THE BIOMERIX RESORBABLE POLYESTER POLYURETHANE SCAFFOLD

Biomerix has developed a family of cross-linked degradable polyester urethane-urea scaffolds consisting of a non-degradable isocyanate hard segment (diphenylmethane diisocyanate or MDI) and degradable polyester soft segments derived from polyols of polycaprolactone (PCL) and its copolymers with other polyesters such as polyglycolic acid (PGA) and polylactic acid (PLA). The degradation products include well-known biocompatible by-products of resorbable aliphatic polyesters. The non-degradable hard segment is <1% by volume and has been shown to undergo total resorption via phagocytosis (internalization of MDI remnants and digestion of the polymeric material). The Biomerix resorbable scaffolds offer unique features which differentiate the biomaterial from other resorbable porous biomaterials, including:

Biomerix Biomaterial Unique Features

- Open-cell 3D scaffold made from cross-linked polyester polyurethane-urea
- Optimally constructed to mimic the nature and function of the extracellular matrix
- Supports robust fibrovascular tissue ingrowth
- Superior biomechanical properties – elastomeric and resilient

Biointegration. Structurally designed to support robust fibrovascular ingrowth and remodeling, the Biomerix Biomaterial offers a fully accessible, interconnected macroporous morphology with over 90-95% void content. Cell sizes range from 250 to 500 µm, and pore sizes range from 100 to 200 µm. The open-cell three-dimensional morphology is optimally constructed to mimic the nature and function of the extracellular matrix (ECM), paving the way for cells to migrate, proliferate, attach and regenerate new tissue.

Biocompatibility. The platform's base chemistry is derived from well-established biomedical polyurethane and polyester chemistries which have been used in medical devices targeted at soft tissue repair, orthopedics, and vascular applications.

Engineered Degradation Profiles: Custom degradation profiles can be engineered by varying the composition of the degradable soft segment, the stoichiometric ratio of the hard:soft segment, and the degree of cross-linking in the formulation.

Biomechanical Properties. The Biomerix Biomaterial is elastomeric and demonstrates resilient recovery after being deformed in both compression and tensile modes. The elastic nature of the Biomaterial, especially in its recovery characteristics when subjected to dynamic loading, is unique in an open-cell matrix and allows the Biomaterial to be used in applications where resilience is critical.

Customizable Properties: The properties and form factors of the biomaterial can be customized to meet application requirements. Customizable physical properties include density, cell size, and biomechanical properties. A range of form factors can be fabricated, including flat, three-dimensional, tubular, and other complex shapes.

Figure 1 shows an SEM of a resorbable formulation with an *in-vitro* degradation profile of about 24 months. **Figure 2** shows the *in-vitro* degradation profiles of various resorbable formulations ranging from 4 months to 16 months. **Table 3** shows the mechanical properties of a MDI-PCL formulation with low cross-linking.

FIGURE 1. SEM at 23X Magnification

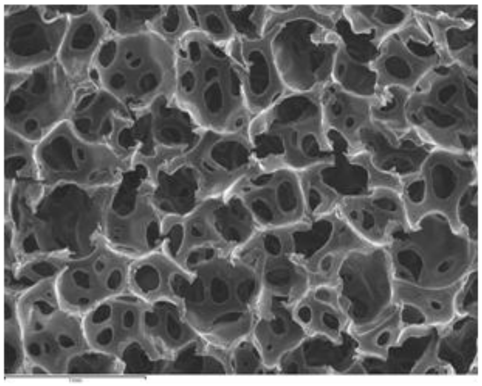

FIGURE 2. *In-Vitro* Degradation Profile

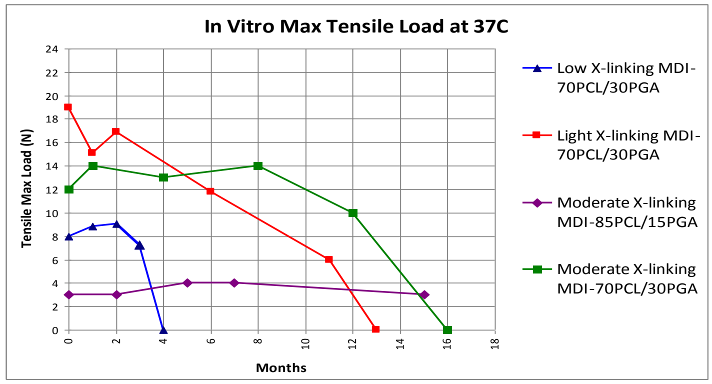

Table 3: Biomerix MDI-PCL Formulation Properties

Material Property	MDI-PCL *Batch Reference: HFX-092613-1*
Average Cell Size	326 µm
Density	3.9 lb/ft^3
Permeability	312 Darcy
Compressive Strength	0.5 psi
Tensile Strength Parallel	52 psi
Tensile Strength Perp.	36 psi
Elongation Parallel	236%
Elongation Perpendicular	250%

Biomerix developed its resorbable biomaterial platform to pursue applications in orthopedics, advanced wound care, soft tissue repair, gastrointestinal, plastic/reconstructive surgery, and regenerative medicine. In summary, the Biomerix resorbable bioscaffolds 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.
- Compatible with a wide range of cell types, ideal for regenerative medicine applications.
- Allows for incorporation and release of drugs, cellular components, and growth factors.
- Amenable to coatings to functionalize the biomaterial surface.