secant group

Part of the SOLESIS Family of Companies

Hydralese®MT Foams

Bioresorbable Elastomeric Foams for Orthopedic Devices

Translational Product Development



From Core Polymer Capabilities to Proprietary Polymer Platform

secant group
Part of the SOLESIS Family of Companies

Solesis brings together specialized textile, polymer-processing, and single-use capabilities within one applied biomaterials organization. Hydralese® extends this foundation into a patented, proprietary, bioresorbable polymer platform.

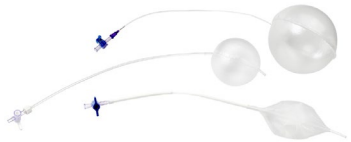
secant group



Medical textiles and engineered structures

Custom woven, knitted, and braided components for implantable and interventional medical devices.

POLYZEN



Polymer films, coatings, and components

Custom polymer processing, films, coatings, and components for medical device and delivery system applications.

CharterMedical



Single-use containment and fluid management

Single-use solutions supporting biological fluid management, bioprocessing, cryopreservation, and advanced therapy workflows.

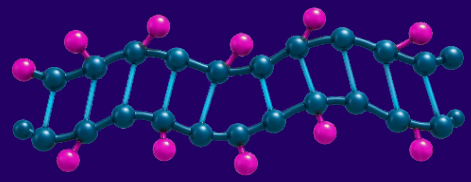
Shared Solesis enabling foundation

- Materials science
- Precision processing
- Analytical and quality systems
- Regulated manufacturing
- Scale-up and supply

PROPRIETARY PLATFORM EXTENSION

Hydralese®

A proprietary family of bioresorbable poly(glycerol ester) polymers engineered and manufactured within the Solesis organization.



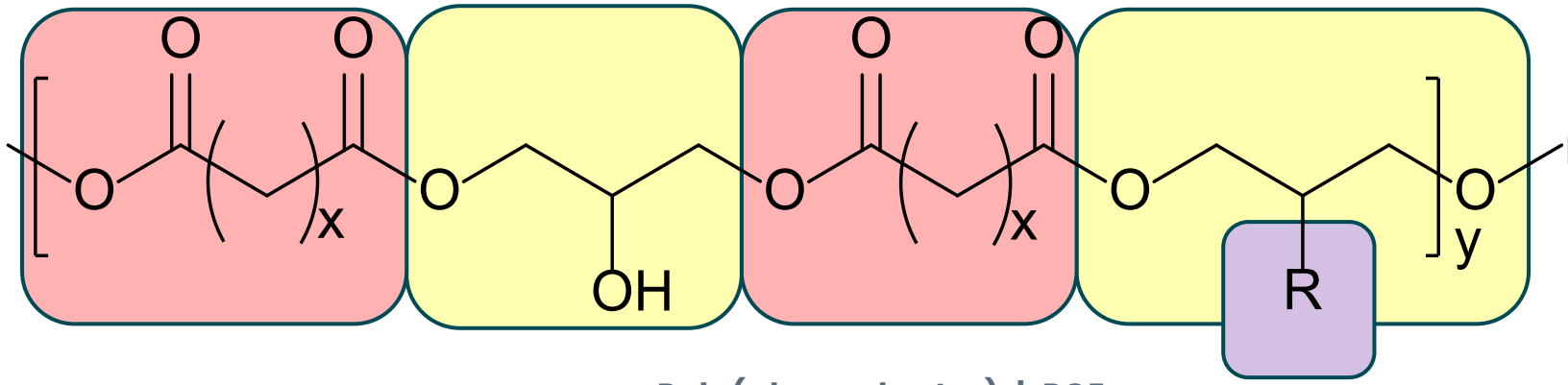
- Common materials-science and polymer-processing foundation
- Integrated synthesis, analytical, quality, and manufacturing capabilities
- Engineered for customization that can be applied to many healthcare applications

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

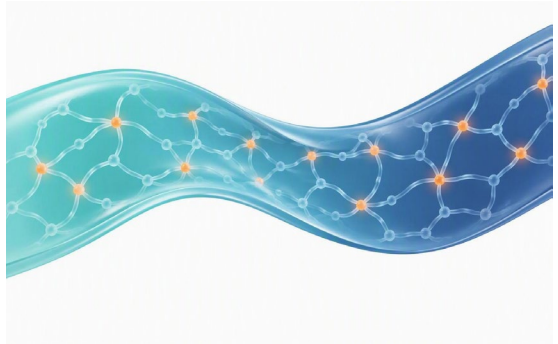
A Modular Polymer Architecture for Tunable Device Properties

Four addressable chemistry levers enable application-specific optimization.

01 Diacid selection | 02 Polyol modification | 03 Monomer feed ratio | 04 Crosslinker



Poly(glycerol ester) | PGE



Elastomeric, resorbable Hydralese® materials

01 Diacid selection

Modulates material behavior

- Tunes hydrophobicity

02 Polyol selection

Building blocks for tuning structure

- Tunes hydrophobicity
- Provides sites for branching, crosslinking, & functionalization

03 Monomer feed ratio

Controls polymer architecture

- Modifies molecular weight & chain topology

04 Crosslinker

Modulates elastomer properties

- Controls final material mechanics & degradation
- Crosslinked materials are poly(glycerol ester) urethanes (PGEU)

One polymer family. Multiple chemistry levers. Tunable Hydralese® performance.

Nicholson, B. et al. Water-mediated preparations of polymeric materials. *US Patent 9,359,472, 2016*.

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese®

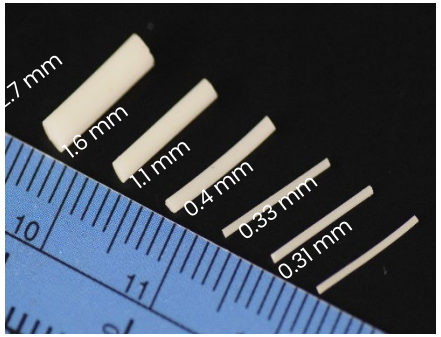
Form Factor Flexibility

We process and manufacture multiple form factors — all at ambient conditions

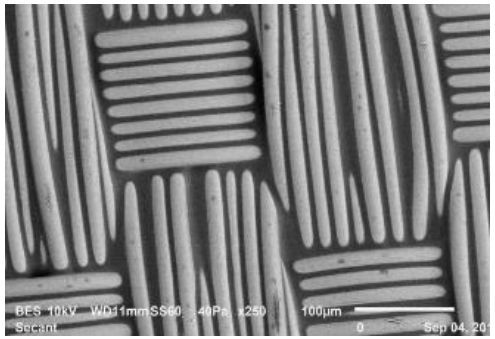


Solid Implants of Various Diameters & Core/Sheath Implants

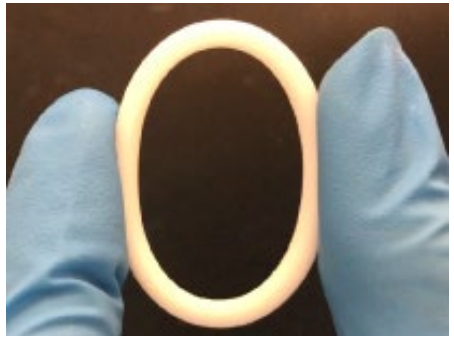




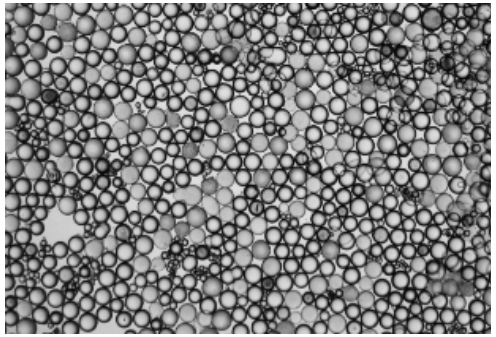
Coatings



Closed Geometry



Injectable Microparticles



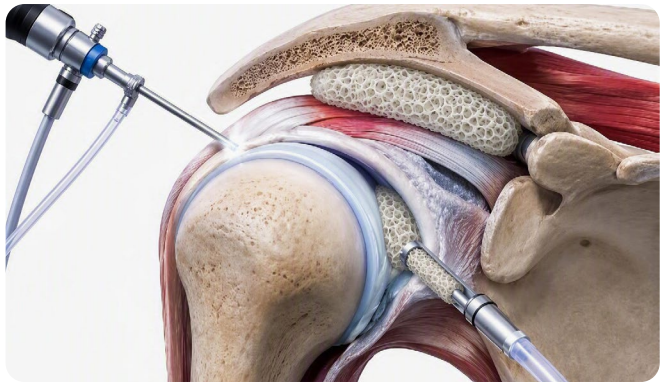
Moldable Foams



COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

One material science base, three paths to market

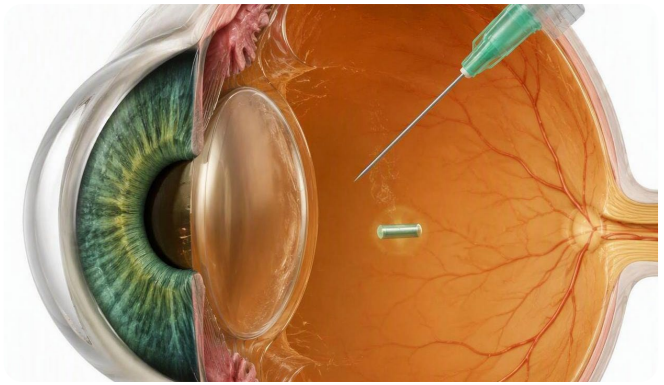
Hydralese®**MT**, **Rx**, and **Tx**



Hydralese® **MT**

One polymer platform, various implantable device form factors.

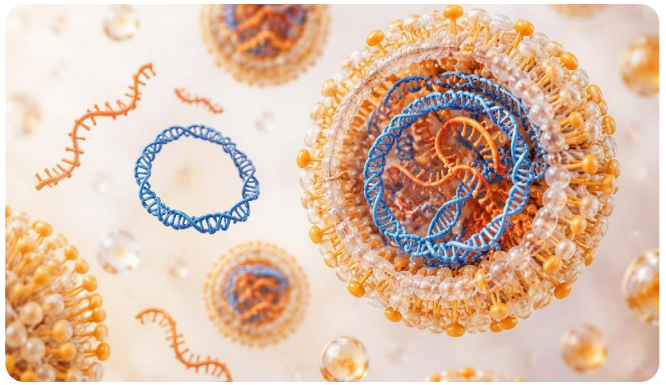
ORTHOPEDICS · VASCULAR



Hydralese® **Rx**

One material, many long-acting therapeutic delivery routes.

OCULAR · WOMEN'S HEALTH · METABOLIC



Hydralese® **Tx**

PGE+ polymer engines for non-viral payload delivery**.**

DNA · mRNA · NUCLEIC ACIDS

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese®MT

The Temporary Support Challenge

Soft-tissue repair requires support that evolves with the healing process.

secant group
Part of the SOLESIS Family of Companies

1 **Implantation**

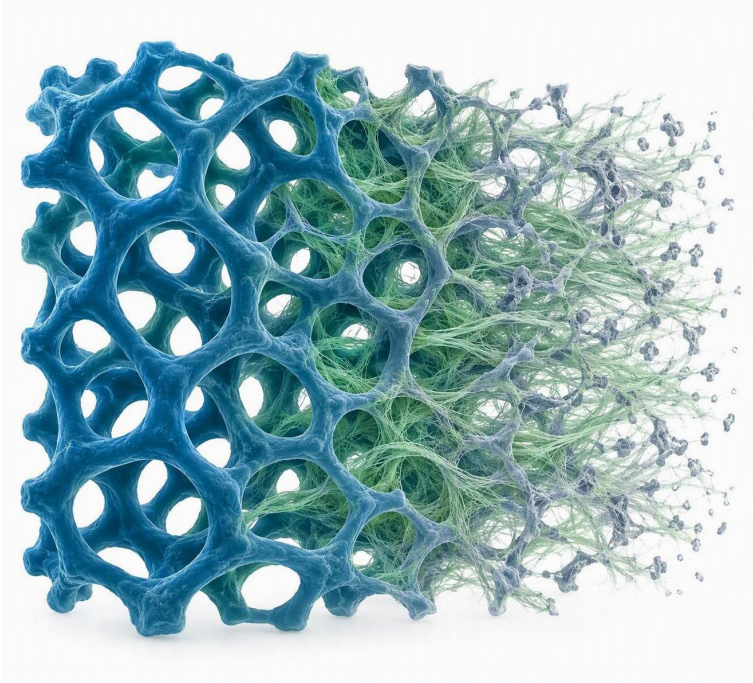
2 **Early mechanical support**

3 **Tissue ingrowth and remodeling**

4 **Progressive material resorption**

- Initial support must be mechanically appropriate.
- The implant should remain functional during the intended healing window.
- Architecture must permit the desired tissue response.
- Material persistence should align with the application.

HYDRALESE®MT RESPONSE Chemistry, foam architecture, and surface coating are engineered to this timeline for each application.



COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese®MT

Design Strategy

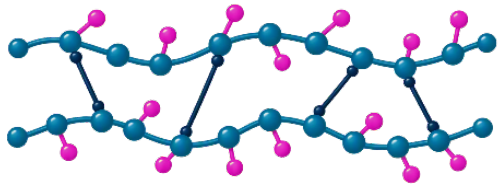
secant group
Part of the SOLESIS Family of Companies

Hydralese®MT integrates polymer chemistry, foam architecture, and functional performance.

Polymer chemistry

Urethane-crosslinked network

- Adjustable formulation
- Adjustable crosslink density
- Network structure defines behavior

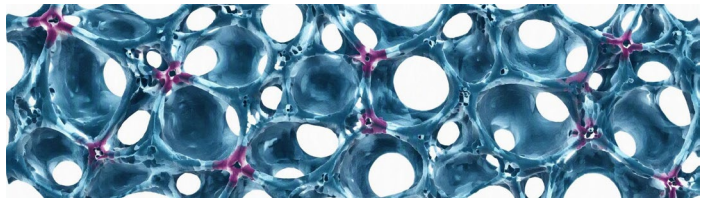


- Backbone chemistry
- Crosslinking and architecture
- Functional groups and end groups

Foam architecture

Controlled porogen-based processing

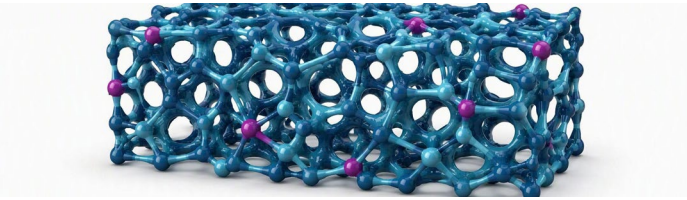
- Open-cell, interconnected pore network
- Porosity greater than 85%
- Tunable pore-size distribution



Functional performance

Designed around the device timeline

- Tissue-like compliance
  (Effective Young's modulus as low as 10-100 kPa)
- Structural integrity during healing
- Resorption from months to years
- Adjustable surface characteristics through coatings



Application-specific foam design

TAKEAWAY Chemistry, processing, and morphology act together — the platform is a design framework, not a single foam specification.

Simplified network motif for illustration only; no proprietary chemical structure disclosed. Variables interact; they are not independently tunable.

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese®MT

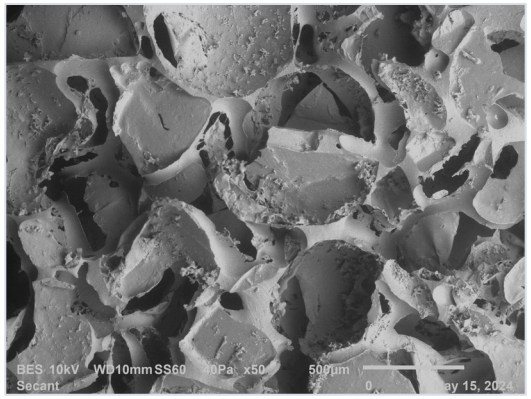
Foam Architecture Control

Porosity and pore size are set by processing — and verified by micro-CT.

secant group
Part of the SOLESIS Family of Companies

Porosity

Set by porogen volume fraction

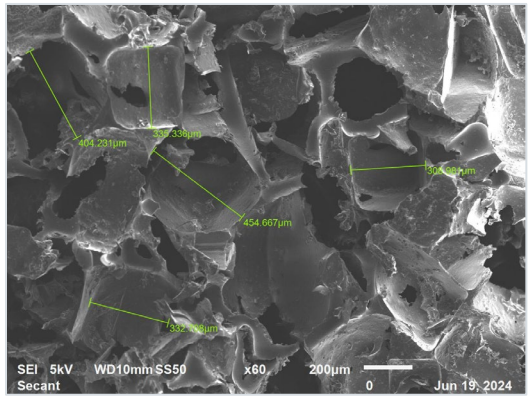


Cross section, 85% (v/v)

- 75 – 90% (v/v) evaluated
- Void space drives implant flexibility and compressibility
- Open-cell network throughout

Pore size

Controlled by sieving porogen granules



Cross section, 300–600 µm porogen

- Pore sizes produced within 45-850 µm range
- Distribution tracks the sieved granule fraction

Verified structure

Confirmed by computed tomography



Micro-CT reconstruction, 85% theoretical porosity

- Target porosity 85% (v/v)
- Measured void space 84.7% (v/v); PGEU 15.3%
- Residual porogen 0.0% (v/v)
- Pore connectivity greater than 99.8%

TAKEAWAY Architecture is engineered, not incidental — porosity and pore size are dialed in by process and confirmed by micro-CT.

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese®MT

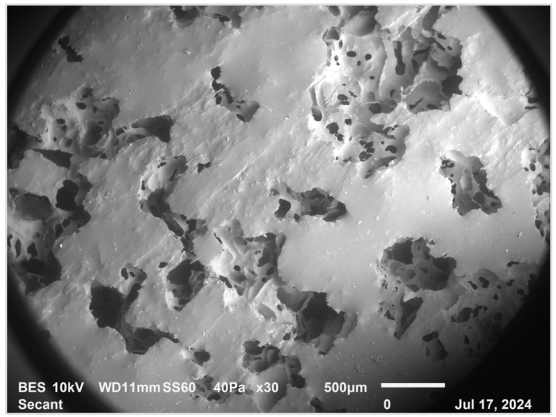
Engineered Surfaces

Spray-applied PGEU coatings tune the outer surface without changing the bulk foam.

secant group
Part of the SOLESIS Family of Companies

Coating process

PGEU applied by spray

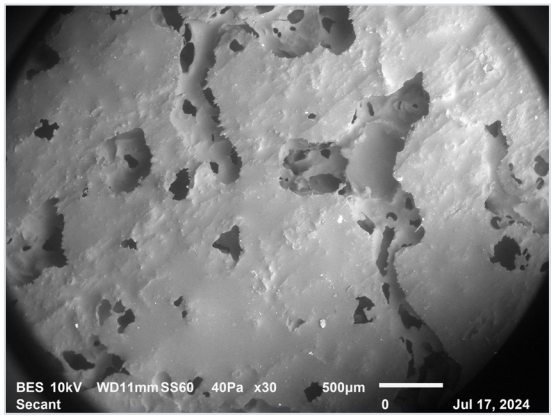


Coated surface, 5 passes

- Coating and substrate share PGEU chemistry
- Thickness set by number of nozzle passes
- 5, 10, and 30 passes evaluated

Surface control

From open pore to smooth skin

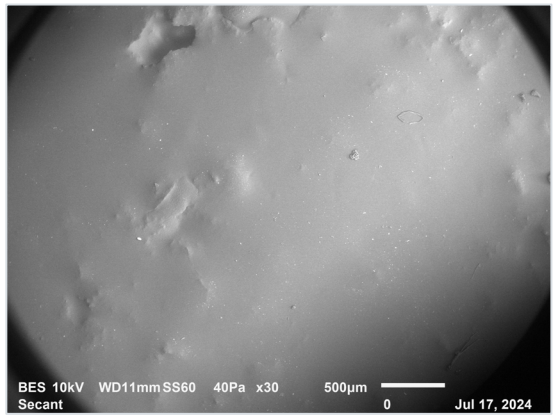


Coated surface, 10 passes

- Outer surface progressively smoothed from uncoated to fully sealed
- Bulk pore network preserved beneath the skin

Functional gain

Mechanics without added bulk



Coated surface, 30 passes

- Even thin coatings increase toughness; resist cracking during deformation.
- Suture retention strength improved
- Modulates tissue ingrowth into scaffold

TAKEAWAY Surface and bulk are separate design levers — coating adds handling and fixation strength while the foam architecture is retained.

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese®MT

VOLL MEDICAL

secant group
Part of the SOLESIS Family of Companies

Final Foam Construction

Engineered Hydralese® foam subacromial spacer for repair of massive rotator cuff tears

The construction

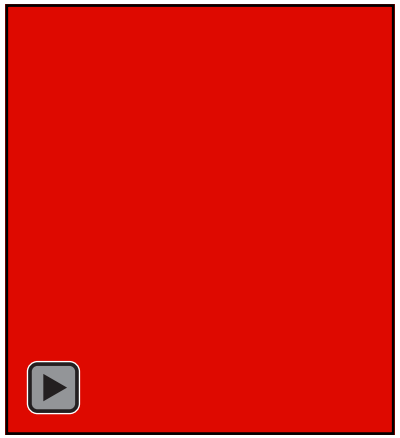
Open-cell PGEU foam with PGEU coating



- Controlled, high porosity PGEU foam with >99.8% pore interconnectivity
- Spray-applied PGEU outer coating
- Processed at ambient conditions

Performance profile

Soft, elastic, and handleable



- Soft and flexible; relevant stiffness regime for soft tissues
- Compresses and recovers
- Smooth and tough surface allows and suture retention
- Cytocompatible and non-immunogenic

Lead application

Subacromial spacer for rotator cuff repair



Porous construct in situ

- Placed between the acromion and humeral head for temporary separation during healing
- Self-expands and orients during implantation; resorbs as the repair matures
- 10+ patients implanted in a first-in-human study

TAKEAWAY The final construct is a coated, resorbable PGEU foam spacer — now in first-in-human use for temporary subacromial support during rotator cuff healing.

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese® MT

Preclinical Evidence

A 53-week bilateral sub-acromial implantation study in rats.

VOLL MEDICAL

secant group
Part of the SOLESIS Family of Companies

Study design

Coated PGEU spacer, rat model

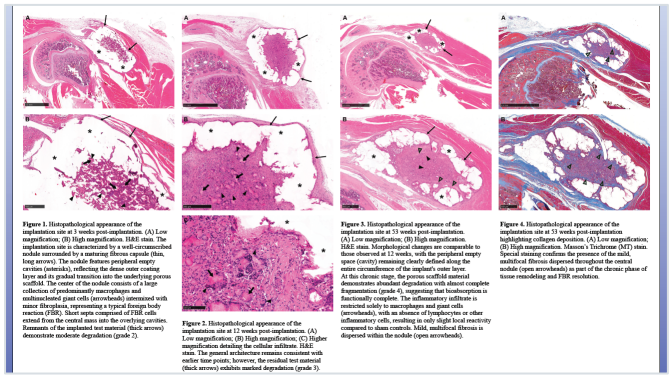


Figure 1. Histopathological appearance of the implantation site at 3 weeks post-implantation. (A) Low magnification; (B) High magnification. H&E stain. The implantation site is characterized by a well-circumscribed nodule surrounded by a maturing fibrous capsule (thin, long arrows). The nodule features peripheral empty cavities (asterisks), reflecting the dense outer coating layer and its gradual transition into the underlying porous scaffold. The center of the nodule consists of a large collection of predominantly macrophages and multinucleated giant cells (arrowheads) intermixed with minor fibroplasia, representing a typical foreign body reaction (FBR). Short septa comprised of FBR cells extend from the central mass into the enveloping cavities. Remnants of the implanted test material (thick arrows) demonstrate moderate degradation (grade 2).

Figure 2. Histopathological appearance of the implantation site at 12 weeks post-implantation. (A) Low magnification; (B) High magnification; (C) Higher magnification detailing the cellular infiltrate. H&E stain. The general architecture remains consistent with earlier time points; however, the residual test material (thick arrows) exhibits marked degradation (grade 3).

Figure 3. Histopathological appearance of the implantation site at 53 weeks post-implantation. (A) Low magnification; (B) High magnification. H&E stain. Morphological changes are comparable to those observed at 12 weeks, with the peripheral empty space (cavity) remaining clearly defined along the entire circumference of the implant's outer layer. At this chronic stage, the porous scaffold material demonstrates abundant degradation with almost complete fragmentation (grade 4), suggesting that bioabsorption is functionally complete. The inflammatory infiltrate is restricted solely to macrophages and giant cells (arrowheads), with an absence of lymphocytes or other inflammatory cells, resulting in only slight local reactivity compared to sham controls. Mild, multifocal fibrosis is dispersed within the nodule (open arrowheads).

Figure 4. Histopathological appearance of the implantation site at 53 weeks post-implantation highlighting collagen deposition. (A) Low magnification; (B) High magnification. Masson's Trichrome (MT) stain. Special staining confirms the presence of the mild, multifocal fibrosis dispersed throughout the central nodule (open arrowheads) as part of the chronic phase of tissue remodeling and FBR resolution.

Present by Voll Medical at ESTP Symposium, September 2026

- Bilateral sub-acromial implantation
- 3 male and 3 female Sprague Dawley rats per group
- Compared against a sham surgical procedure

Safety and local response

Non-adverse, well-contained

- Surgical procedure well tolerated across all subjects
- All animals survived to scheduled termination with normal body-weight gain
- No abnormal clinical signs; no systemic toxicity noted
- Implant sites well circumscribed within a maturing fibrous capsule
- Macrophages, multinucleated giant cells, and mild fibroplasia — a localized, expected foreign-body reaction

Biodegradation kinetics

Time-related resorption over 53 weeks

- Moderate degradation at 1 week
- Marked degradation at 12 weeks
- Advanced degradation at 53 weeks
- Physical integrity retained through the initial phases of healing
- At 53 weeks only trace material remained, with mild fibrosis and tissue at a steady state of repair

TAKEAWAY Degradation was progressive and controlled across 53 weeks, with a strictly non-adverse foreign-body response and localized tissue restoration.

Voll Medical / VIVOX preclinical study of a coated PGEU-based sub-acromial spacer. Findings are specific to the evaluated formulation, configuration, and model.

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese® MT

VOLL MEDICAL

secant group
Part of the SOLESIS Family of Companies

First-in-Human Clinical Evidence

A coated Hydralese® subacromial spacer in first-in-human use

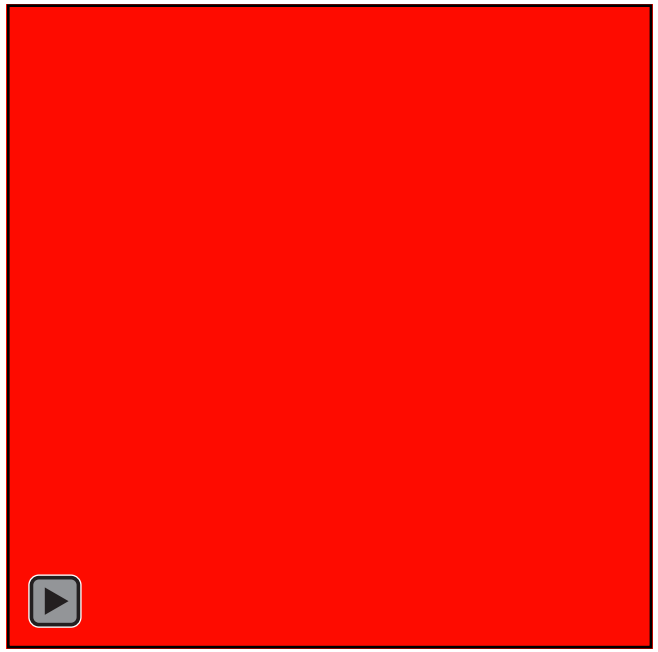
FIH Study

Coated PGEU subacromial spacer

- **Design:** ~15 patient First-in-Human study evaluating Hydralese® biodegradable foam spacers for massive rotator cuff tears.
- **Status:** Multi-center enrollment in Israel and Italy with ~10 patients treated to date.
- **Primary endpoints:** procedural success, safety, pain reduction, and improved shoulder function/ROM.
- **Early results:** Significant pain reduction and improved ROM observed at 3 months while the implant remains functional.
- Study expansion underway with larger implant geometries and additional porosity variants.

Functional Performance

3-month post-surgery ROM assessment



First patient treated with Voll Spacer. Treated by Dr. Yariv Goldstein, Head of Shoulder Unit, Assuta Ashdod University Hospital

Imaging follow-up

MRI at 6 weeks and 3 months

- Spacer identifiable in the sub-acromial space at both timepoints
- Measured spacer dimension 9.9 mm at 6 weeks and 10.2 mm at 3 months
- Dimensions stable between 6 weeks and 3 months, consistent with the intended degradation profile
- Spacer remained correctly positioned in the sub-acromial space, with no migration observed
- No imaging evidence of adverse fluid collection or inflammatory reaction at the implant site
- Imaging supports device integrity and placement through the 3-month follow-up

TAKEAWAY Early clinical experience shows the spacer can be placed and remains identifiable on MRI through three months — an initial view of device performance

First-in-human, investigational use only

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese®MT

secant group
Part of the SOLESIS Family of Companies

What We Want You to Walk Away With

Three things to remember about the Hydralese® PGEU foam platform

1. Built for soft tissue

- PGEU combines flexibility, elasticity, controlled biodegradation, and demonstrated biocompatibility
- Porous constructs can fully recover their shape after compression
- Coated surfaces show increased toughness and can moderate tissue integration

2. Backed by evidence

- 53-week preclinical study: progressive, controlled degradation with a non-adverse, localized tissue response
- First-in-human use: the spacer is placed successfully and remains identifiable on MRI through three months
- Early pain reduction and restoration of range of motion at three months

3. Tunable by design

- Polymer chemistry, porosity, pore size, and coatings are independent design levers
- Architecture and mechanics can be matched to a specific device and indication
- Processed at ambient conditions in multiple form factors, suitable for a wide range of projects and applications

One tunable, biodegradable foam platform — proven in the lab, validated *in vivo*, and ready to be engineered around your device.

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.

Hydralese®

Questions

Come see Solesis at Booth 17 to learn more about

Hydralese®**MT**



Discuss your next MedTech project at Booth 17

Alex Stahl, Ph.D

Alex.Stahl@secant.com

COPYRIGHT ©2026 SECANT GROUP. ALL RIGHTS RESERVED.