Embody, Inc.
TAPESTRY® Biointegrative Implant
Instructions for Use

Device Description
The TAPESTRY Biointegrative Implant 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. TAPESTRY is conformable and designed for easy placement between the tendon and surrounding tissue and may be secured in place using standard fixation techniques. TAPESTRY is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, and is available with or without a co-packaged polyethylene Insertion Sleeve, which is used to maintain the implant's orientation and facilitate easy application onto the tendon. The Insertion Sleeve is discarded after use and not implanted. Preclinical studies of TAPESTRY showed dense collagenous fibrous connective tissue ingrowth into and around the scaffolding

TAPESTRY is designed for standalone use. At the discretion of the surgeon, TAPESTRY may be hydrated with sterile isotonic solution.

TAPESTRY is resorbed, and inflammatory quiescence is achieved, between 52 and 72 weeks after implantation. The device is not intended to prevent adhesions.

TAPESTRY is MR Safe.

Indications for Use
TAPESTRY is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Contraindications
TAPESTRY is not designed, marketed, or intended for use except as described in the indications for use and is contraindicated in the following situations:

- TAPESTRY is not indicated to replace damaged tendons or to reinforce the strength of any tendon repair.
- TAPESTRY is not indicated for patients with a known history of hypersensitivity to bovine-derived materials.

Warnings

- Do not reuse or re-sterilize.
- Do not use if the product package is damaged or opened.

Precautions

- TAPESTRY should not be applied until bleeding and infection are controlled.

Potential Adverse Reactions

- Infection is an inherent risk with any surgical procedure.
- Allergic reaction

Instructions for Use
1. Follow standard procedures for treatment of the injured tendon.
2. Determine the tendon width and length in millimeters (mm) and select appropriate size of TAPESTRY to provide protective coverage of the tendon repair.
3. Apply TAPESTRY with the dyed side away from the tendon and the blue stripes aligned along the native tendon fiber alignment.
4. To pass TAPESTRY under a tendon, use the Insertion Sleeve. Remove and discard the Insertion sleeve and affix TAPESTRY to the tendon. TAPESTRY can be trimmed to fit the surgical site.
5. Close the incision(s) using standard technique.
6. Application of TAPESTRY does not modify the postoperative treatment. The surgeon must determine motion and strength requirements according to standard practice.

Storage
Store at room temperature (15° to 30°C / 59 to 86°F). Avoid excessive heat or humidity.

How Supplied
TAPESTRY is supplied sterile for single use, with or without a co-packaged polyethylene Insertion Sleeve, in a dual sterile barrier system consisting of an inner foil pouch and outer Tyvek pouch. The inner foil pouch contains the implant and Insertion Sleeve (if included). The dual sterile barrier system is further supplied inside a shelf box. Contents of the Tyvek pouch are sterile and non-pyrogenic unless the package is opened or damaged. The TAPESTRY implant and packaging do not contain natural rubber latex.

Catalog Number	Size (width x height)
TP-2030-01	20 x 30mm
TP-3030-01	30 x 30mm
TP-4030-01	40 x 30mm
TP-7025-02	70 x 25mm*
TP-2550-01	25 x 50mm
TP-7050-02	70 x 50mm*
TS-5040-02	50 x 40 x 25mm*
TS-4030-02	40 x 30 x 20mm*

*provided with an Insertion Sleeve

Caution: Federal law restricts this device to sale by or on the order of a physician.

Manufactured exclusively by:
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US Patents 10,653,817 and 10,617,787

Symbol	Title/Meaning	Reference Number	Standard Title and Designation Number
 www.embody-inc.com	Consult electronic instructions for use	5.4.3	ISO 15223-1 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
	Use-by date	5.1.4	
	Do not re-use	5.4.2	
LOT	Lot number	5.1.5	
REF	Catalogue number	5.1.6	
STERILE R	Sterilized using irradiation	5.2.4	
	Temperature limit	5.3.7	
	Do not resterilize	5.2.6	
	Non-pyrogenic	5.6.3	
	Manufacturer	5.1.1	
Rx Only	Prescription use only	N/A	21 CFR 801.109
MADE IN USA	Made in the USA	N/A	N/A