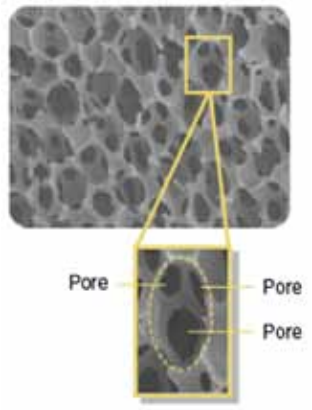
PROTOCOL

Biomerix 3D Scaffold™



Part Number:	B3DS
Version:	1.0
Storage:	Store material in a cool, dry, dark place. Minimize exposure to UV light. Material should not be subject to temperatures exceeding 150 ºC.
Batch Number:	Marked on package

Material Description

The Biomerix 3D Scaffold is a biodurable, reticulated, three-dimensional matrix comprised of polycarbonate polyurethane-urea. The morphology consists of an interconnected three-dimensional network of cells and pores with a high void content of 90-95%. The material has demonstrated compatibility with hematopoietic, mesenchymal, human embryonic, and induced pluripotent stem cells in both static and dynamic culture environments, and supports in-vivo cellular proliferation and viability in preclinical models.

Biocompatibility

The Biomerix BiomaterialTM has passed all ISO-10993 mandated biocompatibility testing required for a permanent, blood contacting implant.

Table 1: Biocompatibility Testing Results

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
Short-Term Intramuscular Implant – 2 Weeks	No reaction
Short-Term Intramuscular Implant – 12 Weeks	No reaction
Material-Mediated Pyrogenicity	Non-pyrogenic

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Material Properties

The specifications for the Biomerix Biomaterial™ are noted in **Table 2** below.

Table 2: Biomerix Biomaterial™

Property	Requirement
Permeability	>250 Darcy
Average cell size	<385 µm
Density	3.5-3.9 lb/ft3 / 0.056-0.063 g/cc
Compressive strength	1.0-1.8 psi / 6.89-12.41 kPa
Tensile strength	≥36 psi / 248.2 kPa
Elongation	>180%

Regulatory Clearances

Four devices utilizing the Biomerix BiomaterialTM have received U.S. 510(k) regulatory clearance including the Biomerix Ventral Hernia Repair Mesh (K093123), Biomerix Composite Surgical Mesh (K082941), Biomerix Rotator Cuff Repair Surgical Mesh (K070961), and Biomerix Vascular Occlusion Device (K043371).

Storage, Handling, and Use Instructions

- Material is not for human clinical use.
- Material is not sterile. For in-vivo studies, ethylene oxide or gamma radiation sterilization is recommended. For laboratory cell culture studies, sterilization using isopropyl alcohol is recommended; see Scaffold Preparation Instructions section below. Autoclaving is not recommended.
- Material should not be subject to temperatures exceeding 150 ºC.
- Store material in a cool, dry, dark place. Minimize exposure to UV light.

Scaffold Preparation Instructions

- Soak or gently stir Biomerix 3D Scaffolds in 70/30 isopropyl alcohol/water mixture for 20 minutes. Ensure that the scaffolds are fully immersed in the IPA/water mixture.
- Remove the scaffolds from the mixture and squeeze the scaffolds by using a spatula to remove the majority of the mixture.
- Air dry the scaffolds, preferably in a sterile culture hood, for 3-5 minutes.
- Transfer the scaffolds into standard phosphate buffer solution. Ensure that the scaffolds are fully immersed in the buffer solution and soak or gently stir for 10 minutes. Repeat the buffer wash process three times, using fresh buffer solution each time and squeezing the scaffolds with a spatula between successive buffer treatment processes.
- Transfer the scaffolds to cell culture media.

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