Certificate of Conformance (COC) – Surgalign FibreX Demineralized Bone Matrix

ORIGIN BIOLOGICS
Life Enhancing Allografts

FORM	
Document No.	FORM-0305
Parent SOP	SOP-0075
Revision	00
Effective Date	09 MAR 2021

DONOR DESCRIPTION

Donor Number	OB20-0091
Age	59
Gender	FEMALE

CONSENT	YES	NO	NOT DETERMINED
Research/Education	☑	☐	☐
International	☑	☐	☐

ELIGIBILITY DETERMINATION	YES	NO	NOT DETERMINED
EU criteria per EU Directive 2006/17/EC including HTLV I/II	☐	☐	☑

PRODUCT DESCRIPTION

Freeze dried, aseptically processed bone (demineralized bone fibers) cleansed with a validated process that utilizes Gentamicin. Final product is terminally sterilized via validated irradiation process. Storage is 15°C to 30°C.

Product ID Number(s)	OB20-0091	Lot No. Range	-021 thru -028
Customer Part Number			FBX-0002
Expiration Date			30 APR 2023

PRODUCT ANALYSIS

MICROBIAL TESTING *Tissue is subjected to microbiological testing at recovery and processed and sterilized under validated conditions to be considerably free of specific aerobic / anaerobic microorganisms and fungal contaminants whose presence would preclude tissue from processing or transplantation.*

The above listed product complies with the requirements as set forth by the American Association of Tissue Banks (AATB) and the Food and Drug Administration (FDA) for human tissue for transplantation.

TEST	RESULT
Sterility Dose Report	PASS
Residual Calcium	PASS
Donor Osteoinductivity Potential	PASS
Residual Moisture	PASS

DONOR ELIGIBILITY AND SEROLOGICAL TESTING

Donor eligibility (screening and testing) is performed in accordance with AATB standards and FDA regulations (21 CFR 1271). Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor eligibility is determined by a Board-Certified Physician (Medical Director).

Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493. The testing was conducted using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens where applicable. The records of this testing are maintained at Origin Biologics, 6635 S. Eastern Avenue, Suite 100, Las Vegas, NV 89119. The following required testing was performed and found to be negative or non-reactive:

Antibody to Human Immunodeficiency Virus 1 & 2 (HIV 1 & 2)
Human Immunodeficiency Virus Type 1 (HIV-1 NAT)
Hepatitis B Core IgG/IgM Antibody (HBcAb)
Rapid Plasma Reagin or Serologic Test for Syphilis (RPR or STS)
Antibody to Hepatitis C (HCV)
Hepatitis C Virus (HCV-NAT)
Hepatitis B Surface Antigen (HBsAg)

Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II) and HBV NAT may have been performed at the time of donor screening and were found to be acceptable for transplantation.

Quality Representative: Michelle Haider **Date:** 29 July 2021

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