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Manufactured by:
BioLab Sciences, Inc.
7662 E Gray Rd Suite 107
Scottsdale, Arizona 85260

FEI#: 3014573577

PRODUCT DESCRIPTION:
Cell Factor is derived from donated eligible allogeneic birth tissues, aseptically processed, and stabilized through lyophilization and packaged in sterile vials for use by a licensed physician end user.
As per FDA 21 C.F.R. § 1271.3 (d) (3) "Cell Factors" (CF) are not considered HCT/Ps by the FDA (Food and Drug Administration). Cell Factors are neither a 351 nor 361 product. Cell Factor is produced in an FDA registered facility and follows 21 CFR 1271 Human Cellular Therapy and Tissue Product (HCTP) standards as related to the recovery of the donated tissue, storage, screening, initial processing and labeling of the tissue. There are no claims as it relates to outcomes. This is provided to a licensed medical physician for possible disease diagnosis and/or treatment at their discretion. It is highly recommended that the physician review this information with their patient. Clinical data and information is available upon request and is for education and disease state awareness communication only.
Cell Factors are aseptically processed, stabilized via lyophilization, and are derived from allogeneic placental tissues. Cell Factors are processed using a proprietary process, and once lyophilized are loaded into a 2cc sterile vial. All originating tissues are obtained from consenting donors, tested for infectious diseases, and determined eligible for transplant by a licensed trained medical physician.

PROCESSING: LOT
The allograft tissue is processed to extract and preserve the structure of the cell factors. The cell factors are characterized and quantified by a sequencing assay. Preparation and quality assurance methodologies applicable to the original allograft tissue is performed and comply with standards as set by the FDA and American Association of Tissue Banks (AATB), found in 21 CFR 1271 and all applicable state requirements. Technical Quality Assurance standards throughout the manufacturing process are rigorously followed and reviewed. Cell factors are extracted, stabilized, and packaged using aseptic techniques in ultra-clean controlled micro-environments. Lot-to Lot validated sterility testing is performed.

DONOR ELIGIBILITY & RELEASE:
Donated tissue is recovered and processed by an FDA registered tissue bank according to the standards required for transplantation. The donor has been determined to be eligible by a medical director, and therefore the tissue is suitable for transplant once processed, according to CGTP standards, prior to the cell factors being released for use.
Blood specimens collected from the donor at the time of tissue recovery and are tested by a CLIA certified laboratory registered with the FDA for the relevant communicable disease agents found in Table below. Donors that have non-reactive or negative serological screening test results and have been thoroughly screened against a medical and high-risk behavior criterion will be acceptable. Tissues are from informed consented donors, who completed a medical history and risk assessment interview, have had a physical examination, and made available medical records. Collection & transport records along with microbiology culture results, are included in the final review. Once all criteria have been met, the Medical Director determines the eligibility of the donor. The medical eligibility requirements and Donor Acceptance Criteria Policy exceed what is required by the FDA and AATB.

INFECTIOUS DISEASE TESTING	
BLOOD TEST	**ACCEPTABLE RESULT**
Hepatitis B surface Ag	Negative / Non-Reactive
Hepatitis B core ab	Negative / Non-Reactive
Hepatitis B NAT	Negative / Non-Reactive
Hepatitis C Ab	Negative / Non-Reactive
Hepatitis C NAT	Negative / Non-Reactive
HIV–1/2 Ab	Negative / Non-Reactive
HIV NAT	Negative / Non-Reactive
HTLV 1/2 Abs	Negative / Non-Reactive
Syphilis	Negative / Non-Reactive
West Nile Virus NAT	Negative / Non-Reactive

In addition to the pre-clinical safety testing and review, a lot-to-lot bioanalytical testing is performed of the validated process validation, as well as a comprehensive, Quality Assurance review of the processing & packaging records, finished tissue microbiology cultures, and the labeling associated with CFs for distribution. The names and addresses of organizations involved in the recovery, screening, testing, processing, eligibility determination of the donated tissue and the release of Cell Factor for distribution can be made available upon request.

INTENDED USE:
The intended use for the Cell Factor is at the discretion and direction of a trained medical professional where intervention may be beneficial at the site of injury and including, but not limited to applications to tunneled or undermined wounds or injuries. Cell Factor is supplied aseptically and intended for one time use in a single patient. This product is intended for use by a trained medical professional. For questions regarding the product or how to use the product please contact the distributor.

SUGGESTED INSTRUCTIONS FOR USE:
Note: The outside of the vial is NOT sterile.
1. Inspect and review the information on the outside of the packaging.

2. Open the outer package and remove vial.
3. Use aseptic technique to sterilize the vial stopper once the tapper seal has been removed.
4. Combine the product with 1ml of sterile medium of the physician's choice into vial (do not shake, gently roll until reconstituted.
5. Use appropriate tool or instrument needed to deliver mixed product for the designated procedure.
6. After preparing the area to be treated, place product into or on area of the patient as required.

PRODUCT STORAGE & USE:
It is the responsibility of the dispensing service, distributor and/or end user to maintain, the cell factors in its original package and in a controlled environment of >0°C-37°C (>32°F-98°F) and is ready for use. Once opened, the product must be used immediately or discarded. The product is for one-time use only and for one patient. See package label for expiration date.

PACKAGING, LABELING AND SHIPPING:
Each lot is identified by its own unique ID and is packaged in a sterile, single-patient-use vial which is labeled with the expiration date, product description, and size. Do not x-ray or irradiate the product.

STERILIZATION:
This product is not able to be listed as "STERILE" ($SAL10^{-6}$). USP 71 Sterility testing has been performed and negative of any growth.

CONTRAINDICATIONS:
There are no known contraindications.

POTENTIAL COMPLICATIONS:
No known potential complications

WARNINGS & PRECAUTIONS:
- Do not sterilize.
- Discard all open and unused portions.
- Do not use if the package or vial seal is broken, open, damaged or looks to be tampered with. Notify the distributor immediately.
- Do not use beyond its expiration date.
- The cell factors must be stored in a temperature range of >0°C-37°C (>32°F-98°F). Do not use and discard if required storage procedures and temperatures have not been maintained.
- Antibiotics are used during initial processing of the allogeneic tissue and tissue, and therefore the final product has been thoroughly rinsed. While we are confident all residuals of the antibiotics used have been removed there is a possibility that an undetectable level of antibiotics may still be present.

This product should be used with caution where an active infection is present. If the physician determines that the clinical circumstances require use in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken. The donor tissue is processed following FDA standards however donor screening methods may be limited to detect all diseases. Careful donor screening, testing, and processing are performed as a part of the qualification of all tissue donors and preparation of all products. As with any tissue-derived product, there are limits to the screening, testing, and processing methods that can be employed, and donated tissue cannot be guaranteed to be free of all pathogens or unwanted constituents, nor can the risk for disease transmission be eliminated.

WARRANTY STATEMENT
This product is unique and does not constitute a product under liability laws. No implied warranties of merchantability or fitness for a particular purpose are applicable. No implied warranties exist as to defects in biologics which cannot be detected, removed, or prevented by reasonable use of available scientific procedures or techniques. Furthermore, ALL WARRANTIES ARE DISCLAIMED, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ADVERSE EVENTS:
Adverse reactions must be promptly reported by the trained medical professional to the distributor.

RETURNS:
If the product arrives damaged, is mislabeled or if there is any issue, contact the distributor immediately for instructions regarding disposal and product replacement.

SYMBOLS	
	Manufacturer
	Consult Instructions For Use
	Expiration Date
	Temperature Limits
	Do not X-ray or irradiate
	Not Sterile
	Single use only; Do not reuse.
	Federal (USA) law restricts the use or sale by anyone other than a licensed physician, dentist, and podiatrist.
	LOT
	Do Not Use If Inner Container Is Damaged