

Baxter

Dura-Guard

DURAL REPAIR PATCH



CLINICALLY
EFFECTIVE

**DURAL
REPAIR^{1,2}**

Please see Indications and Important Risk Information on page 4.



CEREBROSPINAL FLUID LEAKS POSE SIGNIFICANT RISKS TO PATIENTS



The risk of cerebrospinal fluid (CSF) leak after craniotomy ranges from 4% to 32%.³



Primary watertight dural closure is a mainstay in intracranial surgery as revision surgery carries additional risks for patients.^{3,4}



CSF leaks are among the most frequently reported indicators for surgical revisions.³

INCREASED RISK FACTORS FOR CSF LEAK INCLUDE:



Surgical Factors:

- Approach (infratentorial vs supratentorial)³
- Size of craniotomy⁵
- Surgical location⁵

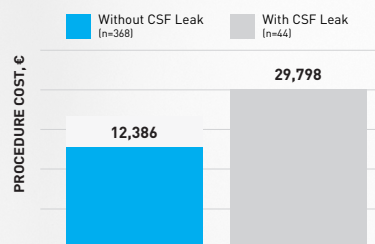


Patient Factors:

- Age⁵
- High body mass index⁶
- Immune status⁶

COST OF POSTOPERATIVE CSF LEAKS⁷

There are also cost implications related to CSF leaks. In a retrospective evaluation, procedures involving CSF leaks cost, on average, 141% more than procedures that did not result in a postoperative CSF leak.⁷ This report revealed that CSF leaks occur with high frequency and incur significant costs across all types of neurosurgical procedures.⁷



141%
AVERAGE COST INCREASE
DUE TO CSF LEAKS

CLINICAL EFFICACY

Anson and Marchand performed a 35-patient retrospective study analyzing the efficacy of glutaraldehyde-processed bovine pericardium for dural closure in cranial and craniospinal procedures.²

Included multiple complex procedures:

14 meningioma resections	12 posterior fossa craniotomies
5 Chiari decompressions	2 penetrating and blunt traumas
2 dura-based metastases	

Benefits of bovine for dural grafts



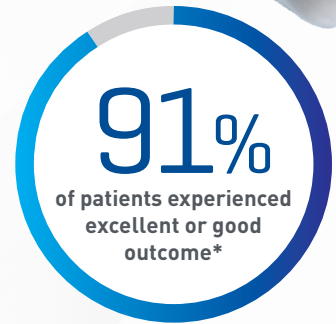
Biocompatible and low immunogenicity



Excellent strength yet supple



Easy to cut, manipulate and suture



* Fair or poor outcomes in 9% of patients were not related to the product.

USED BY NEUROSURGEONS FOR ALMOST 25 YEARS⁸

DURA-GUARD Dural Repair Patch remains a proven dural substitute.^{1,2}



Promotes watertight closure

Supports reapproximation around the suture line and has demonstrated resistance to CSF leakage.²

APPLICATION OF DURA-GUARD DURAL REPAIR PATCH



Scan the QR code to watch the video

Please see Indications and Important Risk Information on page 4.

Product Description	Size	Pack Factor	Product Code
Dura-Guard Dural Repair Patch	2 cm x 9 cm	1 per pack	DG0209SN
Dura-Guard Dural Repair Patch	4 cm x 4 cm	1 per pack	DG0404SN
Dura-Guard Dural Repair Patch	6 cm x 8 cm	1 per pack	DG0608SN
Dura-Guard Dural Repair Patch	8 cm x 14 cm	1 per pack	DG0814SN
Dura-Guard Dural Repair Patch	10 cm x 16 cm	1 per pack	DG1016SN

DURA-GUARD DURAL REPAIR PATCH INDICATIONS AND IMPORTANT RISK INFORMATION

INDICATIONS FOR USE:

For use as a dura substitute for the closure of dura mater during neurosurgery.

IMPORTANT RISK INFORMATION:

Dura-Guard Dural Repair Patch is not designed, sold, or intended for use except as indicated.

Do not use **Dura-Guard** Dural Repair Patch in patients with a known sensitivity to bovine material.

As with any surgical procedure, dehiscence at the surgical site, hematoma, seroma, fever, and infection are possible complications. Other potential complications specific to dura-related procedures include, but are not limited to: death, seizure, cerebrospinal fluid leakage or fistula, meningitis, adhesion formation, pseudomeningocele or hydrocephalus. Monitor patient for adverse reactions and take appropriate therapeutic action.

The Rinse Procedure must be followed or a sterile inflammatory reaction in the adjoining host tissue may result. Do not pour the storage solution into the rinse bath.

To avoid damage to the product, do not expose to any chemicals or substances other than those specified in this Rinse Procedure. Antimycotics (anti-fungals) must not come in contact with **Dura-Guard** Dural Repair Patch as they are believed to alter the cross-link characteristics of tissue fixed in aldehyde preparations.

Do not freeze. Damage to the sterile barrier may result. Do not use if freeze indicator is activated.

The product must remain moist at all times.

Do not use **Dura-Guard** Dural Repair Patch in patients with a known sensitivity to bovine material.

Synovis products differ; substitution of one product for another product may be harmful to the patient.

Do not resterilize. Do not subject to steam, gas (ethylene oxide), or radiation sterilization as these may damage

Dura-Guard Dural Repair Patch.

Do not use if the container is not properly sealed prior to opening, as sterility may be compromised. Do not place the container in sterile field as the outside of the container is not sterile. This product is for single use only. Once the container seal is broken, use immediately, do not reseal container or reuse **Dura-Guard** Dural Repair Patch. Any unused pieces of **Dura-Guard** Dural Repair Patch must be discarded as biohazardous waste. Failure to observe these warnings may result in surgical infection.

Rinse surgical gloves to remove glove powder prior to touching **Dura-Guard** Repair Patch.

Rx Only. For safe and proper use of this device refer to the complete Instructions for Use.

References

1. **Dura-Guard** Dural Repair Patch Instructions for Use.
2. Anson JA, Marchand EP. Bovine pericardium for dural grafts: clinical results in 35 patients. *Neurosurgery*. 1996;39(4):764-768.
3. Schebesch KM, Brawanski A. Clinical experience with Hemopatch® as a dural sealant in cranial neurosurgery. *Cureus*. 2019;11(2):e4013.
4. Nowak S, Schroeder H, Fleck S. Hemopatch as a new dural sealant: a clinical observation. *Clin Neurol Neurosurg* 2019;176:133-137.
5. Hutter G, von Felten S, Sailer M, et al. Risk factors for postoperative CSF leakage after elective craniotomy and the efficacy of fleece-bound tissue sealing against dural suturing alone: a randomized controlled trial. *J Neurosurg*. 2014;121:735-744.
6. Fraser S, Gardner P, Koutourousiou M, et al. Risk factors associated with postoperative cerebrospinal fluid leak after endoscopic endonasal skull base surgery. *J Neurosurg*. 2018;128:961-1272.
7. Grotenhuis JA. Cost of postoperative cerebrospinal fluid leakage: 1 year, retrospective analysis of 412 consecutive nontrauma cases. *Healthcare Econ*. 2005;64:490-494.
8. **Dura-Guard** Dural Repair Patch 501(K) Summary of Safety and Effectiveness. June 29, 1998.