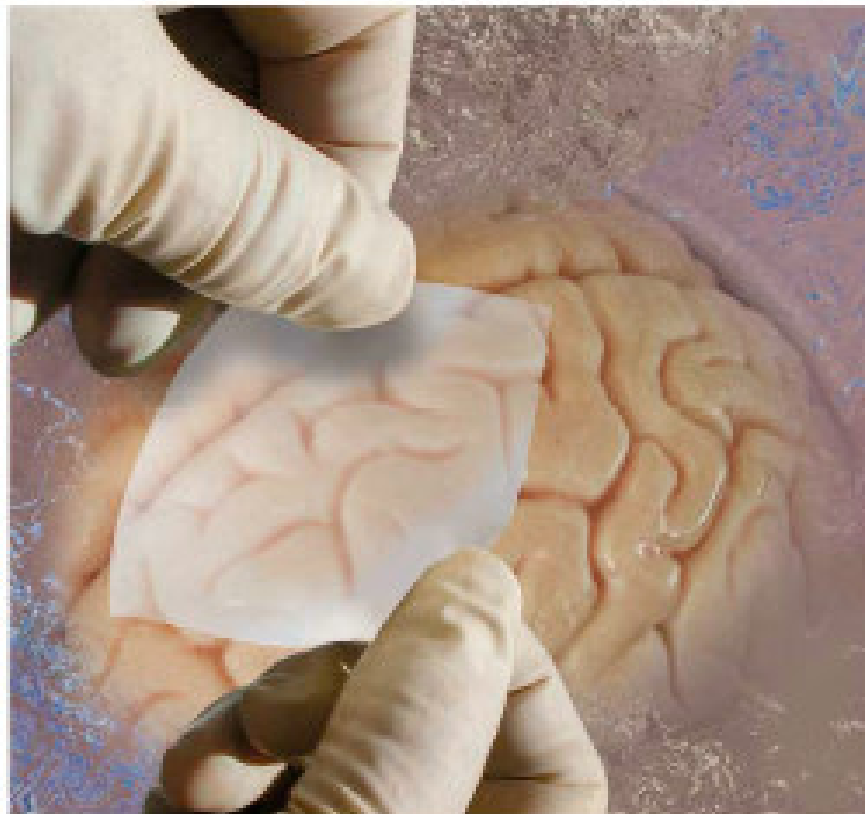
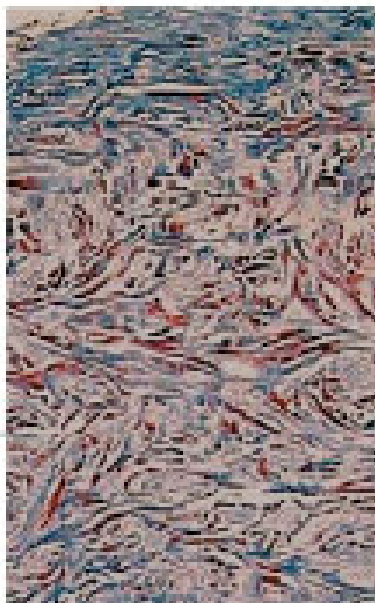
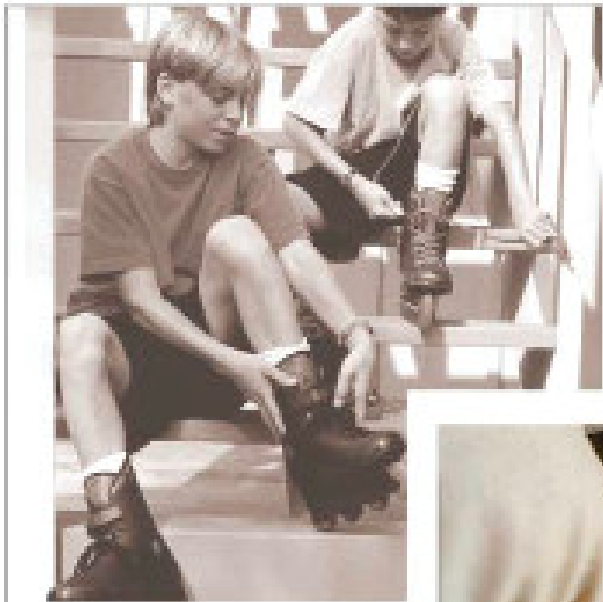




Medtronic

DUREPAIR® DURA REGENERATION MATRIX



Dura Regeneration Matrix

What is Durepair® Dura Regeneration Matrix?



Durepair® Dura Regeneration Matrix is a collagen implant designed to repair defects of the dura mater. The gold standard in dural grafting is to use the patient's own tissue because it is biocompatible and is eventually remodeled into new tissue that permanently repairs the defect. **Durepair** represents a new, patented, "off-the-shelf" technology that comes close to mimicking grafts of the patient's own tissues. Studies have already shown that this implant is, like the gold standard, biocompatible, infiltrated by blood vessels and cells, and is slowly transformed into new living tissue that repairs the defect.

Dura repair may be required during the following neurosurgical and spinal procedures:

- Cranial reconstruction
- Tumor removal—all craniotomies
- Skull base
- Spinal procedures
- Neurovascular procedures
- Posterior fossa decompressions
- Aneurysm clipping

Features

- Easy to suture like natural tissue
- Is not a permanent *implant*
- May be sutured in place or utilized as an on-lay graft
- Packaged dry, stored at room temperature and hydrates rapidly (\approx 1 minute)
- White in color in a dry state; translucent when hydrated
- Drapable
- Strong material

Benefits

- Needle may be passed through material with little resistance, and the material closes around the suture hole to prevent CSF leakage
- Remodeled into natural dura
- One product, two solutions. On-lay technique is appropriate where CSF pressure is low.
- Reduces OR time; material is ready to use off the shelf. No need for refrigeration.
- Enables visualization of the dural defect beneath the graft
- Readily conforms to curved surfaces
- As strong as native dura

Microstructure Comparison

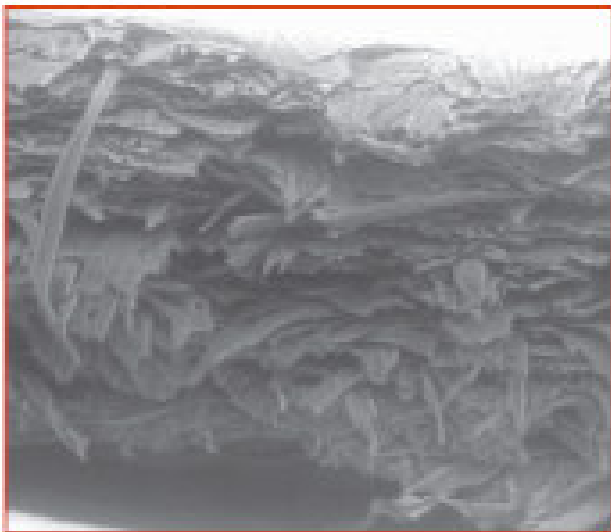
These scanning electron micrographs of Durepair, and two competitive products demonstrate that Durepair is composed of an array of strong collagen cables that form a porous matrix into which host cells and supporting blood vessels can penetrate. DuraGen® also has large pores, but the filamentous microstructure results in a weak product. The pericardium products (EnDura™ and Dura-Guard®) have a dense collagen microstructure that is strong, however, the small pores limit cell and blood vessel penetration.



Durepair SEM 500X



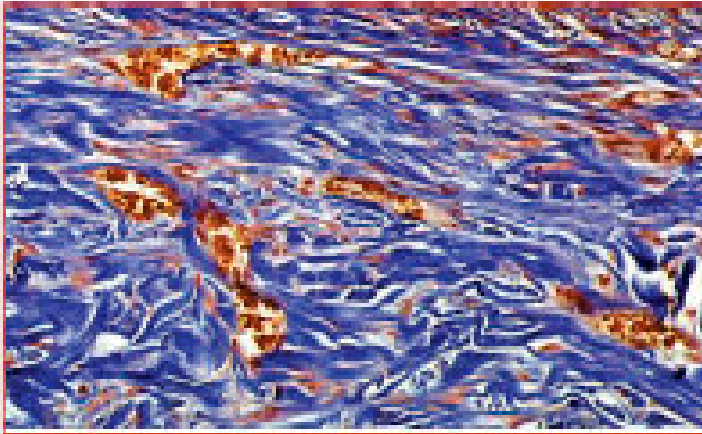
Duragen Plus SEM 500X



EnDura SEM 500X

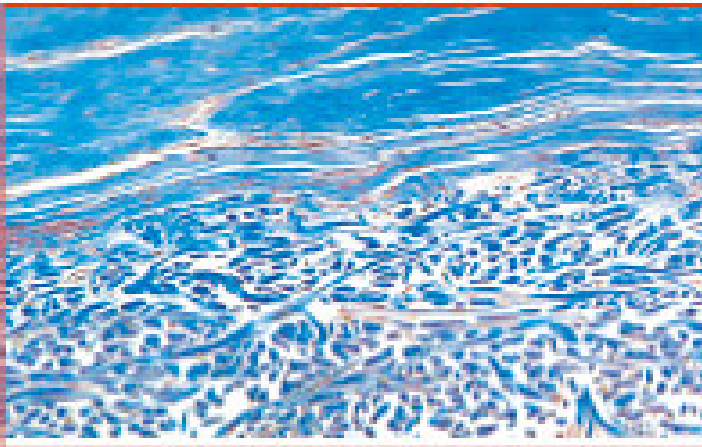
Durepair Remodeling in an Animal Duraplasty Model

1 Month



The Durepair collagen fibers (stained blue) are seen infiltrated by blood vessels filled with red blood cells (stained red). The individual cells between the collagen fibers are the fibroblasts responsible for building a new dura.

3 Month



The blue top layer is new collagen being built on top of the implant. The Durepair implant is populated with blood vessels and fibroblasts. NOTE: No inflammatory cells are present.

6 Month

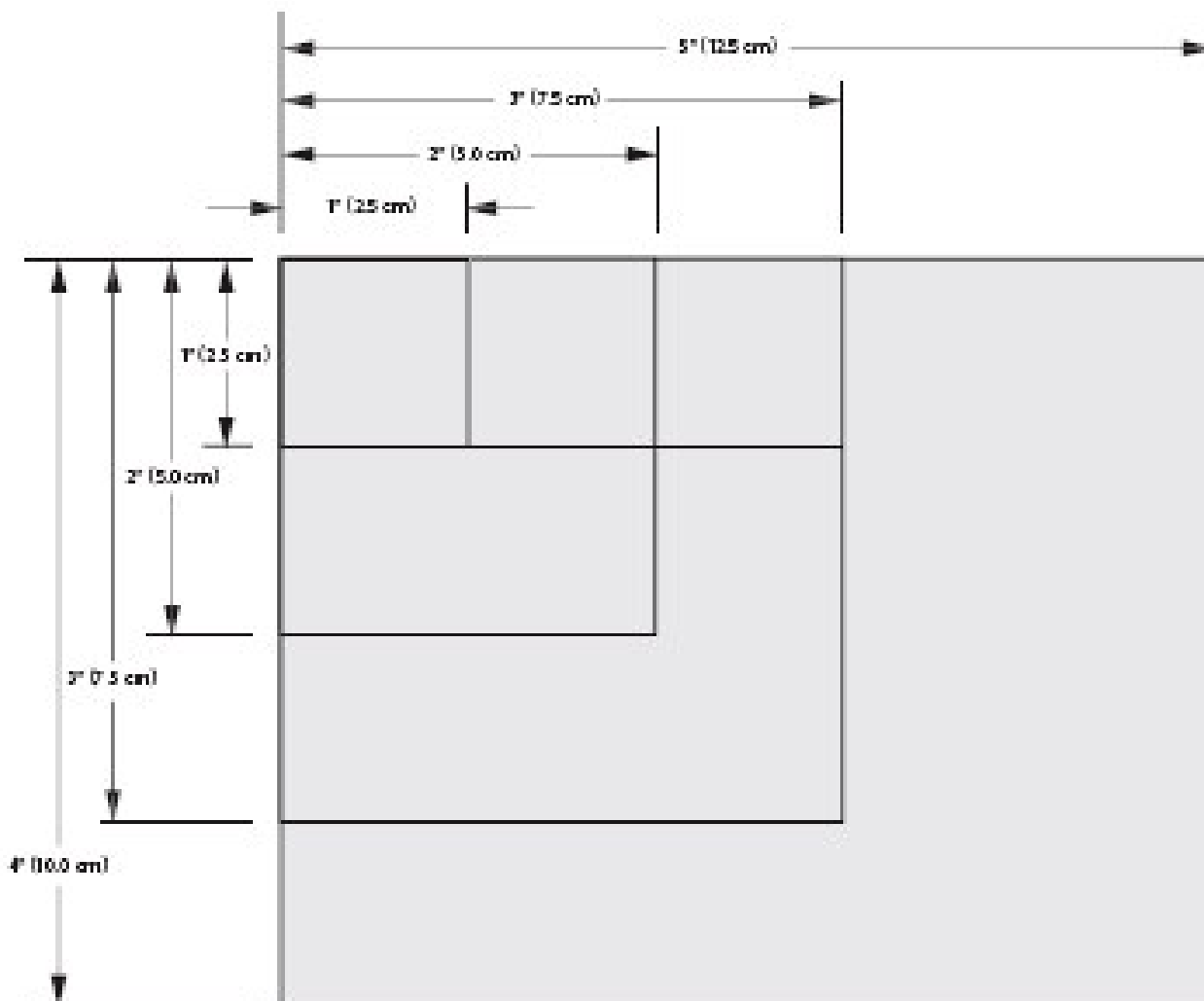


The Durepair implant is being remodeled. The new host top collagen layer seen at three months is now seen to be blending with the underlying Durepair collagen fibers. Similarly, the collagen fibers, obvious at one and three months, are now less distinct. The cells populating Durepair are depositing new collagen while breaking down and replacing the Durepair Regeneration Matrix.

Medtronic Durepair® Dura Regeneration Matrix

Table of Product Codes

REF. No.	Description
62111	Durepair Dura Regeneration Matrix, 1" x 1" (2.5cm x 2.5cm)
62151	Durepair Dura Regeneration Matrix, 1" x 1" (2.5cm x 2.5cm) (5 pack)
62106	Durepair Dura Regeneration Matrix, 1" x 3" (2.5cm x 7.5cm)
62152	Durepair Dura Regeneration Matrix, 1" x 3" (2.5 cm x 7.5cm) (5 pack)
62100	Durepair Dura Regeneration Matrix, 2" x 2" (5.0cm x 5.0cm)
62103	Durepair Dura Regeneration Matrix, 2" x 2" (5.0cm x 5.0cm) (5 pack)
62105	Durepair Dura Regeneration Matrix, 3" x 3" (7.5cm x 7.5cm)
62107	Durepair Dura Regeneration Matrix, 3" x 3" (7.5cm x 7.5cm) (5 pack)
62110	Durepair Dura Regeneration Matrix, 4" x 5" (10.0cm x 12.5cm)



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Refer to product package insert for instructions, warnings, precautions and complications.

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Durepair® is a registered trademark of TET Biosciences, Inc.
 DuraGen® is a registered trademark of Inogen Life Sciences.
 Dura-Guard® is a registered trademark of Synovis Life Technologies, Inc.



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