LIQOSEAL®

Instruction for Use, English [EN]

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

STERILE
Sterilized with irradiation. For single use only. Do not re-sterilize.

STORAGE
- Store in a dark, dry place between -30°C and -15°C.
- Use the device prior to the 'use by' specified on the package.

DESCRIPTION
LIQOSEAL® is a flexible patch which consists of two layers: the adhesive white foam layer and the blue sealing layer (see Figure 1).

One side of the patch consists of an adhesive white foam layer (foam-shaped, consisting of bioresorbable co-polyester); the adhesive layer. The white foam needs to be placed on the dura mater and will strongly adhere to the dural tissue due to the incorporated adhesive component and buffer salt.
This foam layer, with the incorporated PEG-NHS adhesive, reacts with amines in the dural tissue in a moist environment, forming covalent bonds between the device and the tissue.
The other side of the product, the blue sealing layer is a sheet made from blue colored bioresorbable polyurethane (PU). This layer forms the watertight seal, intended to reduce CSF leakage. The colorant is added to clearly distinguish between the sides of the product, so the correct side [white layer] will be placed to the dura.

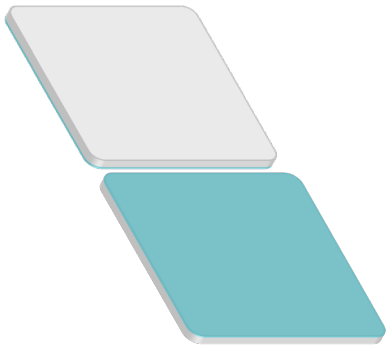

Figure 1 LIQOSEAL® with an adhesive white foam layer and blue sealing layer - schematic drawing

LIQOSEAL® is sterilized by radiation and packed in a blister package. The device is single-use and is a prescription product.

Table 1 Product specification

Catalogue #	Dimensions [cm]
DS01-015/05	5 (+/- 0.5) x 5 (+/- 0.5) (length x width)
DS01-024/08	8 (+/- 0.5) x 8 (+/- 0.5) (length x width)

INDICATIONS
LIQOSEAL® is indicated for use as an adjunct to standard methods of cranial dural repair to provide a watertight closure of the dura mater and reduce cerebrospinal fluid (CSF) leakage.

CONTRAINDICATIONS
- Do not use in the presence of an infection.

WARNINGS
- LIQOSEAL® is for single use only. Do not re-sterilize or re-use. Structural integrity and/or function may be impaired through cleaning, re-sterilization, or re-use and may cause adverse patient reactions. Accordingly, Polyganics will not be responsible for any direct or consequential damages or expenses resulting from re-use of (or any part of) the LIQOSEAL®.
- After taken out of freezer, do not place LIQOSEAL® back in the freezer when not used.
- Sterile unless package has been opened or damaged. Discard open unused patches.
- LIQOSEAL® should only be used by surgeons who are trained in dural closure during cranial surgery. Accordingly, Polyganics will not be responsible for any direct or consequential damages or expenses resulting from use by untrained personnel. The physician should consult recent literature on current medical practice on dural closure procedures.
- LIQOSEAL® should not be used when damaged.
- Do not press LIQOSEAL® before application.
- Do not wet LIQOSEAL® with any liquid before application.
- After storage and before use, do not expose LIQOSEAL® to high temperatures (above 40°C).

PRECAUTIONS
- LIQOSEAL® has not been tested in:
  - pregnant or breastfeeding women;
  - patients younger than 18 years;
  - patients with compromised immune system or autoimmune disease.
- Aluminum pouch and blister are not sterile.
- Keep aluminum pouch closed until usage.
- Do not apply more than 1 LIQOSEAL®.
- LIQOSEAL® is not intended to be explanted however, whenever required, the explantation procedure should be as follows:
  - during the length of the neurosurgical procedure; take LIQOSEAL® by one of the edges (tweezers are preferred) and rinse the space between the device and the dura mater with abundant saline solution while slightly pulling, until the complete device is removed. A new device can be applied thereafter;
  - after the procedure; on discretion of surgeon.
- Before placement of LIQOSEAL® on the dura mater; all other devices (such as hemostatic agents) should be removed to apply on a clean dura surface.
- LIQOSEAL® can be used in procedures involving autologous and collagen based duraplasty materials, with the following limitations:
  - large defects (>1 cm) can only be repaired with galea aponeurotica or periosteum since LIQOSEAL® does not adhere to collagen based substitutes, adipose or muscle tissue
  - LIQOSEAL® should overlap the duraplasty material in all instances with a minimum of 5 mm on all sides on clean dura mater.

ADVERSE EFFECTS
Potential, but not observed, risks and adverse events associated with the use of LIQOSEAL® may include, but are not limited to the effects of using non-autologous material, such as an allergic reaction to any of the device components and CSF leak and its associated complications such as infection, re-operation or longer hospital stay.

NOTE: These recommendations are designed to serve only as a general procedure. They are not intended to supersede the

institutional protocols or professional clinical judgment concerning patient care.
SURGICAL PROCEDURE

Pre-operative

1. Take the package with LIQOSEAL® out of the freezer at least **10 minutes** and maximum of 8 hours, before use. Either use or dispose the device.
2. Immediately remove the outer box and keep the pouch closed until usage. Pouch and blister are **not sterile**.

Intra-operative

1. Dura mater should be closed with standard method of suturing.
2. Rinse the dura mater surface from particles (such as bone dust) with physiological saline.
3. Dura mater surface should be moist (remove excessive fluid if applicable).
4. In case of bleeding, this should be stopped. Do not use LIQOSEAL® as a hemostatic agent.
5. Open the aluminum pouch and also the inner blister (both not sterile).
6. **DO NOT press LIQOSEAL® before application (white foam layer should not be compressed manually since it will not expand after being compressed).**
7. If the size of the trepanation is smaller than LIQOSEAL®, cut into the required size.
8. Cutting should be done by using a dry and sterile instrument (e.g. scissors) with the white side facing up.
9. Before placement on the dura mater; all other devices (such as hemostatic agents) should be removed to apply on a clean dura surface.
    a. Place the white side of the dry LIQOSEAL® against the dura mater, without pre-moistening the patch, with a gap of maximum 3 mm or smaller.
    b. Cover at least 5 mm beyond the margins (on the clean dura surface) of the gaps at all edges.
10. To position LIQOSEAL® correctly, compress LIQOSEAL® with the fingers; compression of the foam fixates the patch and is necessary for adhesion.
11. For an equal pressure distribution;
    a. Use a moist gauze (gauze should not be dripping) and cover the complete LIQOSEAL® with this gauze.
    b. Hold down LIQOSEAL® with a gentle pressure; equal to approximately one (1) kilogram, for a minimum of two (2) minutes.
12. Remove the light pressure and gauze carefully after at least two (2) minutes. There is no residual product which needs to be removed since the entire LIQOSEAL® will fully resorb. Avoid repositioning of LIQOSEAL®.

DISPOSAL

Dispose contaminated implantation and packaging materials utilizing standard hospital procedures and universal precautions for bio-hazardous waste.

USED SYMBOLS

	Consult instructions for use
	Do not use if package is damaged
	Manufacturer
	Use by date (year – month)
	Catalog number
	Do not reuse
	Do not re-sterilize
	Lot number
	Sterilized with radiation
	Keep dry
	Storage temperature limits
	MR Safe

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