

LIQOSEAL[®]

CERTAINTY IN WATERTIGHT DURAL CLOSURE



READY-TO-USE, SOFT AND PLIABLE
DURAL SEALANT PATCH

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TRANSFORMING PATIENT
RECOVERY

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Cerebrospinal fluid (CSF) leakage is a widely recognized complication after neurosurgical procedures. It represents a significant patient burden, resulting in increased morbidity, prolonged hospital stays, possible surgical revisions, and enhanced costs.^{1,2} Incidence rates vary depending on age, indication, location of surgery and underlying pathology, but in total CSF leakage occurs in 4-32% of surgical cases.^{3,4}

Achieving **watertight dural closure** to provide effective control of CSF leakage is a challenge. A puncture from a single needle is sufficient to cause leakage, and during prolonged operative procedures, the fragile dura mater shrinks due to dehydration, further complicating closure.

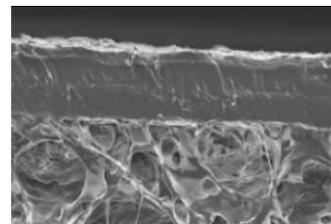
Effective dural sealants should reduce the risk of CSF leakage after cranial surgery by enhancing dural closure. However, a recent review showed that existing commercially available **dural sealants have not proven to significantly reduce post-operative CSF leakage** compared to suturing alone (8.2% versus 8.4% respectively).³

“There is a critical need for more effective and easy-to-use sealants that offer prolonged dural adherence” (Kinaci et al. 2018)

LIQOSEAL® dural sealant patch, was developed in collaboration with a non-profit consortium of neurosurgeons (Brain Technology Institute) to achieve an effective and enduring watertight dural closure throughout the critical 30-day healing period allowing the dura mater to regenerate.

“New synthetic dural sealant with extreme dura adherence and burst pressure. Fibrotic layer formation (‘neodura’) on top of the device” (van Doormaal et al. 2018)

- Excellent ease-of-use⁵
- Effective leakage control⁵ - the right strength and resilience to endure the fluctuating intradural fluid pressures and lasting adherence to the dura mater
- Extraordinary adhesion to the dura mater^{6,7}
- Bridges dural gaps up to 10 mm⁹
- Does not adhere to brain tissue (data on-file)
- Acute and long-term watertight closure of the suture-line for gaps up to 3mm - no CSF leakage⁸
- Scaffold for new fibrotic layer formation (dura regeneration, ‘neodura’)^{5,7}



Polyurethane sheet for sealing against leakage

Lactide-caprolactone copolymer foam with a synthetic adhesive for adherence to the dura

LIQOSEAL® indicated for use as an adjunct to standard methods of cranial dural repair during surgery, providing watertight closure of the dura mater to effectively control CSF leakage.

Key features and benefits

- **EFFECTIVE** – Watertight dural closure provides effective control of CSF leakage after cranial surgery, resulting in reduced patient burden and health care costs.
- **ENDURING** – Strong and durable tissue adherence enables LIQOSEAL® to endure fluctuating physiological CSF pressures throughout the critical 30-day healing period.
- **SUPPORTS HEALING** – LIQOSEAL® supports regeneration of the dura mater by acting as a scaffold for new fibrotic layer formation (‘neodura’).
- **EASY TO USE** – The soft and pliable patch is easy to apply and ready to use, requiring no time-consuming preparation or applicators.
- **SAFE** – The smart composition from synthetic, bioresorbable polymers, defines timely resorption and ensures a good safety profile, with no clinically significant post-operative swelling, minimizing the risk of neural compression.
- **DEDICATED DEVELOPMENT** – LIQOSEAL® was developed in close collaboration with neurosurgeons using an evidence-based approach, in direct response to their demands for more effective dural sealants.
- **PROVEN TECHNOLOGY** – LIQOSEAL® uses Polyganics’ proprietary bioresorbable polymer technology, already applied worldwide in multiple clinical areas.

Ordering information

Article number	Size
DS01-024/08	8x8 cm

LIQOSEAL® is supplied as 1 unit per box. It is packed in a Tyvek blister and subsequently placed in an aluminum pouch and carton box. LIQOSEAL® is a double-layered patch (white color site and green-blue fluid barrier) and is indicated for single use. It is supplied sterile. It should be stored in the freezer (< -15°C/0°F). The shelf life is at least 18 months. Within 8 months the device is considered to be essentially resorbed and integrated (based on animal data)⁵

References

- 1- Hutter G, von Felten S, Sailer M, Schulz M, Mariani L. 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. Neurosurgery. 2014. Sep; 121:724-744
- 2- Grotenhuis J. Costs of postoperative cerebrospinal fluid leakage: 1-year, retrospective analysis of 412 consecutive nontrauma cases. Surg Neurol. 2005, Dec; 64(6):490-3
- 3- Kinaci A, Algra A, Heuts S, O'Donnell D, van der Zwan A, van Doormaal T. Effectiveness of Dural Sealants in Prevention of Cerebrospinal Fluid Leakage After Craniotomy: A Systematic Review. World Neurosurg. 2018 Oct;118:368-376
- 4- Van Doormaal T, Kinaci A, van Thoor S, Redegeld S, Bergmann W, van der Zwan A. Usefulness of sealants for dural closure: evaluation in an in vitro model. Operative neurosurgery. 2017 Volume 0, Number 0:1-8
- 5- Kinaci A, van der Zwan A, van Doormaal T. EANS2018 Brussels, poster: Evaluation of a new dural sealant patch in a porcine craniotomy model
- 6- Kinaci A, van der Zwan A, van Doormaal T. EANS2018 Brussels, poster: Development of a dural sealant patch preventing cerebrospinal fluid leakage after cranial surgery
- 7- Van Doormaal T, Kinaci A, van Thoor S, Redegeld S, van der Zwan A. AANS 2018 New Orleans . poster. Cerebrospinal fluid prevention using a dural sealant; evaluation of current possibilities and design of a new synthetic patch.
- 8- ENCASE-1: Single-arm, open-label, multi-center (Zurich, CH; Utrecht, NL; Tilburg, NL) study to evaluate the safety and performance of Dura Sealant Patch in reducing CSF leakage following elective cranial surgery. Objective: Clinically assess the safety and performance of the Dura Sealant Patch as a means of reducing intra-as well as post-operative CSF leakage in patients (n=40) undergoing elective cranial intradural surgery with a dural repair closure procedure (clinicaltrial.gov identifier: NCT03566602)
- 9- based on in vitro and preclinical data

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The information presented in this brochure is intended to inform and demonstrate this product. LIQOSEAL® is CE-marked as an adjunct in cranial dural repair to provide a watertight closure of the dura mater and reduce CSF leakage. LIQOSEAL® is a registered trademark of and manufactured by Polyganics, The Netherlands

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