



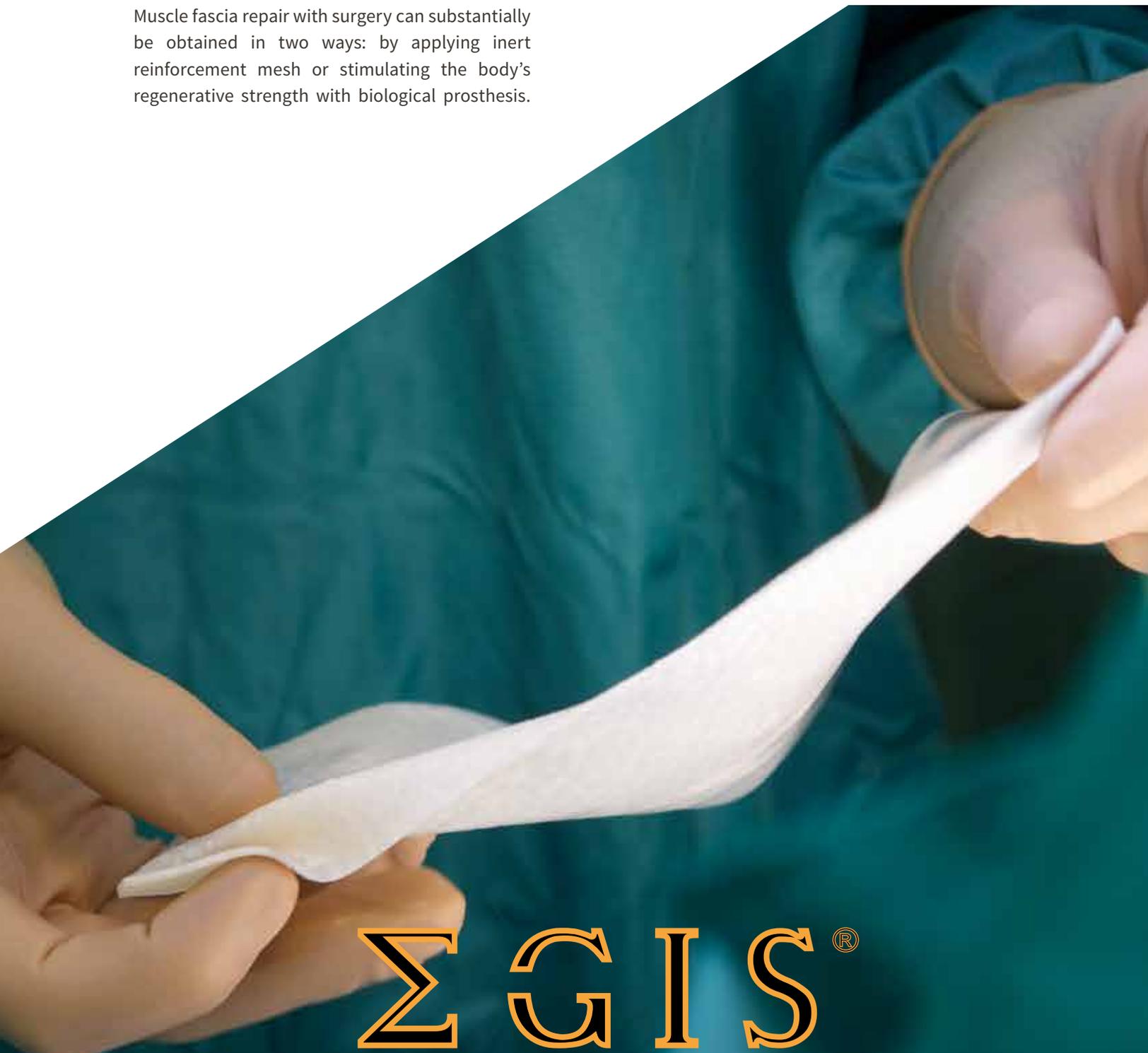
ΣGIS®

Acellular Dermal Matrix

ΣGIS®

Regenerative Force

Muscle fascia repair with surgery can substantially be obtained in two ways: by applying inert reinforcement mesh or stimulating the body's regenerative strength with biological prosthesis.



ΣGIS®

Innovation and Myth

The term EGIS® comes from the Greek aegis and identifies the indestructible skin which covered Zeus' shield, fashioned by Hephaestus. EGIS® is a highly valuable protective membrane and is currently the result of the most advanced research in the biotechnology field.

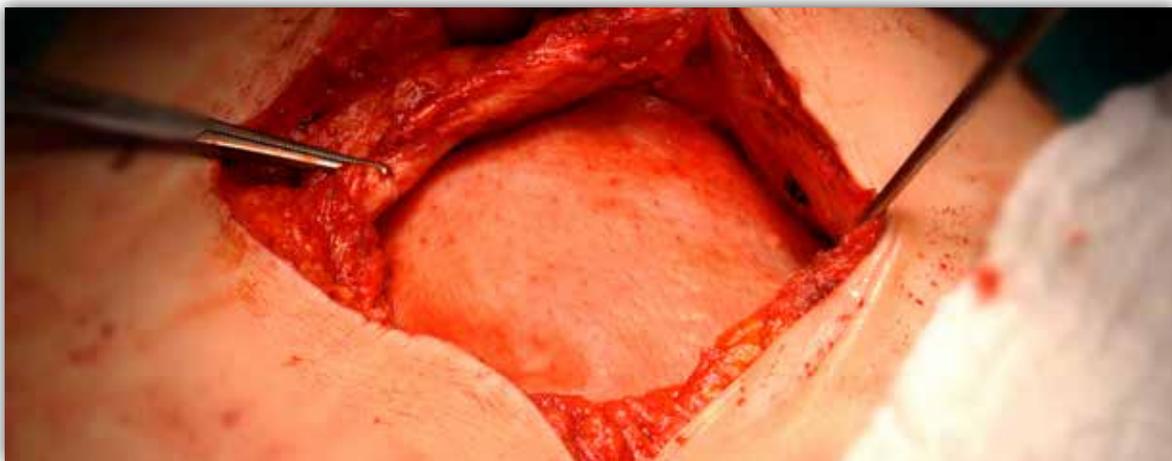
Regenerative surgery

REPAIR OF THE MUSCLE FASCIA with biological prostheses that are not artificially altered (not cross-linked) is based on biological processes which lead to the reconstruction of the missing fascia with tissue newly formed by the body itself. The mechanisms which the organism uses to regenerate the scaffolds of natural biomaterial have been known for only a few decades:

- Inflammation: the body's initial reaction to the implant.
- Regeneration: healing phase. Granulation tissue formation.
- Remodelling: replacement of the biological prosthesis with new connective tissue.

Reparative surgery

THE REPAIR OF THE MUSCLE FASCIA with synthetic or cross-linked patches is based on the concepts of physical and mechanical resistance, but from a biological viewpoint no tissue generation phase is included. Synthetic patches and artificially modified biological patches (cross-linked) induce defence reactions in the body. After an initial inflammatory phase, these inert materials steer the organism's healing process towards encapsulation of the implant.^{1,2,3}



Reparative surgery benefits from the properties of the biomaterials ability to reproduce a certain function from a physical and mechanical viewpoint; however, regenerative surgery is based on the ability of active biomaterials to transform themselves into autologous tissue with anatomical-functional recovery.

Clinical outcome and anatomical-functional recovery

The choice of biomaterial has proven to be crucial for guiding tissue healing processes not just towards a positive clinical outcome, but also towards an anatomical-functional recovery.

EGIS® is a natural non-cross-linked matrix composed exclusively of porcine derived collagen (ADM-Acellular Dermal Matrix) which is fundamentally the same as human collagen. Thanks to its bioavailability it is recognized by the body as if it were part of it. It acts as an active scaffold in the granulation phase guiding healing towards long term clinical success (anatomical-functional recovery).

Natural matrix, mechanical properties

Recent studies have demonstrated that early complications after biological matrix implant may depend on imperfect decellularisation of the matrix, and on the presence of cross-linked substances or preservatives.^{4,5,6}

The exclusive production process which EGIS® undergoes was developed in order to guarantee a completely natural product, not cross-linked, and without the presence of any chemicals which can amplify the inflammatory phenomenon and slow down the regular progression of tissue regeneration.

The native protein structure gives EGIS® excellent mechanical properties able to fully withstand intra-abdominal pressure.

To guarantee the characteristics of EGIS® over time, the final phase of the production process includes freeze-drying to remove all liquids using exact pressure and temperature values.

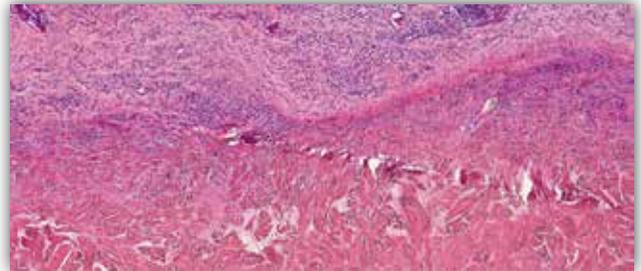
This process makes the final product dry, excellent for correct storage at room temperature and which only requires simple rehydration before the implantation.

The histology demonstrates the remodelling process performed on the EGIS® porcine dermal implant. In the upper part infiltration by the fibroblastic cells and rich neovascularisation can be observed.

EGIS® tensión de tracción

Anchura: 6mm Espesor: 0,8 mm

Carga Máxima: 70N; Resistencia de tracción: 15Mpa;
 Porcentaje de dilatación a la tracción: 38%;
 Módulo Tangente: 80Mpa



The EGIS® matrix is obtained from the central section of the porcine dermis taken from the animal's back. The high density of the collagen fibres guarantees the functional mechanical resistance.

Active natural matrix

Nowadays the concept of biocompatibility is not sufficient for securing the effectiveness of a biomaterial. Its performance must go beyond the threshold of passive tolerability. It must be active, not inert, in order to enhance the biological process of Guided Tissue Regeneration.⁷ EGIS® originated as a completely natural product. It is composed of collagen obtained from porcine dermis which is fundamentally the same as human collagen. EGIS® maintains the original structure and excellent mechanical resistance of proteins without needing induced structural modifications (cross-linking) thus providing immediate bioavailability.

As a natural extracellular matrix EGIS® maintains the structure of the pre-existing microvascular network. This allows the patient's blood to easily permeate the matrix accelerating cell migration and tissue regeneration.



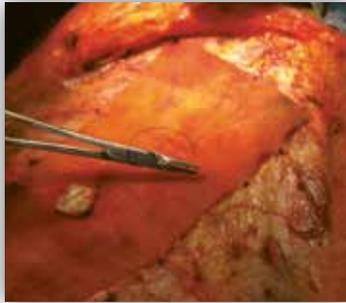
Inert grafts

The structural alteration (cross-linking) of a biological matrix may lengthen the remodelling time or completely stop it significantly limiting cell migration. From a biological viewpoint these artificially modified products behave similarly to synthetic meshes provoking a reaction in the body which results in encapsulation.



Implantation Procedure:
Primary matrix stability.
Intimate contact with vascularized tissue.

Indications

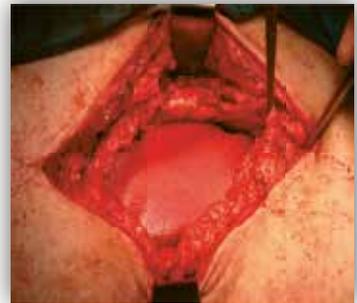


Protection and regeneration of soft tissues in thorax-abdominal sites

EGIS® maintains the original structure and excellent mechanical resistance of proteins without the need for chemical reinforcements (cross-linking) promoting tissue regeneration. Thoracic wall defects, which in the past were repaired with synthetic prostheses were not able to withstand infections, and are now widely treated with biological matrices.⁸

Incisional hernia treatment

EGIS® is able to withstand pressures much higher than those exercised on the peritoneum, including when under strain. Its natural integrity means it can also be implanted in contact with the loops. The concept of using surgical mesh to repair hernias was introduced more than 50 years ago. Repair with biological prosthesis is now widely recognized as superior to repair with direct suturing or synthetic prostheses.⁹



Prevention and treatment of parastomal hernia

The surgical treatment procedure for parastomal hernias is closing of the defect by direct suturing or reinforcement with prosthesis. The prophylactic use of surgical mesh to close the defect at the time of the stoma's creation is now widespread to prevent the onset of new hernias. The synthetic mesh implant in these indications is not recommended due to the high risk of skin erosion and fistula formation.¹⁰

In association with VAC therapy

When the defect is too extensive for a primary closing of the walls, VAC therapy is performed to allow healing of the wound by secondary intention by applying negative pressure to the site. EGIS® is indicated in association with this therapy, before the wound bed is ready for a skin graft which completes the closing.¹¹



Laparoscopic surgery

EGIS® is also available in 0.8 mm thickness. Its softness and malleability makes it easy to use in laparoscopic operations. EGIS® does not encounter any difficulties passing through a trocar and can be easily sutured with metallic or reabsorbable staples using common staplers.

References

| Format Thickness | 5 x 5 cm | 10 x 10 cm | 8 x 15 cm | 15 x 10 cm | 21 x 12 cm | 26 x 18 cm | 30 x 21 cm |
|---------------------|----------|------------|-----------|------------|------------|------------|------------|
| 1,5 mm | EG05-15 | EG10-15 | EG08-15 | EG15-15 | EG21-15 | EG26-15 | EG30-15 |
| 0,8 mm | EG05-08 | EG10-08 | EG08-08 | EG15-08 | EG21-08 | EG26-08 | EG30-08 |

Bibliography

- 1 Liang HC, Chang Y, Hsu CK, Lee MH, Sung HW. Effects of Crosslinking degree of an acellular biological tissue on its tissue regeneration pattern. *Biomaterials*. 2004
- 2 Butler CE, Burns NK, Campbell KT, Mathur AB, Jaffari MV, Rios CN. Comparison of cross-linked and non-cross-linked porcine acellular dermal matrices for ventral hernia repair. *Journal of the American College of Surgeons*, 2010.
- 3 Corey R. Deeken, Lora Melman, Eric D. Jenkins, Suellen C. Greco, Margaret M. Frisella, Brent D. Matthews; Histologic and Biomechanical Evaluation of Crosslinked and Non-Crosslinked Biologic Meshes in a Porcine Model of Ventral Incisional Hernia Repair. *Journal of the American College of Surgeons*, 2011.
- 4 Maryellen Sandor, Hui Xu, Jerome Connor, Jared Lombardi, John R. Harper, Ronald P. Silverman, and David J. McQuillan; Host Response to Implanted Porcine-Derived Biologic Materials in a Primate Model of Abdominal Wall Repair. *Tissue Engineering Part A*, 2008.
- 5 James M. Anderson, Analiz Rodriguez, David T. Chang; FOREIGN BODY REACTION TO BIOMATERIALS. *Semin Immunol*. 2008
- 6 Badylak SF, Gilbert TW; Immune response to biologic scaffold materials. *Semin Immunol*, 2009.
- 7Cornwell KG, Landsman A, James KS.; Extracellular matrix biomaterials for soft tissue repair. *Clin Podiatr Med Surg*. 2009
- 8 Phillip S. Ge, Taryne A. Imai, Armen Aboulian, Timothy L. Van Natta. The Use of Human Acellular Dermal Matrix for Chest Wall Reconstruction. *The Annals of Thoracic Surgery*, 2010.
- 9 CN BROWN, JG FINCH. Which mesh for hernia repair? *Ann R Coll Surg Engl*, 2010.
- 10 Nicholas Jonathan Slater, Bibi M. E. Hansson, Otmar R. Buyne, Thijs Hendriks, Robert P. Bleichrodt. Repair of Parastomal Hernias with Biologic Grafts: A Systematic Review. *J Gastrointest Surg*, 2011.
- 11 B. G. Scott, M. A. Feanny, A. Hirshberg. EARLY DEFINITIVE CLOSURE OF THE OPEN ABDOMEN: A QUIET REVOLUTION. *Scandinavian Journal of Surgery* 2005.

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