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(54) **IMPLANT WITH AN INTERFERENCE FIT FASTENER**

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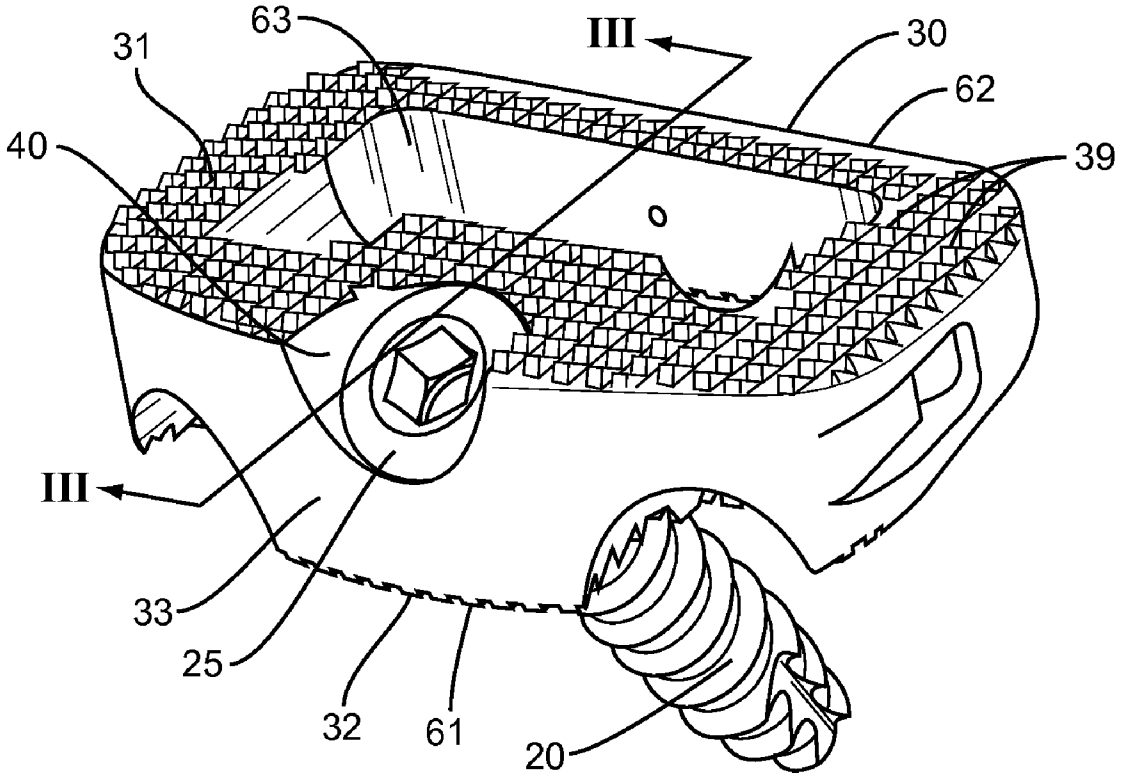
(57) **ABSTRACT**

An implant with an interference fit fastener for attaching the implant to a bone. The interference fit prevents backout of the fastener after the attachment. The implant may include a passage with a first end and second end. The passage may include a first interference section between the first and second ends. A fastener with an elongated shape may be sized to extend through the passage to attach the implant to the bone. The fastener may include a second interference section. During insertion of the fastener through the passage and into the bone, the second interference section of the fastener may contact against and modify or be modified by the first interference section of the passage. This modification may create the interference fit between the implant and the fastener that prevents backout. The interference sections may remain in contact or may move apart once the fastener is fully attached to the bone.



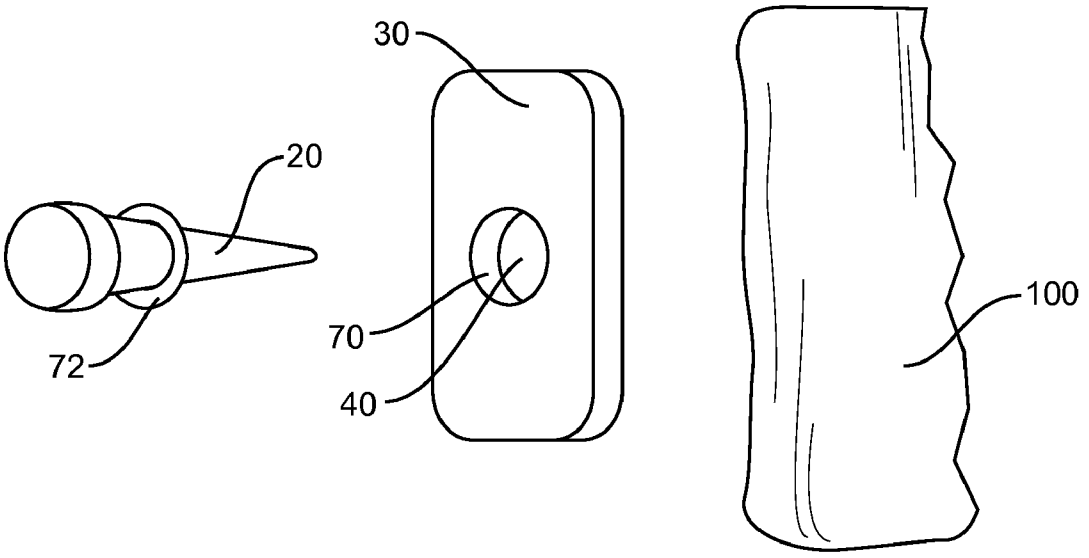


FIG. 1

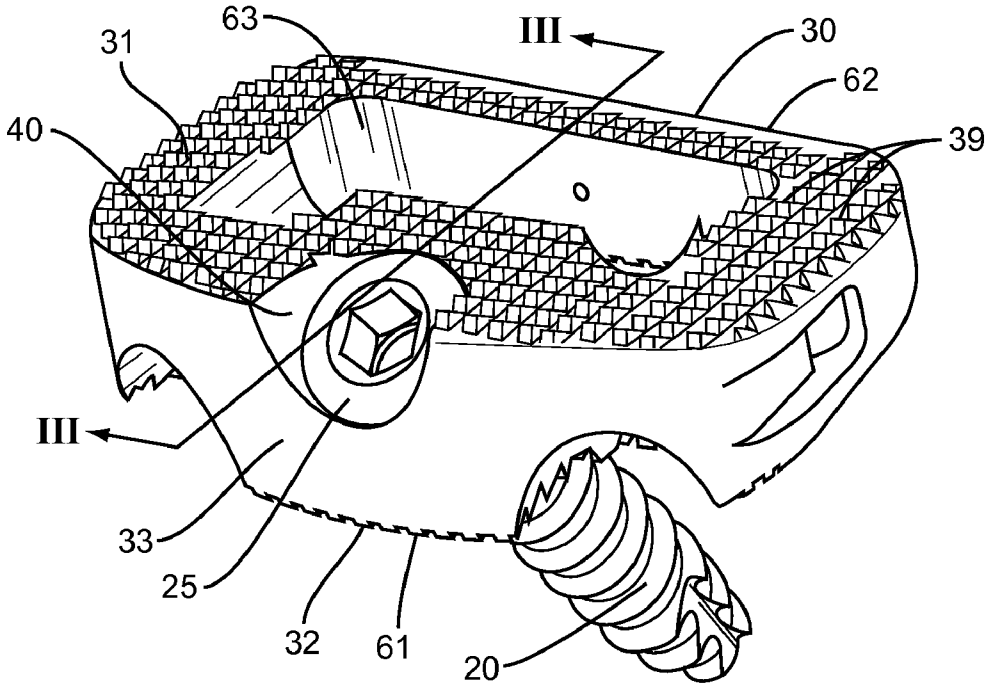


FIG. 2

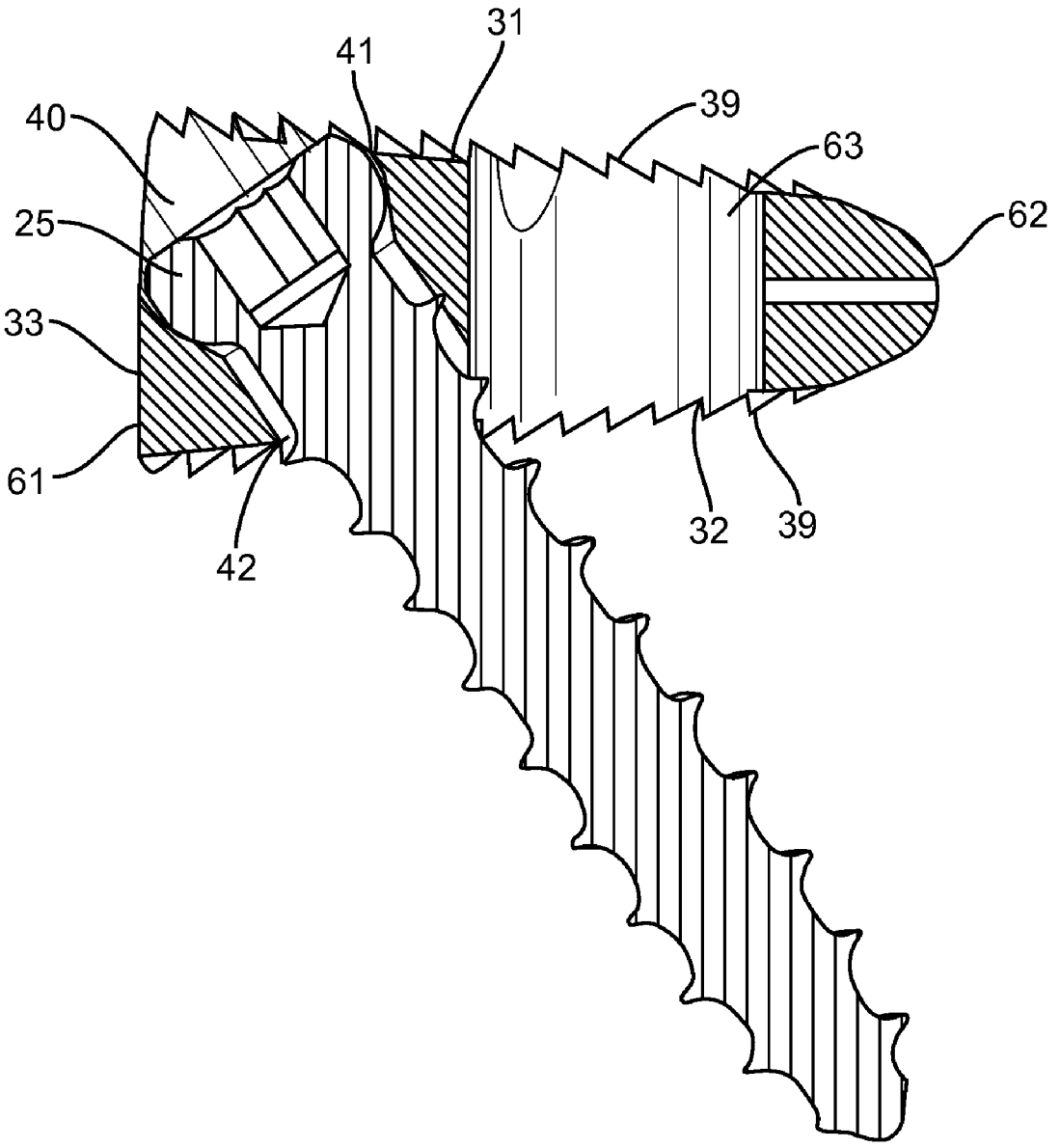


FIG. 3

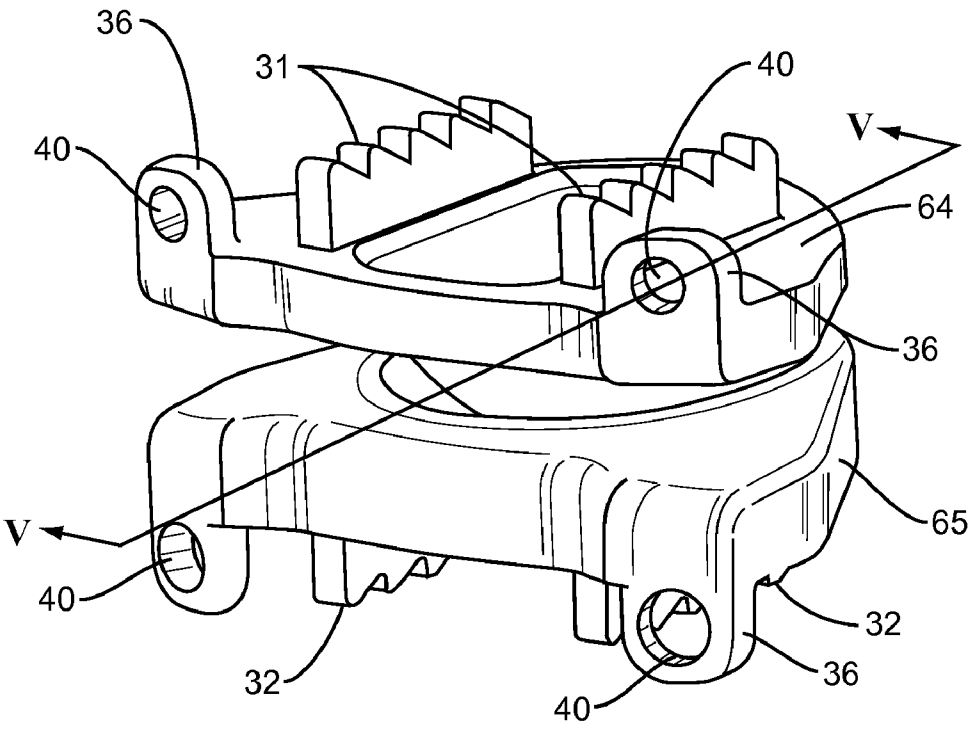


FIG. 4

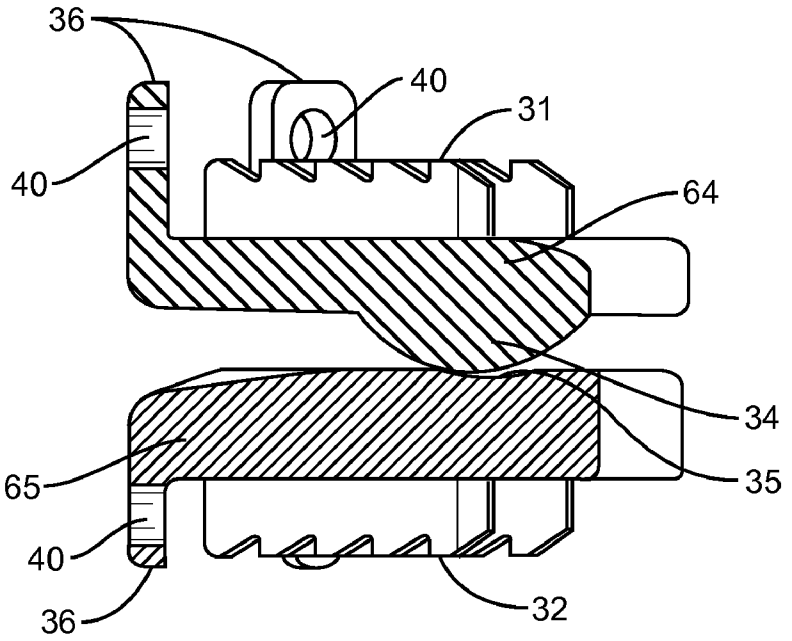


FIG. 5

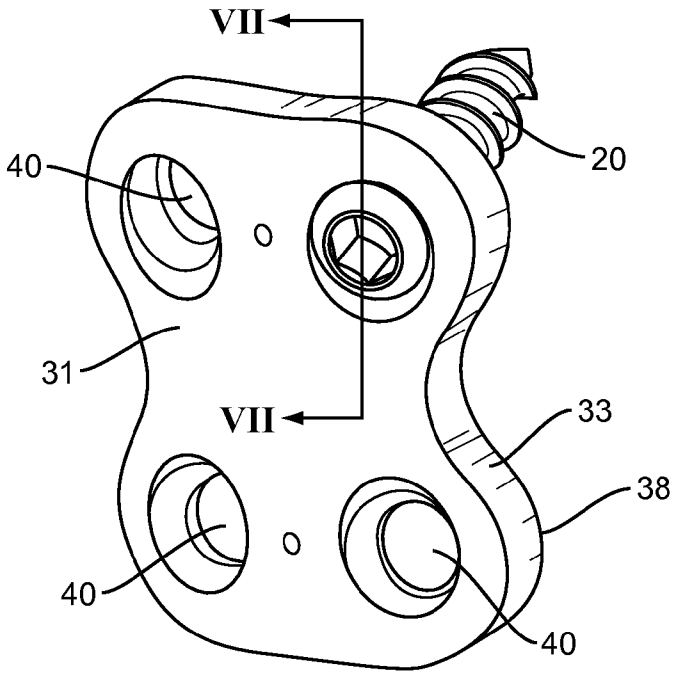


FIG. 6

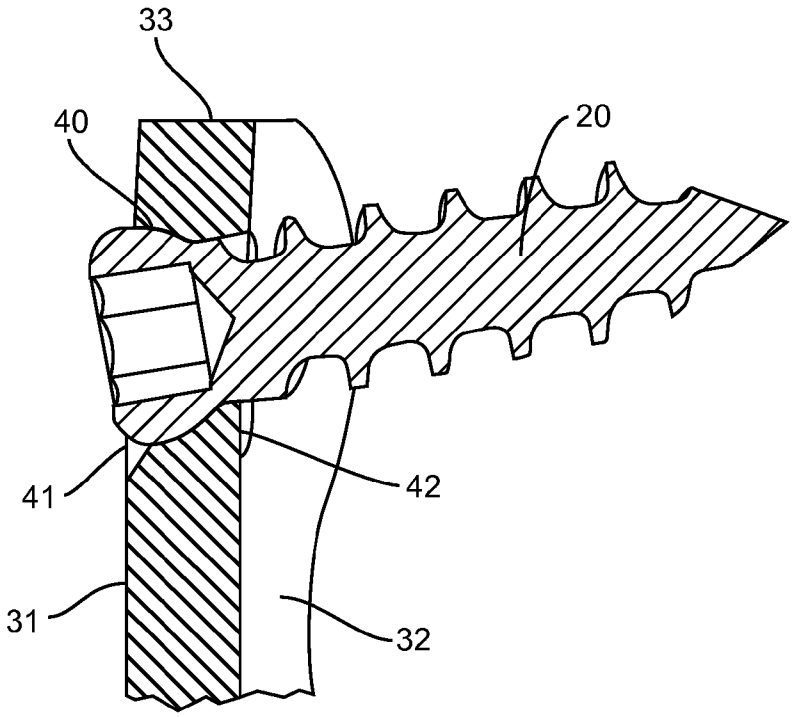


FIG. 7

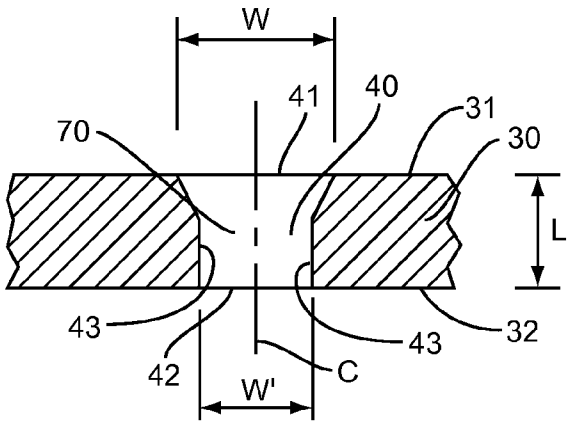


FIG. 8

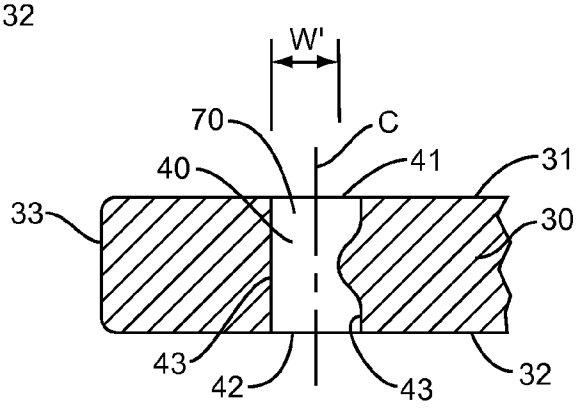


FIG. 10

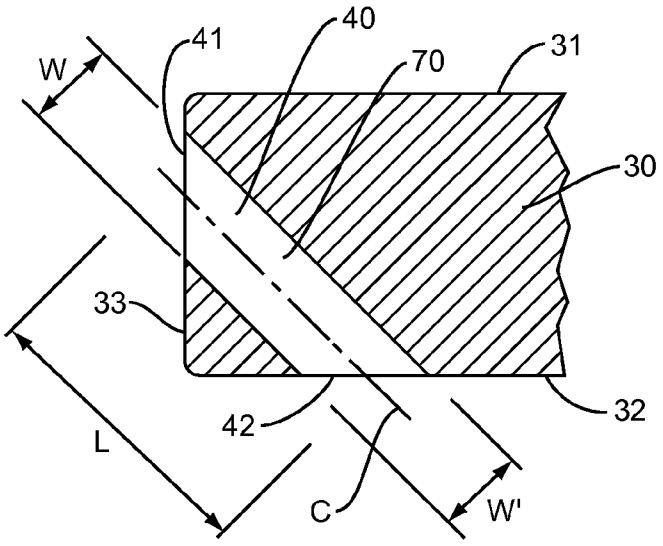


FIG. 9

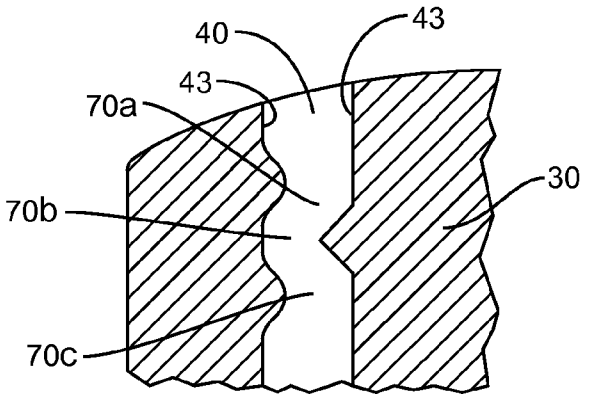


FIG. 11

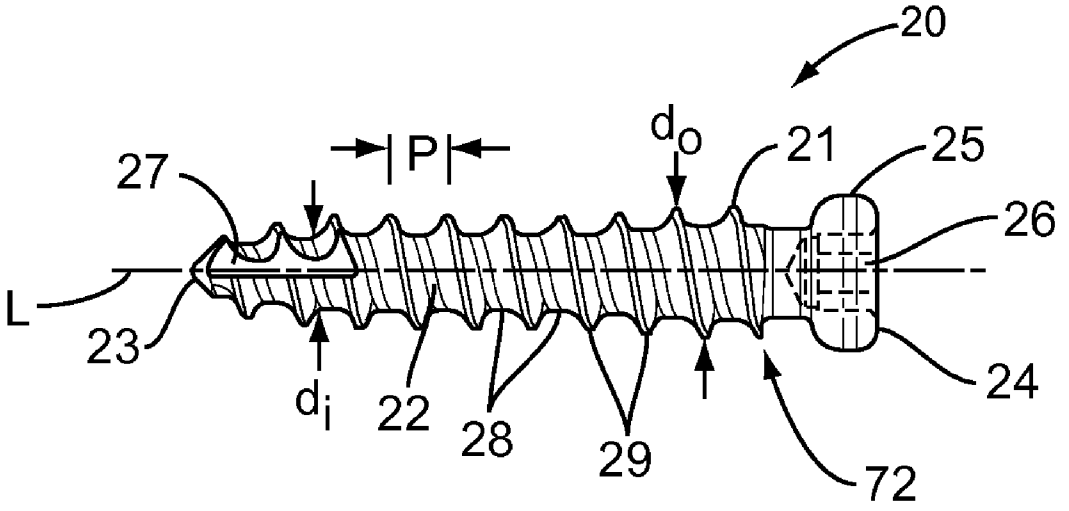

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FIG. 12

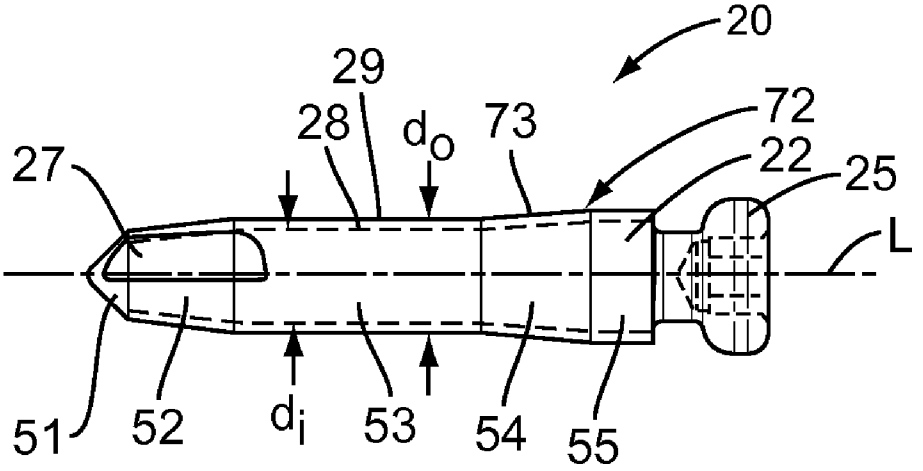
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FIG. 13

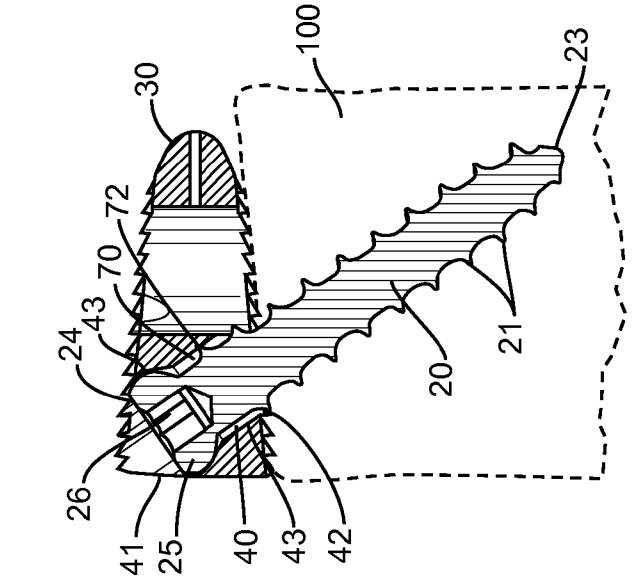

FIG. 16

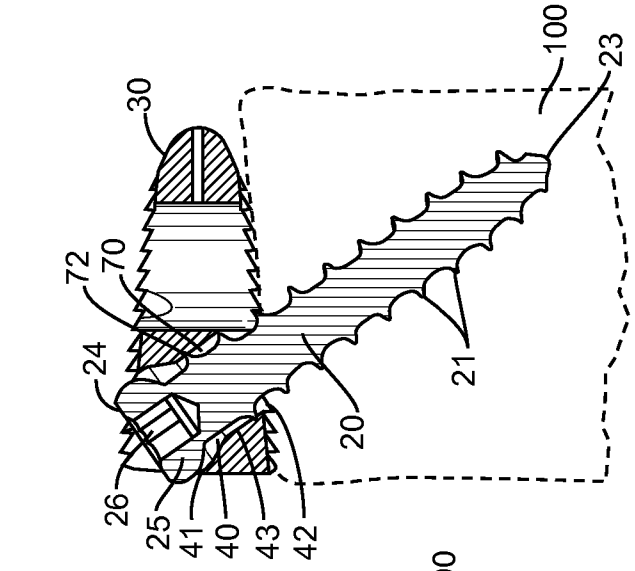

FIG. 15

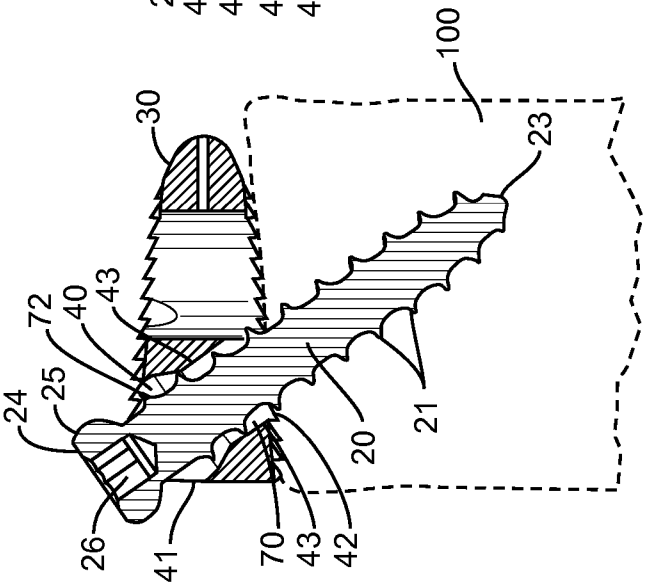

FIG. 14

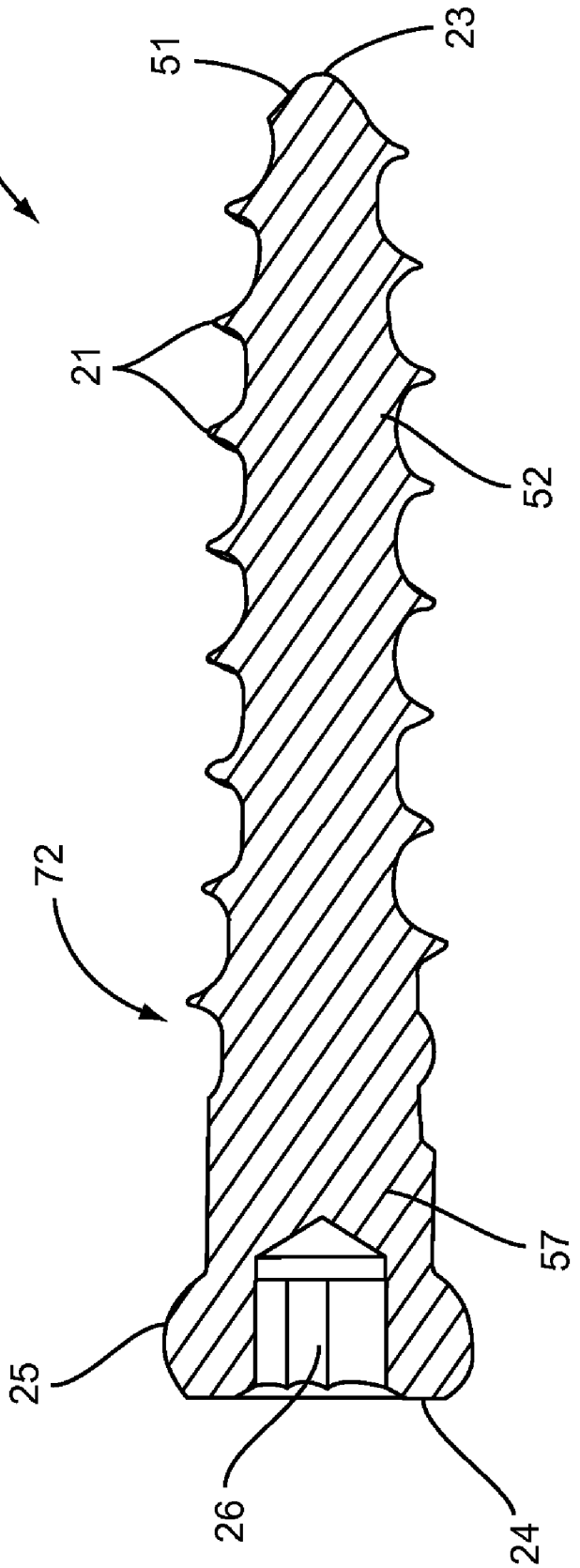

FIG. 17

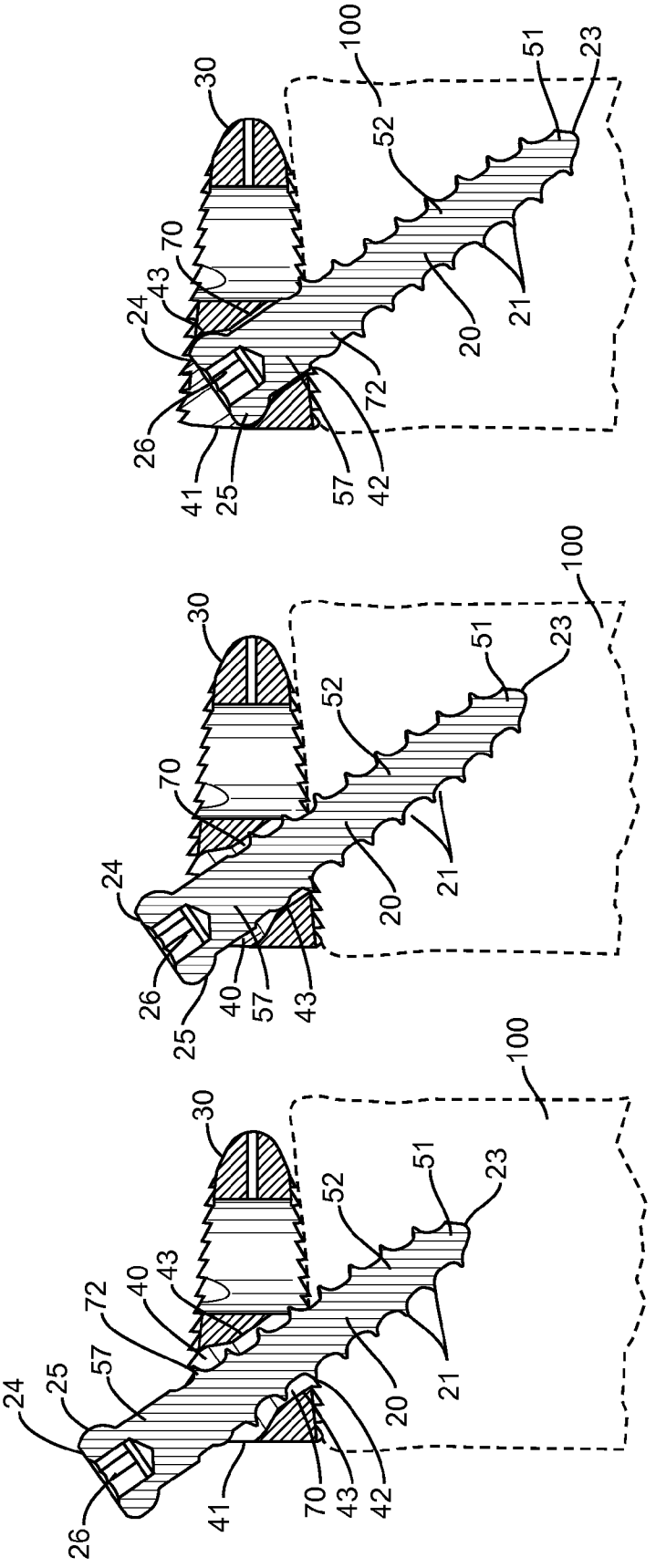

FIG. 20

FIG. 19

FIG. 18

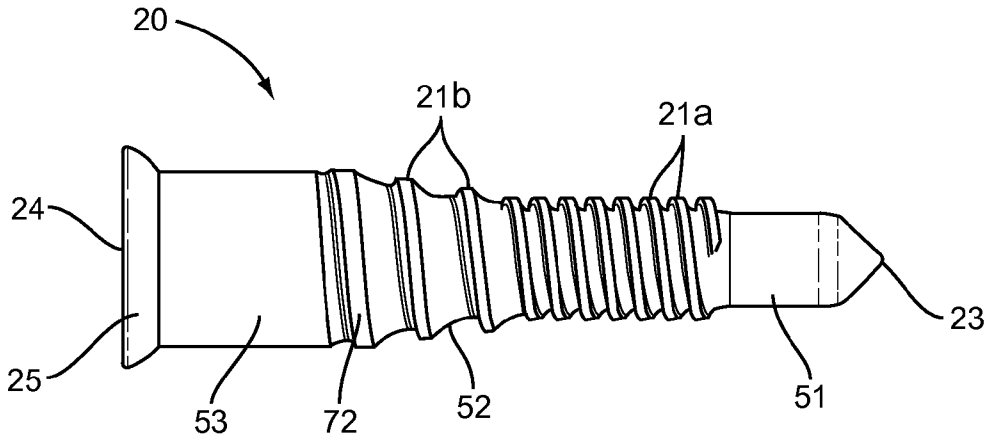

FIG. 21

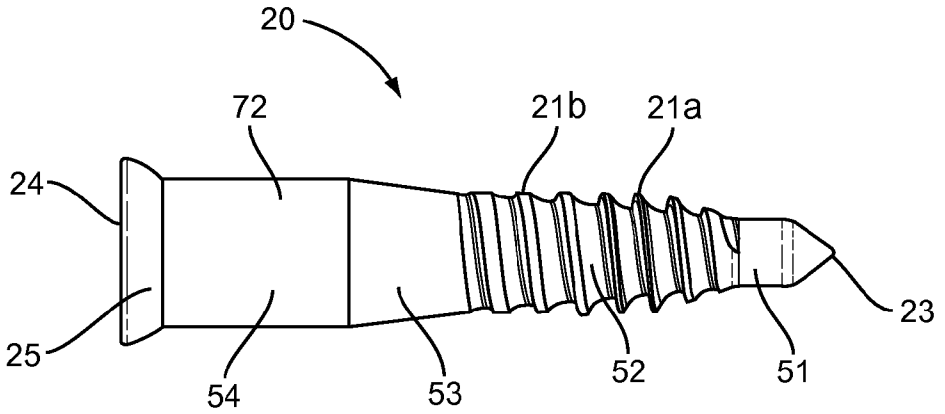

FIG. 22

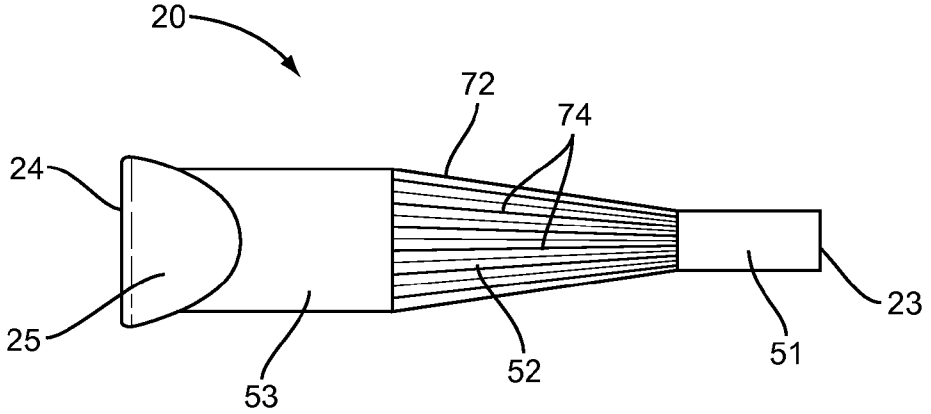

FIG. 23

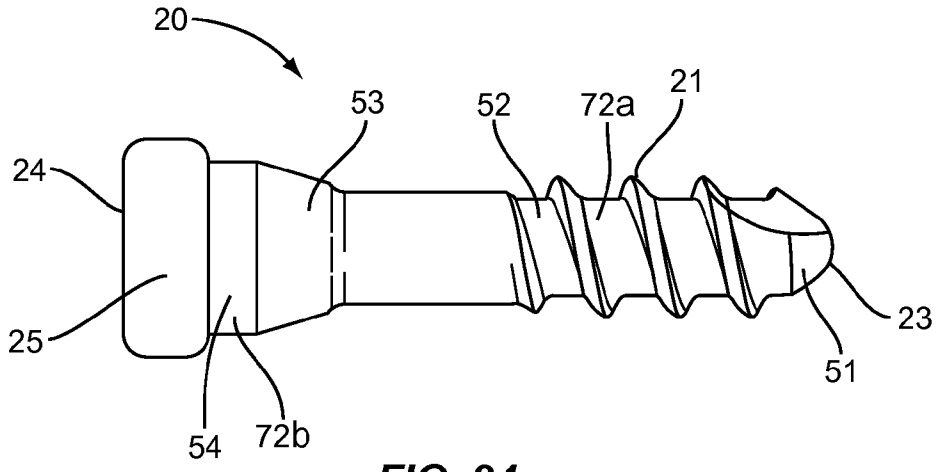

FIG. 24

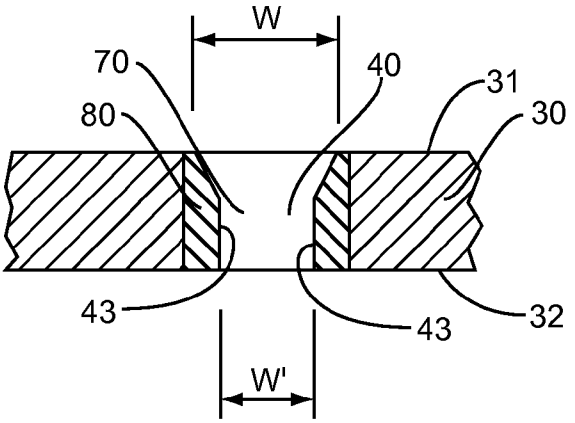

FIG. 25

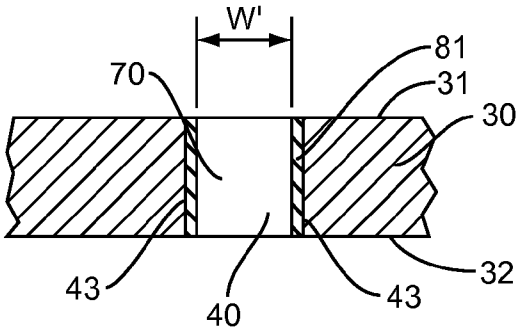

FIG. 26

IMPLANT WITH AN INTERFERENCE FIT FASTENER

BACKGROUND

[0001] The present application is directed to an implant attached to a bone with a fastener and, more particularly, to a fastener and an implant with different hardnesses with one being modified during insertion of the fastener through a passage in the implant to create an interference fit.

[0002] Various types of implants are inserted into a patient and attached with a fastener to a bone. The fastener extends through the implant and into the bone maintaining the implant against the bone. The fastener may also be configured to apply a compressive force against the implant. The implant and fastener should be structured to prevent the fastener from being non-threaded or otherwise removed from the bone and/or implant. This backward movement of the fastener relative to the bone and/or implant is referred to as backout. Backout may be caused by subsidence of the bone after attachment of the implant, or unthreading of the fastener from the bone.

[0003] Mechanisms have been developed to prevent backout of a fastener. One type of mechanism includes a snap ring that attaches to the implant and extends over a passage through the implant that receives the fastener. The snap ring is contacted during insertion of the fastener causing the snap ring to move away from the passage to allow insertion. Once the fastener passes, the snap-ring rebounds over the passage and head of the fastener. Drawbacks of these mechanisms include that the snap ring may become detached from the implant, and the snap ring may not rebound over the fastener. Further, a surgeon may have difficulty determining the position of the snap ring during a surgical procedure.

[0004] Another mechanism includes a projection that is movable by the surgeon between a locked orientation that extends over the passage in the implant and an unlocked orientation away from the passage. The projection is in the unlocked orientation when the fastener is inserted into the passage and driven into the bone. After insertion, the projection is moved by the surgeon to the locked orientation over the passage and the proximal end of the fastener. A drawback of this design is it requires the surgeon to perform an additional step after insertion of the fastener. It may also be difficult for a surgeon to determine that the projection is properly positioned over the fastener.

SUMMARY

[0005] The present application is an implant that attaches to a bone and methods of using the implant. The implant may include a passage with a first end and second end. The passage may include a first interference section between the first and second ends. A fastener with an elongated shape may be sized to extend through the passage to attach the implant to the bone. The fastener may include a second interference section. During insertion of the fastener through the passage and into the bone, the second interference section of the fastener may contact against and modify or be modified by the first interference section of the passage. This modification may create an interference fit between the implant and the fastener that prevents backout. The first and second interference sections may remain in contact once the fastener is fully attached to the bone, or may move apart.

[0006] The various aspects of the various embodiments may be used alone or in any combination, as is desired.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. **1** is a schematic perspective view of a fastener and implant positioned at a bone according to one embodiment of the present application.

[0008] FIG. **2** is a perspective view of a fastener positioned in a passage through an implant according to one embodiment.

[0009] FIG. **3** is a sectional view cut along line III-III of FIG. **2**.

[0010] FIG. **4** is a perspective view of an implant according to one embodiment.

[0011] FIG. **5** is a sectional view cut along line V-V of FIG. **4**.

[0012] FIG. **6** is a perspective view of a fastener positioned in a passage through an implant according to one embodiment.

[0013] FIG. **7** is a sectional view cut along line VII-VII of FIG. **6**.

[0014] FIG. **8** is a sectional view of a passage through an implant according to one embodiment.

[0015] FIG. **9** is a sectional view of a passage through an implant according to one embodiment.

[0016] FIG. **10** is a sectional view of a passage through an implant according to one embodiment.

[0017] FIG. **11** is a sectional view of a passage through an implant according to one embodiment.

[0018] FIG. **12** is a side view of a fastener according to one embodiment.

[0019] FIG. **13** is a side schematic view of the fastener of FIG. **12**.

[0020] FIG. **14** is a sectional view of a fastener inserted a first amount into a bone according to one embodiment.

[0021] FIG. **15** is a sectional view of a fastener inserted a second amount into a bone according to one embodiment.

[0022] FIG. **16** is a sectional view of a fastener inserted a third amount into a bone according to one embodiment.

[0023] FIG. **17** is a sectional view of a fastener according to one embodiment.

[0024] FIG. **18** is a sectional view of a fastener inserted a first amount into a bone according to one embodiment.

[0025] FIG. **19** is a sectional view of a fastener inserted a second amount into a bone according to one embodiment.

[0026] FIG. **20** is a sectional view of a fastener inserted a third amount into a bone according to one embodiment.

[0027] FIG. **21** is a side view of a fastener according to one embodiment.

[0028] FIG. **22** is a side view of a fastener according to one embodiment.

[0029] FIG. **23** is a side view of a fastener according to one embodiment.

[0030] FIG. **24** is a side view of a fastener according to one embodiment.

[0031] FIG. **25** is a sectional view of an insert attached to an implant according to one embodiment.

[0032] FIG. **26** is a sectional view of a coating applied to an implant according to one embodiment.

DETAILED DESCRIPTION

[0033] The present application is directed to an implant with a self-locking bone fastener that attaches the implant to

a bone. The implant includes a passage to receive the fastener. Sidewalls of the implant and the fastener include different hardnesses causing one to be modified when the fastener is inserted into the implant. The modification causes an interference fit between the fastener and implant to prevent backout of the fastener.

[0034] FIG. **1** schematically illustrates a fastener **20** sized to fit within a passage **40** in an implant **30**. The fastener **20** functions to extend through the passage **40** and attach the implant **30** to the bone **100**. The fastener **20** includes an interference section **72** with a larger diameter than an interference section **70** of the passage **40**. The fastener **20** is also constructed of a material with a different hardness than the interference section **70**. One of the interference sections **70**, **72** is modified as the fastener **20** passes into the passage **40** and creates an interference fit. The interference fit at least prevents the fastener **20** from backing out of the bone **100** after attachment of the implant **30**.

[0035] The implant **30** is attached to the bone **100** by one or more fasteners **20** and may include a variety of shapes and configurations. FIGS. **2** and **3** include the implant **30** as a spacer configured to be positioned within an intervertebral space formed between vertebral members. The implant **30** includes a superior surface **31** configured to contact against a first vertebral member and an inferior surface **32** configured to contact against a second vertebral member. Teeth **39** may extend outward from one or both of the surfaces **31**, **32** to facilitate insertion into the intervertebral space and/or maintain the position within the intervertebral space. A sidewall **33** extends between the surfaces **31**, **32**. The height of the spacer measured between the surfaces **31**, **32** may be constant, or may vary as best illustrated in FIG. **3** with the height increasing from a first lateral sidewall **61** to a second lateral sidewall **62**. A central passage **63** may extend through spacer and through the surfaces **31**, **32**.

[0036] Implant **30** may also include an artificial disc as illustrated in FIGS. **4** and **5**. The implant **30** includes a first member **64** and a second member **65** configured to be positioned within the intervertebral space formed between vertebral members. The first member **64** includes a superior surface **31** configured to contact against the first vertebral member, and an inferior surface **32** is formed on a second member **65** to contact against the second vertebral member. The first member **64** also includes a convex section **34** that extends outward and mates with a concave section **35** in the second member **65**. The convex and concave sections **34**, **35** form a ball-and-socket arrangement that forms the artificial disc. Flanges **36** are positioned on the members **64**, **65** and include passages **40** each sized to receive a fastener **20**. Each of the flanges **36** and passages **40** may include different shapes, sizes, and orientations, or each may be substantially the same as best illustrated in FIG. **4**. The passages **40** align with an exterior of the first and second vertebral members when the convex and concave sections **34**, **35** are positioned within the intervertebral space. In another embodiment, the implant **30** does not include flanges **36** and the passages **40** extend directly through the first and second members **64**, **65** in a similar manner as illustrated in FIGS. **2** and **3**.

[0037] Implant **30** may also include a plate as illustrated in FIGS. **6** and **7**. The plate includes a first surface **31** that faces away from the bone **100** and a second surface **32** that faces towards and contacts against the bone **100**. Sidewalls **33** extend between the first and second surfaces **31**, **32**. The plate may be substantially flat or may be curved. The thickness measured between the surfaces **31**, **32** may be the same throughout the plate or may vary. One or more passages **40** extend through the plate from the first surface **31** to the second surface **32**. One or more of the passages **40** may also be positioned at least partially through the sidewalls **33**.

[0038] The implant **30** is constructed of a material with a different hardness than the fastener **20**. This difference causes the implant **30** to modify or be modified by the fastener **20** during insertion and create an interference fit that prevents backout of the fastener **20**. Implant materials include but are not limited to polyaryletherketone (PAEK), polyetheretherketone (PEEK), carbon-reinforced PEEK, polyetherketoneketone (PEKK), polysulfone, polyetherimide, polyimide, ultra-high molecular weight polyethylene (UHMWPE), plastics, titanium, titanium alloy, stainless steel, and metallic alloys.

[0039] A passage **40** extends through the implant **30** to receive the fastener **20**. As illustrated in FIG. **8**, the passage **40** generally includes a first end **41** and a second end **42** with a length L measured along an axis C between the first and second ends **41**, **42**. Passage **40** further includes sidewalls **43** that extend between the ends **41**, **42**. A diameter W is measured across the passage **40** between the sidewalls **43**. The diameter W may vary along the length L. FIG. **8** includes a diameter W that is wider at the first end **41** than the second end **42**. The wider diameter W at the first end **41** forms a receptacle for seating a head **25** of the fastener **20** within the passage **40** as illustrated in FIGS. **2** and **3**. FIG. **9** includes another passage **40** with a constant diameter W along the entire length L.

[0040] The passage **40** may extend through the implant **30** at various orientations. FIGS. **2** and **3** include the passage **40** angled relative to the superior and inferior surfaces **31**, **32** with an axis neither parallel nor perpendicular to the surfaces **31**, **32**. The first end **41** extends through both the superior surface **31** and sidewall **33** and the second end **42** extends through the inferior surface **32**. The amount of the angle relative to the superior and inferior surfaces **31**, **32** may vary depending upon the context of use. Other configurations as illustrated in FIG. **9** include an angled orientation with the first end **41** of the passage **40** being isolated to just within the sidewall **33**. FIGS. **4-7** include the passage **40** extending more directly through the implant **30** between opposing surfaces.

[0041] The passage **40** includes an interference section **70** that is interacts with the fastener **20** during insertion. In one embodiment as illustrated in FIG. **8**, the interference section **70** includes a diameter W' that is narrower than the diameter W. The interference section **70** may include different shapes and lengths. FIG. **8** includes the interference section **70** extending along a limited distance of the length L, and specifically in proximity to the second surface **32**. FIG. **9** includes the interference section **70** extending the entire length L of the passage **40** as the diameter W is constant along the length L (i.e., W equals W').

[0042] The interference section **70** may be symmetrical about the axis C. FIGS. **8** and **9** each include symmetrical interference sections **70**. The interference section **70** may also include various other configurations. FIG. **10** includes an extension on one of the sidewalls **43** that forms the interference section **70**. THe passage **40** may also include multiple interference sections **70**. FIG. **11** includes three interference sections **70***a*, **70***b*, **70***c*. The multiple sections **70** may each include the same or different shapes and/or diameters W'.

[0043] The interference section **70** includes a solid surface that engages the fastener **20**. In one embodiment, the implant **30** includes a unitary one-piece construction. Therefore, the interference section **70** is constructed from the same material and from the same single structure as the remainder of the implant **30**. In another embodiment as illustrated in FIG. **25**, the interference section **70** is formed by an insert **80** that is attached to the implant **30**. The insert **80** forms the passage **40** and the interference section **70**. The insert **70** may be attached to the implant **30** in various manners, including but not limited to interference fit, thread fit, mechanical fasteners, and adhesive. Another embodiment includes a coating **81** applied to the sidewalls **43** of the passage **40** as illustrated in FIG. **26**. The coating **81** reduces a width of the passage **40** and creates the interference section **70**.

[0044] The passage **40** may include a circular shape when viewed along the axis C. However, passage **40** may also include other shapes including but not limited to oval, rectangular, square, and elliptical. The term diameter is used to define the distance across the passage **40** between the sidewalls **43** and should be construed in a manner to also apply to passages that are not circular.

[0045] The fastener **20** functions to extend through the passage **40** and attach the implant **30** to the bone **100**. Fastener **20** may include various shapes and configurations to perform this function. Fastener **20** may be constructed from a variety of materials, including but not limited to titanium, titanium alloy, stainless steel, metallic alloys, polyaryletherketone (PAEK), polyetheretherketone (PEEK), carbon-reinforced PEEK, polyetherketoneketone (PEKK), polysulfone, polyetherimide, polyimide, ultra-high molecular weight polyethylene (UHMWPE), and plastics.

[0046] FIG. **12** illustrates a fastener **20** with an elongated shape that extends along a longitudinal axis L and generally includes a shank **22** and a head **25**. The fastener **20** includes a distal tip **23** at an end of the shank **22** and an opposing proximal end **24** at the head **25**. The distal tip **23** is preferably tapered to a point to facilitate movement through the bone **100**, although the tip **23** may include other non-tapered configurations. The length of the body **20** measured between the tip **23** and end **24** may vary.

[0047] The fastener **20** may include one or more helical threads **21** that wrap around the longitudinal axis and extend along the shank **22** and/or head **25**. The thread **21** may extend along the entire length of the fastener **20**, or just along a limited length. The thread **21** defines a root **28** in proximity to the longitudinal axis L and a crest **29** distanced from the longitudinal axis L. The fastener **20** includes a minor diameter di measured between the roots **28**, and a major diameter do measured between the crests **29**. One or both of the diameters di, do may be constant or may vary along the length of the fastener **20**.

[0048] The crests **29** may be tapered to facilitate self-tapping, or may be truncated and substantially flat. The crests **29** may be constant or may vary along the length of the thread **21**. The thread **21** includes a depth measured from the root **28** to the crest **29**. FIG. **12** includes the thread depth being consistent along the length the shank **22**. The depth may also vary along the length as necessary. The thread **21** may also include the same or different angles and/or pitch along the length. FIG. **12** includes the thread angle and pitch being the same along the length of the thread **21**.

[0049] A receptacle **26** may extend into the head **25** to receive a tool for applying torque to the fastener **20**. The receptacle **26** may include a variety of shapes to receive a tool with a variety of drive types including but not limited to slotted, Phillips, hexagonal, Torx, spline drive, and double hex.

[0050] The cross-sectional shape of the head **25** may also vary, including but not limited to pan head, button, round, countersunk, and oval. The head **25** may further include the same size and shape as the shank **22**. The cross-sectional shape of the shank **22** may be circular or may also be other shapes. The term diameter is again used and applies to these various shapes.

[0051] One or more self-tapping flutes **27** may be positioned at the distal tip **23**. The flutes **27** are non-threaded and extend into the shank **22** to facilitate insertion and movement through the bone **100**.

[0052] Fastener **20** also includes an interference section **72** that extends along a longitudinal section of the length. The interference section **72** includes a greater diameter than the diameter W' of the interference section **70** of the passage **40**. This difference in size causes the interference section **72** to contact against and modify or be modified by the interference section **70** to create an interference fit between the fastener **20** and the implant **30**. In one embodiment, just the thread **21** creates the interference section **72**. Other embodiments include the central body of the shank **22** formed the interference section **72**. The length L of the interference section **72** measured along the longitudinal axis L may vary.

[0053] FIG. **13** illustrates a theoretical side view of the screw of FIG. **12**. The dashed lines extending along the shank **22** illustrate the minor diameter di defined by the roots **28**, and the solid lines **29** illustrate major diameter do defined by the crests **29**. FIG. **13** includes the solid lines of the crests **29** parallel to the dashed lines of the roots **28** as the thread depth is the same along the length of the shank **22**.

[0054] The fastener **20** includes one or more longitudinal sections **50** each extending along a length of the longitudinal axis L. The sections **50** may include constant or varying diameters di, do. A first section **51** extends inward from the distal tip **23**. The fastener of FIG. **13** includes a first section **51** with a tapered shape that widens in a proximal direction away from the tip **23**. The thread **21** may or may not extend along the first section **51**. In one embodiment, the thread **21** begins along the first section **51**. Second and fourth sections **52**, **54** are positioned along the shank **22** and each includes a tapered shape that increases towards the proximal end of the fastener **20**. The tapers may be the same or may be different. Sections **52**, **54** each include a linear taper. Tapers may also be non-linear (i.e., curved taper). FIG. **13** includes the fourth section **54** with a sharper taper than the second section **52**. Third and fifth sections **53**, **55** each include constant diameters di, do along their lengths.

[0055] In this embodiment, the interference section **72** is formed by a portion of the fourth section **54** and the fifth section **55** in the fastener **20** of FIG. **13**. Positioning a starting edge **73** (i.e., distal edge) of the interference section **72** facilitates modifying of one of the interference sections **70**, **72**.

[0056] FIGS. **14-16** illustrate the steps of attaching the implant **30** to a bone **100** with the fastener **20**. The passage **40** in this embodiment features a wide first end **41** that tapers down and leads into the interference section **70**. As illustrated in FIG. **14**, the fastener **20** is inserted through the passage **40** with the distal tip **23** contacting against the bone **100**. At this amount of insertion, the threads **21** are engaging the bone **100** but are not contacting against the sidewalls **43** of the passage

40. The interference section 72 of the fastener 20 is positioned away from the interference section 70 of the passage 40.

[0057] FIG. 15 illustrates the fastener 20 inserted a further distance into the bone 100. At this point of insertion, the threads 21 at the interference section 72 are in contact with the interference section 70. In this example, the implant 30 is constructed of a softer material than the fastener 20. The sidewalls 43 are solid and substantially smooth and not pre-tapped. As the fastener 20 is rotated and moved through the passage 40, the interference section 72 modifies the interference section 70 and creates an interference fit. The interference section 72 may be self-tapping as it cuts the sidewalls 43, or may be thread-forming as it deforms the sidewalls 43. The interference section 72 is distanced away from the head 25 for modifying to occur prior to the head 25 bottoming out in the passage 40.

[0058] FIG. 16 illustrates the fastener 20 fully inserted into the bone 100. The amount of insertion is controlled by the head 25 contacting against the passage 40. In this embodiment, the head 25 and passage 40 are configured for the head 25 to fit within and be recessed within the passage 40. The interference section 72 remains engaged with the interference section 70 with this contact forming the interference fit to prevent fastener 20 backout.

[0059] The embodiment of FIGS. 14-16 may also be used with the fastener 20 constructed of a softer material than the implant 30. As the fastener 20 moves through the passage 40, the interference section 72 of the fastener 20 is modified by the interference section 70. This may include just the thread 21 be modified as it moves past the interference section 70, or may also include modification of the main body of the shank 22.

[0060] FIG. 17 includes a fastener 20 with a first longitudinal section 51 that includes the distal tip 23, a second threaded longitudinal section 52, and a third longitudinal section 53 each being positioned distally from the head 25. The second longitudinal section 52 includes a gradually tapering shape with the diameters di, do increasing towards the proximal end. The interference section 72 is positioned at the proximal end of the second section 52. A thread 21 extends along the length of the section 52. Section 57 is positioned between the interference section 72 and a distal edge of the head 25. The longitudinal section 57 is non-threaded and includes a diameter dm that is smaller than the major diameter do of the interference section 72.

[0061] FIGS. 18-20 illustrate the steps of attaching the implant 30 to the bone 100 with this fastener 20. These steps include the fastener 20 constructed of a harder material than the implant 30. FIG. 18 includes the fastener 20 inserted a first amount with the first section 51 and a portion of the second section 52 extending into the bone 100. The diameter of the portion of the second section 52 within the passage 40 is smaller than the passage 40 with the thread 21 spaced from the sidewall 43.

[0062] FIG. 19 illustrates the fastener 20 inserted a greater distance into the bone 100. At this point of insertion, the interference section 72 contacts against and modifies the interference section 70. The sidewall 43 is solid and is not pre-tapped. The interference section 72 is spaced a distance from the head 25 to modify the interference section 70 prior to the head 25 being seated in the implant 30.

[0063] FIG. 20 illustrates the fastener 20 fully inserted into the bone 100. The head 25 is bottomed out in the passage 40 and in contact with the sidewall 43. Further, the interference section 72 has moved beyond the interference section 70. In this embodiment, the interference section 72 is moved beyond the second end 42 of the passage 40 and into the bone 100. The fastener 20 is prevented from backing out of the bone 100 as the threads 21 no longer align with the contours that were formed in the interference section 70. Therefore, any potential movement out of the bone 100 is prevented as the thread 21 on the interference section 72 contacts against the implant 30. FIG. 20 also illustrates that the longitudinal section 57 does not contact against the sidewall 43. In a similar arrangement as FIG. 20, the fastener 20 may be constructed such that the interference section 72 may move longitudinally beyond the interference section 70 but remain within the passage 40.

[0064] The embodiment of FIGS. 18-20 may also be performed with the implant 30 be constructed from a harder material than the fastener 20. The fastener 20 is modified as it is inserted through the passage 40. The interference section 72 is modified by the contact with the interference section 70.

[0065] Fasteners 20 may include other configurations to interact with the interference section 70 and attach the implant 30 to the bone 100. FIG. 21 includes a fastener 20 with a first thread 21*a* extending along a first section 51, and a second thread 21*b* extending along second and third sections 52, 53. The threads 21*a*, 21*b* may include one or more different aspects, including outer diameters, thread angle, and pitches. The interference section 72 is formed by a portion of the second section 52 and the third section 53. In this embodiment, the first thread 21*a* is configured to attach to the bone 100, and the second thread 21*b* is configured to engage with and modify or be modified by the interference section 70. Fasteners 20 may also include more than two different threads 21. Examples of multiple thread fasteners 20 are disclosed in US Patent Publication No. 2007/0233122 herein incorporated by reference in its entirety.

[0066] The interference section 72 may also be formed along a non-threaded section of the fastener 20. FIG. 22 includes a fastener 20 with a first section 51, threaded second section 52, and non-threaded third and fourth sections 53, 54. The interference section 72 is formed by the fourth section 54 with the distal edge formed at the intersection of the third and fourth sections 53, 54. FIG. 23 includes a fastener 20 with the interference section 72 formed by the second section 52. A series of engagement features 74 are positioned in the second section 52. The engagement features 74 may include grooves that are cut into the main body of the shank 22. The grooves may be longitudinal, radial, or helical. Engagement features 74 may also include protrusions that extend outward from the surface of the main body of the shank 22. The engagement features 74 facilitate engagement with the interference section 70 and/or inhibit further rotation that could cause backout of the fastener 20. In a similar embodiment, one or more flutes 27 are positioned proximal to the interference section 72.

[0067] Fastener 20 may also include multiple modifying sections 72 located along the length. FIG. 24 includes an embodiment with a first interference section 72*a* located along a second section 52, and a second interference section 72*b* located along the fourth section 54. The first interference section 72*a* includes a thread 21 and is sized to initially modify or be modified by the interference section 70. The second interference section 72*b* is positioned proximally from the first interference section 72*a*. The second interference section 72*b* is also sized to contact against the interfer-

ence section **70**. In this example, the second interference section **72***b* includes a larger diameter than the first interference section **72***a*.

[0068] During insertion of the fastener **20** into the passage **40**, the first interference section **72***a* moves through the passage **40** and modifies or is modified by the interference section **70**. Further insertion of the fastener **20** moves the second interference section **72***b* into the interference section **70** and results in further modification. The fastener **20** may include a size for a double interference fit with the first interference section **72***a* moving beyond the interference section **70** and modifying or being modified by the interference section **70** to prevent backout. The second interference section **72***b* may remain in the interference section **70** and form a second interference fit. The fastener **20** may further include more than two separate modifying sections **72**.

[0069] The various fasteners **20** used to attach the implant **30** to the bone **100** may include different structures. The fasteners **20** described above include different combinations of these structures. The various interference sections **70**, tapers, longitudinal sections **50**, diameters di, do, threads **21**, heads **25**, tips **23**, receptacles **26**, etc. may be combined in a variety of different combinations within a fastener **20** depending upon the context of use and are included within the scope of the present application.

[0070] The modification of one of the interference sections **70**, **72** creates the interference fit that prevents backout. The modification may include a self-tapping engagement as material is cut to form threads on the softer interference section **70**, **72**. The modification may also include thread-forming engagement caused by deformation of the softer interference section **70**, **72**. The modification may also include a variety of other deforming, cutting, and otherwise general altering of the softer interference section **70**, **72**. The modifications caused by the engagement between the sections **70**, **72** are permanent.

[0071] The implants **10** may include more than one passage **40** and be attached to the bone **100** by more than one fastener **20**. In these embodiments, at least one of the passages **40** includes an interference section **70** that is modified by a fastener **20**. The other passages **40** may or may not include an interference section **70**. Further, with implants **30** with multiple passages **40**, each of the passages **40** may include the same or different structure. Likewise, the fasteners **20** may each be the same or one or more may be different.

[0072] The implants **30** may be attached to a variety of different bones **100** within the patient. These include the vertebrae as well as the long bone of the patient.

[0073] In one embodiment, the implant **30** is constructed of PEEK and the fastener **20** is constructed of titanium. The sidewalls **43** of the passage **30** are solid and non-threaded.

[0074] The implants **30** may be implanted within a living patient for the treatment of various spinal disorders. The implants **30** may also be implanted in a non-living situation, such as within a cadaver, model, and the like. The non-living situation may be for one or more of testing, training, and demonstration purposes.

[0075] Spatially relative terms such as "under", "below", "lower", "over", "upper", and the like, are used for ease of description to explain the positioning of one element relative to a second element. These terms are intended to encompass different orientations of the device in addition to different orientations than those depicted in the figures. Further, terms such as "first", "second", and the like, are also used to describe various elements, regions, sections, etc and are also not intended to be limiting. Like terms refer to like elements throughout the description.

[0076] As used herein, the terms "having", "containing", "including", "comprising" and the like are open ended terms that indicate the presence of stated elements or features, but do not preclude additional elements or features. The articles "a", "an" and "the" are intended to include the plural as well as the singular, unless the context clearly indicates otherwise.

[0077] The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

What is claimed is:

1. A medical device for treating a patient comprising:
an implant;
a solid, non-threaded passage that extends through the implant and includes a first interference section with a first diameter;
a fastener with an elongated shape and a distal end and a proximal end, the fastener including a second interference section located between the ends that includes a second diameter that is greater than the first diameter;
one of the first and second interference sections constructed from a harder material and the other constructed from a softer material;
a surface of the interference section constructed from the softer material being modified by insertion of the fastener into the passage to create an interference fit between the implant and the fastener.

2. The device of claim **1**, wherein the second interference section is non-threaded.

3. The device of claim **1**, wherein at least a portion of the passage is tapered.

4. A medical device for treating a patient comprising:
an implant;
a passage that extends through the implant and includes an interference section with solid non-threaded sidewalls, the interference section includes a first diameter;
a fastener with an elongated shape and a distal end and a proximal end, the fastener includes a modifying section located between the ends that includes a second diameter that is greater than the first diameter;
the fastener constructed from a harder material than the implant with the modifying section modifying the interference section during insertion of the fastener into the passage and creating an interference fit between the implant and the fastener.

5. The device of claim **4**, wherein the modifying section includes a thread.

6. The device of claim **4**, wherein the interference section is constructed from a material that is permanently modified by the modifying section.

7. The device of claim **4**, wherein the modifying section includes a tapered diameter that increases from a distal portion towards a proximal portion.

8. The device of claim **4**, further comprising a second modifying section longitudinally spaced away from the modifying section, the second modifying section including a third diameter that is greater than the first diameter and different than the second diameter.

9. The device of claim **4**, wherein the modifying section includes grooves that extend into an outer surface of the fastener and are aligned along a longitudinal axis of the fastener.

10. The device of claim **4**, wherein the fastener includes a head and a shank, the head including a head diameter that is greater than the shank and the second diameter, the modifying section being spaced away from the head towards the distal end.

11. The device of claim **10**, wherein a first distance measured along a longitudinal axis of the fastener between a distal edge of the head and a proximal edge of the modifying section is greater than a second distance measured between first and second ends of the passage.

12. The device of claim **4**, wherein the implant is constructed from PEEK.

13. A medical device for treating a patient comprising:

an implant;

a fastener with a head positioned at an end of a shank, the fastener includes a modifying section located along the shank with a modifying section diameter larger than a remainder of the shank and smaller than the head;

a passage that extends through the implant and includes an interference section with solid non-threaded sidewalls, an interference section diameter being smaller than the modifying section diameter;

the fastener being constructed of a harder material than the passage;

a first distance measured along a longitudinal axis of the fastener between the distal edge of the head and a proximal edge of the modifying section being greater than a second distance measured along a longitudinal axis of the passage between a contact surface that receives the head and the second end.

14. The device of claim **13**, wherein the passage further includes a receptacle at the first end to receive the head, the contact surface being positioned at a bottom of the receptacle.

15. The device of claim **13**, further comprising a first thread extending along a first longitudinal section of the fastener and a different second thread extending along a second longitudinal section of the fastener.

16. The device of claim **13**, wherein the modifying section is positioned inward from distal and proximal ends of the shank.

17. The device of claim **13**, wherein the implant includes first and second sides, and sidewalls that extend between the first and second sides, a first end of the passage being positioned at the first side and a second end of the passage being positioned at the second side.

18. The device of claim **13**, further comprising a coating positioned over the solid non-threaded sidewalls.

19. A medical device for treating a patient comprising:

an implant;

a passage that extends through the implant and includes a first interference section with solid non-threaded sidewalls, the first interference section includes a first diameter;

a fastener with an elongated shape and a distal end and a proximal end, the fastener including a second interference section located between the ends that includes a second diameter that is greater than the first diameter;

the first interference section constructed from a harder material than the second interference section with the second interference section being permanently modified during insertion of the fastener into the passage.

20. A method of attaching an implant to a bone comprising:

inserting a fastener into a first end of a passage that extends through the implant;

moving a first interference section of the fastener through a second interference section of the passage, the second interference section including a solid sidewall;

contacting the first interference section against the second interference section and modifying one of the interference sections due to a difference in hardnesses between the fastener and the implant.

21. The method of claim **20**, further comprising inserting the fastener a greater distance into the passage and moving the first interference section beyond the second interference section.

22. The method of claim **20**, further comprising permanently modifying one of the interference sections due to the difference in the hardnesses between the fastener and the implant.

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