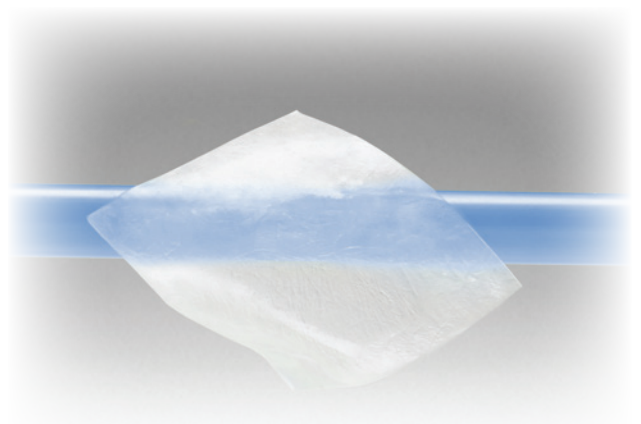


DURAMESH DURAMESH LYO

Transparent equine pericardium membrane for duraplasty



biosynth
LIFE SCIENCES

DURAMESH DURAMESH LYO

Duramesh and Duramesh Lyo (previously marketed as AudioMesh Neuro and Lyomesh Neuro VR, respectively) are biological membranes derived from equine deantigenated pericardium, intended to be used as surgical collagen membranes during neuro surgical procedures for a CSF-impermeable sealing of Dura Mater defects. Duramesh is conserved in a liquid, alcoholic-based solution, while Duramesh Lyo is freeze-dried.

The reason why choosing equine source, lies in the immunity of the horse to Bovine Spongiform Encephalopathy (BSE)¹.

BSE, also called “mad cow disease” is a contagious infection caused by a prion, a pathogen impossible to sterilize without damaging the structure of the membrane. Thanks to equine BSE free source, it's possible to deantigenate and sterilize the membrane conserving native collagen fibers network, as shown in SEM imaging analysis. This particular process, gives to the membrane Duramesh / Duramesh Lyo unique features, particularly useful for its surgery purpose.

Biosynth processing technology, in fact, enables to keep native collagen fibers and make them compact, thus reducing pericardium thickness. After the treatment, the layer

becomes transparent, allowing to keep the visual check of the underneath tissues during the whole surgery.

At the same time, the membrane remains extremely resistant: for this reason, Duramesh Duramesh Lyo is suitable even for those surgeries with a high CSF pressure – such as in the posterior cranial fossa – where a very tight fixation is recommended.

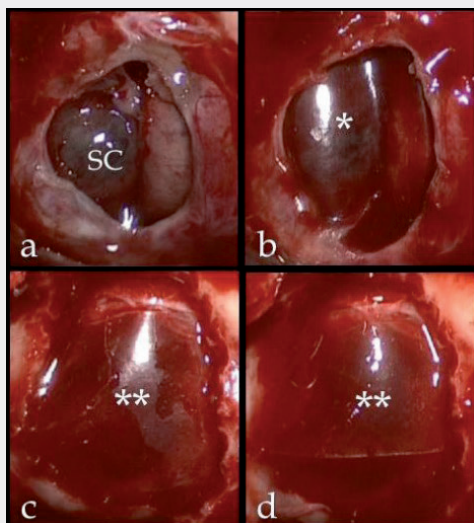
Moreover, the membrane acquires a shape memory, so that it will easily lay flat providing an excellent adaptability to any anatomy.

The collagen compacting procedure increases the sheet suturing resistance of the membrane as well. The sheet traction and pressure resistance indexes are higher than the ones of the collagen gel obtained through purification and artificial reticulation.

Liquid conserved membrane – Duramesh

The conservation in liquid gives to the membrane a high handling, thanks to its pre-hydrated state.

The conservation liquid needs to be rinse as described in the Instruction For Use.



A: Intraoperative image showing a thinned suprasellar cistern descending into the sellar cavity after the removal of a pituitary adenoma;

B: A pericardium sheet was used to protect and enforce the suprasellar cistern and prevent its postoperative rupture and consequent CSF leak;

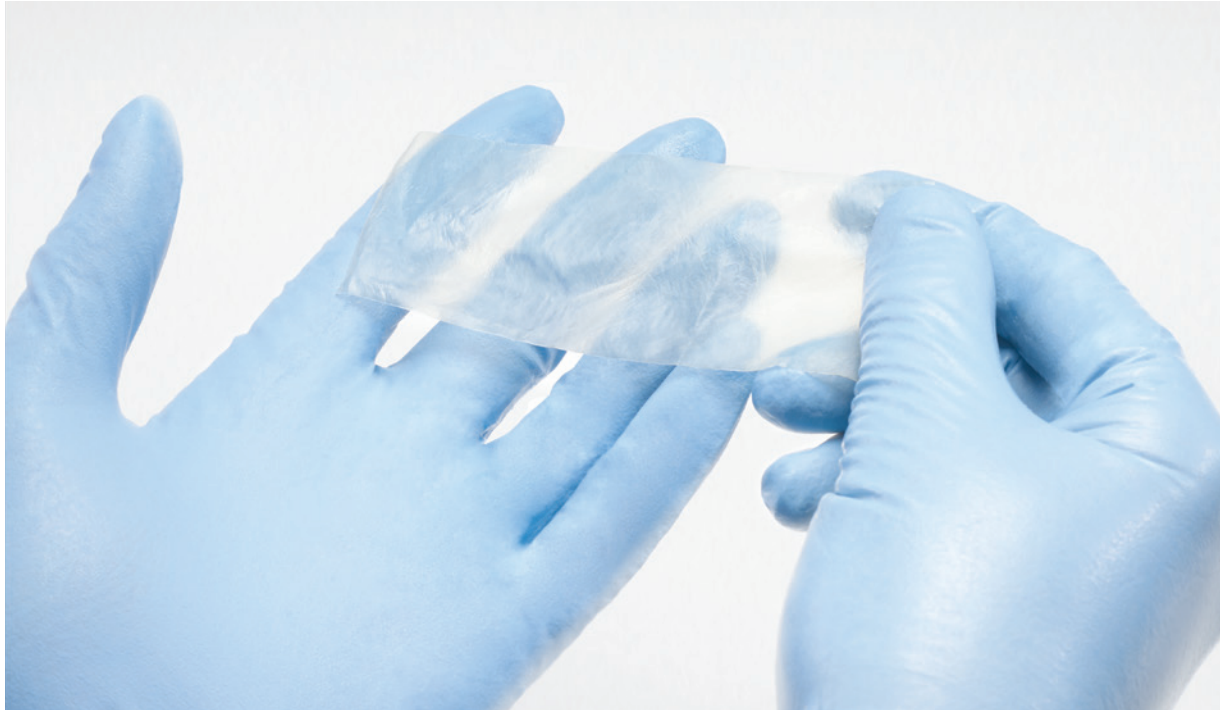
C, D: Multiple layers of Duramesh dural substitute placed in extradural space to close the sellar floor. The high transparency of Duramesh is visible.

*: Single layer of Duramesh placed intradurally, over the Suprasellar Cistern;

** : Duramesh placed extradurally;

SC: suprasellar cistern.

1 - Equine tissues for medical devices: safety concerning prion diseases transmissible to humans; E. Scanziani, Dept. of Veterinary Sciences and Public Health - University of Milan, Italy 2012



Freeze-dried membrane – Duramesh Lyo

Duramesh Lyo is ready for use since it doesn't need to be rinsed. It can be rehydrated directly in the operating field.

Duramesh / Duramesh Lyo

- Is water tight and prevents CSF leakages
- Thanks to its high mechanical resistance it can be easily fixed with fibrin glue and/or suturing points²
- Differently from other devices currently on the market which are thicker and harder, the transparency, biocompatibility and adaptability of Duramesh – Duramesh Lyo make this membrane an excellent dural substitute
- Doesn't adhere to the cerebral cortex³

Duramesh /Duramesh Lyo is a membrane derived from equine pericardium and processed chemically to remove cells, pathogens and pyrogenic elements.

Duramesh /Duramesh Lyo has to be used as Dura Mater replacement or reinforcement in neurologic surgeries to grant CSF impermeability. The dense network of collagen fibers provides a high resistance of the graft and grants to the cells an optimal tissue to regenerate Dura Mater. Thanks to these characteristics, the membrane blocks any leakage of CSF, essential requirement for a fast and safe Dura Mater healing. Duramesh /Duramesh Lyo is thin and transparent and – since it's free from any additives – is highly tolerable.

Reabsorption time is about 3 months.

2 - Equine pericardium for dural grafts: clinical consideration and technical note; A. Sacchelli, Division of Neurosurgery of Villa Maria Cecilia Hospital, Cotignola, Italy

3 - Equine pericardium for dural grafts: Clinical results in 200 patients. Montinaro A., Gianfreda C.D., Proto P., Division of Neurosurgery, "V. Fazzi" Hospital, Lecce, Italy

Duramesh - Duramesh Lyo: A reliable versatile solution in duraplasty

- Class III medical device according to European classification 93/42/CEE and following edits
- Certified according to EN ISO 13485
- Beta rays sterilized
- Double sterile packaging for hygienic transfer to the sterile surgery area
- Hundred thousand units sold in more than 15 years (device previously known as Audiomesh Neuro / Lyomesh Neuro)

WARNINGS

Duramesh - Duramesh Lyo is intended for use in cranial and spinal procedures where the reinforcement or substitution of the dura mater is needed.

Duramesh - Duramesh Lyo is contraindicated in patients with known sensitivity to equine derived materials. Do not use in repair of neural tube defects or anterior spinal surgeries with dural resection. See instruction for use for additional information.

HOW TO START

STEP 1 - OPEN

- Before implantation, rinse Duramesh in saline or isotonic solution as written in the Instructions For Use. Duramesh Lyo can be hydrated directly in place

STEP 2 - IMPLANTATION

- Duramesh - Duramesh Lyo can be easily cut and shaped with scissors

STEP 3 - FIXATION

- During on-lay procedure, the implant should overlap the dura defect by about 1 cm to ensure a proper adhesion and a safe CSF-tight barrier⁴
- Duramesh - Duramesh Lyo can be sutured, glued (with fibrin glue) or both at surgeon's choice, depending by the fixation needed
- Other sealants can also be used to fix the membrane water-tightly

Please refer to the package insert and other labeling for a complete list of indications, contraindications, precautions and warnings.

For further information on Biosynth Products, please contact your local Biosynth Representative.

Bibliography:

- Equine pericardium for dural grafts: clinical consideration and technical note; A. Sacchelli, Division of Neurosurgery of Villa Maria Cecilia Hospital, Cotignola, Italy
- Equine tissues for medical devices: safety concerning prion diseases transmissible to humans; E. Scanziani, Dept. of Veterinary Sciences and Public Health - University of Milan, Italy
- Equine pericardium for dural grafts: Clinical results in 200 patients. Montinaro A., Gianfreda C.D., Proto P. Division of Neurosurgery, "V.Fazzi" Hospital, Lecce, Italy
- Use of Duramesh Lyo augmented with TissuePatchDural™ for repair of dural defect in spinal cord herniation - Clinical Series - Mr Marcel Ivanov, MD, PhD, MSc, FRCS Consultant Neurosurgeon and Spine Surgeon, Sheffield Teaching Hospitals, UK - 2015

⁴ - Use of Duramesh Lyo augmented with TissuePatchDural™ for repair of dural defect in spinal cord herniation - Clinical Series - Mr Marcel Ivanov, MD, PhD, MSc, FRCS Consultant Neurosurgeon and Spine Surgeon, Sheffield Teaching Hospitals, UK - 2015

DURAMESH DURAMESH LYO

REFERENCES TAB AND SPECIFICATIONS

Duramesh			Duramesh Lyo		
Device	Ref. Code	Dimension (mm)	Device	Ref. Code	Dimension (mm)
Duramesh	R 20.09 H	Disc, ø 9	Duramesh Lyo	LYO-20.09H	Disc, ø 9
Duramesh	R 20.10 H	Disc, ø 14	Duramesh Lyo	LYO-20.10H	Disc, ø 14
Duramesh	R 20.11 H	Disc, ø 50	Duramesh Lyo	LYO-20.11H	Disc, ø 50
Duramesh	R 20.12 H	Disc, ø 75	Duramesh Lyo	LYO-20.12H	Disc, ø 75
Duramesh	R 20.13 H	Disc, ø 125	Duramesh Lyo	LYO-20.13H	Disc, ø 125
Duramesh	R 003X120 H	3 x 120	Duramesh Lyo	LYO-003X120H	3 x 120
Duramesh	R 006X140 H	6 x 140	Duramesh Lyo	LYO-006X140H	6 x 140
Duramesh	R 010X010 H	10 x 10	Duramesh Lyo	LYO-010X010H	10 x 10
Duramesh	R 010X030 H	10 x 30	Duramesh Lyo	LYO-010X030H	10 x 30
Duramesh	R 010X100 H	10 x 100	Duramesh Lyo	LYO-010X100H	10 x 100
Duramesh	R 010X140 H	10 x 140	Duramesh Lyo	LYO-010X140H	10 x 140
Duramesh	R 015X200 H	15 x 200	Duramesh Lyo	LYO-015X200H	15 x 200
Duramesh	R 015X030 H	15 x 30	Duramesh Lyo	LYO-015X030H	15 x 30
Duramesh	R 020X030 H	20 x 30	Duramesh Lyo	LYO-020X030H	20 x 30
Duramesh	R 020X070 H	20 x 70	Duramesh Lyo	LYO-020X070H	20 x 70
Duramesh	R 020X100 H	20 x 100	Duramesh Lyo	LYO-020X100H	20 x 100
Duramesh	R 020X140 H	20 x 140	Duramesh Lyo	LYO-020X140H	20 x 140
Duramesh	R 020X200 H	20 x 200	Duramesh Lyo	LYO-020X200H	20 x 200
Duramesh	R 020X250 H	20 x 250	Duramesh Lyo	LYO-020X250H	20 x 250
Duramesh	R 025X030 H	25 x 30	Duramesh Lyo	LYO-025X030H	25 x 30
Duramesh	R 030X040 H	30 x 40	Duramesh Lyo	LYO-030X040H	30 x 40
Duramesh	R 030X060 H	30 x 60	Duramesh Lyo	LYO-030X060H	30 x 60
Duramesh	R 040X050 H	40 x 50	Duramesh Lyo	LYO-040X050H	40 x 50
Duramesh	R 040X070 H	40 x 70	Duramesh Lyo	LYO-040X070H	40 x 70
Duramesh	R 040X100 H	40 x 100	Duramesh Lyo	LYO-040X100H	40 x 100
Duramesh	R 050X050 H	50 x 50	Duramesh Lyo	LYO-050X050H	50 x 50
Duramesh	R 050X110 H	50 x 110	Duramesh Lyo	LYO-050X110H	50 x 110
Duramesh	R 060X080 H	60 x 80	Duramesh Lyo	LYO-060X080H	60 x 80
Duramesh	R 060X120 H	60 x 120	Duramesh Lyo	LYO-060X120H	60 x 120
Duramesh	R 060X140 H	60 x 140	Duramesh Lyo	LYO-060X140H	60 x 140
Duramesh	R 070X080 H	70 x 80	Duramesh Lyo	LYO-070X080H	70 x 80
Duramesh	R 075X075 H	75 x 75	Duramesh Lyo	LYO-075X075H	75 x 75
Duramesh	R 120X160 H	120 x 160	Duramesh Lyo	LYO-120X160H	120 x 160
Duramesh	R 100X125 H	100 x 125	Duramesh Lyo	LYO-100X125H	100 x 125
Duramesh	R 130X130 H	130 x 130	Duramesh Lyo	LYO-130X130H	130 x 130

DURAMESH DURAMESH LYO

PROPERTIES

- Biocompatible, native and resorbable graft
- Equine BSE-Free source
- Can be sutured or glued for fixing, or both
- Transparent membrane to allow visual control
- Shape memory for easy handling
- Suitable for both overlay and underlay technique
- 100% impermeable to CSF
- Available in liquid or freeze-dried

