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Cerafix® Dura Repair

Cerafix® Mimics The Architecture Of Native Dura

Cerafix® is made of PLGA (Polyglactin 910) and PDO (Polydioxanone); polymers commonly found in fully resorbable suture material.

Cerafix®

Native Dura

Benefits of Cerafix®:[1]

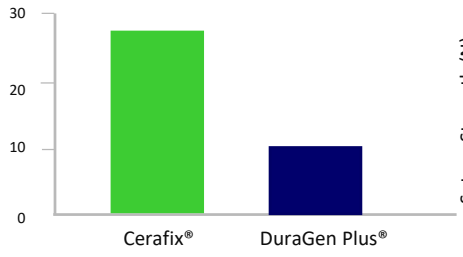
- Resorbs after effective neoduralization and defect closure
- Contains no animal based tissue
- Composed of fully resorbable biocompatible polymers
- Facilitates cellular infiltration, tissue integration, neoduralization
- Fully resorbed in 13-26 weeks
- Compatible with magnetic resonance imaging
- No reported CSF leaks

SAFE

- ✓ No risk of allergic reaction or disease transmission associated with biologics [4]
- ✓ Low rates of cortical adhesions [4]
- ✓ Minimal inflammatory response [4]
- ✓ Effective protection against CSF leaks [5]
- ✓ No abrasion of cortical tissue; non-irritant [4]

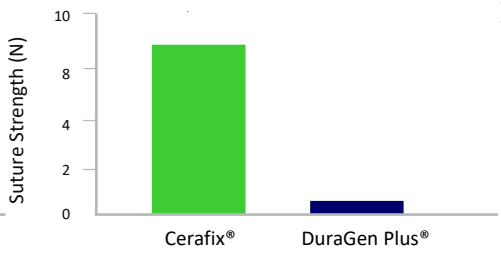
Comparative Analysis of the Mechanical Strength of Cerafix® Dura Substitute & DuraGen Plus® Dural Regeneration Matrix[3]

Tensile Strength



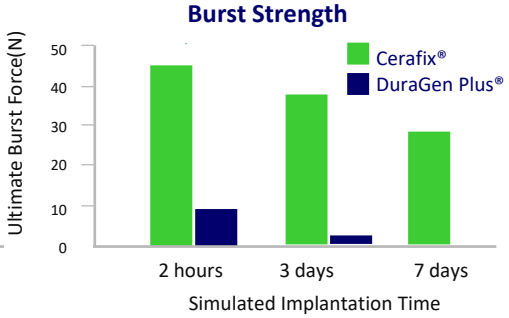
Cerafix® demonstrates superior tensile strength compared to DuraGen Plus®. Cerafix® is highly resistant to tearing during placement and fixation, ensuring structural integrity while subjected to the forces encountered during application to a dural defect during closure.

Suture Pullout Strength



Cerafix® demonstrates increased suture pullout strength compared to DuraGen Plus®. Cerafix® is ideally suited for use with interrupted tacking sutures, which eliminates risk of migration and provides added security during closure.

Burst Strength



Cerafix® demonstrates greater burst strength compared to DuraGen Plus®. Cerafix® is designed to withstand intra-cranial pressures (ICP) upon closure of the dura mater, and does so for a longer amount of time than DuraGen Plus®.

Description:
Cerafix® Dura Substitute is a resorbable implant for repair of dural defects and is to be used with tensionless sutures.

Indications[7]:
Cerafix ® Dura Substitute is indicated as a dura substitute for the repair of dura mater. This device is indicated for defects of 28.3cm2 or less in area.

Contraindications:
Cerafix® Dura Substitute must not be used for repair of spinal neural tube defects; anterior spinal surgery with dura resection (e.g., transoral surgery). In infected regions. To cover dura defects involving mastoid air cells. Large defects at the skull base following surgery. Specifically, an area greater than 28.3 cm2.

Warnings:
Do Not Resterilize. Do not use if the product package is damaged of open

Precautions:
Rinse surgical gloves to remove any glove powder prior to handling Cerafix® Dura Substitute. Tensionless suturing technique should be used. Cerafix Dura Substitute should be cut to size ensuring a 1 cm overlap of the existing dura. Cerafix® Dura Substitute device safety and efficacy has not been evaluated for pediatric and pregnant patients.

Adverse Events:
Possible complications can occur with any neurosurgical procedure and include cerebrospinal fluid leaks, infection, delayed hemorrhage and adhesion formation.

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

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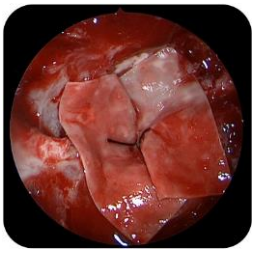
Cerafix®: Available Sizes

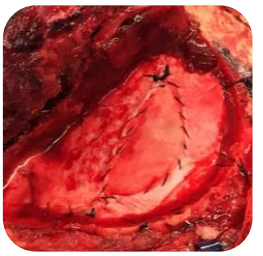
Part Number	Size	Units Per
C1-1x1	2.5 cm x 2.5 cm	1
C1-1x3	2.5 cm x 7.5 cm	1
C1-2x2	5.0 cm x 5.0 cm	1
C1-3x3	7.5 cm x 7.5 cm	1
C1-4x5	10.0 cm x 12.5 cm	1

Case Studies:[2]



Expanded Endoscopic Resection of Pituitary Meningioma.

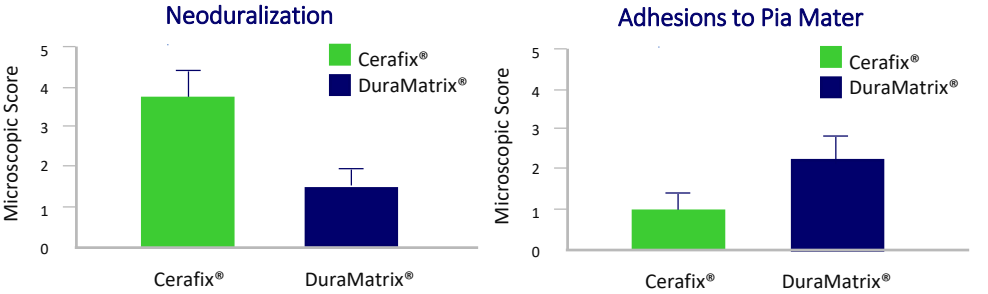
Cerafix® easily rolled and applied through the use of an endoscope; fixed in place with a non-tension suture.



Craniotomy and Supratentorial Aneurysm Clipping

Cerafix® was utilized to repair the dura mater and was secured in place with a running suture applied in a non-tension fashion in order to achieve a water-tight closure.

Comparison of Cerafix® and DuraMatrix® Neoduralization and Adhesions[6]



Histopathology revealed increased neoduralization and reduced cortical adhesion in defects repaired with Cerafix® versus site repaired with DuraMatrix ®. (Microscopic Score: 5 = 100% of field. 0 = 0% of field).

References 1-6: Data on File Acera Surgical. 7 See Cerafix IFU and FDA 510k 161278

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