TUTOMESH®
Soft Tissue Replacement with Tutomesh®
an Avital, Acellular Xenogenic Collagen Membrane

perfect results
Tutomesh® is an avital, acellular, xenogenic collagen membrane made from bovine pericardium, which meets all standards of safety and quality, for instance according to the German Medical Device Act (MPG) or according to the European Directives (93/42/EEC and 2003/32/EC). The raw material exclusively originates from BSE-free countries and is subjected to the proven Tutoplast® process.

Tutomesh® consists of 92% native collagen type I, which is maintained in its three-dimensional structure and for its biomechanical properties. This renders the transplant extremely resistant to tensile forces without impeding the remodeling process after implantation.

With the use of meshes, the recurrence rate, particularly after the repair of incisional hernias, has dropped decisively throughout the past years. However, this success was at the price of new risks like for instance foreign-body sensation, mesh encapsulation, granuloma formation, mesh migration, adhesion, seroma, or mesh shrinkage.

Especially, when it comes to large and potentially infected incisional hernias, or to laparostoma where primary abdominal wall closure may not be achieved, alloplastic materials reach their limits. Therefore, the majority of surgeons consider the implantation of alloplastic material being contra-indicated in such cases.

During the recent years, biological meshes as an appropriate alternative to autogenic or allogenic materials moved into the focus of interest. For almost a decade, surgeons in the USA have applied acellular human dermis for the repair of complicated incisional hernias. However, these materials have limited availability, are expensive, and raise public ethical concerns, particularly in Europe. In addition, due to their elasticity, the efficacy seems to be constrained.

Allogenic meshes are rarely used outside of the USA. In contrast, xenogenic materials – from different origins (for instance bovine, porcine, and equine) and with different methods of preservation of the raw tissue – are more and more accepted as a useful option to replace autografts or synthetic materials.

**Tutomesh®**

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Tutomesh® is a natural collagen membrane without further treatment for cross-linking. If handled and placed appropriately, the mesh acts as a scaffold which allows the in-growth of vessels and fibroblasts, with their deposition of site-specific collagen. In this way Tutomesh® is gradually replaced by the patients own tissue, which will transform into the site specific tissue by time.

Tutomesh® is a medical device manufactured in Germany and it carries the €-mark (€1275).
After a ventral approach, the hernia sack is being prepared. Depending on the availability of mobile peritoneum, the peritoneal defect may be closed.

The posterior fascial layer of the rectus muscle is split and dissected bluntly. The medial part of the fascia is reverted ventrally. Tutomesh® is then fixated at the medial edge of the lateral portion of the posterior rectus fascia. If the peritoneal defect could not be closed, it is recommended to place Tutomesh® with the smooth side facing the abdominal cavity, in order to avoid or minimize adhesions. As the remodeling of Tutomesh® into the patients own vital tissue requires unimpeded migration of cells (e.g. fibroblast) and vessel in-growth, its contact to well vascularized tissue is necessary.

For the fixation of the Tutomesh®, monofilament and slowly resorbable suturing material is recommended. In order to prevent the suture from cutting the mesh, the edge of the Tutomesh® should be folded-in for approximately 1 cm. Clinical practice suggests that the mesh is perfectly positioned by fixing the mesh at the four points with interrupted sutures; in between these points with single knots, Tutomesh® may be fixed with running sutures.

The medial part of the posterior rectus sheath is folded up in medial direction and closed by a running suture. In this way a second layer can be obtained, which contributes to the stabilization of the abdominal wall.

According to histological examinations and animal experiments, we conclude that in the first phase of tissue remodeling, native collagen is arranged as known from scar tissue. In the later course, this tissue may become site specific and merely distinguishable from the patient’s genuine tissue.1

Clinical experience with Tutomesh® in the repair of incisional hernias

In a retrospective study, Urbach et al. report the outcome of 43 patients, who had surgery for a complicated incisional hernia (except one patient). Out of more than 300 patients, who received Tutomesh®, these 43 patients fulfilled the inclusion criteria, which were set among others to a minimum follow-up of two years or a complicated incisional hernia.

The average follow-up was 40 months, the average hernia size was 9.7 cm. 73% of the patients were overweight or obese. Only patients classified as ASA II (58.1%) or III (41.9%) participated. A relapse occurred in 9.3% of the cases; all these relapses happened during the first two years, no relapse was reported later than two years after surgery. This finding compares favorably to any other published result, particularly in the view of the negative patient selection.

Rueda reported 30 cases of incisional hernia repair (clean or clean-contaminated) with Tutomesh®, performed between February 2008 and February 2009 and a follow-up of up to 1 year. The only adverse event found was one seroma, no other complication occurred. Although the follow-up period may be short and the patient selection is not as unfavorable as in Urbach’s study, this experience supports the above mentioned findings.

Francioni and Testini demonstrated in a number of cases with most difficult laparotomies (for instance severe peritonitis, stercoral contamination) that Tutomesh® provides an excellent opportunity to close the abdomen in a single-stage procedure with an amazingly uneventful post-operative period.

Sampietro published outstanding results after using Tutomesh® in patients suffering from autoimmune diseases like Morbus Crohn and colitis ulcerosa, who underwent several surgical procedures before.

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<th>Study results Urbach (Offenbach)</th>
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Collagen Membrane (Tutomesh®)
Retrolective Study Offenbach (Urbach et al.)

**Criteria for patient inclusion:**
- **Method:** Mesh position sublay or posterior wall of the rectus sheet
- **Follow up:** 24–60 months (medium 40)
- **Size of the defect:** >4 cm
- **Material:** Xenogenic collagen (Tutomesh®)

**Criteria for patient exclusion:**
- **Method:** Mesh position onlay, inlay or IPOM
- **Size of the defect:** <4 cm
- **Material:** Other meshes, laparostoma treated with hypobaric therapy

**Results:**
- **Patients:** 43 (follow-up after 1, 2, 3 and 5 years)
- **Age:** 64 ± 12.4 years
- **Smokers:** 29.3% (COPD 9.3%)
- **BMI:** 28.5 ± 4.0 (postoperative 28.8 ± 4.5)
- **Size of defect:** 9.7 cm ± 4.5 cm
- **Recurrence rate:** 9.3% (within the first 2 years after operation)
- **Wound infection rate:** 5.3% (within the first 3 months after operation)
- **Mesh infection:** 0%
- **Seroma:** 7.9%
- **Sensitivity disorders:** 18.2% (after 1 year), 5.9% (after 2 years)
- **Chronic pain:** 2.3% (in the incisional area)
- **Mean hospital stay:** 10.1 days
- **No cases of mesh infection, migration or shrinkage**

4 Rueda M. et al.: Empleo de malla de colágeno en la reparacion de hernias ventrales. Presented at the meeting of the Spanish hernia society 2009 (Murcia)
6 Testini M. et al.: La chirurgia die laparoceliin presenza di un campo operatorio contaminato; l’esperienza con una protesi biologica. Presented at the meeting of the Italian society of abdominal surgery 2008 (Bari)
7 Saxena A K. et al.: Delayed three-stage closure of giant omphalocele using pericard patch. Hernia 2008; Vol 12; 201 - 203
Process of tissue remodeling

Histological specimens of Tutomesh® before and after implantation show the milestones of tissue remodeling from the native Tutomesh® as an acellular, avital tissue before implantation to the gradual replacement by patient’s tissue with vessels and vital cells after 9 and 36 months.

**Histology (movat pentachrome staining) of a bovine membrane processed by Tutoplast®**
Collagen is stained in yellow, elastin fibers appear in red. The biological mesh is avital and therefore no cells, which may cause inflammatory reactions, are detectable.

**Histology (movat pentachrome staining) 9 months after Tutomesh® implantation**
Collagenous tissue with blood vessels (marked by the arrow in the picture) and vital cells (marked by the arrow heads in the picture) signal revascularization. The newly deposited collagen cannot be morphologically distinguished from the patient’s own tissue.

**Histology (movat pentachrome staining) 36 months after Tutomesh® implantation**
The tissue shows significant revascularization with blood vessels and cells; it is completely remodeled and integrated into the abdominal wall. The regular structure of the new tissue is clearly visible.

36 months after implantation, Tutomesh® usually is completely remodeled.

As seen in the right picture, after 36 months the implant has developed into stable connective tissue with a smooth and shiny surface, just as typical for the location.
Tutogen Medical GmbH (an RTI-Biologics company, FL (USA)) develops, produces and markets allogenic and xenogenic tissues for all surgical disciplines. As a common feature, both allogenic and xenogenic materials are subjected to the same preservation process, the Tutoplast® process, unrivaled for safety, quality and reliability. Together with RTI-Biologics, Tutogen Medical GmbH is one of the leading companies for avital, acellular allogenic and xenogenic tissue transplants.

Since the early 1970s, the Tutoplast® process has been a landmark for the preservation and sterilization of tissues. Several million of Tutoplast® processed allogenic and xenogenic transplants were successfully implanted since then. The Tutoplast® process is a unique, multi-step preservation and sterilization process for connective and musculoskeletal tissues. It eliminates and inactivates antigens and pathogens while it maintains the biomechanical properties and the structure of the processed tissue. The inactivation and elimination capability of the entire process regarding viruses, prions and pathogens was confirmed by independent laboratories.

Tutoplast® processed tissues are sterile (SAL10−6)!
If a surgical procedure requires a liquid-tight transplant, please ask for Tutopatch®.
All deliveries are subject to the terms and conditions of Tutogen Medical GmbH, Status August 2007. These can be seen and printed out under http://www.tutogen.de/de/pdf/agb.pdf. Upon request we will send you the terms and conditions by mail.

Xenogenic products are preserved by the Tutoplast® process. Xenogenic products are certified as Medical Devices in the EU (CE 1275). As for the availability of products in your country it may vary depending on your national regulations for xenogenic products. Please contact the local distributor or Tutogen Medical GmbH Germany for details.

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