DuraGen®
Dural Graft Matrix

SYMBOLS USED ON LABELING

Consult Instructions for Use	**Rx ONLY** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner.
Expiration date	Manufacturer
Do not re-use	Do not re-sterilize
LOT Lot number	Do not use if package is damaged.
STERILE EO Sterilized using Ethylene Oxide	15°C 59°F 30°C 86°F Temperature Limit
REF Catalog Number.	

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DESCRIPTION

DuraGen® Dural Graft Matrix is an absorbable implant for repair of dural defects. DuraGen matrix is an easy to handle, soft, white, pliable, nonfriable, porous collagen matrix. DuraGen matrix is supplied sterile, nonpyrogenic, for single use in double peel packages in a variety of sizes.

INDICATIONS FOR USE

DuraGen matrix is indicated as a dura substitute for the repair of dura mater.

CONTRAINDICATIONS

DuraGen matrix is not designed, sold or intended for use except as described in the indications for use and is contraindicated in the following situations:

- For patients with a known history of hypersensitivity to bovine derived materials.
- For repair of spinal neural tube defects; anterior spinal surgery with dural resection (e.g., transoral surgery).
- Should be used with caution in infected regions.
- Not recommended to cover dural defects involving mastoid air cells.
- Not recommended for large defects at the skull base following surgery.

INSTRUCTIONS FOR USE

DuraGen matrix is packaged in a double peel package. Peel open the outer package. The inner package is sterile and may be placed on the sterile field.

- Rinse surgical gloves, if necessary, to remove any glove powder prior to touching the product.
- Remove product from package using a gloved hand and aseptic technique so as not to crush the matrix.
- DuraGen matrix, in the dry state, can be cut to the desired shape using aseptic technique. DuraGen matrix must be large enough to overlap the remaining dura by a minimum of one (1) centimeter.
- Apply dry with smooth side towards brain and then moisten with saline.
- DuraGen matrix can be repositioned as necessary.
- DuraGen matrix is an onlay graft and does not require sutures.
- Suturing is not required, but tensionless, atraumatic stay sutures may be used if desired.
- Closed suction wound drainage is recommended for 1–3 days post-operatively.
- Discard any unused pieces of DuraGen matrix.

SAFETY

DuraGen matrix is manufactured from collagen obtained from bovine deep flexor tendon, which is classified by European Standards as a Category IC material (no detectable infectivity for Bovine Spongiform Encephalopathy (BSE)). Bovine tendon is known to be one of the purest sources of Type I collagen that is commercially available.

The collagen used to manufacture DuraGen matrix is currently used in the manufacture of an artificial skin, absorbable hemostatic sponges, and absorbable wound dressings. The manufacturing process for DuraGen matrix meets USA and European Standards for animal tissue sourcing, handling and inactivation of viruses and transmissible agents. This process involves a treatment with sodium hydroxide that is a recognized method of inactivation of Spongiform

Encephalopathy pathogens.

A viral inactivation study for the DuraGen matrix manufacturing process was conducted by an independent certified laboratory. In this study, the sodium hydroxide reduced the viral titer to non-detectable levels for the following viral strains: Human Immunodeficiency Virus Type I (HIV), Bovine Viral Diarrhea (BVD), Infectious Bovine Rhinotracheitis (IBR), Parainfluenza Virus Type 3 (PI3), Vesicular Stomatitis (VSV).

WARNINGS

- Do Not Resterilize!
- Do not use if the product package is damaged or opened.
- DuraGen matrix is generally not recommended for extensive skull base surgery with dural resection, however; DuraGen matrix can be used to augment other forms of specific repair (i.e., Fascia lata).

PRECAUTIONS

- Rinse surgical gloves to remove any glove powder prior to handling DuraGen matrix.
- If DuraGen matrix is to be sutured, tensionless suturing technique must be used to prevent tearing DuraGen matrix.
- DuraGen matrix should be cut to size ensuring an overlap to cover the existing dura.

- Use caution when using DuraGen matrix in conjuction with surgical sealants. Clinical experience suggests that there may be an increased risk of cerebrospinal fluid (CSF) leakage in these situations.
- Fibrin glue may be used with caution as an adjunct to repair, especially if used in skull base procedures or intradural spinal surgery.

ADVERSE EVENTS

Possible complications can occur with any neurosurgical procedure and include cerebrospinal fluid leaks, infection, delayed hemorrhage and adhesion formation. In clinical evaluations involving 1096 patients, postoperative wound infection rates for DuraGen matrix were reported at approximately the same rate as the control group. Postoperative cerebrospinal fluid leaks were reported in 3 of 67 patients who underwent intradural posterior fossa procedures. Macroscopic evaluations revealed minimal adhesion formation only when there was significant disruption of the pia-arachnoid. There were no reports of graft encapsulation, neomembrane formation or foreign body reactions. There were no reports of graft rejection at histology.

SINGLE-USE DEVICE

DuraGen Dural Graft Matrix is supplied in a single-use package and is guaranteed to be sterile and non-pyrogenic unless opened or damaged. The product is intended for use as an absorbable implant and is not to be reused. Reuse of the device can result in contamination and/or disease transmission. Any attempt to resterilize or reuse the product/components will damage the matrix and impair its ability to function as intended. All unused pieces must be discarded.

STORAGE

Store at room temperature.

HOW SUPPLIED

DuraGen Dural Graft Matrix is supplied sterile, in single use, double peel packages in a variety of sizes. Contents of the package are guaranteed sterile and nonpyrogenic unless the package is opened or damaged.

Reference Number:	Size:	Quantity:
ID1101	1 in x 1 in, 2.5 cm x 2.5 cm	single unit
ID1105	1 in x 1 in, 2.5 cm x 2.5 cm	5 units/box
ID1301	1 in x 3 in, 2.5 cm x 7.5 cm	single unit
ID1305	1 in x 3 in, 2.5 cm x 7.5 cm	5 units/box
ID2201	2 in x 2 in, 5 cm x 5 cm	single unit
ID2205	2 in x 2 in, 5 cm x 5 cm	5 units/box
ID3301	3 in x 3 in, 7.5 cm x 7.5 cm	single unit
ID3305	3 in x 3 in, 7.5 cm x 7.5 cm	5 units/box
ID4501	4 in x 5 in, 10 cm x 12.5 cm	single unit

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PRODUCT INFORMATION DISCLOSURE

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RETURNED GOODS POLICY

• Authorization, from customer service, must be obtained prior to returning product.
• Sterile product must be returned in unopened, undamaged cartons, packed to prevent damage.
• Non-sterile product must be returned in unused saleable condition in original package.
• Custom or special order products will not be accepted for credit.
• Credit will be issued for goods returned prior to ninety days from ship date with a restocking charge. This assumes that the product returned is not damaged and can be verified to have not been used or opened.