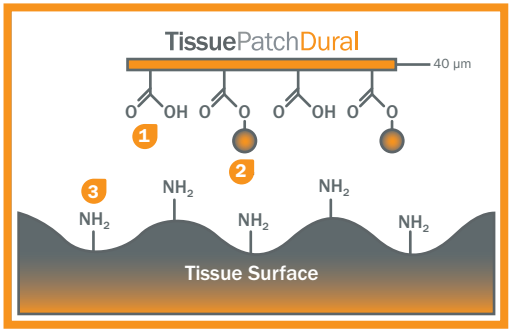
TissuePatchDural™

the rapid barrier

The Synthetic Self-Adhesive Barrier to Cerebrospinal Fluid Leaks

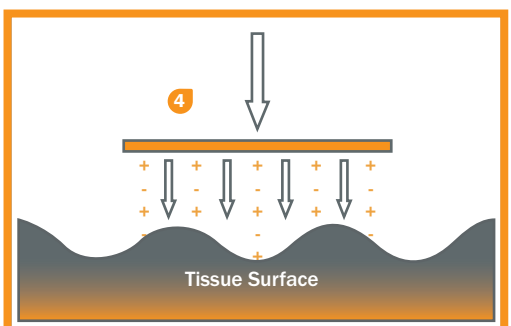
TissuePatch**Dural**™ has a fused multi-laminate structure containing patented reactive polymers for chemical bonding to tissue surface, and a non-adhesive backing material for ease of handling and prevention of post-surgical adhesions. The patch remains in position until largely absorbed in 50 days.



Mode of Action

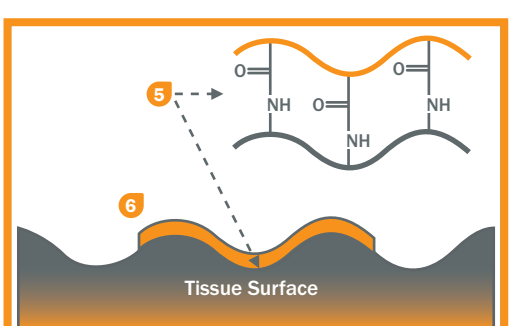
TissuePatch**Dural**™ : The chemistry

1. Carboxylic acid groups provide initial “tack” via electrostatic interactions
2. Functionalised carboxylic acid groups on contact surface
3. Tissue surface rich in protein groups containing amine and other nucleophilic functionalities



TissuePatch**Dural**™ : Ready to use and easy to apply

4. Moderate pressure is applied for several seconds allowing contact adhesive to hold **Tissue**Patch**Dural**™ onto tissue surface.
5. Amide bonds form rapidly between **Tissue**Patch**Dural**™ and the tissue surface
6. The patch is strongly adhered within 30 seconds and is flush to the surface to seal the wound



TissuePatchDural™ is ready to Apply

It Adheres,

It Seals,

It's Absorbed

TissuePatchDural™ represents a significant advance in preventing Cerebrospinal Fluid leakage

- Ready to use multi-laminate film with an adhesive and barrier surface
- Simply swab site, apply with T-Dural logo facing and press to surface anatomy
- Clings, bonds and seals within 30 seconds
- Prevents leaks, withstands dynamic stresses, with limited swelling as it hydrates
- Stays where applied and remains intact until largely absorbed in 50 days

Adjunctive use of **Tissue**Patch**Dural**™ as a barrier to Cerebrospinal Fluid leakage in Dural Repair: An *in vivo* study.

A total of six subjects were included in this study with two identical operative sites per subject. Study groups were; suture only (control) and suture plus **Tissue**Patch**Dural**™ (treated). Recovery time points were 14 and 28 days.

Results

Acute performance:
Was 100% effective at preventing CSF losses from previously sutured dural defects. Of the suture-only sites 5 out of 6 displayed residual CSF leakage, with two requiring additional treatment with **Tissue**Patch**Dural**™.

Macroscopic assessment:
All tissues were normal. On the **Tissue**Patch**Dural**™ sites the remains of the patch after 28 days were visualised as degrading transparent gel. The 'suture only' sites were reported as visibly slightly more fibrosed than the treated durotomies. No other remarkable features were noted.

Histology

Where **Tissue**Patch**Dural**™ was applied, the sealant was clearly seen (at both time points) in place secured on top of the external surface of the dura where originally applied and forming an effective seal. **Tissue**Patch**Dural**™ provoked minimal inflammatory response localised immediately adjacent to the remaining material. This response was less than the response to the sutures used as the primary means of closure. There was no evidence of damage to the underlying brain adjacent to or remote from the dural repair.

Conclusion

TissuePatch**Dural**™ is safe and effective and has potential to provide a useful adjunct in the reduction of CSF leaks during and after neurosurgical procedures.

***Full study, data on file Tissuemed Ltd**

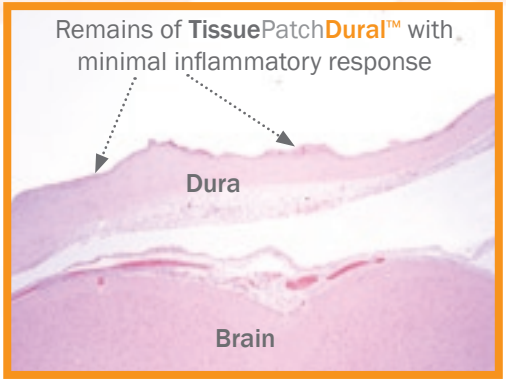


Figure 1. x20 - 14 days

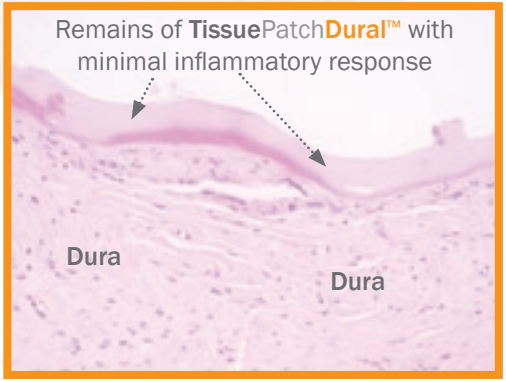


Figure 2. x200 - 14 days

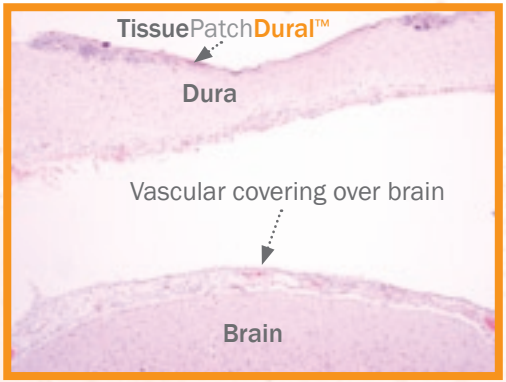


Figure 3. x40. 28 days

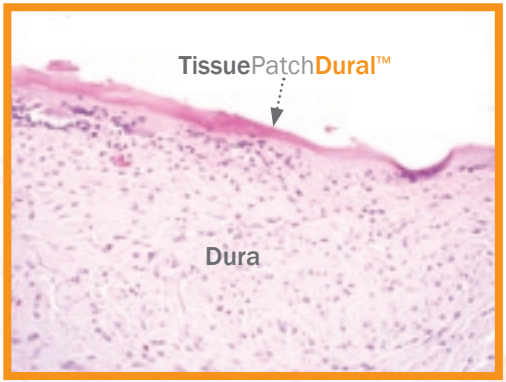
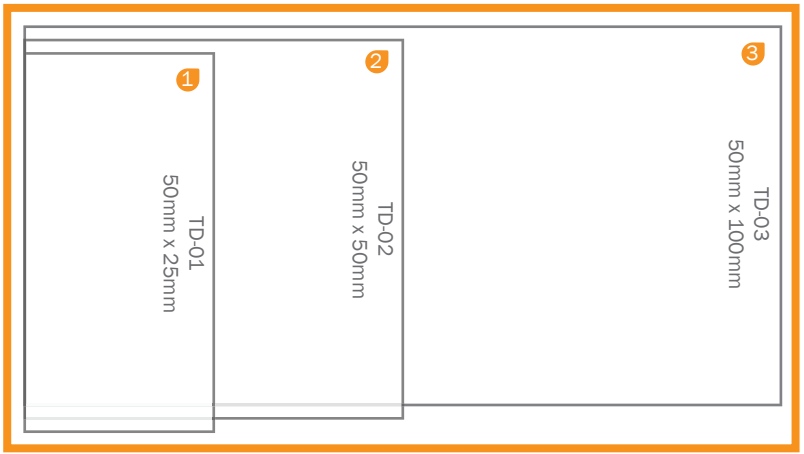


Figure 4. x200. 28 days

Ordering Information



Pack contents; 1 x **Tissue**Patch**Dural**™, Single Packed, Sterile, 1 x Instructions for Use, Triple Patient Notes Stickers

Tissuemed® surgical sealant films CE 0088

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This product is not available for sale in the United States

Indications
TissuePatch Dural is indicated for use to seal and reinforce against CSF leakage in neurosurgery. TissuePatch Dural is intended for use as an adjunct in neurosurgery. It is not intended to replace sutures, staples or clips, as appropriate, in tissue approximation. Furthermore it is not intended to be used as a dura mater substitute.