SYNTHECEL® Dura Repair

Assurance and Versatility for Dura Reconstruction.
SYNTHECEL Dura Repair is an assured and versatile solution for your dura reconstruction needs.

- Clinically proven
- One product choice for excellent onlay or suture performance
- Excellent handling
- Non-animal derived, no risk of transmissible diseases
- Non-pyrogenic
- MR safe

Conformable
SYNTHECEL Dura Repair thickness is similar to human dura and conforms to the brain.

Sutureable
SYNTHECEL Dura Repair is excellent in sutureability.


SYNTHECEL Dura Repair performance was demonstrated in a prospective, randomized, controlled study¹.

SYNTHECEL Dura Repair demonstrated excellent seal quality during surgeon preference evaluation.

SYNTHECEL Dura Repair demonstrated excellent strength during surgeon preference evaluation.

¹ Rosen, Charles L., et al. Results of the Prospective, Randomized, Multicenter Clinical Trial Evaluating a Biosynthesized Cellulose Graft for Repair of Dural Defects. Neurosurgery. 2011 Nov;69(5):1093-103; discussion 1103-4. SYNTHECEL Dura Repair (62 units). Control group: Duraform Dural Graft implant (15 units), Duragen II Dural Regeneration Matrix (8 units), Duragen Dural Graft Matrix (10 units), Durepair Regeneration Matrix (2 units), Duragen Plus (1 unit), and Preclude Dura Substitute (1 unit).
Naturally Formed, Biosynthesized Cellulose.

SYNTHECEL Dura Repair is composed of biosynthesized cellulose and water.

- Layers, biosynthesized cellulose
- Interconnected, cellulose fibers
- Naturally formed by Gluconacetobacter xylinus
TECHNIQUE OVERVIEW

Package:
Provided sterile and must not be reused or re-sterilized. Do not use past expiration date, if package has been compromised or if the implant is dry.

Storage:
Store at room temperature, must not be frozen (5°C/41°F) or exposed to temperatures above 40°C/104°F. If there is a ‘√’ in the temperature indicator window, product is ok to use. If there is an ‘X’ in the temperature indicator window, do not use the product.

Application:
Step 1:
Open carton and outer pouch. Pass sterile, inner pouch onto the sterile field. Rinse surgical gloves to remove glove powder prior to handling the implant. Implant is packaged wet and ready to use. Protective plastic sheeting prevents implant from drying out. No rinsing or soaking for re-hydration is required.

Step 2:
When ready to use, open inner pouch and remove implant using aseptic technique. Immediately prior to use, remove and discard the protective plastic sheeting from both sides of the implant using aseptic technique. Do not allow implant to dry out prior to implantation.

Step 3:
Apply implant with or without sutures. Trim and size the implant to completely cover the defect with an overlap of sufficient size to allow sutures (if desired) to be placed along the margin of the implant 3 to 4 mm from the edge. Tensionless atraumatic sutures may be used if desired. Use non-absorbable, smallest appropriate diameter suture with a tapered (non-cutting) needle of appropriate size to anchor the material. Final suture selection should be determined by surgeon preference and the nature of the dural repair. A watertight closure should be achieved to minimize the possibility of CSF leakage. Ensure the edges of the implant are not folded. Allow sufficient size so that suturing does not place implant or surrounding dura under tension. Implant can be repositioned if required prior to suturing. Use caution when repositioning the implant to avoid tears.

Step 4:
Close remaining cranial layers to preference and clinical need. Discard all unused pieces of SYNTHECEL Dura Repair.

Please refer to package insert for complete indications, contraindications, warnings and precautions.
SYNTHECEL Dura Repair
A Size for all your Clinical Needs.

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Size</th>
<th>Units Per</th>
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<tbody>
<tr>
<td>A SC.400.006.015</td>
<td>1 in x 1 in (2.5 cm x 2.5 cm)</td>
<td>1</td>
</tr>
<tr>
<td>B SC.400.019.015</td>
<td>1 in x 3 in (2.5 cm x 7.5 cm)</td>
<td>1</td>
</tr>
<tr>
<td>C SC.400.025.015</td>
<td>2 in x 2 in (5.0 cm x 5.0 cm)</td>
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<tr>
<td>D SC.400.056.015</td>
<td>3 in x 3 in (7.5 cm x 7.5 cm)</td>
<td>1</td>
</tr>
<tr>
<td>E SC.400.120.015</td>
<td>4 in x 5 in (10.0 cm x 12.0 cm)</td>
<td>1</td>
</tr>
</tbody>
</table>

Images shown are to scale in inches. Products are sold sterile.

Description: SYNTHECEL Dura Repair is composed of biosynthesized cellulose and water and has a unique construction of non-woven, interconnected cellulose fibers which creates its strength. SYNTHECEL Dura Repair functions as a mechanical layer which covers and repairs the dural defect while preventing further cerebrospinal fluid (CSF) leakage. SYNTHECEL Dura Repair is immunologically inert and has demonstrated minimal foreign body response. SYNTHECEL Dura Repair is a non-resorbable dural graft that is not intended for temporary use. The SYNTHECEL Dura Repair is MR safe.

Indications: SYNTHECEL Dura Repair is intended for use as a dura replacement for the repair of dura mater in adults.

Contraindications: SYNTHECEL Dura Repair must not be implanted in patients who have known allergy or sensitivity to the implant materials (cellulose).

WARNINGS: The safety and effectiveness of SYNTHECEL Dura Repair has not been studied in:
- Patients that are less than 18 years of age.
- Patients who also required use of dural adhesive or sealant.
- Patients who had systemic infection (e.g. urinary tract infection, active pneumonia) or evidence of any surgical site infection, fever > 38.3°C (101°F), positive blood culture and/or a positive chest x-ray for acute infectious process.
- Patients who were acute cranial trauma surgical cases.
- Patients who had chemotherapy and/or radiation treatment within 12 weeks prior to surgery, or had chemotherapy and/or radiation treatment planned 10 weeks post surgery.
- Patients who had compromised immune system or autoimmune disease.

PRECAUTIONS: SYNTHECEL Dura Repair is provided sterile and should not be re-sterilized. Do not use if packaging or seal has been damaged or opened. SYNTHECEL Dura Repair should be stored at room temperature; must not be frozen (5°C/41°F) or exposed to temperatures above 40°C/104°F. SYNTHECEL Dura Repair is intended for single patient use only. Discard opened or unused product. Immediately prior to use: carefully remove and discard the protective plastic sheeting from both sides of the device using aseptic technique to avoid damage to the implant (e.g. tearing). Do not use if SYNTHECEL is damaged. Do not allow implant to dry out prior to implantation. Tension should be avoided if suturing the SYNTHECEL Dura Repair. Ensure the edges of the implant are not folded.

SYNTHECEL Dura Repair should be used with caution in restricted areas of the skull, (e.g., posterior fossa) due to the potential for local mass effect.

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