

Baxter

Dura-Guard

DURAL REPAIR PATCH



DURA-GUARD HAS HELPED NEUROSURGEONS MITIGATE CSF LEAKS FOR OVER 25 YEARS.

DURAL CLOSURE AND CSF LEAKS REMAIN TOP CHALLENGES IN NEUROSURGERY PROCEDURES.

Despite significant advances in technology and neurosurgical technique, dural closure and cerebral spinal fluid (CSF) leak prevention remain top challenges in a range of neurosurgery procedures.¹ CSF leaks can lead to a variety of complications including increased intra-cranial pressure, spinal herniation, dural-cutaneous fistula, epidural abscess and subdural hematoma.² CSF leaks may also result in significant medical costs due to re-operation, prolonged hospital stay and need for additional intervention.³

DURA-GUARD IS A LONG-LASTING IMPLANT WITH INTRINSIC MATERIAL PROPERTIES DESIGNED TO PREVENT CSF LEAKS.



Promotes Watertight Closure⁴

Easy to suture and contour to anatomy



Handling Characteristics

Similar to Native Dura⁵

Flexible yet strong graft material



Does Not Promote Calcification⁶

Highest levels of biocompatibility



Good for High and Low Pressure CSF Sites^{7*}



*Preclinical data. Results may not correlate to results in humans.

DURA-GUARD MINIMIZES CSF LEAKS AND OTHER COMPLICATIONS FOLLOWING CRANIAL PROCEDURES.

Williams et al. (2013) performed a prospective, single-blinded, randomized clinical trial comparing use of DURA-GUARD to DURAGEN in augmentation duraplasty for Chiari malformation. Note: When comparing all operative, post-operative and cost parameters, no statistical difference was found between treatment groups.

DURA-GUARD (n=18)

DURA-GUARD patients experienced no CSF leaks, wound infections or readmissions.

At month 2, DURA-GUARD patients had a significantly higher mean total Quality of Life Questionnaire score.



CSF LEAKS



QUALITY OF LIFE

DURAGEN (n=16)

Two DURAGEN patients experienced CSF leaks and 7 were readmitted.

Quality of Life Questionnaire scores between DURA-GUARD and DURAGEN were not statistically significant when comparing final survey results.

DURA-GUARD OFFERS LOWS RISK OF INFLAMMATORY RESPONSE, HIGH BIOCOMPATIBILITY AND IS ASSOCIATED WITH FAVORABLE OUTCOMES.

Anson and Marchand (1996) performed a 35 patient retrospective study analyzing efficacy of DURA-GUARD for dural closure in cranial and craniospinal procedures.⁶



91%
OF PATIENTS
EXPERIENCED AN EXCELLENT
OR GOOD OUTCOME^{6†}

INCLUDED MULTIPLE COMPLEX PROCEDURES:

- 12 posterior fossa craniotomies
- 5 Chiari decompressions
- 2 penetrating and blunt traumas

† "Excellent" = no deficit, normal mentation and employment;
"Good" = mild deficit, but normal mentation and employment
Fair or poor outcomes in 9% of patients were not related to the product.

Literature shows bovine pericardium is an effective xenograft that is associated with reduced risk of infection and inflammation.^{8,9} DURA-GUARD is an inert source material with low immunogenicity that facilitates effective migration of fibroblasts, reducing risk of calcification.⁶ **DURA-GUARD's handling properties, efficacy and outcomes make it an ideal choice for dural closure.⁶**

For more information, contact your Baxter representative or visit www.advancedsurgery.baxter.com

DURA-GUARD INDICATIONS FOR USE

DURA-GUARD is intended for use as a dura substitute for the closure of dura mater during neurosurgery.

CONTRAINDICATIONS & ADVERSE REACTIONS:

DURA-GUARD is not designed, sold or intended for use except as indicated.

WARNINGS:

Failure to rinse the product may result in a sterile inflammatory reaction. Do Not freeze. The patch must remain moist at all times.

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

Advancing the art of healing

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