BIOTAPE XM® TISSUE MATRIX

150866-0

The following languages are included in this packet:

English (en)
Deutsch (de)
Nederlands (nl)
Français (fr)
Español (es)
Italiano (it)
Português (pt)
中文-Chinese (sch)
Türkçe (tk)

For additional languages, visit our website www.wmt.com

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.

CE 0086*

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EC REP

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
BIOTAPE XM® TISSUE MATRIX
(150866-0)

OUTLINE:

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Storage temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture

	Manufacturer
	Sterilized using ethylene oxide
	Do not resterilize
	For prescription use only
	Authorized EC Representative in the European Community
	Do not use if package is damaged

GENERAL PRODUCT INFORMATION

The BIOTAPE XM® Tissue Matrix is a sterile, non-perforated processed porcine collagen dermal matrix.

A. INDICATIONS

The BIOTAPE XM® Tissue Matrix is intended to reinforce soft tissue where weakness exists, specifically, for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, and other tendons. The BIOTAPE XM® Tissue Matrix is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear and suture or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair.

B. CONTRAINDICATIONS

BIOTAPE XM® Tissue Matrix is contraindicated for use in any patient with known sensitivity to porcine products, or on patients with history of multiple or serum allergies.

Not for reconstruction of cardiovascular defects.

Not for reconstruction of central nervous system or peripheral nervous system defects.

C. POTENTIAL COMPLICATIONS

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Although Wright Medical cannot recommend a particular surgical technique suitable for all patients, a detailed surgical technique is available for surgeon reference.

D. PRECAUTIONS

DO NOT use BIOTAPE XM® Tissue Matrix if either the outer foil bag or either of the inner pouches are damaged or torn. Damaged packaging may result in degradation or contamination of the product.

Do not use product beyond indicated expiration date.

E. ADVERSE REACTIONS

Adverse reactions that are possible with the use of a porcine dermal matrix include, but are not limited to, contamination, infection, inflammation, adhesion, drainage, seroma formation, hematoma, and fever.

If an infection or allergic reaction occurs, the entire matrix may have to be revised or removed.

F. HANDLING AND STERILIZATION

BIOTAPE XM® Tissue Matrix is supplied sterile in a sealed package and is intended for single use only. Only the inner-most pouch is sterile. The outer foil bag and middle pouch cannot be placed in the sterile field. Do not use if package is damaged. Immediately return damaged product to Wright Medical Technology, Inc.

DO NOT RE-STERILIZE. Re-sterilization may damage the product.

Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Strict aseptic technique should be followed when preparing the product for use.

G. STORAGE CONDITIONS

STORE AT ROOM TEMPERATURE. Do not use product if temperature exceeds 99 °F (37 °C) or indicator (located on foil bag) is black. Immediately return product to Wright Medical Technology, Inc.

H. DIRECTIONS FOR USE

1. Remove from packaging using an aseptic technique.
2. Only the inner-most pouch is sterile. The outer foil bag and middle pouch cannot be placed in the sterile field.
3. The matrix may be trimmed to the required dimension prior to or after rehydration.
4. The matrix must be rehydrated in sterile saline for a minimum of 10 minutes, but no more than 1 hour.
5. The matrix is rehydrated when it is soft and pliable throughout. The matrix may require a gentle massage to complete the rehydration process.
6. After use, handle and dispose of any unused portions of the matrix in accordance with accepted medical practice and applicable laws and regulations.

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.