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INTEGRA™

Suturable DuraGen™

Dural Regeneration Matrix

U.S. Patent 5,997,895

CE 0086

ENGLISH

DESCRIPTION

Suturable DuraGen™ Dural Regeneration Matrix is an absorbable implant for repair of dural defects. Suturable DuraGen is an easy to handle, soft, white, pliable, nonfriable, porous collagen matrix with a mechanically strengthened collagen component. Suturable DuraGen is supplied sterile, nonpyrogenic, for single use in double peel packages in a variety of sizes. Suturable DuraGen may be applied using either onlay or suturing technique depending on clinical need and surgeon preference.

INDICATIONS FOR USE

Suturable DuraGen is indicated as a dural substitute for the repair and restoration of dural defects in cranial and spinal surgical procedures. Suturable DuraGen readily conforms to the surface of the brain and overlying tissues. Suturable DuraGen may be used to close dural defects following traumatic injury, excision, retraction or shrinkage. Suturable DuraGen may be used to supplement primary closure.

Suturable DuraGen may be used in the following procedures:

- Cranial Convexity: may be used to cover large defects following surgery, especially for dural loss from excision, contraction, retraction and/or shrinkage;

- Brain Swelling: intra-operative brain swelling or anticipated postoperative swelling;

- Posterior Fossa Surgery: 1) General use as a dural graft, 2) decompression craniectomy and dural release for infarcts, i.e., Posterior Inferior Cerebellar Artery (PICA) infarcts, 3) anticipated swelling after trauma, and 4) may be used in Chiari decompression procedures;

- Spinal Surgery: 1) General use as a spinal dural graft, especially useful for defects arising from pinhole tears, disc surgery, and spinal stenosis decompression, 2) after resection of intradural tumors, 3) onlay graft after dural approximation with sutures, and 4) as a separation layer between the dura and overlying tissues.

MODE OF ACTION

Upon implantation, Suturable DuraGen provides a scaffold for the infiltration of fibroblasts and a substrate for the deposition of new collagen. Suturable DuraGen matrix is gradually absorbed and replaced by endogenous connective tissue. Histological evaluation of post-implantation specimens from 100 patients demonstrated that fibroblasts penetrate into and proliferate within the collagen matrix. The porous structure of the collagen matrix facilitates the ingrowth of fibroblasts into the dural regeneration matrix. Fibroblasts were observed on the collagen matrix fibers, which provided a scaffold for the deposition of new collagen. This pattern of fibroblastic proliferation into the collagen matrix was initiated as early as 4 days post implantation, and was well established by 15 days. Graft encapsulation and/or neomembrane formation were not observed. In samples examined after 1 year and up to 5 years postoperatively, the collagen matrix was fully collagenized and incorporated into the dura. Encapsulation, delayed hemorrhage or pseudotumor formation did not occur.

CONTRAINDICATIONS

Suturable 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.
- Should be used with caution in infected regions.

INSTRUCTIONS FOR USE

- Suturable 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.

- Hydrate Suturable DuraGen in sterile saline or equivalent irrigating solution. Keep immersed until ready for use.

- When applied using an onlay technique or a suture technique, Suturable DuraGen should be cut generously to ensure that the graft overlaps the existing dura at the margin of the defect.

Instructions for Use – Onlay Technique

- Suturable DuraGen may be used as an onlay graft and does not require sutures.

- Suturable DuraGen can be cut to the desired shape using aseptic technique. When used as an onlay graft the matrix must be large enough to overlap the remaining dura by a minimum of one (1) centimeter.

- Suturable DuraGen can be repositioned as necessary.

- Apply with the smooth (non-textured) side toward the neural tissue.

Instructions for Use – Suturing Technique

- Suturable DuraGen may be sutured in place. Suture and needle selection should be determined by clinical need and surgeon preference.

- Apply with the smooth (non-textured) side toward the neural tissue.

- Suture bites should be taken 2-3 millimeters from the edge of the graft. Use minimum appropriate tension when suturing or when placing a knot.

Additional Instructions

- Closed suction wound drainage is recommended for 1–3 days postoperatively.
- Discard any unused pieces of Suturable DuraGen.

SAFETY

Suturable DuraGen is manufactured from collagen obtained from bovine deep flexor tendon, which is classified by European Standards as a Category C 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 Suturable DuraGen is currently used in the manufacture of an artificial skin, absorbable hemostatic sponges, and absorbable wound dressings. The manufacturing process for Suturable DuraGen 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 Suturable 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.
- Suturable DuraGen should be used with caution for extensive skull base surgery with dural resection. Suturable DuraGen can be used to augment other forms of specific repair (e.g., Fascia lata).
- Suturable DuraGen should be used with caution for posterior fossa procedures (e.g., Chiari decompressions).
- Use caution in repair of spinal neural tube defects or anterior spinal surgery with dural resection (e.g., transoral surgery).
- Use caution when covering dural defects involving mastoid air cells.

PRECAUTIONS

- Rinse surgical gloves to remove any glove powder prior to handling Suturable DuraGen.
- When applied using an onlay technique or a suture technique, Suturable DuraGen should be cut generously to ensure that the graft overlaps the existing dura at the margin of the defect.
- Use caution when using Suturable DuraGen in conjunction 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 porous collagen matrix were reported at approximately the same rate as the control group in which the dura was either left opened or sutured. 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

Suturable DuraGen 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 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 (15°C-30°C). Avoid excessive heat or humidity. Do not refrigerate.

HOW SUPPLIED

Suturable DuraGen 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.

Ref. Number:	Size:	Quantity:
DURS1391ITL	1 in x 3 in (2.5 cm x 7.5 cm)	single unit

DURS1395ITL	1 in x 3 in (2.5 cm x 7.5 cm)	5 units/box
DURS2291ITL	2 in x 2 in (5 cm x 5 cm)	single unit
DURS2295ITL	2 in x 2 in (5 cm x 5 cm)	5 units/box
DURS3391ITL	3 in x 3 in (7.5 cm x 7.5 cm)	single unit
DURS3395ITL	3 in x 3 in (7.5 cm x 7.5 cm)	5 units/box
DURS4591ITL	4 in x 5 in (10 cm x 12.5 cm)	single unit

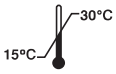
PRODUCT INFORMATION DISCLOSURE

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 THIS PRODUCT. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. INTEGRA INTENDS THAT THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS HAVING RECEIVED PROPER TRAINING IN THE USE OF THE DEVICE.

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.
- 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

	Consult Instructions for Use
	Expiration date
	Do not re-use
	Lot number
	Sterilized using Ethylene Oxide
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner
	Manufacturer
	Catalog number
	Do not re-sterilize
	Product complies with requirements of directive 93/42/EEC
	Store at room temperature (15°C - 30°C). Avoid excessive heat and humidity. Do not refrigerate
	Authorized Representative in the European Community.
	Do not use if package is damaged

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