THE BIOMERIX BIOMATERIAL

Material Description

The Biomerix Biomaterial is a ***non-resorbable***, reticulated, cross-linked, polycarbonate polyurethane-urea matrix. Structurally designed to support fibrovascular tissue ingrowth, the biomaterial offers a fully interconnected, macroporous morphology with over 90-95% void content. Cell sizes range from 250 to 500 µm. The open-cell three-dimensional morphology is optimally constructed to mimic the nature and function of the extracellular matrix (ECM). Together, these features of the Biomerix scaffolds are ideal for applications that require natural tissue healing. **Figures 1 and 2** below show the Biomerix Biomaterial morphology and various form factors.

FIGURE 1. SEM at 23X Magnification

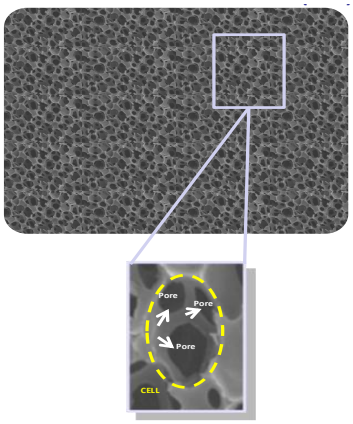
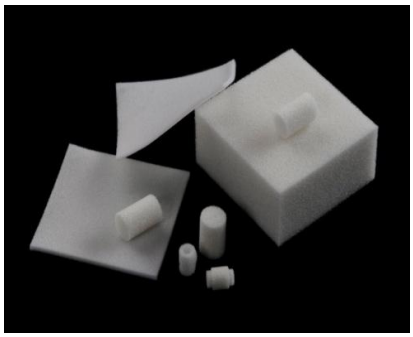


FIGURE 2. Biomaterial Form Factors



Biomerix Biomaterial Formulations

Biomerix has developed a range of formulations tailored to meet the requirements of specific applications. **Table 1** below provides the properties of different biomaterial formulations. Custom formulations can be developed upon request.

Table 1: Biomerix Biomaterial Formulations & Properties

Description:	Standard	Stiff	Midrange	Soft	Microporous
Formulation:	HF3[(a)]	HF2[(a)]	HF2.5[(b)]	SF3[(b)]	HFX[(b)]
Batch Number:	*HF3-050213-1*	*HF2-022013-1*	*HFX-090413-1*	*HFX-031813-1*	*HFX-051513-1*
Average Cell Size	306 µm	604 µm	463 µm	377 µm	253 µm
Density	3.7 lb/ft^3	4.5 lb/ft^3	3.9 lb/ft^3	2.7 lb/ft^3	6.8 lb/ft^3
Permeability	270 Darcy	272 Darcy	216 Darcy	311 Darcy	76 Darcy
Compressive Strength	1.6 psi	4.2 psi	2.3 psi	1.1 psi	1.7 psi
Tensile Strength Parallel	80 psi	74 psi	64 psi	68 psi	84 psi
Tensile Strength Perp.	49 psi	42 psi	45 psi	32 psi	63 psi
Elongation Parallel	211%	145%	196%	219%	262%
Elongation Perpendicular	236%	159%	198%	243%	282%

(a) Validated formulation. (b) R&D formulation.

Biocompatibility

The Biomerix Biomaterial™ has passed all ISO-10993 mandated biocompatibility testing required for a permanent, blood contacting implant as shown in **Table 2** below.

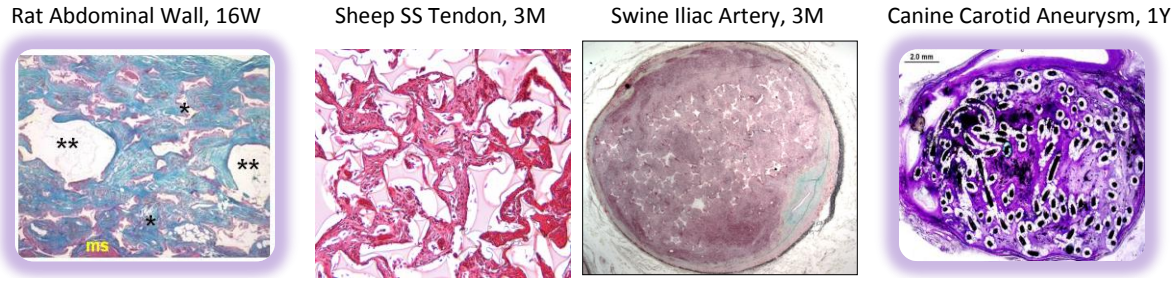
Table 2: Biocompatibility Testing Results[1]

Biological Test	Result
Cytotoxicity: MEM Elution	Non-cytotoxic (Grade 0)
Sensitization: Kligman Maximization	Grade I - weak allergic potential
Intracutaneous Injection	Negligible irritant
Systemic Injection	Negative
Subchronic Toxicity: 14-day	Non-toxic
Genotoxicity: Ames Mutagenicity	Non-mutagenic
Genotoxicity: Chromosomal Aberration	Non-clastogenic
Genotoxicity: Bone Marrow Micronucleus	Non-clastogenic
Hemolysis	Non-hemolytic (1.5%)
Complement Activation	Meets requirements
Prothrombin Time	No adverse effect on prothrombin coagulation time
Unactivated Partial Thromboplastin Time	Meets requirements
Intramuscular Implant – 2 Weeks	No reaction
Intramuscular Implant – 12 Weeks	No reaction
Neurological Implant in Rabbits – 12 Weeks	Well-tolerated, biocompatible material
Neurological Implant in Rabbits – 24 Weeks	Well-tolerated, biocompatible material
Systemic Toxicity Via Neurological Implant	No local or systemic signs of toxicity
Thrombogenicity Study in Dogs	Amount of thrombosis not significant
Material-Mediated Pyrogenicity	Non-pyrogenic

Preclinical and Clinical Evidence

Preclinical studies have shown that the biomaterial supports a progressive healing response characterized by rapid fibrovascular tissue ingrowth, robust vascularization throughout the porous structure, and complete biointegration with surrounding host tissue without encapsulation as shown in **Figure 1** below. Clinically, the superior healing profile of devices incorporating the Biomerix Biomaterial have resulted in improved outcomes, including reduced recurrence rates (*Biomerix Rotator Cuff Repair Patch*)[2] and reduced pain outcomes (*Biomerix REVIVE Surgical Mesh*).[3]

FIGURE 1. Biomerix Biomaterial Biointegration



[1] Data on file at Biomerix Corp.

[2] Encalada-Diaz I et. al. **Rotator Cuff Repair Augmentation Using a Novel Polycarbonate Polyurethane Patch: Preliminary Results at Twelve Months Follow-up**. *J Shoulder Elbow Surg*. 2011 Jul;20(5):788-94.

[3] Fine A. **Laparoscopic Repair of Inguinal Hernia with Biomimetic Matrix**. *JSLS*. 2012 Oct-Dec;16(4):564-8.

Regulatory Clearances

To date, the Biomerix Biomaterial has received ten regulatory clearances in the U.S., European Union, and Canada for indications in soft tissue repair, plastic/reconstructive surgery, orthopedics (tendon repair), and peripheral vascular embolization.

New Biomerix Initiatives

Biomerix is developing its second biomaterial platform, a family of cross-linked ***resorbable*** polyester urethane-urea scaffolds with the same differentiated advantages as the non-resorbable biomaterials, namely a highly porous, open-celled 3-D morphology; high void content (>95%); and superior biomechanical properties, specifically elastomeric, flexible, and resilient properties. Biomerix has developed various formulations with controlled, *in-vitro* degradation profiles ranging from 4 months to 2+ years. The resorbable biomaterials platform allows the Company and its partners to pursue new application areas which require degradable biomaterials including soft tissue repair, orthopedics, plastic/reconstructive, gastrointestinal, advanced wound care, and regenerative medicine.

Intellectual Property

The Company's intellectual property portfolio includes 9 issued patents protecting the non-resorbable Biomerix Biomaterial in the U.S., Australia, China, Hong Kong, India, Israel, and Japan; 3 patent applications on the resorbable Biomerix Biomaterial; and pending device patents in soft tissue repair. Most importantly, the seminal patent covering the Biomerix Biomaterial™ (US #7,803,395 and US #8,337,487 *Reticulated Elastomeric Matrices, Their Manufacture and Use in Implantable Devices)* protects all implantable uses of the material, as well as the processes for manufacturing the materials.

Summary

In summary, Biomerix offers a revolutionary and patent-protected technology platform comprised of non-resorbable & resorbable synthetic porous urethane biomaterials, which are chemically based on safe, established biomaterials with a long history of clinical use (i.e., polycarbonate polyurethanes, degradable polyesters). These porous biomaterials enable medical technology customers to incorporate a differentiated, value-added biomaterial that offers unique functionalities, including:

- Promotes tissue ingrowth and biointegration with the defect site.
- Prevents encapsulation of the device.
- Supports robust and durable angiogenesis.
- Fills voids or defects in soft tissue, hard tissue, and vascular sites.
- Engenders enhanced healing, reducing recurrence rates.
- Reduces fibrotic scarring, minimizing pain outcomes.
- Provides optimal platform for 3D cell culture and regenerative medicine applications.
- Allows for incorporation and release of active agents.