

LIQOSEAL[®]

**DEDICATED DEVELOPMENT
IN THE MANAGEMENT OF CSF LEAKAGE**



POLYGANICS

TRANSFORMING PATIENT
RECOVERY

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Device in development.
Not commercially available yet.
Pending availability in the EU as of 2019

LIQOSEAL

An innovative approach in achieving watertight dural closure

- LIQOSEAL[®], dural sealant patch is composed of bioresorbable polymers and that provides both the right strength and resilience to counter the fluctuating intradural fluid pressures and a durable adherence to the dura mater

Combing the best of 2 worlds in your dural closure and repair strategy

'Given the high cost of sealants...we advocate a critical attitude toward sealant application as an adjunct to classic dural closure'

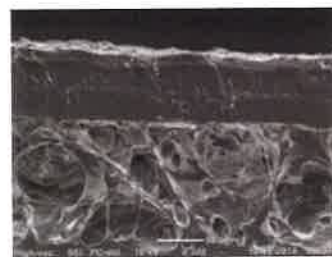
van Doormaal T, et al. 2017. Usefulness of Sealants for Dural Closure: Evaluation in an In Vitro Model. Operative Neurosurgery 0:1-8

Development of LIQOSEAL[®] is in close collaboration with the Brain Technology Institute (BTI), Utrecht, The Netherlands. BTI is a non-profit organization, founded in 2013 by UMC-Utrecht (NL), UH-Zurich (CH) and the Toronto University Health Network (CA).

LIQOSEAL[®] is indicated for use as an adjunct to standard methods of dural closure, such as suturing, to provide a watertight closure of the dura mater to prevent CSF leakage after dural closure procedure.

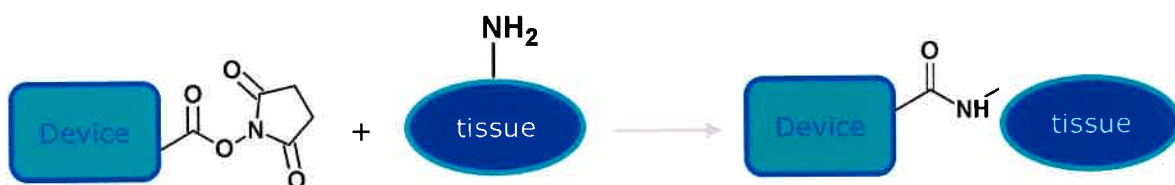
The device is composed of a mix of proprietary resorbable and tissue-friendly synthetic polymers with a proven history of effective use in other medical devices.

- Unique combination of a soft and pliable patch for easy and manual application to the target site and a patent protected adhesive layer for strong tissue adherence
- Bridges dural gaps up to 3-10 mm
- Watertight closure of the suture-line
- No need for premixing or use of an applicator nor additional suturing to the dura mater.



Proprietary polyurethane (PU) sheet for sealing against leakage

Lactide-caprolactone copolymer (LCC) foam with a synthetic adhesive for adhesion to the dura



Preclinical data reveal an excellent ease-of-use and safety profile

'New synthetic dural sealant with extreme dura adherence and burst pressure. Resorbed in 6-12 months. Fibrotic layer formation on top of the device'

van Doormaal T, et al. 2018. Cerebrospinal fluid leak prevention using a dural sealant; evaluation of current possibilities and design of a new synthetic patch. AANS, New-Orleans, Poster 439470

- Soft and pliable
- Does not swell
- Normal physiological and behavioral response, no systemic inflammatory reactions
- Strong adhesion to dura mater
- Does not adhere to brain tissue
- Scaffold for new fibrotic layer formation ('neo dura')



LIQOSEAL

The first in human study focuses on the safety and performance of LIQOSEAL in the reduction of CSF leakage

- This data will serve as basis for future comparative multi-centre studies.

Device	Dura Sealant Patch
Clinical Investigation Title	ENCASE Single-arm, open-label, multicenter study to Evaluate the safety and performance of Dura Sealant Patch in reducing CSF leakage following elective cranial surgery
Number of subjects	40 subjects
Patient population	Patients undergoing an elective cranial surgery (supra- and infratentorial) with dural closure
Study sites	The Netherlands: UMC-Utrecht, MC-Tilburg Switzerland: UH-Zurich
Duration	7 months (up to 4 months enrolment and 3 months follow-up) 1 st enrolment expected in Q4 2018
Primary Objective	Clinically assess the safety and performance of LIQOSEAL [®] , dural sealant patch as a means of reducing intra- as well as post-operative CSF leakage in patients undergoing elective cranial intradural surgery with a dural repair closure procedure
Primary Endpoint	Combined endpoint of any neurosurgical events defined as: - Safety: Incidence of wound infection confirmed by increase of CRP and positive cultures up to 30 days after surgery - Performance (a) Incidence of intra-operative CSF leakage after patch application at 15 cmH ₂ O of Positive End Expiratory Pressure (PEEP); (b) Incidence of percutaneous CSF leak confirmed by β -2 transferrin test up to 30 days after surgery
Secondary Endpoints [summarized]	Safety: Incidence device related AEs throughout the study up to 90 days after surgery Performance: Incidence of post-operative CSF (percutaneous & pseudomeningocele) up to 90 days after surgery Additional endpoints: Ease of use and application LIQOSEAL [®] , dural sealant patch
Inclusion criteria [summarized]	Male and female subjects who are \geq 18 years old Not pregnant/breastfeeding Subjects who are planned for an elective intracranial intradural surgery in whom a dural incision of at least 2 cm in length is necessary, which will be closed
Exclusion Criteria [summarized]	Subjects with any type of dural diseases in planned dural closure area Subjects requiring local radiotherapy in planned surgical area/radiotherapy within 90 days after surgery/require any device passing dural layer Primary closure of the dura mater with synthetic, non-autologous or autologous material other than galea A gap > 3 mm after primary closure of the dura mater

For more information, please contact

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LIQOSEAL®

LIQOSEAL®, dural sealant patch

Durable Closure Of Dura Mater.

Composition & IP

- Flexible and patent protected polyurethane (PU) sheet for sealing against leakage
- Unique and patented blend of lactide-caprolactone copolymer (LCC) foam with a synthetic adhesive for strong and lasting adhesion to the dura
- Protected design and a proprietary manufacturing process

Features	Benefits
• Ready-to-use-patch	• No premixing or applicator needed after opening the package
• One size (8x8 cm)	• Suitable to cover a wide range of suture closed dura surfaces
• Soft and pliable device	• Easy manual application to the dura
• Strong adherence to the dura	• Watertight closure of the dura (gaps up to 3mm) • Does not adhere to brain matter
• High pressure resilience	• Control of fluctuating intradural fluid pressures
• Does not swell	• Minimizes the chance on neural compression
• Scaffold for fibrotic layer formation	• Supports dura mater regeneration during the critical healing period

Dura Sealant Patch
8 x 8 cm