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 reutiliser 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
	Temperatura di conservazione Storage temperature Lagertemperatur Température de stockage Temperatura de almacenamiento Temperatura de armazenamento Temperatura de depozitare
REF	Numero di catalogo Catalog number Katalognummer Numéro 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

MANUFACTURER:
MAGGI s.r.l.
Fraz. San Pietro, 10
Piovà Massaia – 14026 (AT) Italy
MANUFACTURING PLANT:
MAGGI srl
Via Tetti Castagno, 5/A
Andezeno – 10020 (TO) Italy

EXAFLEX
EXAFLEX Exaflex is a high density collagen matrix, consisting of non-crosslinked pericardium derived from bovine younger than 20 months of age.The product promotes the formation of new collagen and the subsequent vascularization of the implant.The implant will be gradually remodeled and replaced with host tissue. The product does NOT induce inflammation.

INDICATIONS:
The Exaflex membrane is intended for implantation for surgical repair in case of lack of soft tissue and for positioning of breast implants. Breast reconstructive surgery.

CONTRAINDICATIONS:
Proven or suspected sensitivity to bovine-derived products. The product has not been tested on pregnant women. The product must not come into contact with the central nervous system and the eye. Do not use the product after the expiration date.

ADVERSE REACTION:
As with any surgical procedure, the general risks include: infections, allergic reactions. edema, ecchymosis, foreign body reactions, acute or chronic inflammatory reactions, seroma, adhesions and laxity of the repaired tissue. The patient has to be aware of these risks, besides other risks associated with surgery in general and with anesthesia.

NOTE FOR THE PHYSICIAN:
The physician should report indications, contraindications, warnings and precautions mentioned in this document to the patient.

PRECAUTIONSI:
The product is disposable, therefore after opening the package any leftover sheet cannot be reused or re-sterilized.Check the integrity of the package before use; do not use in case of any damage.
Improper use may cause surgical complications. Do not use the product unless stored as prescribed by the manufacturer.

CAUTION:
The product must never be dehydrated during its use; constantly soak it in sterile saline solution. If you are forced to use the product in contaminated sites, it is recommended to take appropriate local and systemic measures to contain the contamination/infection.

STORAGE:
The product must be stored in a clean environment. The storage temperature must not be lower than 0° C / 32°F. DO NOT store in cold-storage rooms.

TRANSPORT:
Transport in undamaged packages can take place under normal conditions. Both the product and the original packaging can be exposed to temperature changes for short periods.

INSTRUCTIONS:
The following instructions are not references for surgical technique and do not replace institutional protocols or professional clinical evaluation on the patient care. Check that the product package is in good condition and that the primary packaging containing the membrane is intact. Open the packages following the aseptic principles of the operating room. Rehydrate the membrane by immersion in sterile saline solution at room temperature. The product can be soaked for long periods, 2 hours or more. The product may be soaked in antibiotic-saline solution.
Use the product according to surgical needs.

Revision 02 del 08/01/2021

COMPLY WITH USES AND TECHNIQUES PERMITTED BY THE LOCAL PROVISIONS

CE 0373 UK

INSTRUCTIONS FOR USE AND PRECAUTIONS:
PATIENT SELECTION: Carefully consider the risk-benefit ratio of performing a breast reconstruction surgery with EXAFLEX and a breast implant for patients with significant comorbidities. There is an increased risk of postoperative wound complications associated with obesity, smoking, immunosuppression induced diabetes, malnutrition, poorly oxygenated tissues (e.g. COPD) and pre- and post-operative breast radiation. Physicians should exercise extreme caution in this group of patients.

INTRAOPERATIVE TECHNIQUE: Carefully evaluate the mastectomy skin flaps to ensure that they are well perfused before proceeding to breast reconstruction with EXAFLEX. If sufficient healthy tissue from the patient's mastectomy is present, surgeons have the option of either perform a direct reconstruction with breast implant or a series of two-stage procedures (expander and, later, implant).

- Avoid direct procedure with implant in case there is poor perfusion of the skin flaps, when the skin closure is under excessive tension, or if the size of the breast implant is too large (>500 ml).
- Any portion of skin on the mastectomy skin flap that appears ischemic, should be removed and care should be taken to avoid excessive tension of the mastectomy skin flaps at the time of closure, which might contribute to skin flap ischemia.
- The pocket created for the breast implant or expander must match precisely the implant or expander, so as to avoid any potential space for fluid accumulation within the breast pocket. Drainage should be placed in the implant or expander's space and in the space between the skin flap and EXAFLEX, in order to reduce the risk of fluid accumulation.
- As with any surgical implant, a sterile technique must be used and the contact of implant with patient's skin must be minimized.

POSTOPERATIVE CARE: Drainage should be left in place until the amount of drainage reaches a level below 20 - 30 ml every 24 hours. The typical waiting time for drainage removal is 1 - 2 weeks, but should be adapted to the clinical circumstances and volume of the drained fluid.

PREPARATION OF THE EXAFLEX MEMBRANE

The membrane has two sides, one smooth and non-stick, the other rough. The smooth side must be placed in contact with the implant, the rough side in contact with the skin flaps. Rehydrate the EXAFLEX membrane for at least 5 minutes soaking it in sterile saline.

Detection of the smooth side: look at the card

Instructions in the last revision

www.maggiortopedia.com