprehensive income	$ 1,029.4	$ 724.2	$ 649.3

The accompanying notes are an integral part of these consolidated financial statements.

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EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)

	Years Ended December 31,		
	2019	**2018**	**2017**
Cash flows from operating activities			
Net income	$ 1,046.9	$ 722.2	$ 583.6
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	89.3	77.4	81.9
Non-cash operating lease cost	25.3	—	—
Stock-based compensation (Notes 2 and 14)	81.3	71.0	61.6
Inventory write off	73.1	—	—
Impairment charges (Note 4)	40.6	118.8	31.0
Change in fair value of contingent consideration liabilities, net (Note 11)	(6.1)	(5.7)	(9.9)
Deferred income taxes	12.1	(27.3)	17.8
Purchased in-process research and development	24.0	—	6.7
Other	(2.8)	13.0	(6.2)
Changes in operating assets and liabilities:			
Accounts and other receivables, net	(88.0)	(28.7)	(27.8)
Inventories	(105.4)	(65.7)	(124.0)
Accounts payable and accrued liabilities	(63.5)	192.5	93.8
Income taxes	43.2	(157.8)	293.7
Prepaid expenses and other current assets	(6.8)	15.7	(9.9)
Other	16.2	1.4	8.4
Net cash provided by operating activities	1,179.4	926.8	1,000.7
Cash flows from investing activities			
Capital expenditures	(254.4)	(238.7)	(168.1)
Deposit of cash in escrow	—	—	(25.0)
Purchases of held-to-maturity investments (Note 7)	(130.2)	(210.0)	(804.9)
Proceeds from sales and maturities of held-to-maturity investments (Note 7)	50.0	578.1	654.7
Purchases of available-for-sale investments (Note 7)	(437.9)	(249.3)	(529.8)
Proceeds from sales and maturities of available-for-sale investments (Note 7)	359.9	223.2	448.7
Acquisitions (Notes 8 and 9)	(100.2)	—	(192.9)
Payment for acquisition option	(35.0)	—	—
Investments in intangible assets and in-process research and development	(24.0)	(3.0)	(7.4)
Other	(24.0)	(23.6)	(22.5)
Net cash (used in) provided by investing activities	(595.8)	76.7	(647.2)
Cash flows from financing activities			
Proceeds from issuance of debt	18.9	688.0	994.7
Payments on debt and finance lease obligations	(28.9)	(1,125.3)	(818.4)
Purchases of treasury stock	(263.3)	(795.5)	(763.3)
Proceeds from stock plans	160.5	147.0	113.8
Payment of contingent consideration	—	(15.1)	—
Other	(2.8)	(0.3)	—
Net cash used in financing activities	(115.6)	(1,101.2)	(473.2)
Effect of currency exchange rate changes on cash and cash equivalents	(3.0)	(6.5)	7.9
Net increase (decrease) in cash and cash equivalents	465.0	(104.2)	(111.8)
Cash and cash equivalents at beginning of year	714.1	818.3	930.1
Cash and cash equivalents at end of year	$ 1,179.1	$ 714.1	$ 818.3

The accompanying notes are an integral part of these consolidated financial statements.

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EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in millions)

	Common Stock		Treasury Stock					
	Shares	Par Value	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
BALANCE AT DECEMBER 31, 2016	242.6	$ 242.6	31.0	$ (2,499.3)	$ 1,167.8	$ 3,906.3	$ (198.4)	$ 2,619.0
Impact to retained earnings from adoption of ASU 2016-09						9.3		9.3
BALANCE AT JANUARY 1, 2017	242.6	242.6	31.0	(2,499.3)	1,167.8	3,915.6	(198.4)	2,628.3
Net income						583.6		583.6
Other comprehensive income, net of tax							65.7	65.7
Common stock issued under equity plans	3.0	3.0			110.8			113.8
Stock-based compensation expense					61.6			61.6
Shares issued to acquire business			(2.8)	264.3	2.2			266.5
Purchases of treasury stock			7.7	(763.3)				(763.3)
Retirement of treasury stock	(33.6)	(33.6)	(33.6)	2,746.2	(175.5)	(2,537.1)		—
BALANCE AT DECEMBER 31, 2017	212.0	212.0	2.3	(252.1)	1,166.9	1,962.1	(132.7)	2,956.2
Impact to retained earnings from adoption of ASU 2016-16 and ASU 2018-02						10.4	(7.8)	2.6
BALANCE AT JANUARY 1, 2018	212.0	212.0	2.3	(252.1)	1,166.9	1,972.5	(140.5)	2,958.8
Net income						722.2		722.2
Other comprehensive income, net of tax							2.0	2.0
Common stock issued under equity plans	3.2	3.2			143.8			147.0
Stock-based compensation expense					71.0			71.0
Shares issued in payment for contingent consideration liabilities			(0.3)	32.2	2.7			34.9
Purchases of treasury stock			5.5	(795.5)				(795.5)
BALANCE AT DECEMBER 31, 2018	215.2	215.2	7.5	(1,015.4)	1,384.4	2,694.7	(138.5)	3,140.4
Net income						1,046.9		1,046.9
Other comprehensive loss, net of tax							(17.5)	(17.5)
Common stock issued under equity plans	2.9	2.9			157.6			160.5
Stock-based compensation expense					81.3			81.3
Purchases of treasury stock			1.5	(263.3)				(263.3)
BALANCE AT DECEMBER 31, 2019	218.1	$ 218.1	9.0	$ (1,278.7)	$ 1,623.3	$ 3,741.6	$ (156.0)	$ 4,148.3

The accompanying notes are an integral part of these consolidated financial statements.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

Edwards Lifesciences Corporation ("Edwards Lifesciences" or the "Company") conducts operations worldwide and is managed in the following geographical regions: United States, Europe, Japan, and Rest of World. Edwards Lifesciences is focused on technologies that treat structural heart disease and critically ill patients. The products and technologies provided by Edwards Lifesciences are categorized into the following main areas: Transcatheter Aortic Valve Replacement, Transcatheter Mitral and Tricuspid Therapies, Surgical Structural Heart, and Critical Care.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Edwards Lifesciences and its majority-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company reviews its investments in other entities to determine whether the Company is the primary beneficiary of a variable interest entity ("VIE"). The Company would be the primary beneficiary of the VIE, and would be required to consolidate the VIE, if it has the power to direct the significant activities of the entity and the obligation to absorb losses or receive benefits from the entity that may be significant to the VIE. Based on the Company's analysis, it determined it is not the primary beneficiary of any VIEs; however, future events may require VIEs to be consolidated if the Company becomes the primary beneficiary.

Use of Estimates

The consolidated financial statements of Edwards Lifesciences have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") which have been applied consistently in all material respects. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates.

Foreign Currency Translation

When the local currency of the Company's foreign entities is the functional currency, all assets and liabilities are translated into United States dollars at the rate of exchange in effect at the balance sheet date. Income and expense items are translated at the weighted-average exchange rate prevailing during the period. The effects of foreign currency translation adjustments for these entities are deferred and reported in stockholders' equity as a component of "*Accumulated Other Comprehensive Loss*." The effects of foreign currency transactions denominated in a currency other than an entity's functional currency are included in "*Other (Income) Expense, net.*"

Revenue Recognition

Revenue is recognized when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products or services.

The Company generates nearly all of its revenue from direct product sales and sales of products under consignment arrangements. Revenue from direct product sales is recognized at a point in time when the performance obligation is satisfied upon delivery of the product. Revenue from sales of consigned inventory is recognized at a point in time when the performance obligation is satisfied once the product has been implanted or used by the customer. The Company periodically reviews consignment inventories to confirm the accuracy of customer reporting. The Company also generates a small portion of its revenue from service contracts, and recognizes revenue from service contracts ratably over the term of the contracts. Sales taxes and other similar taxes that the Company collects concurrent with revenue-producing activities are excluded from revenue. The Company does not typically have any significant unusual payment terms beyond 90 days in its contracts with customers. In addition, the Company receives royalty payments for the licensing of certain intellectual property and recognizes the royalty when the subsequent sale of product using the intellectual property occurs.

The amount of consideration the Company ultimately receives varies depending upon the return terms, sales rebates, discounts, and other incentives that the Company may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The Company includes estimated amounts in the transaction price to the extent it is

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely upon an assessment of historical payment experience, historical relationship to revenues, estimated customer inventory levels, and current contract sales terms with direct and indirect customers.

The Company's sales adjustment related to distributor rebates given to the Company's United States distributors represents the difference between the Company's sales price to the distributor and the negotiated price to be paid by the end-customer. This distributor rebate is recorded as a reduction to sales and a reduction to the distributor's accounts receivable at the time of sale to a distributor. The Company periodically monitors current pricing trends and distributor inventory levels to ensure the credit for future distributor rebates is fairly stated.

The Company also offers volume rebates to certain group purchasing organizations ("GPOs") and customers based upon target sales levels. Volume rebates offered to GPOs are recorded as a reduction to sales and an obligation to the GPOs, as the Company expects to pay in cash. Volume rebates offered to customers are recorded as a reduction to sales and either accounts receivable if the Company expects a net payment from the customer, or as an obligation to the customer if the Company expects to pay in cash. The provision for volume rebates is estimated based on customers' contracted rebate programs, projected sales levels, and historical experience of rebates paid. The Company periodically monitors its customer rebate programs to ensure that the allowance and liability for accrued rebates is fairly stated.

Product returns are typically not significant because returns are generally not allowed unless the product is damaged at time of receipt. In limited circumstances, the Company may allow customers to return previously purchased products, such as for next-generation product offerings. For these transactions, the Company defers recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount of product to be returned when the next-generation products are shipped to the customer.

The Company sells separately priced service contracts, which range from 12 months to 36 months, to owners of its hemodynamic monitors. The Company invoices the customer the total amount of consideration at the inception of the contract and recognizes revenue ratably over the term of the contract. As of December 31, 2019 and December 31, 2018, $8.4 million and $7.6 million, respectively, of deferred revenue associated with outstanding service contracts was recorded in "*Accrued and Other Liabilities*" and "*Other Long-term Liabilities.*" During 2019, the Company recognized as revenue $5.5 million that was included in the balance of deferred revenue as of December 31, 2018, and during 2018, the Company recognized as revenue $2.9 million that was included in the balance of deferred revenue as of December 31, 2017.

A limited number of the Company's contracts with customers contain multiple performance obligations. For these contracts, the transaction price is allocated to each performance obligation based on its relative standalone selling price charged to other customers.

The Company applies the optional exemption of not disclosing the amount of the transaction price allocated to unsatisfied performance obligations for contracts with an original expected duration of one year or less.

Shipping and Handling Costs

Shipping costs, which are costs incurred to physically move product from the Company's premises or third party distribution centers, including storage, to the customer's premises, are included in "*Selling, General, and Administrative Expenses*." Handling costs, which are costs incurred to store at the Company's premises, move, and prepare products for shipment, are included in "*Cost of Sales*." For the years ended December 31, 2019, 2018, and 2017, shipping costs of $71.5 million, $70.6 million, and $72.6 million, respectively, were included in "*Selling, General, and Administrative Expenses*."

Cash Equivalents

The Company considers highly liquid investments with original maturities of three months or less to be cash equivalents. These investments are valued at cost, which approximates fair value.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Investments

The Company invests its excess cash in fixed-rate debt securities, including time deposits, commercial paper, U.S. government and agency securities, asset-backed securities, corporate debt securities, and municipal debt securities. Investments with maturities of one year or less are classified as short-term, and investments with maturities greater than one year are classified as long-term. Investments that the Company has the ability and intent to hold until maturity are classified as held-to-maturity and carried at amortized cost. Investments in debt securities that are classified as available-for-sale are carried at fair value with unrealized gains and losses included in "*Accumulated Other Comprehensive Loss*." The Company determines the appropriate classification of its investments in fixed-rate debt securities at the time of purchase and reevaluates such designation at each balance sheet date.

The Company also has long-term equity investments in companies that are in various stages of development. These investments are reported at fair value or under the equity method of accounting, as appropriate. Equity investments that do not have readily determinable fair values are recorded at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. The Company accounts for investments in limited partnerships and limited liability corporations, whereby the Company owns a minimum of 5% of the investee's outstanding voting stock, under the equity method of accounting. These investments are recorded at the amount of the Company's investment and adjusted each period for the Company's share of the investee's income or loss, and dividends paid.

Realized gains and losses on investments that are sold are determined using the specific identification method, or the first-in, first-out method, depending on the investment type, and recorded to "*Other (Income) Expense, net*." Income relating to investments in fixed-rate debt securities is recorded to "*Interest Income.*"

The Company periodically reviews its investments for impairment. When the fair value of an investment declines below cost, management uses the following criteria to determine if such a decline should be considered other-than-temporary and result in a recognized loss:

- the duration and extent to which the market value has been less than cost;
- the financial condition and near term prospects of the investee/issuer;
- the reasons for the decline in market value;
- the Company's ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value; and
- the investee's performance against product development milestones.

Allowance for Doubtful Accounts

The Company records allowances for doubtful accounts based on customer-specific analysis and general matters such as current assessments of past due balances and economic conditions. When evaluating its allowances for doubtful accounts related to receivables from customers in certain European countries that have historically paid beyond the stated terms, the Company's analysis considers a number of factors, including evidence of the customer's ability to comply with credit terms, economic conditions, and procedures implemented by the Company to collect the historical receivables. Additional allowances for doubtful accounts may be required if there is deterioration in past due balances, if economic conditions are less favorable than the Company has anticipated, or for customer-specific circumstances, such as financial difficulty. The allowance for doubtful accounts related to both short-term and long-term receivables was $14.7 million and $13.6 million at December 31, 2019 and 2018, respectively.

Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or market value. Market value for raw materials is based on replacement costs, and for other inventory classifications is based on net realizable value.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

A write-down for excess or slow moving inventory is recorded for inventory which is obsolete, nearing its expiration date (generally triggered at six months prior to expiration), is damaged, or slow moving (generally defined as quantities in excess of a two-year supply). The allowance for excess and slow moving inventory was $42.6 million and $30.3 million at December 31, 2019 and 2018, respectively.

The Company allocates to inventory general and administrative costs that are related to the production process. These costs include insurance, manufacturing accounting personnel, human resources personnel, and information technology. During the years ended December 31, 2019, 2018, and 2017, the Company allocated $56.6 million, $45.0 million, and $39.3 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2019 and 2018 were $22.8 million and $18.3 million, respectively.

At December 31, 2019 and 2018, $128.7 million and $106.5 million, respectively, of the Company's finished goods inventories were held on consignment.

Property, Plant, and Equipment

Property, plant, and equipment are recorded at cost. Depreciation is principally calculated for financial reporting purposes on the straight-line method over the estimated useful lives of the related assets, which range from 10 to 40 years for buildings and improvements, from 3 to 15 years for machinery and equipment, and from 3 to 5 years for software. Leasehold improvements are amortized over the life of the related facility leases or the asset, whichever is shorter. Straight-line and accelerated methods of depreciation are used for income tax purposes. Construction in progress is not depreciated until the asset is ready for its intended use and placed into service.

Depreciation expense for property, plant, and equipment was $84.7 million, $74.9 million, and $74.1 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Impairment of Goodwill and Long-lived Assets

Goodwill is reviewed for impairment annually in the fourth quarter of each fiscal year, or whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. Goodwill is tested for impairment at the reporting unit level by first performing a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying value. If the reporting unit does not pass the qualitative assessment, then the Company performs a quantitative impairment test. The Company determined, after performing a qualitative review of each reporting unit, that it is more likely than not that the fair value of each of its reporting units substantially exceeds the respective carrying amounts. Accordingly, in 2019, 2018, and 2017, the Company did not record any impairment loss.

Indefinite-lived intangible assets relate to in-process research and development acquired in business combinations. The estimated fair values of in-process research and development projects acquired in a business combination which have not reached technological feasibility are capitalized and accounted for as indefinite-lived intangible assets subject to impairment testing until completion or abandonment of the projects. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If the project is abandoned, all remaining capitalized amounts are written off immediately. Indefinite-lived intangible assets are reviewed for impairment annually, or whenever an event occurs or circumstances change that would indicate the carrying amount may be impaired. An impairment loss is recognized when the asset's carrying value exceeds its fair value. In-process research and development projects acquired in an asset acquisition are expensed unless the project has an alternative future use.

Management reviews the carrying amounts of other finite-lived intangible assets and long-lived tangible assets whenever events or circumstances indicate that the carrying amounts of an asset may not be recoverable. Impairment indicators include, among other conditions, cash flow deficits, historic or anticipated declines in revenue or operating profit, and adverse legal or regulatory developments. If it is determined that such indicators are present and the review indicates that the assets will not be fully recoverable, based on undiscounted estimated cash flows over the remaining amortization periods, their carrying values are reduced to estimated fair market value. Estimated fair market value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. For the purposes of identifying and measuring impairment, long-lived

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

assets are grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities.

In 2019, the Company recorded a $40.6 million charge related to the impairment of certain in-process research and development assets. In 2018, the Company recorded a $116.2 million charge related to the impairment of certain developed technology and in-process research and development assets. See Note 4 for further information. In 2017, the Company did not record any impairment loss related to its in-process research and development assets.

Income Taxes

The Company is subject to income taxes in the United States and numerous foreign jurisdictions. Significant judgment is required in evaluating the Company's uncertain tax positions and determining its provision for income taxes. The Company recognizes the financial statement benefit of a tax position only after determining that a position would more likely than not be sustained based upon its technical merit if challenged by the relevant taxing authority and taken by management to the court of last resort. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon settlement with the relevant tax authority. The Company recognizes interest and penalties related to income tax matters in income tax expense. The Company has made an accounting policy election to recognize the U.S. tax effects of global intangible low-taxed income as a component of income tax expense in the period the tax arises.

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. The Company evaluates quarterly the realizability of its deferred tax assets by assessing its valuation allowance and adjusting the amount, if necessary. The factors used to assess the likelihood of realization are both historical experience and the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in the applicable taxing jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

Research and Development Costs

Research and development costs are charged to expense when incurred.

Earnings per Share

Basic earnings per share is computed by dividing net income by the weighted-average common shares outstanding during a period. Diluted earnings per share is computed based on the weighted-average common shares outstanding plus the effect of dilutive potential common shares outstanding during the period calculated using the treasury stock method. Dilutive potential common shares include employee equity share options, nonvested shares, and similar equity instruments granted by the Company. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The table below presents the computation of basic and diluted earnings per share (in millions, except for per share information):

	Years Ended December 31,		
	2019	2018	2017
Basic:			
Net income	$ 1,046.9	$ 722.2	$ 583.6
Weighted-average shares outstanding	208.3	209.2	210.9
Basic earnings per share	$ 5.03	$ 3.45	$ 2.77
Diluted:			
Net income	$ 1,046.9	$ 722.2	$ 583.6
Weighted-average shares outstanding	208.3	209.2	210.9
Dilutive effect of stock plans	3.9	4.4	5.0
Dilutive weighted-average shares outstanding	212.2	213.6	215.9
Diluted earnings per share	$ 4.93	$ 3.38	$ 2.70

Stock options, restricted stock units, and market-based restricted stock units to purchase approximately 0.5 million, 1.1 million, and 1.9 million shares for the years ended December 31, 2019, 2018, and 2017, respectively, were outstanding, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive.

Stock-based Compensation

The Company measures and recognizes compensation expense for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options, restricted stock units (service-based, market-based, and performance-based), and employee stock purchase subscriptions. Stock-based compensation expense is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period (vesting period) on a straight-line basis. For performance-based restricted stock units, the Company recognizes stock-based compensation expense if and when the Company concludes that it is probable that the performance condition will be achieved, net of estimated forfeitures. The Company reassesses the probability of vesting at each quarter end and adjusts the stock-based compensation expense based on its probability assessment. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Upon exercise of stock options or vesting of restricted stock units, the Company issues common stock.

Total stock-based compensation expense was as follows (in millions):

	Years Ended December 31,		
	2019	2018	2017
Cost of sales	$ 14.7	$ 11.4	$ 9.2
Selling, general, and administrative expenses	51.2	46.3	40.7
Research and development expenses	15.4	13.3	11.7
Total stock-based compensation expense	$ 81.3	$ 71.0	$ 61.6

Upon a participant's retirement, all unvested stock options and performance-based restricted stock units are immediately forfeited. In addition, upon retirement, a participant will immediately vest in 25% of service-based restricted stock units for each full year of employment with the Company measured from the grant date. All remaining unvested service-based restricted stock units are immediately forfeited. For market-based restricted stock units, upon retirement and in certain other specified cases, a participant will receive a pro-rated portion of the shares that would ultimately be issued based on attainment of the performance goals as determined on the vesting date. The pro-rated portion is based on the participant's whole months of service with the Company during the performance period prior to the date of termination.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Derivatives

The Company uses derivative financial instruments to manage interest rate and foreign currency risks. It is the Company's policy not to enter into derivative financial instruments for speculative purposes.

Derivative financial instruments involve credit risk in the event the counterparty should default. It is the Company's policy to execute such instruments with global financial institutions that the Company believes to be creditworthy. The Company diversifies its derivative financial instruments among counterparties to minimize exposure to any one of these entities. The Company also uses International Swap Dealers Association master-netting agreements. The master-netting agreements provide for the net settlement of all contracts through a single payment in a single currency in the event of default, as defined by the agreements.

The Company uses foreign currency forward exchange contracts, cross currency swap contracts, and foreign currency denominated debt to manage its exposure to changes in currency exchange rates from (1) future cash flows associated with intercompany transactions and certain local currency expenses expected to occur within the next 13 months (designated as cash flow hedges), (2) its net investment in certain foreign subsidiaries (designated as net investment hedges) and (3) foreign currency denominated assets or liabilities (designated as fair value hedges). The Company also uses foreign currency forward exchange contracts that are not designated as hedging instruments to offset the transaction gains and losses associated with certain assets and liabilities denominated in currencies other than their functional currencies resulting principally from intercompany and local currency transactions.

The Company at times has used interest rate swaps to convert a portion of its fixed-rate debt into variable-rate debt. These interest rate swaps were designated as fair value hedges and met the shortcut method requirements under the accounting standards for derivatives and hedging. Accordingly, changes in the fair values of the interest rate swaps were considered to exactly offset changes in the fair value of the underlying long-term debt.

All derivative financial instruments are recognized at fair value in the consolidated balance sheets. For each derivative instrument that is designated as a fair value hedge, the gain or loss on the derivative included in the assessment of hedge effectiveness is recognized immediately to earnings, and offsets the loss or gain on the underlying hedged item. The Company reports in "*Accumulated Other Comprehensive Loss*" the gain or loss on derivative financial instruments that are designated, and that qualify, as cash flow hedges. The Company reclassifies these gains and losses into earnings in the same line item and in the same period in which the underlying hedged transactions affect earnings. Changes in the fair value of net investment hedges are reported in "*Accumulated Other Comprehensive Loss*" as a part of the cumulative translation adjustment and would be reclassified into earnings if the underlying net investment is sold or substantially liquidated. The portion of the change in fair value related to components excluded from the hedge effectiveness assessment are amortized into earnings over the life of the derivative. The gains and losses on derivative financial instruments for which the Company does not elect hedge accounting treatment are recognized in the consolidated statements of operations in each period based upon the change in the fair value of the derivative financial instrument. Cash flows from net investment hedges are reported as investing activities in the consolidated statements of cash flows, and cash flows from all other derivative financial instruments are reported as operating activities.

Recently Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued an amendment to the guidance on leases. The amendment improves transparency and comparability among companies by recognizing lease assets and lease liabilities on the balance sheet and by disclosing key information about leasing arrangements. The guidance was effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach was required upon adoption. Reporting entities could elect to adjust comparative periods and record the cumulative effect adjustment at the beginning of the earliest comparative period, or to not adjust comparative periods and record the cumulative effect adjustment at the effective date.

The Company adopted the new guidance as of the effective date of January 1, 2019 with no adjustments to the comparative period presented in the financial statements. In addition, the Company elected the package of practical expedients permitted under the transition guidance to not reassess (1) whether any expired or existing contracts are, or contain, leases, (2)

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

the lease classification for expired or existing leases, and (3) initial direct costs for existing leases. The Company implemented internal controls and system solutions to enable the preparation and disclosure of financial information about its leasing arrangements upon adoption.

The adoption of the guidance resulted in the recognition of right-of-use assets and additional lease liabilities for operating leases of $58.7 million as of January 1, 2019. The guidance did not have an impact on the Company's consolidated statements of operations. See Note 6 for disclosures related to the Company's leases.

New Accounting Standards Not Yet Adopted

In January 2020, the FASB issued an amendment clarifying the interaction between accounting standards related to equity securities, equity method investments, and certain derivatives. The guidance is effective for fiscal years beginning after December 15, 2020. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In December 2019, the FASB issued an amendment to the guidance on income taxes which is intended to simplify the accounting for income taxes. The amendment eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, and the recognition of deferred tax liabilities for outside basis differences. The amendment also clarifies existing guidance related to the recognition of franchise tax, the evaluation of a step up in the tax basis of goodwill, and the effects of enacted changes in tax laws or rates in the effective tax rate computation, among other clarifications. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company is currently evaluating the impact the guidance will have on its consolidated financial statements.

In August 2018, the FASB issued an amendment to the accounting guidance on cloud computing service arrangements. The guidance aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance also requires an entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The guidance is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In August 2018, the FASB issued an amendment to the accounting guidance on retirement benefits. The guidance modifies the disclosure requirements for employers that sponsor defined benefit pension or other postretirement plans. The guidance is effective for fiscal years ending after December 15, 2020 and must be applied retrospectively to all periods presented. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In August 2018, the FASB issued an amendment to the accounting guidance on fair value measurements. The guidance modifies the disclosure requirements on fair value measurements, including the removal of disclosures of the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation processes for Level 3 fair value measurements. The guidance also adds certain disclosure requirements related to Level 3 fair value measurements. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In June 2016, the FASB issued an amendment to the guidance on the measurement of credit losses on financial instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the “incurred loss” model with an “expected loss” model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The guidance is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Early adoption is permitted for annual periods after December 15, 2018.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

3. INTELLECTUAL PROPERTY LITIGATION EXPENSES (INCOME), NET

The Company incurred intellectual property litigation expenses, including settlements and external legal costs, of $33.4 million, $214.0 million and $39.2 million during 2019, 2018 and 2017, respectively. In January 2019, the Company reached an agreement with Boston Scientific Corporation ("Boston Scientific") to settle all outstanding patent disputes for a one-time payment to Boston Scientific of $180.0 million, which was included as an expense in 2018. The settlement covers alleged past damages and no further royalties will be owed by either party.

In November 2017, the Company recorded a $112.5 million litigation gain related to the theft of trade secrets.

4. SPECIAL CHARGES

Impairment of Long-lived Assets

In December 2019, the Company recorded a charge of $40.6 million related to the impairment of certain in-process research and development assets, and in December 2018, the Company recorded a charge of $116.2 million related to the impairment of certain developed technology and in-process research and development assets. These assets were acquired as part of the acquisition of Valtech Cardio Ltd. ("Valtech"). The Company measured the amount of the impairments by calculating the amount by which the carrying values exceeded the estimated fair values, which were based on projected discounted future net cash flows. Based on market and clinical trial developments at the time of the impairments, the Company re-evaluated the clinical development plans for the technologies acquired from Valtech, which resulted in a reduction to the projected near-term discounted future net cash flows related to the acquired mitral technology for the 2018 charge, and related to the acquired mitral and tricuspid technology for the 2019 charge. The impairments were recorded to the Company’s Rest of World segment.

In June 2017, the Company recorded a $31.2 million charge related to the impairment of one of its cost method investments and an associated long-term asset related to the Company's option to acquire this investee. The Company concluded that the impairment of these assets was other-than-temporary based upon a recent review of the investee's clinical data and trial results, which did not support continuation of the product development effort, and the financial condition and near-term prospects of the investee.

Acquisition of Intellectual Property

In March 2019, the Company recorded a $24.0 million charge related to the acquisition of early-stage transcatheter intellectual property and associated clinical and regulatory experience.

Charitable Foundation Contribution

In December 2017, the Company contributed $25.0 million to the Edwards Lifesciences Foundation, a related-party not-for-profit organization whose mission is to support health- and community-focused charitable organizations. The contribution was irrevocable and was recorded as an expense at the time of payment.

Gain on Step Acquisition

In December 2017, the Company acquired Harpoon Medical, Inc. As a result of the acquisition, the Company remeasured at fair value its previously held ownership in Harpoon Medical, Inc. and recognized a gain of $6.5 million. See Note 8 for further information.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. SPECIAL CHARGES (Continued)

Realignment Expenses

In March 2018, the Company recorded a $7.1 million gain related to the curtailment of its defined benefit plan in Switzerland resulting from the closure of its manufacturing plant.

In September 2017, the Company recorded a $10.2 million charge related primarily to severance expenses (impacting 232 employees) and other costs associated with the planned closure of its manufacturing plant in Switzerland. As of December 31, 2019, payments related to the realignment were complete.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. OTHER CONSOLIDATED FINANCIAL STATEMENT DETAILS

Composition of Certain Financial Statement Captions

Components of selected captions in the consolidated balance sheets are as follows:

	As of December 31,	
	2019	2018
	(in millions)	
Accounts receivable, net		
Trade accounts receivable	$ 552.3	$ 465.8
Allowance for doubtful accounts	(8.7)	(8.9)
	$ 543.6	$ 456.9
Inventories		
Raw materials	$ 118.0	$ 111.5
Work in process	121.7	144.8
Finished products	401.2	350.7
	$ 640.9	$ 607.0
Property, plant, and equipment, net		
Land	$ 98.0	$ 90.7
Buildings and leasehold improvements	619.8	497.4
Machinery and equipment	466.3	432.4
Equipment with customers	35.6	41.1
Software	87.9	92.4
Construction in progress	265.0	168.8
	1,572.6	1,322.8
Accumulated depreciation	(512.3)	(455.3)
	$ 1,060.3	$ 867.5
Accrued and other liabilities		
Employee compensation and withholdings	$ 295.8	$ 226.1
Litigation and insurance reserves (Note 18)	20.0	196.7
Taxes payable	52.9	31.3
Accrued rebates	67.1	80.0
Property, payroll, and other taxes	51.4	39.5
Research and development accruals	51.4	48.9
Fair value of derivatives	6.4	4.4
Accrued marketing expenses	17.5	22.3
Accrued professional services	10.1	11.0
Accrued realignment reserves	16.7	6.8
Accrued relocation costs	17.4	11.3
Other accrued liabilities	89.8	64.3
	$ 696.5	$ 742.6

In 2019, the Company recorded a $73.1 million charge to "*Cost of Sales*," primarily comprised of the write off of inventory related to strategic decisions regarding its transcatheter aortic valve portfolio, including the decision to discontinue its *CENTERA* program.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. OTHER CONSOLIDATED FINANCIAL STATEMENT DETAILS (Continued)

Supplemental Cash Flow Information
(in millions)

	Years Ended December 31,		
	2019	2018	2017
Cash paid during the year for:			
Interest	$ 19.9	$ 30.1	$ 19.9
Income taxes	$ 61.5	$ 223.7	$ 143.7
Amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 28.6	$ —	$ —
Non-cash investing and financing transactions:			
Fair value of shares issued in payment for contingent consideration liabilities (Note 11)	$ —	$ 34.3	$ —
Fair value of shares issued in connection with business combinations (Note 8)	$ —	$ —	$ 266.5
Right-of-use assets obtained in exchange for new lease liabilities	$ 49.6	$ —	$ —
Capital expenditures accruals	$ 50.8	$ 18.7	$ 21.6
Retirement of treasury stock	$ —	$ —	$ 2,746.2

6. LEASES

The Company determines whether a contract is, or contains, a lease at inception. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments. The Company's incremental borrowing rate is determined based on the estimated rate of interest for collateralized borrowing over a similar term as the associated lease. Right-of-use assets also include any lease payments made at or before lease commencement and any initial direct costs incurred, and exclude any lease incentives received.

The Company determines the lease term as the noncancellable period of the lease, and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the balance sheet. Certain of the Company's leases include variable lease payments that are based on costs incurred or actual usage, or adjusted periodically based on an index or a rate. The Company's leases do not contain any residual value guarantees.

The Company accounts for the lease and non-lease components as a single lease component for all of its leases except vehicle leases, for which the lease and non-lease components are accounted for separately.

Operating leases are included in "*Operating Lease Right-of-Use Assets*" and "*Operating Lease Liabilities*" on the Company's consolidated condensed balance sheets.

The Company leases certain office space, manufacturing facilities, land, apartments, warehouses, vehicles, and equipment with remaining lease terms ranging from less than 1 year to 21 years, some of which include options to extend or terminate the leases.

Operating lease costs for the year ended December 31, 2019 were $27.9 million. Short-term and variable lease costs were not material for the year ended December 31, 2019.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. LEASES (Continued)

Supplemental balance sheet information related to operating leases was as follows (in millions, except lease term and discount rate):

	December 31, 2019
Operating lease right-of-use assets	$ 80.1
Operating lease liabilities, current portion	$ 25.5
Operating lease liabilities, long-term portion	58.9
Total operating lease liabilities	$ 84.4

Maturities of operating lease liabilities at December 31, 2019 were as follows (in millions):

2020	$ 27.4
2021	20.0
2022	14.2
2023	10.1
2024	5.6
Thereafter	14.5
Total lease payments	91.8
Less: imputed interest	(7.4)
Total lease liabilities	$ 84.4
Weighted-average remaining lease term (in years)	5.3
Weighted-average discount rate	2.8%

As of December 31, 2019, the Company had additional operating lease commitments of $1.6 million for office space that have not yet commenced. These leases will commence during 2020 with lease terms of 6 months to 7 years.

Disclosures related to periods prior to adopting the new lease guidance

Certain facilities and equipment are leased under operating leases expiring at various dates. Most of the operating leases contain renewal options. Total expense for all operating leases was $27.0 million and $27.3 million for the years 2018 and 2017, respectively.

Future minimum lease payments (including interest) under non-cancelable operating leases at December 31, 2018 were as follows (in millions):

	Operating Leases
2019	$ 25.6
2020	21.5
2021	13.5
2022	9.9
2023	6.4
Thereafter	14.3
Total obligations and commitments	$ 91.2

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. INVESTMENTS

Debt Securities

Investments in debt securities at the end of each period were as follows (in millions):

	December 31, 2019				December 31, 2018			
Held-to-maturity	**Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**	**Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Bank time deposits	$ 100.2	$ —	$ —	$ 100.2	$ 20.0	$ —	$ —	$ 20.0
Available-for-sale								
Bank time deposits	$ 13.1	$ —	$ —	$ 13.1	$ —	$ —	$ —	$ —
Commercial paper	34.3	—	—	34.3	56.7	—	—	56.7
U.S. government and agency securities	113.2	0.6	—	113.8	79.7	0.2	(0.7)	79.2
Foreign government bonds	1.7	—	—	1.7	1.7	—	—	1.7
Asset-backed securities	141.2	0.6	(0.1)	141.7	110.6	0.1	(0.5)	110.2
Corporate debt securities	487.0	2.3	(0.1)	489.2	459.8	0.1	(4.3)	455.6
Municipal securities	—	—	—	—	2.8	—	—	2.8
	$ 790.5	$ 3.5	$ (0.2)	$ 793.8	$ 711.3	$ 0.4	$ (5.5)	$ 706.2

The cost and fair value of investments in debt securities, by contractual maturity, as of December 31, 2019 were as follows:

	Held-to-Maturity		Available-for-Sale	
	Cost	**Fair Value**	**Cost**	**Fair Value**
			(in millions)	
Due in 1 year or less	$ 100.2	$ 100.2	$ 237.2	$ 237.6
Due after 1 year through 5 years	—	—	439.1	441.7
Instruments not due at a single maturity date	—	—	114.2	114.5
	$ 100.2	$ 100.2	$ 790.5	$ 793.8

Actual maturities may differ from the contractual maturities due to call or prepayment rights.

The following tables present gross unrealized losses and fair values for those investments that were in an unrealized loss position as of December 31, 2019 and 2018, aggregated by investment category and the length of time that individual securities have been in a continuous loss position (in millions):

	December 31, 2019					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	**Gross Unrealized Losses**	**Fair Value**	**Gross Unrealized Losses**	**Fair Value**	**Gross Unrealized Losses**
Asset-backed securities	73.4	(0.1)	—	—	73.4	(0.1)
Corporate debt securities	81.4	(0.1)	—	—	81.4	(0.1)
	$ 154.8	$ (0.2)	$ —	$ —	$ 154.8	$ (0.2)

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. INVESTMENTS (Continued)

	December 31, 2018					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 0.7	$ (0.1)	$ 56.5	$ (0.6)	$ 57.2	$ (0.7)
Asset-backed securities	4.0	—	61.3	(0.5)	65.3	(0.5)
Corporate debt securities	177.4	(1.1)	203.7	(3.2)	381.1	(4.3)
	$ 182.1	$ (1.2)	$ 321.5	$ (4.3)	$ 503.6	$ (5.5)

Investments in Unconsolidated Affiliates

The Company has a number of equity investments in privately and publicly held companies. Investments in these unconsolidated affiliates are recorded in "*Long-term Investments*" on the consolidated balance sheets, and are as follows:

	December 31,	
	2019	2018
	(in millions)	
Equity method investments		
Cost	$ 10.7	$ 9.1
Equity in losses	(4.5)	(4.7)
Carrying value of equity method investments	6.2	4.4
Equity securities		
Carrying value of non-marketable equity securities	23.1	18.1
Total investments in unconsolidated affiliates	$ 29.3	$ 22.5

Non-marketable equity securities consist of investments in privately held companies without readily determinable fair values, and are reported at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. The Company recorded an upward adjustment of $0.3 million during 2019 based on observable price changes. As of December 31, 2019, the Company had recorded accumulated upward adjustments of $2.0 million based on observable price changes, and accumulated downward adjustments of $1.9 million due to impairment and observable price changes.

During 2019, 2018, and 2017, the gross realized gains or losses from sales of available-for-sale investments were not material.

8. ACQUISITIONS

CAS Medical Systems, Inc.

On February 11, 2019, the Company entered into an agreement and plan of merger to acquire all the outstanding shares of CAS Medical Systems, Inc. ("CASMED") for an aggregate cash purchase price of $2.45 per share of common stock, or an equity value of approximately $100 million. The transaction closed on April 18, 2019, and the cash purchase price was $100.8 million. Acquisition-related costs of $2.0 million were recorded in "*Selling, General, and Administrative Expenses*" during the year ended December 31, 2019.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. ACQUISITIONS (Continued)

CASMED is a medical technology company dedicated to noninvasive monitoring of tissue oxygenation in the brain. The Company plans to integrate the acquired technology platform into its hemodynamic monitoring platform. The acquisition was accounted for as a business combination. Tangible and intangible assets acquired were recorded based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair value of net assets acquired was recorded to goodwill. The following table summarizes the fair values of the assets acquired and liabilities assumed (in millions):

Current assets	$	6.1
Property and equipment, net		1.3
Goodwill		64.4
Developed technology		35.9
Customer relationships		8.8
Deferred tax assets		2.2
Liabilities assumed		(17.9)
Total purchase price		100.8
Less: cash acquired		(0.6)
Total purchase price, net of cash acquired	$	100.2

Goodwill includes expected synergies and other benefits the Company believes will result from the acquisition. Goodwill was assigned to the Company's United States segment and is not deductible for tax purposes. Developed technology assets are being amortized over a weighted-average useful life of 14 years. Customer relationships assets are being amortized over a weighted-average useful life of 10 years.

The results of operations for CASMED have been included in the accompanying consolidated financial statements from the date of acquisition. Pro forma results have not been presented as the results of CASMED are not material in relation to the consolidated financial statements of Edwards Lifesciences.

Harpoon Medical, Inc.

On December 1, 2017, the Company acquired all the outstanding shares of Harpoon Medical, Inc. for an aggregate cash purchase price of $119.5 million, which includes $16.0 million paid previously for a cost method investment and an exclusive option to acquire Harpoon Medical, Inc., and is net of $8.0 million received from the sale of the Company's previous ownership interest. The Company remeasured its previously held ownership in Harpoon Medical, Inc., which had a carrying value at the date of acquisition of $1.5 million and represented approximately 6% of the fully-diluted outstanding shares of Harpoon Medical, Inc., and recognized a gain of $6.5 million in "*Special (Gains) Charges, net*." In addition, the Company agreed to pay up to an additional $150.0 million in pre-specified milestone-driven payments over the next 10 years. The Company recognized in "*Contingent Consideration Liabilities*" a $59.7 million liability for the estimated fair value of the contingent milestone payments. The fair value of the contingent milestone payments are remeasured each quarter, with changes in the fair value recognized within operating expenses on the consolidated statements of operations. For further information on the fair value of the contingent milestone payments, see Note 11.

In connection with the acquisition, the Company placed $10.0 million of the purchase price into escrow to satisfy any claims for indemnification made in accordance with the merger agreement. Funds remaining 12 months after the acquisition date were disbursed to Harpoon Medical, Inc.'s former shareholders. Acquisition-related costs of $0.4 million were recorded in "*Selling, General, and Administrative Expenses*" during the year ended December 31, 2017.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. ACQUISITIONS (Continued)

Harpoon Medical, Inc. is a medical technology company pioneering beating-heart repair for degenerative mitral regurgitation. The Company plans to add this technology to its portfolio of mitral and tricuspid repair products. The acquisition was accounted for as a business combination. Tangible and intangible assets acquired were recorded based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair value of net assets acquired was recorded to goodwill. The following table summarizes the fair values of the assets acquired and liabilities assumed (in millions):

Current assets	$ 3.6
Property and equipment, net	0.3
Goodwill	142.1
In-process research and development assets	53.1
Other assets	0.1
Current liabilities assumed	(0.8)
Deferred income taxes	(12.7)
Total purchase price	185.7
Less: cash acquired	(3.5)
Total purchase price, net of cash acquired	$ 182.2

Goodwill includes expected synergies and other benefits the Company believes will result from the acquisition. Goodwill was assigned to the Company's United States segment and is not deductible for tax purposes. In-process research and development has been capitalized at fair value as an intangible asset with an indefinite life and will be assessed for impairment in subsequent periods. The fair value of the in-process research and development assets was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. The discount rates used to determine the fair value of the in-process research and development assets ranged from 18.0% to 19.0%. Completion of successful design developments, bench testing, pre-clinical studies and human clinical studies are required prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development, and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals. The valuation assumed $41.4 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, net cash inflows were modeled to commence in Europe in 2018, and in the United States and Japan in 2022. The Company does not currently anticipate significant changes to forecasted research and development expenditures, and net cash inflows are now expected to commence in Europe in 2020. Upon completion of development, the underlying in-process research and development asset will be amortized over its estimated useful life.

The results of operations for Harpoon Medical, Inc. have been included in the accompanying consolidated financial statements from the date of acquisition. Pro forma results have not been presented as the results of Harpoon Medical, Inc. are not material in relation to the consolidated financial statements of Edwards Lifesciences.

Valtech Cardio Ltd.

On November 26, 2016, the Company entered into an agreement and plan of merger to acquire Valtech Cardio Ltd. ("Valtech") for approximately $340.0 million, subject to certain adjustments, with the potential for up to an additional $350.0 million in pre-specified milestone-driven payments over the next 10 years. The transaction closed on January 23, 2017, and the consideration paid included the issuance of approximately 2.8 million shares of the Company's common stock (fair value of $266.5 million) and cash of $86.2 million. The Company recognized in "*Contingent Consideration Liabilities*" a $162.9 million liability for the estimated fair value of the contingent milestone payments. For further information on the fair value of the contingent milestone payments, see Note 11.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. ACQUISITIONS (Continued)

Prior to the close of the transaction, Valtech spun off its early-stage transseptal mitral valve replacement technology program. Concurrent with the closing, the Company entered into an agreement for an exclusive option to acquire that program and its associated intellectual property for approximately $200.0 million, subject to certain adjustments, plus an additional $50.0 million if a certain European regulatory approval is obtained within 10 years of the acquisition closing date. The option expired in January 2020.

In-process research and development assets acquired as part of this transaction were capitalized at fair value, which was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. The valuation assumed $87.3 million of additional research and development expenditures would be incurred prior to the date of product introduction and that net cash inflows would commence in 2019. In December 2018, the Company recorded a $116.2 million impairment charge related to Valtech's intangible assets, and in December 2019, the Company recorded a $40.6 million impairment charge to write off the remaining in-process research and development assets. For further information, see Note 4.

CardiAQ Valve Technologies, Inc.

On July 3, 2015, the Company entered into an agreement and plan of merger to acquire CardiAQ Valve Technologies, Inc. ("CardiAQ") for an aggregate cash purchase price of $350.0 million, subject to certain adjustments. The transaction closed on August 26, 2015, and the cash purchase price after the adjustments was $348.0 million. In addition, the Company agreed to pay an additional $50.0 million if a certain European regulatory approval is obtained within 48 months of the acquisition closing date. The Company recognized in "*Contingent Consideration Liabilities*" a $30.3 million liability for the estimated fair value of this contingent milestone payment. The Company does not expect this milestone to be achieved and reversed the liability in 2018. For further information on the fair value of the contingent milestone payment, see Note 11.

In-process research and development assets acquired as part of this acquisition were capitalized at fair value, which was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. Completion of successful design developments, bench testing, pre-clinical studies and human clinical studies are required prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development, and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals. The valuation assumed $97.7 million of additional research and development expenditures would be incurred prior to the date of product introduction and that net cash inflows would commence in late 2018. As a result of certain design enhancements to increase the product's commercial life and applicability to a broader group of patients, the Company has incurred incremental research and development expenditures; however, the Company expects an increase in the net cash inflows, commencing in 2024. Upon completion of development, the underlying research and development intangible asset will be amortized over its estimated useful life.

9. GOODWILL AND OTHER INTANGIBLE ASSETS

Goodwill and in-process research and development assets resulting from purchase business combinations are not subject to amortization. Other acquired intangible assets with finite lives are amortized over their expected useful lives on a straight-line basis, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be used. The Company expenses costs incurred to renew or extend the term of acquired intangible assets.

In April 2019, the Company acquired CASMED. This transaction resulted in an increase to goodwill of $64.4 million and developed technology of $35.9 million. For further information, see Note 8.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)

The changes in the carrying amount of goodwill, by segment, during the years ended December 31, 2019 and 2018 were as follows:

	United States	Europe	Rest of World	Total
	(in millions)			
Goodwill at December 31, 2017	$ 709.3	$ 67.2	$ 350.0	$ 1,126.5
Currency translation adjustment	—	(3.0)	(11.3)	(14.3)
Goodwill at December 31, 2018	709.3	64.2	338.7	1,112.2
Goodwill acquired during the year	64.4	—	—	64.4
Currency translation adjustment	—	(1.4)	(7.5)	(8.9)
Goodwill at December 31, 2019	$ 773.7	$ 62.8	$ 331.2	$ 1,167.7

Other intangible assets consist of the following (in millions):

		December 31,					
		2019			2018		
	Weighted-Average Useful Life (in years)	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Finite-lived intangible assets							
Patents	7.4	$ 185.7	$ (182.1)	$ 3.6	$ 185.8	$ (181.2)	$ 4.6
Developed technology (Note 4)	12.9	153.5	(46.6)	106.9	119.8	(44.2)	75.6
Other	10.0	12.3	(4.4)	7.9	—	—	—
	12.4	351.5	(233.1)	118.4	305.6	(225.4)	80.2
Indefinite-lived intangible assets							
In-process research and development (Note 4)		218.1	—	218.1	263.0	—	263.0
		$ 569.6	$ (233.1)	$ 336.5	$ 568.6	$ (225.4)	$ 343.2

Amortization expense related to other intangible assets for the years ended December 31, 2019, 2018, and 2017 was $4.6 million, $2.5 million, and $7.8 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2020	$ 7.2
2021	7.6
2022	7.9
2023	9.4
2024	13.1

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. DEBT AND CREDIT FACILITIES

In June 2018, the Company issued $600.0 million of fixed-rate unsecured senior notes (the "Notes") due June 15, 2028. Interest is payable semi-annually in arrears, with payments due in June and December of each year. The Company may redeem the Notes, in whole or in part, at any time and from time to time at specified redemption prices. In addition, upon the occurrence of certain change of control triggering events, the Company may be required to repurchase all or a portion of the Notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest. The Notes also include covenants that limit the Company's ability to incur secured indebtedness, enter into sale and leaseback transactions, and consolidate, merge, or transfer all or substantially all of its assets.

The following is a summary of the Notes as of December 31, 2019 and 2018:

	December 31,			
	2019		2018	
	Amount	Effective Interest Rate	Amount	Effective Interest Rate
	(in millions)		(in millions)	
Fixed-rate 4.300% 2018 Notes	$ 600.0	4.329%	$ 600.0	4.329%
Unamortized discount	(1.2)		(1.3)	
Unamortized debt issuance costs	(4.4)		(4.9)	
Total carrying amount	$ 594.4		$ 593.8	

As of December 31, 2019 and 2018, the fair value of the Notes was $667.6 million and $607.0 million, respectively, based on observable market prices in less active markets and categorized as Level 2 (Note 11). The debt issuance costs, as well as the discount, are being amortized to interest expense over the term of the notes.

The Company has a Five-Year Credit Agreement ("the Credit Agreement") which matures on April 28, 2023. The Credit Agreement provides up to an aggregate of $750.0 million in borrowings in multiple currencies. The Company may increase the amount available under the Credit Agreement, subject to agreement of the lenders, by up to an additional $250.0 million in the aggregate. Borrowings generally bear interest at the London interbank offered rate ("LIBOR") plus a spread ranging from 0.9% to 1.3%, depending on the leverage ratio, as defined in the Credit Agreement. The Company also pays a facility fee ranging from 0.1% to 0.2%, depending on the leverage ratio, on the entire credit commitment available, whether drawn or not. The facility fee is expensed as incurred. During 2019, the spread over LIBOR was 0.9% and the facility fee was 0.1%. Issuance costs of $2.4 million are being amortized to interest expense over the term of the Credit Agreement. As of December 31, 2019 and 2018, there were no borrowings outstanding under the Credit Agreement. All amounts outstanding under the Credit Agreement have been classified as long-term obligations in accordance with the terms of the Credit Agreement. The Credit Agreement is unsecured and contains various financial and other covenants, including a maximum leverage ratio, as defined in the Credit Agreement. The Company was in compliance with all covenants at December 31, 2019.

The weighted-average interest rate under all debt obligations was 3.4% and 3.4% at December 31, 2019 and 2018, respectively.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS

The consolidated financial statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on a historical cost basis. Financial instruments of the Company consist of cash deposits, accounts and other receivables, investments, accounts payable, certain accrued liabilities, and borrowings under a revolving credit agreement. The carrying value of these financial instruments generally approximates fair value due to their short-term nature. Financial instruments also include notes payable. See Note 10 for further information on the fair value of the notes payable.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The Company prioritizes the inputs used to determine fair values in one of the following three categories:

Level 1—Quoted market prices in active markets for identical assets or liabilities.

Level 2—Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.

Level 3—Unobservable inputs that are not corroborated by market data.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table summarizes the Company's financial instruments which are measured at fair value on a recurring basis as of December 31, 2019 and 2018 (in millions):

December 31, 2019	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 0.7	$ 31.7	$ —	$ 32.4
Available-for-sale investments:				
Bank time deposits	—	13.1	—	13.1
Corporate debt securities	—	489.2	—	489.2
Asset-backed securities	—	141.7	—	141.7
U.S. government and agency securities	76.1	37.7	—	113.8
Foreign government bonds	—	1.7	—	1.7
Commercial paper	—	34.3	—	34.3
Investments held for deferred compensation plans	88.9	—	—	88.9
Derivatives	—	30.7	—	30.7
	$ 165.7	$ 780.1	$ —	$ 945.8
Liabilities				
Derivatives	$ —	$ 6.4	$ —	$ 6.4
Deferred compensation plans	88.7	—	—	88.7
Contingent consideration liabilities	—	—	172.5	172.5
	$ 88.7	$ 6.4	$ 172.5	$ 267.6

December 31, 2018				
Assets				
Cash equivalents	$ —	$ 11.8	$ —	$ 11.8
Available-for-sale investments:				
Corporate debt securities	—	455.6	—	455.6
Asset-backed securities	—	110.2	—	110.2
U.S. government and agency securities	19.6	59.6	—	79.2
Foreign government bonds	—	1.7	—	1.7
Commercial paper	—	56.7	—	56.7
Municipal securities	—	2.8	—	2.8
Investments held for deferred compensation plans	67.6	—	—	67.6
Derivatives	—	29.9	—	29.9
	$ 87.2	$ 728.3	$ —	$ 815.5
Liabilities				
Derivatives	$ —	$ 5.2	$ —	$ 5.2
Deferred compensation plans	68.5	—	—	68.5
Contingent consideration liabilities	—	—	178.6	178.6
	$ 68.5	$ 5.2	$ 178.6	$ 252.3

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

The following table summarizes the changes in fair value of the contingent consideration obligation for the year ended December 31, 2019 (in millions):

	December 31,	
	2019	2018
Fair value, beginning of year	$ 178.6	$ 244.3
Payments (cash and issued shares)	—	(60.0)
Changes in fair value	(6.1)	(5.7)
Fair value, end of year	$ 172.5	$ 178.6

During 2019 and 2018, the contingent consideration liability related to certain of the Company's previous business acquisitions was reduced by $24.1 million and $26.8 million, respectively, due to delays in product development, which reduced the probability of milestone achievement. These reductions were partially offset by changes in the fair value of the liabilities associated primarily with adjustments to discount rates and accretion of interest due to the passage of time.

Cash Equivalents and Available-for-sale Investments

The Company estimates the fair values of its money market funds based on quoted prices in active markets for identical assets. The Company estimates the fair values of its time deposits, commercial paper, U.S. and foreign government and agency securities, municipal securities, asset-backed securities, and corporate debt securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades and broker-dealer quotes on the same or similar securities, benchmark yields, credit spreads, prepayment and default projections based on historical data, and other observable inputs. The Company independently reviews and validates the pricing received from the third-party pricing service by comparing the prices to prices reported by a secondary pricing source. The Company’s validation procedures have not resulted in an adjustment to the pricing received from the pricing service.

Deferred Compensation Plans

The Company holds investments in trading securities related to its deferred compensation plans. The investments are in a variety of stock, bond, and money market mutual funds. The fair values of these investments and the corresponding liabilities are based on quoted market prices.

Derivative Instruments

The Company uses derivative financial instruments in the form of foreign currency forward exchange contracts and cross currency swap contracts to manage foreign currency exposures. All derivatives contracts are recognized on the balance sheet at their fair value. The fair value of foreign currency derivative financial instruments and the cross currency swap contracts was estimated based on quoted market foreign exchange rates, cross currency swap basis rates, and market discount rates. Judgment was employed in interpreting market data to develop estimates of fair value; accordingly, the estimates presented herein are not necessarily indicative of the amounts that the Company could realize in a current market exchange. The use of different market assumptions or valuation methodologies could have a material effect on the estimated fair value amounts.

Contingent Consideration Liabilities

Certain of the Company's acquisitions involve contingent consideration arrangements. Payment of additional consideration is contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. These contingent consideration liabilities are measured at estimated fair value using either a probability weighted discounted cash flow analysis or a Monte Carlo simulation model, both of which consider significant unobservable inputs. These inputs include (1) the discount rate used to present value the projected cash flows (ranging from 1.5% to 10.6%), (2) the probability of milestone achievement (ranging from 2.0% to 98.5%), (3) the projected

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

payment dates (ranging from 2022 to 2026), and (4) the volatility of future revenue (45.0%). The use of different assumptions could have a material effect on the estimated fair value amounts.

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

The Company uses derivative financial instruments to manage its currency exchange rate risk and its interest rate risk as summarized below. Notional amounts are stated in United States dollar equivalents at spot exchange rates at the respective dates. The Company does not enter into these arrangements for trading or speculation purposes.

	Notional Amount	
	December 31, 2019	December 31, 2018
	(in millions)	
Foreign currency forward exchange contracts	$ 1,336.5	$ 1,378.2
Cross currency swap contracts	300.0	300.0

The following table presents the location and fair value amounts of derivative instruments reported in the consolidated balance sheets (in millions):

		Fair Value	
	Balance Sheet Location	December 31, 2019	December 31, 2018
Derivatives designated as hedging instruments			
Assets			
Foreign currency contracts	Other current assets	$ 14.2	$ 29.1
Foreign currency contracts	Other assets	$ 3.2	—
Cross currency swap contracts	Other assets	$ 13.3	$ 0.8
Liabilities			
Foreign currency contracts	Accrued and other liabilities	$ 6.4	$ 4.4
Foreign currency contracts	Other long-term liabilities	$ —	$ 0.8

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

The following table presents the effect of master-netting agreements and rights of offset on the consolidated balance sheets (in millions):

December 31, 2019	Gross Amounts	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts Presented in the Consolidated Balance Sheet	Gross Amounts Not Offset in the Consolidated Balance Sheet		Net Amount
				Financial Instruments	Cash Collateral Received	
Derivative Assets						
Foreign currency contracts	$ 17.4	$ —	$ 17.4	$ (5.7)	$ —	$ 11.7
Cross currency swap contracts	$ 13.3	$ —	$ 13.3	$ —	$ —	$ 13.3
Derivative Liabilities						
Foreign currency contracts	$ 6.4	$ —	$ 6.4	$ (5.7)	$ —	$ 0.7
December 31, 2018						
Derivative Assets						
Foreign currency contracts	$ 29.1	$ —	$ 29.1	$ (3.6)	$ —	$ 25.5
Cross currency swap contracts	$ 0.8	$ —	$ 0.8	$ —	$ —	$ 0.8
Derivative Liabilities						
Foreign currency contracts	$ 5.2	$ —	$ 5.2	$ (3.6)	$ —	$ 1.6

The following tables present the effect of derivative and non-derivative hedging instruments on the consolidated statements of operations and consolidated statements of comprehensive income:

	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	2019	2018		2019	2018
	(in millions)			(in millions)	
Cash flow hedges					
Foreign currency contracts	$ 23.5	$ 35.9	Cost of sales	$ 40.9	$ (17.3)
			Selling, general, and administrative expenses	$ 1.9	$ (2.3)

	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Recognized in Income on Derivative (Amount Excluded from Effectiveness Testing)	
	2019	2018		2019	2018
	(in millions)			(in millions)	
Net investment hedges					
Cross currency swap contracts	$ 12.5	$ 0.8	Interest expense	$ 6.6	$ 3.5
Foreign currency denominated debt	$ —	$ 6.8			

In June 2018, the Company repaid and dedesignated its €370.0 million of outstanding long-term debt which had been previously designated as a net investment hedge, and concurrently entered into cross currency swap contracts, which were designated as a net investment hedge. The cross currency swaps have an expiration date of June 15, 2028. At maturity of the cross currency swap contracts, the Company will deliver the notional amount of €257.2 million and will receive $300.0 million from the counterparties. The Company will receive semi-annual interest payments from the counterparties based on a fixed interest rate until maturity of the agreements.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative (a)		
		2019	2018	2017
			(in millions)	
Fair value hedges				
Foreign currency contracts	Other (income) expense, net	$ 1.4	$ 0.5	$ —
Interest rate swap agreements	Interest expense	$ —	$ —	$ (1.1)

(a) The gains and losses on the interest rate swap agreements were fully offset by the changes in the fair value of the fixed-rate debt being hedged. In December 2017, the interest rate swap was settled at a loss of $0.7 million, which was amortized to interest expense over the remaining life of the debt.

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative		
		2019	2018	2017
			(in millions)	
Derivatives not designated as hedging instruments				
Foreign currency contracts	Other (income) expense, net	$ 0.3	$ 9.7	$ (11.5)

The following table presents the effect of cash flow hedge accounting on the consolidated statements of operations:

	Location and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships Twelve Months Ended December 31, 2019		
	Cost of sales	Selling, general, and administrative expenses	Other (Income) Expense, net
Total amounts of income and expense line items shown in the consolidated statements of operations in which the effects of fair value or cash flow hedges are recorded	$ (1,114.4)	$ (1,242.2)	$ 8.2
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items	—	—	2.9
Derivatives designated as hedging instruments	—	—	(2.9)
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach	—	—	4.3
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income	$ 40.9	$ 1.9	$ —

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

	Location and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships		
	Twelve Months Ended December 31, 2018		
	Cost of sales	Selling, general, and administrative expenses	Other (Income) Expense, net
Total amounts of income and expense line items shown in the consolidated statements of operations in which the effects of fair value or cash flow hedges are recorded	$ (939.4)	$ (1,088.5)	$ 4.0
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items	—	—	—
Derivatives designated as hedging instruments	—	—	—
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach	—	—	0.5
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income	$ (17.3)	$ (2.3)	$ —

The Company expects that during 2020 it will reclassify to earnings a $6.5 million gain currently recorded in "*Accumulated Other Comprehensive Loss*." For the years ended December 31, 2019, 2018, and 2017, the Company did not record any gains or losses due to hedge ineffectiveness.

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS

Defined Benefit Plans

Edwards Lifesciences maintains defined benefit pension plans in Japan and certain European countries. In 2018, the Company curtailed its defined benefit plan in Horw, Switzerland (see Note 4) and at the end of 2017, redesigned one of its defined benefit plans in Nyon, Switzerland into a defined contribution plan upon changes in local legislation.

	Years Ended December 31,	
	2019	2018
	(in millions)	
Change in projected benefit obligation:		
Beginning of year	$ 97.4	$ 114.9
Service cost	5.2	6.0
Interest cost	0.9	0.8
Participant contributions	1.3	1.2
Actuarial loss	8.2	0.7
Benefits paid	(4.2)	(0.3)
Plan amendment	(4.6)	(2.0)
Settlements and curtailment gain	—	(22.5)
Currency exchange rate changes and other	1.0	(1.4)
End of year	$ 105.2	$ 97.4
Change in fair value of plan assets:		
Beginning of year	$ 60.4	$ 71.2
Actual return on plan assets	2.0	(0.8)
Employer contributions	2.6	3.9
Participant contributions	1.3	1.2
Settlements	—	(14.4)
Benefits paid	(4.2)	(0.3)
Currency exchange rate changes and other	1.1	(0.4)
End of year	$ 63.2	$ 60.4
Funded Status		
Projected benefit obligation	$ (105.2)	$ (97.4)
Plan assets at fair value	63.2	60.4
Underfunded status	$ (42.0)	$ (37.0)
Net amounts recognized on the consolidated balance sheet:		
Other long-term liabilities	$ 42.0	$ 37.0
Accumulated other comprehensive loss, net of tax:		
Net actuarial loss	$ (26.3)	$ (19.4)
Net prior service cost	6.7	2.3
Deferred income tax benefit	4.2	3.6
Total	$ (15.4)	$ (13.5)

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

The accumulated benefit obligation ("ABO") for all defined benefit pension plans was $101.1 million and $93.5 million as of December 31, 2019 and 2018, respectively. The projected benefit obligation and ABO were in excess of plan assets for all pension plans as of December 31, 2019 and 2018.

The components of net periodic pension benefit cost (credit) are as follows (in millions):

	Years Ended December 31,		
	2019	2018	2017
Service cost, net	$ 5.2	$ 6.0	$ 7.9
Interest cost	0.9	0.8	1.0
Expected return on plan assets	(1.4)	(1.3)	(2.0)
Settlements and curtailment gain	—	(7.4)	(6.3)
Special termination benefits	—	—	0.6
Amortization of actuarial loss	0.9	0.8	0.9
Amortization of prior service (credit) cost	(0.2)	(0.1)	0.2
Net periodic pension benefit cost (credit)	$ 5.4	$ (1.2)	$ 2.3

The net actuarial loss and prior service credit that will be amortized from "*Accumulated Other Comprehensive Loss*" into net periodic pension benefit cost in 2020 are expected to be $1.5 million and $(0.7) million, respectively.

Expected long-term returns for each of the plans' strategic asset classes were developed through consultation with investment advisors. Several factors were considered, including survey of investment managers' expectations, current market data, minimum guaranteed returns in certain insurance contracts, and historical market returns over long periods. Using policy target allocation percentages and the asset class expected returns, a weighted-average expected return was calculated.

To select the discount rates for the defined benefit pension plans, the Company uses a modeling process that involves matching the expected duration of its benefit plans to a yield curve constructed from a portfolio of AA-rated fixed-income debt instruments, or their equivalent. For each country, the Company uses the implied yield of this hypothetical portfolio at the appropriate duration as a discount rate benchmark.

The weighted-average assumptions used to determine the benefit obligations are as follows:

	December 31,	
	2019	2018
Discount rate	0.5%	0.9%
Rate of compensation increase	2.7%	2.8%
Social securities increase	1.6%	1.8%
Pension increase	1.8%	1.8%

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

The weighted-average assumptions used to determine the net periodic pension benefit cost are as follows:

	Years ended December 31,		
	2019	2018	2017
Discount rate	0.9%	0.9%	0.7%
Expected return on plan assets	2.3%	2.3%	2.4%
Rate of compensation increase	2.8%	2.6%	2.5%
Social securities increase	1.8%	1.5%	1.4%
Pension increase	1.8%	1.8%	0.3%

Plan Assets

The Company's investment strategy for plan assets is to seek a competitive rate of return relative to an appropriate level of risk and to earn performance rates of return in accordance with the benchmarks adopted for each asset class. Risk management practices include diversification across asset classes and investment styles, and periodic rebalancing toward asset allocation targets.

The Administrative and Investment Committee decides on the defined benefit plan provider in each location and that provider decides the target allocation for the Company's defined benefit plan at that location. The target asset allocation selected reflects a risk/return profile the Company feels is appropriate relative to the plans' liability structure and return goals. In certain plans, asset allocations may be governed by local requirements. Target weighted-average asset allocations at December 31, 2019, by asset category, are as follows:

Equity securities	22.3%
Debt securities	48.3%
Real estate	6.9%
Other	22.5%
Total	100.0%

The fair values of the Company's defined benefit plan assets at December 31, 2019 and 2018, by asset category, are as follows (in millions):

December 31, 2019	Level 1	Level 2	Level 3	Total
Asset Category				
Cash	$ 3.8	$ —	$ —	$ 3.8
Equity securities:				
United States equities	3.0	—	—	3.0
International equities	11.2	—	—	11.2
Debt securities:				
United States government bonds	8.2	—	—	8.2
International government bonds	22.3	—	—	22.3
Real estate	—	4.4	—	4.4
Mortgages	—	2.3	—	2.3
Insurance contracts	—	—	0.9	0.9
Total plan assets measured at fair value	$ 48.5	$ 6.7	$ 0.9	56.1
Alternative investments measured at net asset value (a)				7.1
Total plan assets				$ 63.2

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EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

December 31, 2018	Level 1	Level 2	Level 3	Total
Asset Category				
Cash	$ 7.0	$ —	$ —	$ 7.0
Equity securities:				
United States equities	0.5	—	—	0.5
International equities	9.3	—	—	9.3
Debt securities:				
United States government bonds	6.4	—	—	6.4
International government bonds	23.2	—	—	23.2
Real estate	—	4.1	—	4.1
Mortgages	—	2.2	—	2.2
Insurance contracts	—	—	1.0	1.0
Total plan assets	$ 46.4	$ 6.3	$ 1.0	$ 53.7
Alternative investments measured at net asset value (a)				6.7
Total plan assets				$ 60.4

(a) Certain investments that were measured at net asset value per share have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the total plan assets.

The following table summarizes the changes in fair value of the Company's defined benefit plan assets that have been classified as Level 3 for the years ended December 31, 2019 and 2018 (in millions):

	Insurance Contracts
Balance at December 31, 2017	$ 2.7
Actual return on plan assets:	
Relating to assets still held at December 31, 2018	(1.6)
Currency exchange rate impact	(0.1)
Balance at December 31, 2018	1.0
Purchases, sales and settlements	(0.1)
Balance at December 31, 2019	$ 0.9

Equity and debt securities are valued at fair value based on quoted market prices reported on the active markets on which the individual securities are traded. Real estate investments are valued by discounting to present value the cash flows expected to be generated by the specific properties. Investments in mortgages are valued at cost, which is deemed to approximate its fair value. The insurance contracts are valued at the cash surrender value of the contracts, which is deemed to approximate its fair value. Alternative investments include hedge funds, private equity funds and other miscellaneous investments, and are valued using the net asset value provided by the fund administrator as a practical expedient. The net asset value is based on the fair value of the underlying assets owned by the fund divided by the number of shares outstanding.