

EXAFLEX®

EXAFLEX® High-density collagen matrix, consisting of non-cross-linked bovine pericardium. It comes from cattle less than 20 months old. The product allows the formation of newly formed collagen and the subsequent vascularization of the implant. Subsequently, the implant will be remodeled and replaced with host tissue. In case of contact with the viscera, the EXAFLEX® device reduces the phenomena of adhesion to a minimum.

INDICATIONS FOR USE: The EXAFLEX® membrane and powder are intended for the following uses:

- urinary incontinence, in the reconstruction of the pelvic floor, vulnology
- repair of vaginal and rectal prolapse
- surgical repair of soft tissue deficiencies, placement of breast implants
- repair of the abdominal and thoracic walls
- strengthening of muscle flaps, ligaments and tendons
- hernia repair, vascular surgery, nerve and dura mater repair.
- use in dentistry in the surgical repair of soft tissues and as a barrier effect against epithelial invasion of bone tissue

CONTRAINDICATIONS: Known or presumed sensitivity to derivatives of bovine origin. The product has not been tested on pregnant subjects.

ADVERSE REACTIONS: As with any surgical procedure, adverse reactions are possible.

PRECAUTIONS: The product is disposable, so after opening the package any leftovers cannot be reused or resterilized. Before use, check the integrity of the packaging, otherwise do not use. Improper use could cause complications of a surgical nature. Do not use the product unless stored according to the manufacturer's instructions.

ATTENTION: The product during its use must never be dehydrated, use constant immersion in sterile physiological solution. In case you are forced to use the product in contaminated sites, it is recommended to take appropriate measures at local and systemic level in order to contain the contamination / infection.

STORAGE: The product must be stored in clean and dry environments. The storage temperature during the shelf life of the product should not be below 0 ° C / 32 ° F. DO NOT store in refrigerated cells.

TRASPORTO: Il trasporto a confezione integra può avvenire a condizioni normali. Sia il prodotto che l'imballo originale possono essere sottoposti a sbalzi di temperatura per brevi periodi.

INSTRUCTIONS: The instructions below are not references for surgical technique and do not replace institutional protocols or professional clinical judgments regarding patient care.

Check that the product packaging is in good condition and that the packaging containing the membrane is intact. Open the packaging respecting the asepsis of the operating room.

Rehydrate the membrane by immersion in sterile physiological solution at room temperature. The product can also be kept in the water for long periods, 2 or more hours.

The product can be immersed in antibiotic saline solution.

Use the product according to surgical needs and local regulations.



MANUFACTURER:

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CE 0373

CE 0373	Conforme alla direttiva Europea 93/42/CEE Complies with the European Directive 93/42 / EEC Entspricht der europäischen Richtlinie 93/42 / EWG Conforme à la directive européenne 93/42 / CEE Cumple con la Directiva Europea 93/42 / EEC Em conformidade com a Directiva Europeia 93/42 / EEC Conformă cu Directiva Europeană 93/42 / CEE
STERILE R	Sterile se non aperto o danneggiato / Raggi Beta Sterile if not opened or damaged / Beta rays Steril, wenn nicht geöffnet oder beschädigt / Beta-Strahlen Stérile si non ouvert ou endommagé / Rayons bêta Estéril si no está abierto o dañado / rayos Beta Estéril se não for aberto ou danificado / raios Beta Sterile dacă nu sunt deschise sau deteriorate / raze beta
2	Non riutilizzare Do not reuse Nicht wiederverwenden Ne pas réutiliser No reutilizar Não reutilizar Nu reutilizați
!	Consultare le istruzioni per l'uso Consult the instructions for use Konsultieren Sie die Gebrauchsanweisung Consulter les instructions d'utilisation Consulte as instruções de uso Consultați instrucțiunile de utilizare
TEMPERATURE	Temperatura di conservazione Storage temperature Lagertemperatur Température de stockage Temperatura de almacenamiento Temperatura de armazenamento Temperatura de depositare
REF	Numero di catalogo Catalog number Katalognummer Número de catalogue Número de catálogo Número de catálogo Numărul de catalog
LOT	Codice partita / Numero lotto Match code / lot number Matchcode / Chargennummer Code de correspondance / numéro de lot Código del partido / número de lote Código da partida / número do lote Codul meciului / numărul lotului
⌚	Data di scadenza Expiration date Ablaufdatum Date d'expiration Fecha de caducidad Data de validade Data expirării
📅	Data di fabbricazione Manufacturing date Herstellungsdatum Date de fabrication Fecha de fabricación Data de fabricação Data fabricării