DESCRIPTION

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

INDICATIONS FOR USE
DuraGen® is indicated as a dura substitute for the repair of dura mater.

CONTRAINDICATIONS
DuraGen® 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® 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®, in the dry state, can be cut to the desired shape using aseptic technique. The DuraGen® graft matrix must be large enough to overlap the remaining dura by a minimum of one (1) centimeter.
• Apply dry with smooth and downward brain and dura motion with a smooth dry pad to the defect site.
• Place the defect site under saline irrigation and allow saline to drain through the defect site.
• Using the appropriate size and shape, cut the DuraGen® graft matrix to the proper size, and gently position it over the defect site.
• If necessary, secure the graft matrix with stay sutures.
• Fibrin glue may be used to augment repair especially if used in skull base procedures or intradural spinal surgery.

SAFETY
DuraGen® is manufactured from collagen obtained from bovine deep flexor tendon, which is classified by European Standards as Class IV material (no detectable infectivity for Bovine Spongiform Encephalopathy (BSE)). Bovine tendon is known to be one of the purest sources of Type I collagen which is classified by European Standards as Class IV material. DuraGen® is manufactured from collagen derived from bovine deep flexor tendon.

SYMBOLS USED ON LABELING

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>See instructions for use</td>
</tr>
<tr>
<td></td>
<td>Expiration date</td>
</tr>
<tr>
<td>2</td>
<td>Do not reuse after opening</td>
</tr>
<tr>
<td></td>
<td>Lot number</td>
</tr>
<tr>
<td></td>
<td>Sterile unless package is opened or damaged.</td>
</tr>
<tr>
<td></td>
<td>Method of sterilization—ethylene oxide</td>
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INTEGRA LIFE SCIENCES CORPORATION
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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® 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® is generally not recommended for extensive skull base surgery with dural resection, however, DuraGen® 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®.
- If DuraGen® is to be sutured, tensionless suturing technique must be used to prevent tearing the DuraGen® graft matrix.
- The DuraGen® graft should be cut to size ensuring an overlap to cover the existing dura.

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® 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.

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.

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

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.
- 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.