

CERAFIX[®]

DURA SUBSTITUTE

Description:

Cerafix[®] Dura Substitute is a resorbable implant for repair of dural defects. The device can be applied as an onlay matrix or sutured in place. Cerafix[®] Dura Substitute is a soft, white, pliable, nonfriable, porous polymer matrix. Cerafix[®] Dura Substitute is available in a variety of sizes and is supplied sterile and nonpyrogenic in a single-use nested pouch configuration, which is enclosed in a protective chipboard peel-tab mailer.

Indications:

Cerafix[®] Dura Substitute is indicated as a dura substitute for the repair of dura mater. This device is indicated for defects of 4.9 in² (31.7 cm²) or less in area. For example, 4.0 in x 1.2 in (10.0 cm x 3.1 cm) would be an acceptable defect size.

Contraindications:

Cerafix[®] Dura Substitute is not designed, sold or intended for use except as described in the indications for use and is contraindicated in the following situations:

- 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.
- Use as an onlay matrix in spinal surgery.
- Large skull base defects greater than 1.6 in² (10.3 cm²) following surgery.
- Use on defects greater than 4.9 in² (31.7 cm²) is contraindicated. For example, 4.0 in x 1.2 in (10.0 cm x 3.1cm) would be an acceptable defect size but a greater surface area would be contraindicated.

Warnings:

Do Not Resterilize!

Do not use if the product package is damaged or opened.

Precautions:

- Rinse surgical gloves to remove any glove powder prior to handling Cerafix[®] Dura Substitute.
- Suturing is not required, but if desired, Cerafix[®] can be sutured in place with tensionless suture material.
- 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.

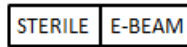
Adverse Events:

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.

Symbols:



Sterile unless package is opened or damaged.
Sterilization Method: E-Beam



Do not reuse after opening



See instructions for use



For prescription use only



MR Safe

YYYY-MM-DD

Expiration Date

Lot number:

Lot Number

Customer Service

844-879-2237 Ext 0

Manufactured for:

Acera Surgical, Inc.
10880 Baur Blvd.
St. Louis, MO 63132

How Supplied:

Cerafix[®] Dura Substitute is supplied sterile, in a single use double peel package in a variety of sizes. Contents of the package are guaranteed sterile and nonpyrogenic unless the package has been opened or damaged. The following table represents the sizes available:

| Part Number | Size |
|-------------|-----------------------------------|
| C1-1X1 | 1 in. x 1 in. (2.5 cm x 2.5 cm) |
| C1-1X3 | 1 in. x 3 in. (2.5 cm x 7.5 cm) |
| C1-2X2 | 2 in. x 2 in. (5.0 cm x 5.0 cm) |
| C1-3X3 | 3 in. x 3 in. (7.5 cm x 7.5 cm) |
| C1-4X5 | 4 in. x 5 in. (10.0 cm x 12.5 cm) |

Instructions for Use:

- Cerafix[®] is packaged in a nested pouch configuration. Peel open the outer foil pouch starting from the chevron sealed edge. The inner TyVek[®] pouch 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 the product from the inner TyVek[®] pouch using a gloved hand and aseptic technique so as not to crush the material.
- Cerafix[®] can be cut to the desired shape in a wet or dry state. Use aseptic technique when cutting the material. The Cerafix[®] Dura Substitute must be large enough to overlap the remaining dura by a minimum of 1 cm.
- Before application of Cerafix[®], soak in sterile hypertonic solution (i.e. saline, water, etc.) for a minimum of 1 minute.
- Apply Cerafix[®] with either side towards the brain.
- Cerafix[®] can be repositioned as necessary.
- Suturing is not required, but if desired, Cerafix[®] can be sutured in place with tensionless suture material. When suturing, bites should be taken 2-3 mm from the edge of the Cerafix[®] Dura Substitute and minimum appropriate tension should be utilized when suturing and placing knots.
- Discard any unused pieces of Cerafix[®] Dura Substitute.