

Organogenesis

# NuCel<sup>®</sup>

NuCel<sup>®</sup> is a cryopreserved amniotic suspension allograft. It consists of extracellular matrix (ECM) scaffold particles<sup>6</sup>, amniotic fluid cells<sup>7</sup>, and contains anti-inflammatory cytokines and angiogenic and regenerative growth factors.<sup>1</sup>



## Amniotic Tissues

Contain multiple growth factors<sup>3,5</sup>

Are known to contain progenitor cells<sup>3,5</sup>

Immune privileged - Well tolerated when transplanted<sup>3,5</sup>

Have angiogenic properties<sup>1</sup>

Regenerative	Angiogenic	Anti-Inflammatory	Osteogenic
Adiponectin	aFGF	HA	BMP-6
BMP-3	ANG	IL-1FS	BMP-7
Galectin-7	APL4	IL-1R2	Fetuin A
HGF	EG-VEGF	IL-1Ra	OPG
IGF II	EGF	IL-4	OPN
IGFBP-1	PDGF-AA	IL-6	Wnt3a
IGFBP-5	PDGF-bb	IL-8	WntSa
TGF-b1	SDF-1	TIMP-1	
	TSP-1	TIMP-2	
		TIMP-3	
		TNFRSF1A	
		TNFRSF1B	

7. Data on File, ASA\_DR-0001. Organogenesis Inc.

# Organogenesis NuCel<sup>®</sup>

## Safety Profile

The tissues in NuCel<sup>®</sup> are collected from fully-consented mothers undergoing scheduled caesarean section births of full-term healthy babies. An appropriate blood sample from the donor is tested for relevant communicable diseases by a laboratory registered with the FDA, and Organogenesis Inc. only releases tissue for transplantation that has negative or non-reactive results for the following<sup>2</sup>:

- anti-HIV-1 and anti-HIV-2
- HIV-1/HBV/HCV NAT
- Hepatitis B surface Antigen (HBsAg)
- Hepatitis B Core total antibody (anti-HBc)
- Hepatitis C anti-body (anti-HCV)
- WNV
- Syphilis
- HTLV I/II

After screening, the amniotic tissue is aseptically processed in a controlled, clean environment following strict technical quality assurance standards.<sup>2</sup>

## Sizing

Organogenesis products are available in a variety of sizes.

### NuCel<sup>®</sup> Amniotic Suspension Allograft

Product Code	Product Description/Size
NC-1000	NuCel Small 0.5cc
NC-1001	NuCel Medium 1.0cc
NC-1002	NuCel Large 2.0cc
NC-1003	NuCel Extra Large 2.5cc



**References:** **1.** Data on file, Report 20190313-ASA1. Organogenesis Inc. **2.** NuCel Allograft Tissue Information and Product Preparation Insert. **3.** Niknejad H, Peirovi H, Jorjani M, Ahmadiani A, Ghanavi J, Selfallan AM. Properties of the amniotic membrane for potential use in tissue engineering. *Eur Cell Mater.* 2008; 15:88-89. **4.** Cooke, M, Tan, E, Mandrycky, C, He, H, O'Connell, J, Tseng, S, Comparison of Cryopreserved Amniotic Membrane and Umbilical Cord Tissue with Dehydrated Amniotic Membrane/Chorion Tissue, *Journal of Wound Care* 2014, 23(10): 465-76. **5.** Friel, Nicole & de Girolamo, Laura & Gomoll, Andreas & Mowry, Katie & Vines, Jeremy & Farr, Jack. Amniotic Fluid, Cells, and Membrane Application. *Operative Techniques in Sports Medicine.* 2016. 25. 10.1053/j.otsm.2016.12.004. **6.** Data on file, 2016-09-06. Organogenesis Inc. **7.** Data on File, ASA\_DR-0001. Organogenesis Inc.