INTEGRA

DuraGen® Secure
Dural Regeneration Matrix
DESCRIPTION
DuraGen® Secure Dural Regeneration Matrix is an absorbable implant for the repair of dural defects. DuraGen Secure Dural Regeneration Matrix is an easy to handle, soft, pliable, non-friable, porous collagen matrix with an anti-migration layer (hydroxypropyl methylcellulose (HPMC)) that, when used as directed, reduces the risk of product migration or displacement, e.g. during irrigation. DuraGen Secure Dural Regeneration Matrix is supplied sterile, non-pyrogenic, and in a variety of sizes for single-use.

INDICATIONS FOR USE
DuraGen Secure Dural Regeneration Matrix is indicated as a dura substitute for the repair of dura mater.

CONTRAINDICATIONS
DuraGen Secure Dural Regeneration 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 or anterior spinal surgery with dural resection.
• 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.

WARNINGS
• DO NOT resterilize.
• DO NOT use if any of the product packaging is damaged or opened.
• DO NOT use if the double peel package is not contained in the foil pouch prior to using the product.
• The DuraGen Secure Dural Regeneration Matrix is generally not recommended for extensive skull base surgery with dural resection; however, the DuraGen Secure Dural Regeneration Matrix can be used to augment other forms of specific repair.

PRECAUTIONS
• DO NOT pre-hydrate or wet the matrix prior to placement on the dural repair surface. Apply the DuraGen Secure Dural Regeneration Matrix dry to the dural repair surface. If product is hydrated prior to placement, the matrix may no longer exhibit anti-migration properties, but will still function as an onlay dural graft.
• DuraGen Secure Dural Regeneration Matrix is packaged in double peel packages within a foil pouch moisture barrier. The outer peel package within the foil pouch is not sterile. Therefore, only the sterile inner peel package may be placed in the sterile field.

• Rinse surgical gloves to remove any glove powder prior to handling DuraGen Secure Dural Regeneration Matrix.

• DuraGen Secure Dural Regeneration Matrix should be cut to size ensuring an overlap to cover the patient’s dura surrounding the dural defect by a minimum of one (1) centimeter.

• DuraGen Secure Dural Regeneration Matrix is an onlay dural repair product, however, tensionless sutures may be used, if desired. Use caution when using tensionless sutures to prevent tearing the DuraGen Secure Dural Regeneration Matrix.

• Use caution when using DuraGen Secure Dural Regeneration Matrix in conjunction with surgical sealants. Clinical experience suggests that there may be an increased risk of cerebrospinal fluid (CSF) leakage in these situations.

**DIRECTIONS FOR USE**

**Packaging Configuration and Opening the Package**

1. DuraGen Secure Dural Regeneration Matrix is packaged in double peel packages within a foil pouch moisture barrier, placed inside of a dispenser box. Follow the instructions below and on the package labeling to open the package.

   A. Open the dispenser box and remove the non-sterile foil pouch.
   B. Outside of the sterile field, tear open the foil pouch and remove the double peel package. Note that the outer surface of the outer peel package is non-sterile.
   C. Peel open the outer tray to expose the sterile inner peel package containing the product.
   D. Aseptically transfer the sterile inner peel package into the sterile field.

2. The DuraGen Secure Dural Regeneration Matrix is packaged in the inner tray such that the rough side (collagen side) is facing up towards the white peel-away lid. The other side of the product, facing towards the clear tray, is smooth and glossy (anti-migration layer) and should be applied directly to the dura. (Figure 1)
Sterile Inner Peel Package

Figure 1: Identification of product to show which side to apply to the dura. The side facing the clear tray (anti-migration layer) should be applied to the dura.

3. Rinse surgical gloves to remove any glove powder, if necessary. Also, eliminate any excess fluids, blood, or debris from the surgical gloves. Gloves should be dry prior to handling the product.

4. Open the inner peel package and gently remove the product using aseptic technique. Instruments may be used to handle the product, however, be sure that the instruments are dry and free from debris. Be careful not to crush the matrix.

Product Preparation

The DuraGen Secure Dural Regeneration Matrix, in the dry state, can be cut to the desired size or shape using surgical scissors or other cutting instruments using aseptic technique. The DuraGen Secure Dural Regeneration Matrix must be large enough to overlap the patient’s dura surrounding the dural defect by a minimum of one (1) centimeter.

Dural Repair Site Preparation

1. Ensure hemostasis of the site prior to product application.
2. Irrigate the site, as necessary, to remove any particulates, bone chips, loose clots, etc., and aspirate excess standing fluids.
3. Dry the site using any surgical absorbent and ensure that the dural margins are clear of clots.
4. **DO NOT** wet the DuraGen Secure Dural Regeneration Matrix prior to placement on the dura as this may impair the function of the anti-migration layer. However, if DuraGen Secure Dural Regeneration Matrix is wet prior to application, it will continue to function as an onlay dural graft.

**Applying the Matrix to the Dural Repair Surface**

1. Immediately after drying the site, apply the dry DuraGen Secure Dural Regeneration Matrix with the smooth and glossy side (anti-migration layer) towards the dura.
2. Hold the product in place to ensure complete and even surface contact at the dural margins using gentle pressure for at least 10 seconds, with, for example, dry gloved fingers or surgical instruments.
3. After holding the product in place for at least 10 seconds, continue holding the product and gently moisten the DuraGen Secure Dural Regeneration Matrix with saline to completely hydrate the product. Once the product is fully hydrated, you no longer have to hold the product in place.
4. DuraGen Secure Dural Regeneration Matrix is an onlay graft and does not require sutures. However, tensionless stay sutures may be used if desired.
5. Irrigate the surgical site as necessary.
6. Closed suction wound drainage is recommended for 1-3 days postoperatively.
7. Discard any unused pieces of DuraGen Secure Dural Regeneration Matrix in accordance with your institutional policy.

**SAFETY**

DuraGen Secure Dural Regeneration Matrix is manufactured from collagen obtained from bovine deep flexor tendon, which is classified by European Standards as a Category IC tissue (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 Secure Dural Regeneration Matrix is currently used in the manufacture of dural repair products, artificial skin, absorbable hemostatic sponges, and absorbable wound dressings. The manufacturing process for DuraGen Secure Dural Regeneration 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.

Based on the animal source of the materials used to manufacture this device, viral inactivation studies for the collagen manufacturing process were conducted by an independent certified laboratory.
The assay performed includes spiking representative samples with a known amount of viral titer. In this study, the manufacturing process, which includes a sodium hydroxide step, was shown to reduce the viral titer to acceptable levels (i.e., 6 log reduction) for the following strains: Parainfluenza Virus Type 3 (PI3) and Vesicular Stomatitis (VSV). However, the viral titer for the following strains has not been reduced to acceptable levels: bovine viral diarrhea virus (BVDV), human immunodeficiency virus type 1 (HIV-1), infectious bovine rhinotracheitis (IBR), porcine parvovirus (PPV) and reovirus type-3 (Reo-3). Please be advised, the viral strains tested are not necessarily present in the unprocessed collagen bulk used to manufacture this device.

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 family of Dural Regeneration Matrices 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 Secure Dural Regeneration 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. Any attempts to resterilize or reuse the product will damage the matrix and impair its ability to function as intended. All unused pieces must be discarded.

STORAGE
Store at room temperature (10°C - 25°C; 50°F - 77°F). Avoid excessive heat and humidity. Do not refrigerate.

HOW SUPPLIED
DuraGen Secure Dural Regeneration Matrix is supplied sterile, in single-use packages consisting of a double peel package within a foil pouch moisture barrier. Only the inner peel package is sterile and may be placed into the sterile field. The foil pouch and outer peel package are not sterile. DuraGen Secure Dural Regeneration Matrix is provided in a variety of sizes. Products are guaranteed to be sterile and non-pyrogenic unless the peel packages are opened or damaged.
PRODUCT INFORMATION DISCLOSURE

INTEGRA LIFESCIENCES CORPORATION (“INTEGRA”) HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THESE PRODUCTS. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

RETURNED GOODS POLICY

- Authorization from customer service must be obtained prior to returning product.
- Products must be returned in unopened packages with manufacturer’s 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 Corporation.
- 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 not been used or opened.

SYMBOLS USED ON LABELING

- **STERILE EO**: Sterilized using Ethylene Oxide
- **Do not re-sterilize**
- **Consult Instructions for Use**
- **Do not re-use**
- **Do not use if package is damaged**
- **This product does not contain and is not manufactured with Dry Natural Rubber or Natural Rubber latex**
- **Expiration Date**
- **Catalog Number**
- **Lot Number**
- **Manufacturer**
- **Rx ONLY**: Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner
- **Temperature Limitation**