

Looking for a new solution to prevent CSF leaks?

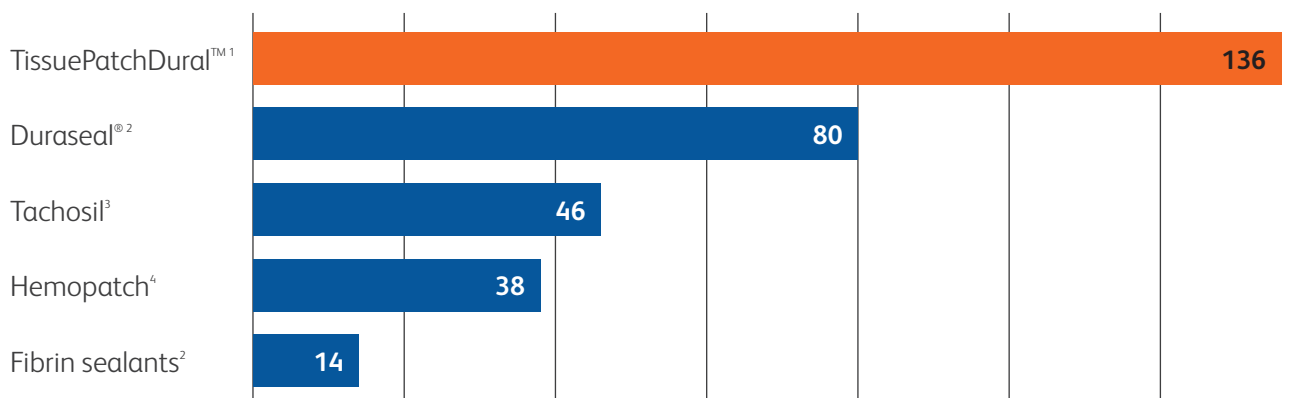
TissuePatchDural™ Sealant Film

The next generation of Cerebrospinal Fluid (CSF) leak prevention



Seal with confidence

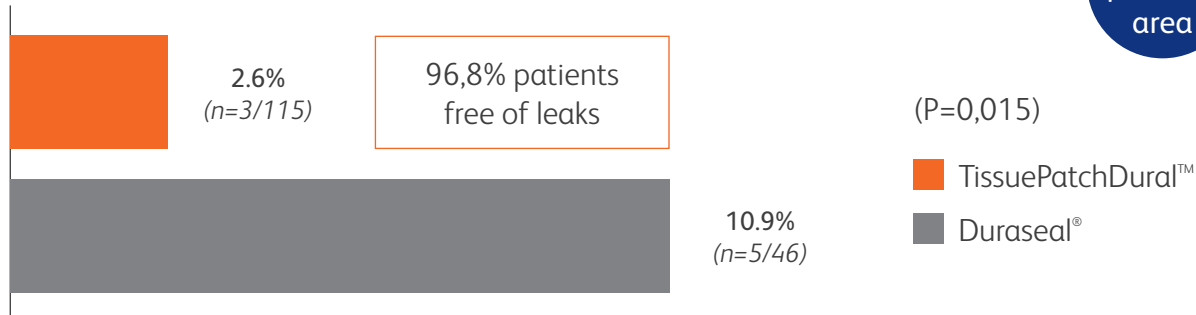
Burst Pressure (mmHg)¹



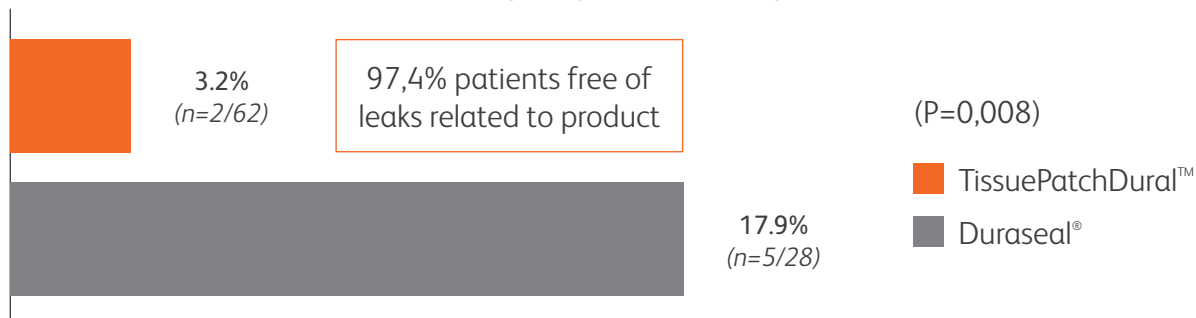
Effectiveness of TissuePatchDural™ vs. Duraseal® in Posterior Fossa surgery⁵

CSF leak incidence in patients undergoing craniotomy and craniectomy

High pressure area



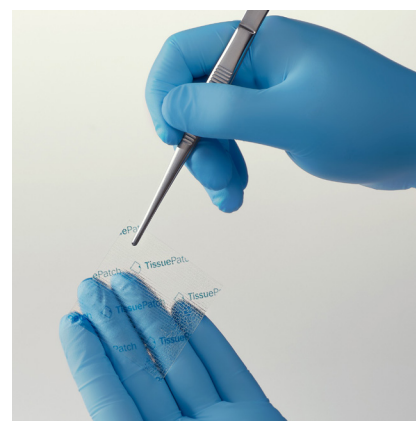
CSF leak incidence in patients undergoing craniectomy



Self-adhesive film	Uniform thickness
	Ready to use
	Designed for both spinal and neuro surgeries
Place	Ease of application
	High transparency
	Low profile for confined spaces (0,04 mm thick)
Seal	Strong adhesive strength
	High burst pressure rating

Ordering information

Product	Code	Size (cm)	Units/box
TissuePatchDural	TD-01	2,5 x 5	5
TissuePatchDural	TD-02	5 x 5	5
TissuePatchDural	TD-03	5 x 10	5
TissuePatchDural	TD-04	10 x 10	5



Indications for use

TissuePatchDural™ is indicated for use to seal and reinforce against fluid (including CSF) and/or blood leakage where the repair of the dura mater is required. TissuePatchDural™ is intended for use as an adjunct.

Contra-indications for use: TissuePatchDural™ is not intended for intravascular use; not intended to be used as a dura mater substitute; not intended to replace sutures, staples or clips, as appropriate, in tissue approximation.

Warnings and safety information:

- TissuePatchDural™ should not be used on patients with a known allergy or sensitization to its constituent components. The use of must be considered on an individual basis.
- TissuePatchDural™ should not be used as the primary means of support. The product is to be used as an adjunct, providing temporary support.
- TissuePatchDural™ is not a thrombogenic haemostat. It should not be used to control arterial bleeds; it can however be used adjunctively to control low pressure oozing/bleeding.
- TissuePatchDural™ should not be used on the skin.
- If there is any evidence of damage to TissuePatchDural™ the product shall NOT be used.
- TissuePatchDural™ should not be used if an active infection is present at the surgical site.
- TissuePatchDural™ adhesion can be affected by contact with solutions containing iodine. Such substances should NOT be applied to the site before sealing with TissuePatchDural™, though can be used following patch application.
- TissuePatchDural™ may swell slightly to a total thickness of <0.5mm. Care should therefore be taken when using the product in confined bony structures where nerves are present.
- TissuePatchDural™ may cause a local, mild inflammatory reaction leading to encapsulation by inflammatory cells with some fibrosis.
- TissuePatchDural™ is for single patient use only and once opened may not be resterilised. Product should not be re-used as this presents numerous hazards including the risk of cross contamination and lack of sterility.
- DO NOT use TissuePatchDural™ if temperature indicator dot is black; this indicates that the product has been exposed to excessive temperatures and is not suitable for use.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions.

References

- 1 Data on file at Tissuemed. Tested in accordance with ASTM F2392
- 2 Campbell P, Bennett S, Driscoll A, Sawhney A. Evaluation of Absorbable Surgical Sealants : In vitro Testing. Medicine. 2005.
- 3 Tachosil Instructions For Use, section 12.1
- 4 Lewis KM, Kuntze CE, Gulle H. Control of bleeding in surgical procedures: critical appraisal of HEMOPATCH (Sealing Hemostat). Med Devices (Auckl). 2015;9:1-10. Published 2015 Dec 22. doi:10.2147/MDER.S90591
- 5 Schiariti M, et al. Two alternative dural sealing techniques in posterior fossa surgery: (Polylactide-co-glycolide) self-adhesive resorbable membrane versus polyethylene glycol hydrogel. Surg Neurol Int. 2014 Dec 3;5:171
- 6 See TissuePatchDural™ complete Instructions for Use for detailed information



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