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Claim Element	Infringement by TAPESTRY Implant
1a A scaffold comprising	The TAPESTRY implant includes a scaffold. “Fully resorbed TAPESTRY implant in vivo demonstrates the formation of dense collagenous connective tissue around and in place of the implant.” <i>See</i> https://embody-inc.com/tapestry/ “In in vitro testing, TAPESTRY, supports the growth and elongation of human connective tissue cells and mesenchymal stem cells (MSCs) cultured under tension that mimics native tissue structure and function.” <i>Id.</i> MECHANISM OF ACTION Patented Collagen Co-polymer Patented Physio-Chemistry Bioengineered 3D Micro-architecture Unique Micro-environment Early cell attachment, infiltration, and elongation^{1,2} New collagen deposition¹ Incorporation into the native tissue¹ New, dense, collagenous tendon-like tissue¹ Neighboring Native Achilles <i>Id.</i> “Preclinical studies of TAPESTRY® Biointegrative Implant showed dense collagenous fibrous connective tissue ingrowth into and around the implant.” <i>See</i> Embody, Inc. TAPESTRY® Biointegrative Implant Instructions for Use (hereinafter, “TAPESTRY Instructions”) at 1. “TEND further supported cellular alignment and upregulation of tenogenic genes from clinically relevant human stem cells within three days of culture. TEND implanted in a rabbit Achilles tendon injury model showed new in situ tissue generation, maturation, and remodeling of dense, regularly oriented connective tissue in vivo.” Abstract, “Biomanufacturing organized collagen-

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	based microfibers as a Tissue Engineered Device (TEND) for tendon regeneration.” See <i>Biomedical Materials</i> 16 (2021) 025025, at 1, Y. Maghdouri-White et al., https://doi.org/10.1088/1748-605X/abb875¹ (hereinafter, “TEND Paper”). “Preclinical studies of TAPESTRY® showed dense collagenous fibrous connective tissue ingrowth into and around the scaffolding.” See TAPESTRY® Biointegrative Implant 510(k) Summary, Oct. 13, 2020 at 1; TAPESTRY® Biointegrative Implant Traditional 510(k) Summary, Sep. 29, 2021 at 1. TAPESTRY Optimized <u>Physio-Chemistry</u> for Tendon The TAPESTRY Biointegrative Implant is a bioengineered implant combining Type 1 Bovine collagen chemistry with a highly aligned & highly porous architecture - Bioengineered micro-architecture & chemistry specifically designed for tendon repair. - Unaligned outer surface for isotropic suture retention strength and structural integrity - Highly aligned and consistent microarchitecture mimics native tendon - Highly porous (>90%) to encourage cell and fluid infiltration - Broad range of sizes & shapes: 20x30mm up to 70x50mm - Room Temperature Storage, no refrigeration required - FDA Clearance October 9, 2020 (K201572) - Indicated for the management and protection of tendon injuries ... “Preclinical studies of TAPESTRY® showed dense collagenous fibrous connective tissue ingrowth into and around the scaffolding” embODY 1. Lin et al., <i>Biomaterials</i> 2014 2. TAPESTRY IUI. See Embody, LSI USA '22 Emerging Medtech Summit Presentation (hereinafter, “LSI Presentation”) at slide 5.
1b one or more electrospun fibers comprising collagen,	The TAPESTRY implant includes one or more electrospun fibers comprising collagen.

¹ Embody, Inc. refers to the Maghdouri-White paper as proof of TAPESTRY’s efficacy on its website at <https://embody-inc.com/tapestry/>.

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	“Aligned TEND was produced by dissolving type I collagen (Collagen Solutions, Eden Prairie, MN) and UHMW PDLA (Corbion, Amsterdam, Netherlands) in 100% DMSO (Gaylord Chemical, Slidell, LA) at a final concentration of 100 mg ml⁻¹ (30 mg ml⁻¹ collagen and 70 mg ml⁻¹ PDLA) for 24 h. This polymer blend was electrospun onto a spoked-wheel collector in a vertical electro-spinning setup.” <i>See</i> TEND Paper at 3. “FTIR was performed on Platinum ATR (Brucker, Billerica, MA) at Old Dominion University (ODU) (Norfolk, VA) to confirm the presence of the three amide bonds characteristic of type I collagen at 1235, 1560, and 1650 nm wavelengths. Bond peaks of electrospun and annealed TEND were compared to collagen and PDLA feedstocks.” <i>Id.</i> at 4. “To overcome current treatment shortcomings and advance the treatment of tendon and ligament injuries, we have developed a novel electrospun Tissue Engineered Device (TEND), comprised of type I collagen and poly(D,L-lactide) (PDLA) solubilized in a benign solvent, dimethyl sulfoxide (DMSO). . . . In all, TEND’s organized microfibers, biological fluid and cell compatibility, strength and biocompatibility make significant progress towards clinically translating electrospun collagen-based medical devices for improving the clinical outcomes of tendon injuries.” <i>Id.</i> at 1. “The TAPESTRY® Biointegrative Implant is composed of collagen and poly(D,L-lactide).” <i>See</i> TAPESTRY Instructions at 1. “BIOSPIN, a hybrid electrospun / pneumatospun technology for highly organized, highly porous collagen-based microfibrillar devices designed for soft tissue augmentation. The BIOSPIN platform technology is used in our TAPESTRY® Biointegrative Implant for tendon and ligament augmentation.” <i>See</i> https://embody-inc.com/our-technology/.
1c wherein a fast Fourier transform (FFT) analysis result of the fibers have adjacent major peaks with about 180° apart from each other.	An FFT analysis result of the TAPESTRY implant’s fibers have adjacent major peaks with about 180° apart from each other.

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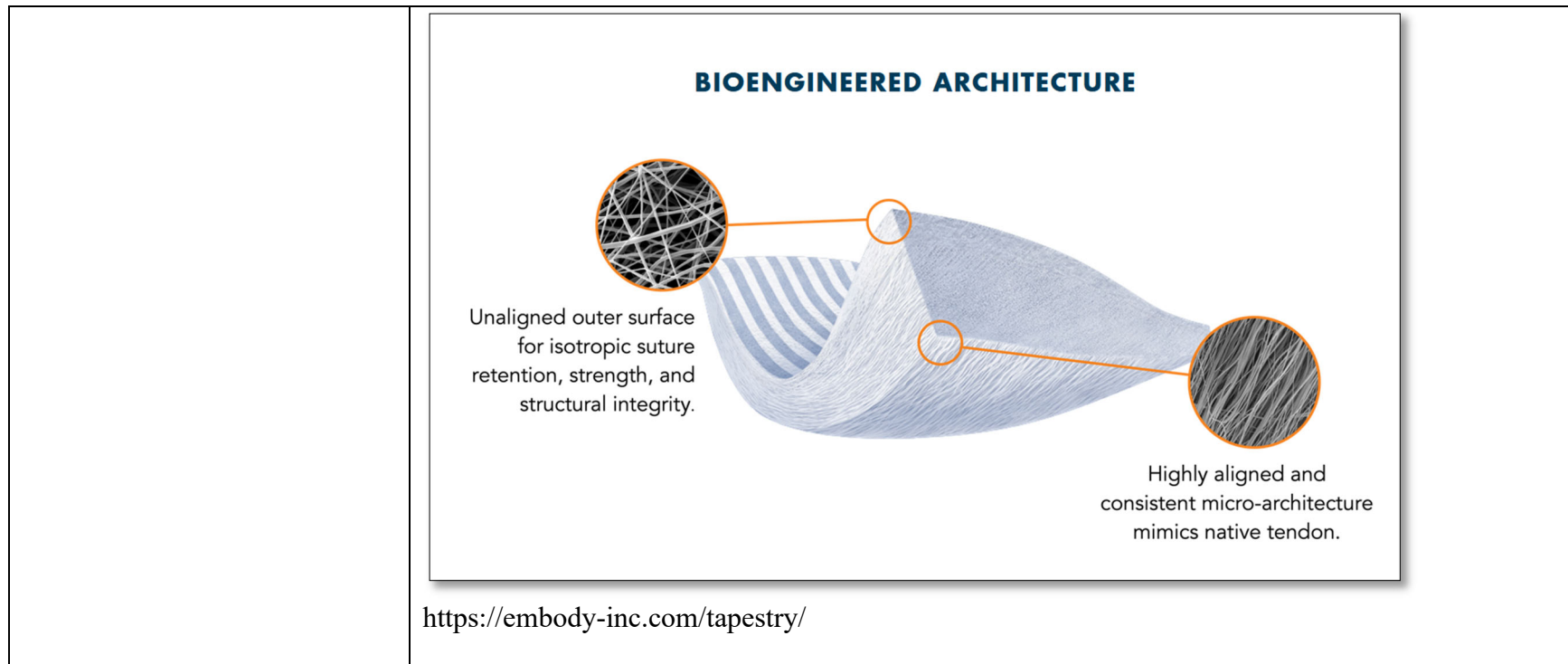


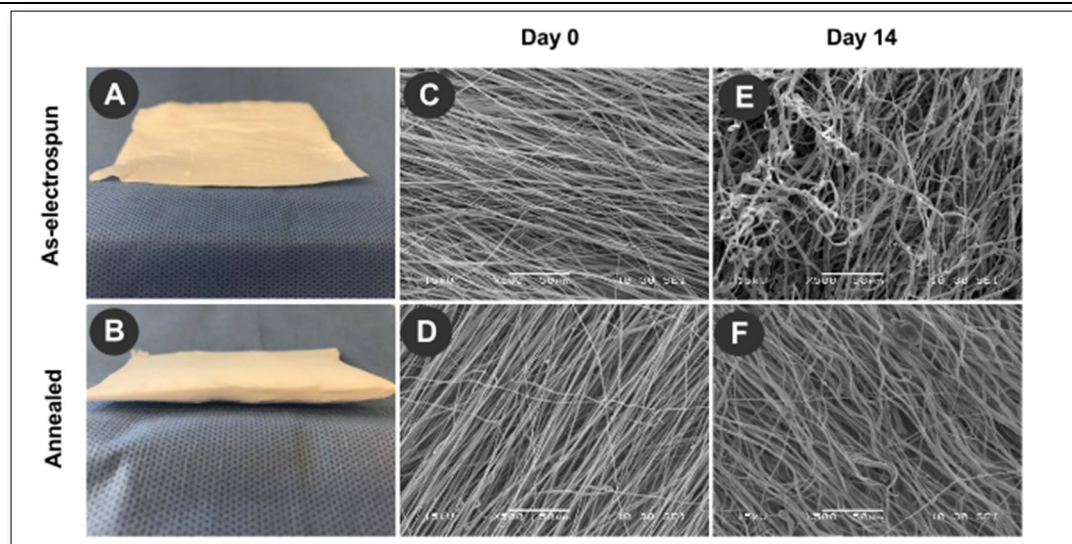
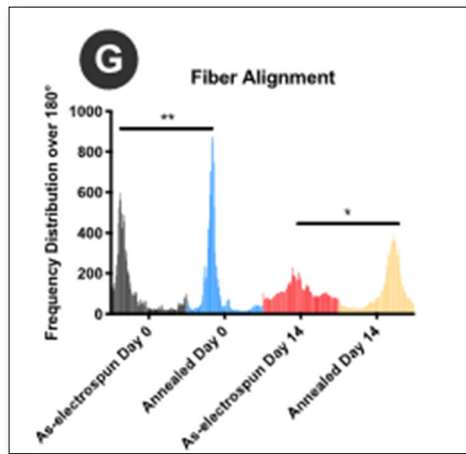
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Figure 2, “Biomanufacturing organized collagen-based microfibers as a Tissue Engineered Device (TEND) for tendon regeneration.” *See* TEND Paper at 8.

“As-electrospun TEND restrained in frames were heated above their glass transition temperature to promote molecular alignment and improve stability. The annealing process resulted in formation of thicker constructs (B) with improved fiber alignment (D), which retained their fiber orientation after 14 d in culture (F).” *Id.*

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Id.

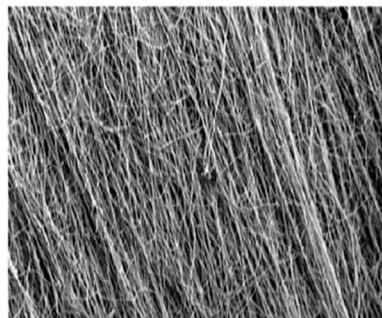
“Hybrid pneumatospinning—electrospinning setup allowed manufacturing of highly aligned collagen:PDLLA fibrous grafts from 100% DMSO.” *Id.* at 7.

“Highly aligned composite implant (70% PDLLA, 30% type I bovine collagen) non crosslinked” TAPESTRY® Biointegrative Implant 510(k) Summary, Oct. 13, 2020, at 2.

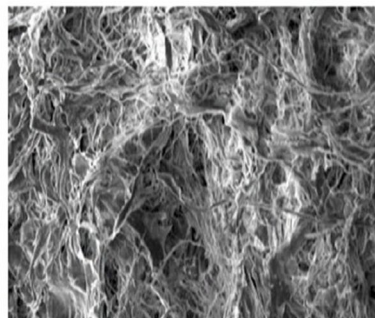
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Superior Micro-Architecture for Tendon Healing¹

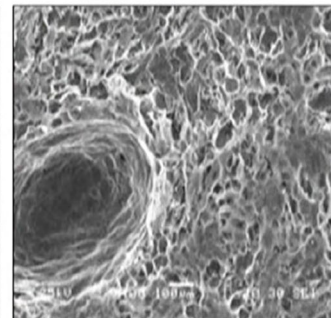
TAPESTRY



Reconstituted Collagen



Acellular Dermis



TAPESTRY is significantly more porous and ordered than conventional biomaterials and is an analog to native tendon structure

EMBODY

1. Embody data on file

LSI Presentation at slide 7.

“Materials and Data Sharing”

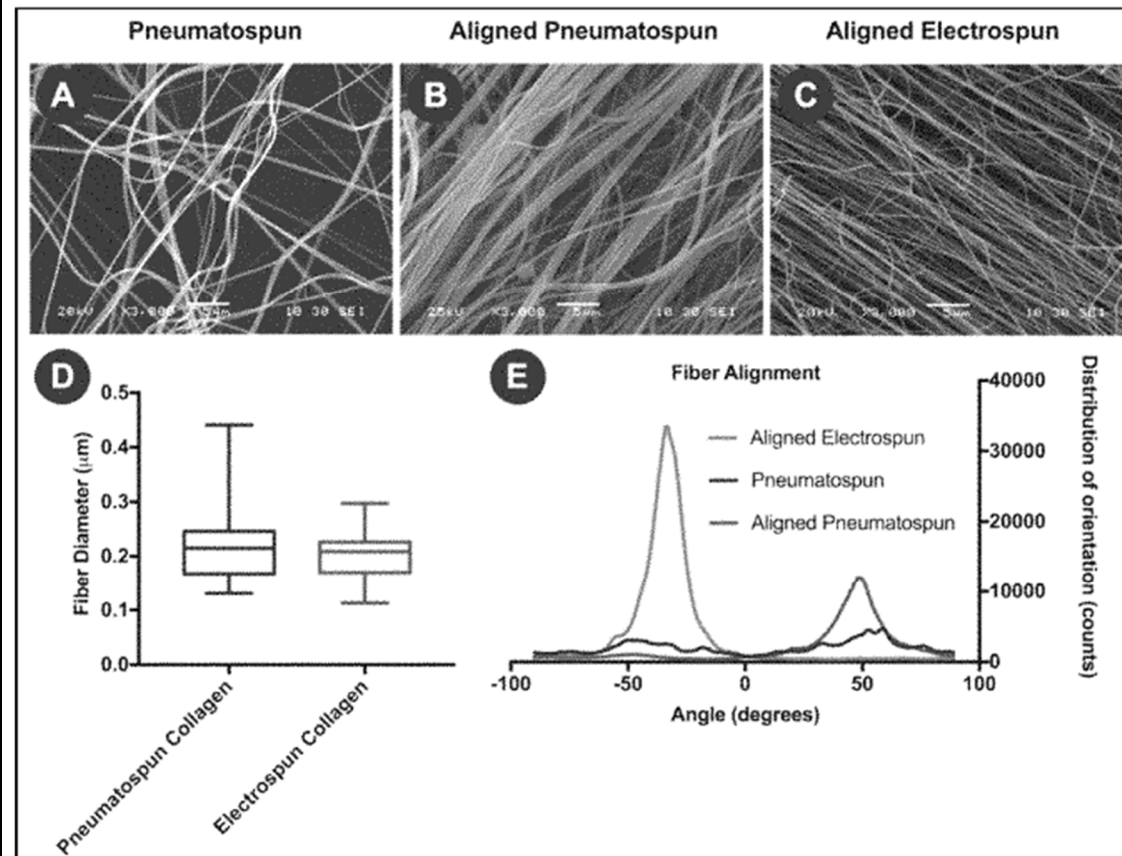
“The biopolymer composition of TEND has been issued per US Patent 10,617,787. Method for producing TEND has been issued per US Patent 10,653,817.” *See* TEND Paper at 19.

“Compositions and blends of biopolymers and copolymers are described, along with their use to prepare biocompatible scaffolds and surgically implantable devices for use in supporting and facilitating the repair of soft tissue injuries.” Patent No. 10,617,787 (“’787 Patent”) at Abstract.

“‘Scaffold’ means a construct formed from biopolymers and copolymers. Such constructs are preferably substantially aligned fibers formed into layers, mats, sheets and tubes.” ’787 Patent at 4:24-26.

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“FIGS. 9A-9C show a comparison of aligned collagen fibers. Scanning electron microscopy revealed the potential for generating isotropic and anisotropic collagen fibers by pneumatospinning (FIG. 9A, FIG. 9B), as compared to aligned electrospun collagen generated using electrospinning (FIG. 9C). Although a wider range of fiber sizes were produced via pneumatospinning, both pneumatospinning and electrospinning produced fibers with 200 nm average diameter (FIG. 9D). Fiber alignment quantified using ImageJ showed a greater degree of alignment in electrospun compared to pneumatospun fibers (FIG. 9E)” Patent No. 10,653,817 (“’817 Patent”) at 5:9-19.



’817 Patent at Figures 9A-9E.

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	“However, electrospun collagen microfibrinous scaffolds consistently demonstrated a significantly higher degree of alignment ($p < 0.05$) than that of the pneumatospun scaffolds (FIG. 9C).” ’817 Patent at 23:45-47. “Device Trade Name: TAPESTRY® Biointegrative Implant” “Device Common Name: Tendon Protector” “The TAPESTRY® Biointegrative Implant device is composed of collagen and poly (D,L–lactide). It is designed to function as a non-constricting, protective layer between the tendon and surrounding tissues.” See 510(k) Summary at page 1 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201572.pdf). “SUMMARY/COMPARISON OF TECHNOLOGICAL CHARACTERISTICS: Material Composition - Highly aligned composite implant (70% PDLLA, 30% type I bovine collagen) non-crosslinked” “Form - Resorbable flat sheet” <i>Id.</i> at 2.
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