TUTOPLAST®

YoMaGen
YoMaYa Medical Trading

Fascia Lata

Allogenic Collagen Membrane

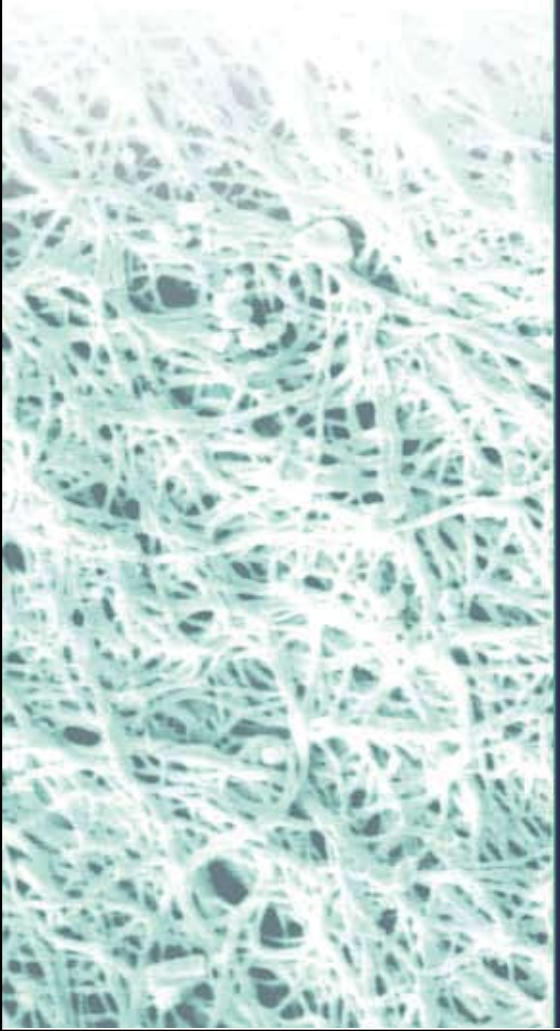
Soft Tissue Substitution With Allogenic Connective Tissue

Sterile

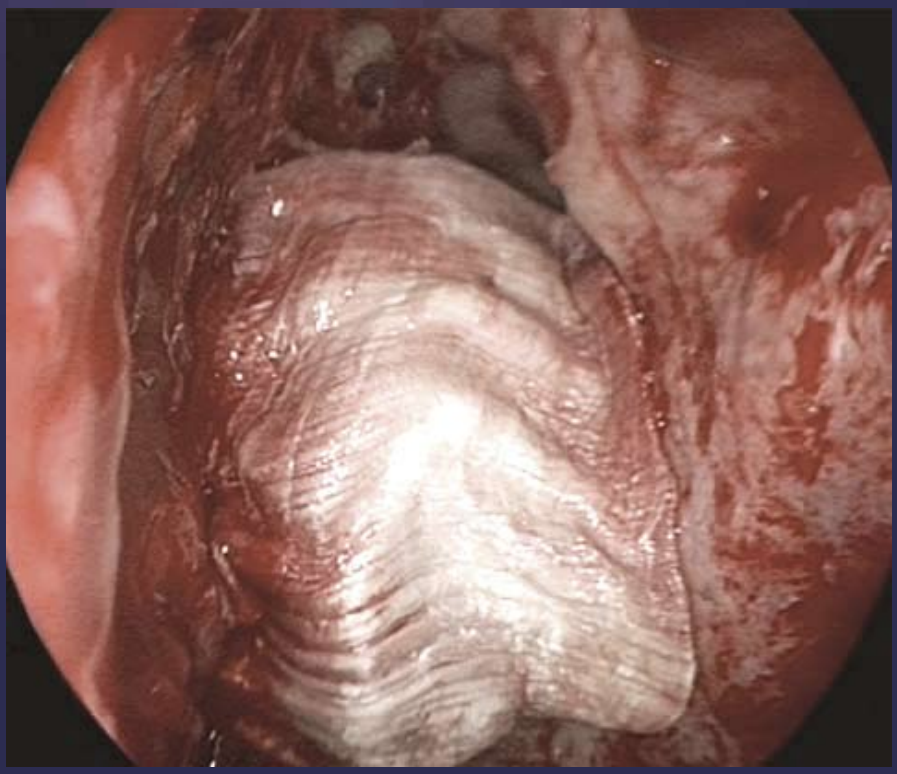
Tearproof

Pliable

Versatile



Condition after 2 layer duraplasty (underlay and onlay) at the anterior skull base using YoMaPlast Fascia Lata.



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Product Features

- **The Tutoplast® process is reliable and proven for tissue preservation and is validated for viral and prion inactivation**
  - Until today no report of infection or allergic reaction with an outstanding safety record
- **Scaffold for the ingrowth of the patient's own tissue**
  - Remodelling usually occurs within 12 months depending on implant site and patient status
  - Offers great strength and adapts smoothly to surface contours
  - Fixation is achieved with suturing, gluing, clipping and / or stapling
- **Long standing clinical experience**
  Clinical applications with equivalent results to autologous fascia lata[3] and long term follow-up:
  - ENT / Neurosurgery[1]
  - Ophthalmology[2]
  - Plastic Surgery[3]

YoMaPlast Fascia Lata

Product Code	Size
139709019	60 mm x 120 mm
139709045	60 mm x 80 mm
139709014	40 mm x 50 mm
139709048	10 mm x 140 mm
139709035	3 mm x 120 mm
139709036	Ø 14 mm

References

1 SCHICK B., BRORS D., IBING R., DRAF W.; Long-term study of endonasal duraplasty and review of the literature; Ann Otol Laryngol 110:2001

2 DETORAKIS E. T., IOANNAKIS K., DRAKONAKI E. E., GANASOULI D., KOZOBOLIS V. P; Processed Fascia Lata as an Alternative Implant Material in Evisceration; Ophthalmic Plastic and Reconstructive Surgery Vol. 21, No. 2, pp 133-137 ©2005

3 GUERDAL C., ERDENER U., ORHAN M., IRKEC M.; Autogenous versus allograft fascia lata in frontal sling surgery long-term results; European Journal of Ophthalmology / Vol. 13 no. 2, 2003 / pp. 202-206

Tutogen Medical GmbH
Industriestraße 6
D - 91077 Neunkirchen am Brand
Germany

Instructions for use

YoMaPlast Fascia lata

Name of the medicinal product
YoMaPlast Fascia lata.

Composition
- Pharmaceutically active substances: dehydrated human fascia lata, sterilised by gamma-irradiation
- Other ingredients: none.

Pharmaceutical form and pack sizes
The packet contains a sterile pre-cut portion of dehydrated human fascia lata. One square centimetre of YoMaPlast Fascia lata consists of approx. 25 mg of human connective tissue.

Class or indication group, mode of action
Transplant of human origin. When implanted into tendon, ligament or fascial defects, YoMaPlast Fascia lata acts as a spacer until replaced by the body's own tissue.

Marketing authorisation holder and manufacturer
Tutogen Medical GmbH, Industriestrasse 6, D-91077 Neunkirchen am Brand.

Indications
Tendon, ligament or fascial defects subject to unidirectional loading. Positive clinical experience has also been gained with use in neurology, orthopaedics, oromaxillofacial surgery, ophthalmology, urology and gynaecology, in plastic surgery, in ENT surgery, and in abdominal procedures.

Contra indications
YoMaPlast Fascia lata should not be used when bi- or multidirectional loading of the transplant is required. YoMaPlast Fascia lata should not be implanted into dead or infected body tissues. A reduction in the healing rate should be expected when implanted into body tissues with compromised blood supply.

Precautions for use
The YoMaPlast transplant remains sterile and endotoxin-free as long as the pack is undamaged. If there is external damage to the pack it must be assumed that the product is not sterile. Should the transplant become unsterile in the course of the operation, it must be discarded. Proper placement and fixation are decisive prerequisites for the successful use of the transplant.

Interactions with other agents
None known.

Warnings
As with any operation, there is a risk of infection. Although the Tutoplast® purification process is capable of virtually eliminating the antigenic properties of the transplant, and during 20 years of use no case of immunological rejection has been observed, the possibility of such a rejection can never be completely excluded.

Dosage
The size of the transplant is determined by the size of the particular tissue defect.
Technical comments for the surgical procedure: it is recommended that YoMaPlast Fascia lata be placed in sterile, endotoxin-free 0.9% saline solution for a few minutes before use. This will render the fascia even more supple, allowing it to be handled more easily during surgical procedures. Either absorbable or non-absorbable suture material may be used for securing YoMaPlast Fascia lata. Absorbable suture material with an atraumatic round-bodied needle should be selected for continuous running sutures. The suture strength will depend on the indication and procedure in question. The suture line should be place with a 2-3 mm margin along the edge of the transplant. YoMaPlast Fascia lata should be used in cases where either tension-free or a unidirectional loading of the material is expected. The tissue is highly resistant to axial loading along the course of the fibres. By contrast, only low transverse loading is possible. Fascia duplication is recommended for suture lines under particular tension.

Method of administration
For implantation.

Overdose and other dosage errors
Not applicable.

Undesirable effects
There are no known side effects.
The transmission of infectious diseases by hitherto unknown or undetectable pathogens cannot be entirely excluded. Patients should be encouraged to report any side effects to their attending physician or dispensing chemist.

Precautions
Expiry date/shelf life:
If the original package is undamaged, YoMaPlast Fascia lata remains stable for five years. The transplant should no longer be used after the expiry date which is stated on the container and outer wrapping.
Signs of spoilage:
If the pack is opened but the transplant not used, the transplant must not be resterilised and should therefore be discarded. After opening the pack any material remaining after the procedure should be destroyed (not resterilisable).
Special storage details:
Store the medical device in a clean, dry place, protected from direct sunlight at room temperature between 15° C and 30° C.
Precautions for disposal:
None.
Date of revision of the text: 02/2007 „06"

Pharmacological and toxicological properties and details on pharmacokinetics and bioavailability:
- pharmacological properties: none
- toxicological properties: none
- pharmacokinetics: The process of absorption and formation of new tissue usually begins after 1-2 days and extends over a period of weeks, months, or years. This transformation process depends on the size of the transplant and the responsiveness of the transplant bed.

Further information is added to the product
Keep medicinal products out of the reach and sight of children.

Order

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