AESCULAP® PATIENT INFORMATION

LYOPLANT[®] ONLAY

WHAT DOES YOUR BODY COME INTO CONTACT WITH AFTER THE IMPLANTATION OF LYOPLANT[®] ONLAY?

MATERIALS AND SUBSTANCES

Dura substitution products are used for dura mater replacement (one layer of the meninges) after surgery to prevent the outflow of cerebrospinal fluid.

The dura substitute Lyoplant[®] Onlay is a biological and absorbable dura substitute made of bovine pericardium and bovine split hide. The collagen-based implant is made of medical suitable material.¹



HOW LONG DOES YOUR IMPLANTED LYOPLANT® ONLAY LAST?

EXPECTED LIFETIME

Lyoplant[®] Onlay is composed of purified collagen and is absorbable, it does not need to be removed. The colonization of the implant by connective tissue cells begins after only a few days. The collagen will be converted into human connective tissue. The complete revitalization takes place within a period of one to three months after implantation. Many years of market experience and clinical trials have proven the safety and effectiveness of Lyoplant[®] Onlay for dura mater substitution.^{1,2}

WHAT YOU AND YOUR DOCTOR SHOULD LOOK OUT FOR!

INTERACTIONS WITH ENVIRONMENTAL CONDITIONS

The dura substitution product Lyoplant[®] Onlay does not interact with magnetic fields during an MRI scan (imaging procedure).

Nevertheless, it is recommended to inform the treating surgeon about any implants before an MRI scan. Show your implant card!

¹ Clinical trial. Neulen et al. Evaluation of efficacy and biocompatibility of a novel semisynthetic collagen matrix as a dural onlay graft in a large animal model, 2011.

² Aesculap AG. Greifzu, F. LYON-Study: Assessment of the performance of Lyoplant(R) Onlay for Duraplasty. A non-interventional, multi-center Post Market Clinical Follow-up (PMCF) Study. 2019.

CONFIGURATIONS

| Sizes | | Content | ArtNo. |
|----------------|---------|---------|----------|
| 2.5 x 2.5 cm | 1" x 1" | 1 piece | 106 7010 |
| 5.0 x 5.0 cm | 2" x 2" | 1 piece | 106 7020 |
| 2.5 x 7.5 cm | 1" x 3" | 1 piece | 106 7030 |
| 7.5 x 7.5 cm | 3" x 3" | 1 piece | 106 7040 |
| 10.0 x 12.5 cm | 4" x 5" | 1 piece | 106 7050 |

Risks, adverse effects and interactions

Potential complications that the manufacturer is currently aware of:

- Infection
- Cerebrospinal fluid leakage
- Adhesion
- Allergic reactions to proteins of bovine origin

Risks, side effects and interactions caused by the patient's comorbidities or in combination with other products are not known.

Incident Reporting

Any serious incident occurring in relation to the device should be reported to B. Braun Australia Pty Ltd and to the Therapeutic Goods Administration.

Phone: 1800 206 045

www.bbraun.com.au

<u>www.tga.gov.au</u>

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