



A Better Approach to Regenerative Medicine

BioDFactor is a human placental tissue-derived allograft that provides a structural matrix to facilitate tissue regeneration.

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A natural approach to regenerative medicine

The unique biologic structure of placental tissue contains the structure, signals and cells required to protect the fetus and aid fetal growth and development. As a liquid tissue matrix, BioDFactor retains this protective function by providing an extracellular matrix for use in vivo. In addition to its structural properties, the placental membrane and amniotic fluid have been found to contain a rich source of proteins, cytokines, growth factors and other chemical compounds, all of which are essential for fetal growth and development. Amniotic fluid also contains multipotent cells that are capable of differentiating into all three germ layers of the human body.¹ Specifically, amniotic fluid derived stem cells have been shown to be broadly multipotent, capable of differentiating into adipogenic, osteogenic, myogenic, endothelial, neurogenic and hepatic cell lineages.¹ While the primary function of BioDFactor is to provide a structural tissue matrix to cover and protect the wound, the presence of residual multipotent cells naturally present in amnion may provide ancillary clinical benefits to the patient.

Extracellular Matrix

Amniotic tissue is an abundant source of collagen that provides an extracellular matrix to act as a natural scaffold for cellular attachment in the body. Collagen provides a structural tissue matrix that facilitates, among other things, cell migration and proliferation in vivo. BioDFactor was developed using a proprietary technique that morselizes the amnion in an effort to preserve its structural properties in an injectable form. This "micro-scaffold" created by the morselized tissue matrix includes the residual proteins, carbohydrates, hyaluronic acid, growth factors, and other chemical compounds naturally present in amniotic fluid and tissue to provide a liquid tissue matrix that is derived from those components essential for fetal growth and development.

Clinicians have used amniotic tissue for over a century as a biologic dressing in a broad range of therapeutic applications.² It has been generally recognized as a versatile wound covering with published clinical results cited extensively in the literature.²

Amniotic membrane is a unique human tissue in that it rarely evokes an immune response in the human body. Numerous clinical studies and scientific journals have characterized the placental organ as "immune privileged." The unique biologic structure of amniotic tissue, coupled with the low risk of an immune response, makes BioDFactor an ideal choice for homologous clinical use.

Clinical Applications For Homologous Use Only

- Tissue voids and defects
- Localized areas of inflammation

Committed to Your Patient's Safety

From donor qualification to pre-release lot testing, BioD is committed to patient safety. We only procure tissue from healthy living donors electing caesarian section. Our tissues are recovered, processed and distributed by FDA and AATB accredited tissue banks.

Donor Screening

- Donors are pre-screened through medical record review and evaluation of pre-natal tests
- Medical Director confirms eligibility through:
 - Behavioral risk assessment
 - Review of blood test results
 - Donor medical history
 - Communicable disease testing

Procurement & Processing

- Aseptic recovery technique during sterile cesarean section
- Infectious disease screening requirements meet or exceed all FDA and AATB requirements
- Culturing and toxicity testing performed prior to lot release



As a liquid allograft, BioDFactor can be injected or applied directly to the surgical site. It is cryopreserved to facilitate an extended shelf life and is easy to handle in the OR.

BioDFactor

BF-010025	S
BF-010050	M
BF-010125	L
BF-010300	XL



BioDFactor is regulated by the FDA under 21 CFR Part 1271 and Section 361 of the Public Health Service Act.

References

- 1 De Coppi, P. et. al., Isolation of amniotic stem cell lines with potential for therapy. *Nature Biotechnology* 2007; Vol. 25, No. 1: 1274-1280.
- 2 Gruss, J., et. al., Human amniotic membrane: a versatile wound dressing. *CMA Journal* 1978; Vol. 118: 1237-1246.

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