DESCRIPTION

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

INDICATIONS FOR USE

DuraGen Plus™ Dural Regeneration Matrix is indicated as a dura substitute for the repair of dura mater.

CONTRAINDICATIONS

DuraGen Plus™ 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 Plus™ 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 Plus™, in the dry state, can be cut to the desired shape using aseptic technique. The DuraGen Plus™ Dural Regeneration Matrix must be large enough to overlap the remaining dura by a minimum of one (1) centimeter.

• Apply dry with either side towards brain and then moisten with saline.

• DuraGen Plus™ can be repositioned as necessary.

• DuraGen Plus™ is an onlay graft and does not require sutures.

• Suturing is not required, but tensionless, atraumatic stay sutures may be used if desired.

• Fibrin glue may be used to augment repair especially if used in skull base procedures or intradural spinal surgery.

• Closed suction wound drainage is recommended for 1–3 days postoperatively.

• Discard any unused pieces of DuraGen Plus™.
SAFETY

DuraGen Plus™ 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 that is commercially available.

The collagen used to manufacture DuraGen Plus™ is currently used in the manufacture of an artificial skin, absorbable hemostatic sponges, and absorbable wound dressings. The manufacturing process for DuraGen Plus™ 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 Plus™ manufacturing process was conducted by an independant 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 Plus™ is generally not recommended for extensive skull base surgery with dural resection, however, DuraGen Plus™ 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 Plus™.
- If DuraGen Plus™ is to be sutured, tensionless suturing technique must be used to prevent tearing the DuraGen Plus™ Dural Regeneration Matrix.
- DuraGen Plus™ Dural Regeneration Matrix 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 Integra’s Dural Regeneration 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.

**STORAGE**

Store at room temperature. Avoid excessive heat or humidity. Do not refrigerate.

**HOW SUPPLIED**

DuraGen Plus™ Dural Regeneration 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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PRODUCT INFORMATION DISCLOSURE

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RETURNED GOODS POLICY

• Authorization from customer service must be obtained prior to returning product.
• Products must be returned in unopened packages with manufacturers’ seals intact to be accepted for replacement or credit unless returned due to a complaint or product defect.
• Determination of a product defect will be made by Integra LifeSciences.
• Credit will be issued for goods returned prior to 90 days from ship date with a restocking charge. This assumes that the product returned is not damaged and can be verified to have
SYMBOLS USED ON LABELING

![Exclamation Mark] See instructions for use

![Hourglass] Expiration date

![Circled 2] Do not reuse after opening

![LOT] Lot number

![STERILE EO] Sterile unless package is opened or damaged
Method of sterilization–ethylene oxide

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

![Manufacturer] Manufacturer

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