



LIVE BEYOND
WITH
LIVEYON[®]

THE FUTURE OF REGENERATIVE MEDICINE

**INSTRUCTIONS FOR USE AND
PRODUCT PREPARATION GUIDE**

ReGen Series®

READ BEFORE USING

The Liveyon ReGen® product is derived from voluntarily donated human umbilical cord. ReGen® can only be sold to, and used by licensed physicians.

Read this entire package insert carefully prior to use.

Single vial use. Intended dosage is 1 vial for 1 patient on one occasion.

Order by physician only, not intended for resale.

For use by a physician under the authority of Section 361 HCT/PS subject to C.F.R. Part 1271

Contents:

1. Aseptic Package

a. Instructions for use

b. Injection Card

c. Injection Labels

I. Part number

II. Description

III. Allograft I.D.

IV. Donor Number

V. Expiration Date

VI. Barcode

2. Sterile Package

a. Container with Cryopreserved **ReGen®** Allograft

Liveyon is the exclusive Worldwide distributor for Genetech Inc., a cGMP compliant sterile laboratory registered with the FDA for the processing, packing, storing, labeling, and distribution of umbilical cord blood stem cell products.

Description

The Liveyon ReGen® product is an allograft product processed and supplied by Genetech Inc. All recovery, processing, and distribution are in accordance with AATB Regulations.

The Liveyon ReGen® product is derived from the umbilical cord of healthy, full term babies and contains various cytokines, proteins, growth factors, and cell populations, that aid in the repair, healing, replacement, or supplementation of a recipient's cells or tissues. Among those proteins include are **Basic Fibroblast Growth Factor (FGF2)**, a mitogen which is involved in many aspects of growth, development, and healing, with a particularly important role in the enhancement of bone and cartilage formation. **Vascular Endothelial Cell Growth Factor (VEGF)**, which is a signaling protein produced by cells that stimulates angiogenesis, and helps restore oxygenation to tissues and cells when blood supply is inadequate such as in a joint. **Stem Cell Factor (SCF)**, which stimulates your body's own stem cells and signals them to a targeted area as well as mediate cell survival, migration, and proliferation depending on the cell type. **Interleukin 1 Receptor Antagonist (IL1-Ra)**, which is a protein released by cells and plays an important role of reducing inflammation among many more.

This allograft container is supplied sterile and prepared aseptically.

Regulatory Classification

The Liveyon ReGen[®] allograft product is an allograft human tissue product for injection and is restricted to homologous use. It's processed and distributed under the FDA requirements for Human Cellular and Tissue based Products (HCT/P) (21 CFR Part 1271), 361 human cell and tissue product, State regulations and guidelines of the American Association of Tissue Banks (AATB)

Applications For Use

The Liveyon ReGen[®] allograft product may be used for a homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent." As defined in 21 CFR 1271.3(c), homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. Administration of this allograft is restricted to a qualified healthcare professional (e.g., physician)

The Liveyon ReGen[®] allograft product is a single use vial and intended for a single patient use only.

Donor Recovery and Screening

The Lot# represents a specific batch of cells that have been processed at a single time. The Donor# represents a unique identification for a single donor.

After authorization for donation is obtained (represented by the mother of the newborn child), collection of the donor tissue is performed in an aseptic manner by an appropriately licensed tissue establishment. Donor eligibility is carefully evaluated as required by the FDA and in accordance with AATB standards and applicable state guidelines. Tissue donors are evaluated for high-risk behaviors and relevant communicable diseases. Screening includes a review of the donor's medical and social history, a physical assessment, serological screening, and tissue collection microbiology. The medical and scientific staff at Genetech Inc. has determined that the donor has met the eligibility requirements.

Each donor is tested and shown to be negative or nonreactive for the following:

PRODUCT TESTING	SPECIFICATIONS	RESULTS
Infectious Disease Tests		
Hepatitis Bs Ag	NOT DETECTED	PASS
Hepatitis Bc Ag	NOT DETECTED	PASS
HTLV I/II Ab	NOT DETECTED	PASS
Hepatitis C Ab	NOT DETECTED	PASS
HIV 1&2 Plus O Ab	NOT DETECTED	PASS
CMV Ab	NOT DETECTED	PASS
RPR (non-Treponemal Syphilis)	NOT DETECTED	PASS
AB/Rh	NOT DETECTED	PASS
HIV-1/HCV/HBV Nat (Ultrio)	NOT DETECTED	PASS

Sterility Assurance Tests

Bacteria/Fungi	NOT DETECTED	PASS
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If additional testing of communicable diseases is performed, all available test results are reviewed as part of donor eligibility.

This testing is performed by a laboratory registered with the US FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). Test kits used are approved by the US FDA. Each Lot# & Donor# go through a United States Pharmacopeia General Chapter 71(USP71) Sterility test to validate the complete absence of bacteria and/or other microorganisms. The medical and scientific staff at Genentech has determined the donor tissue is suitable for transplantation. The testing and medical release records are maintained by Genetech Inc.

Processing

The Liveyon ReGen® allograft product is processed in a controlled sterile environment from a single donor using an aseptic closed loop system designed to prevent contamination and cross-contamination. The donated Umbilical Cord Blood is separated through a centrifuge machine, then washed using a bead separation process that removes all red blood cells and red blood cell contaminants. It is then concentrated into single doses with specific cell counts in a certified BCS class 282 safety cabinet, and cryogenically preserved with a cryopreservation medium that contains 10% Dimethyl Sulfoxide (DMSO). Final products are packaged according to approved specifications and procedures and packaged as ordered.

Note: allograft tissues naturally vary in color from white/off-white or yellow/pale yellow.

Contraindications

Contraindications for the use of this allograft shall be determined by a licensed practitioner.

Warnings

The cryopreservation medium contains 10% DMSO. Do Not Use if the patient has sulfur sensitivity. Careful donor screening, laboratory testing, and tissue processing have been utilized to minimize the risk of the transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, this graft cannot be guaranteed to be free of all pathogens. The same medical/surgical circumstances or complications that apply to any surgical procedure may occur during or following transplantation. **Do not reuse or re-sterilized.**

Packaging and labeling

Each allograft product distributed by Liveyon LLC., is identified by its own unique serial number allograft identification. The allograft is packaged in a pouch. Each pouch features a peel back seal and is heat sealed to provide a sterile barrier and the package label includes graft details such as fluid content. Contents of the package are sterile unless the package has been opened or damaged during transport.

Warning: If the innermost pouch is compromised, or shows evidence of being torn or open, do not use.

Storage

The Liveyon ReGen® allograft products are shipped on dry ice and should be maintained in its original packaging at -60°C or colder until ready for use.

Expiration

See package label for expiration dating

It is the responsibility of the end-user to maintain this allograft in the appropriate storage conditions prior to transplant and to check the expiration date accordingly.

Instructions for use

It is important to read and understand the following instructions prior to clinical use. Improper preparation may adversely affect the success of the surgical procedure.

Prior to Use: Examine packaging – do not use this allograft if:

1. Any part of the package/ product that appear to be missing, tampered with, or damaged.
2. The product label or identifying barcode is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed.

If any of the above conditions exist or are suspected, this allograft should NOT be used!

Preparation for Use of the Liveyon ReGen® Allograft Product

*This product contains Dimethyl Sulfoxide(DMSO) which is an organosulfur compound. It is not recommended to proceed on patients with known DMSO or sulfur based allergies.

**Prophylactic use of an H1 & H2 inhibitor and or a corticosteroid may help to avoid or lessen any inflammatory or allergic response associated with a sulfur sensitivity/allergy or other known allergies.

Recommended Supplies:

- Liveyon ReGen®10 = 10M(1.0×10^7) or ReGen®30 = 30M(1.0×30^7)
- H1 & H2 Inhibitor, 4mg/ml dexamethasone
- Tape, dressing/band aid
- 1 – 10ml syringe
- 0.9% Normal Saline (NS) or PRP for injection (optional)
- 1 – 18ga x 2in. draw needle
- 1 – 23 to 30ga x 2in injection needle (or your preferred needle size)
- Gloves
- Alcohol pads or Chloro-prep
- Absorbent Pad (for clean workspace)
- Extra gauze as needed

Commonly used protocol for orthopedic conditions:

One injection of 10M cells delivered directly to the joint through an intra-articular injection or directly to the affected soft tissue. Doses of 30M cells/1ml of volume can be broken up for multiple joints on a single patient.

Once a package seal has been compromised, the tissue shall either be injected, if appropriate, or properly discarded. Used ReGen® vials should be disposed of in accordance with the recognize procedures for discarding medical waste material.

(Note: It is best to complete the injection within 20 minutes post thaw)

1. Prepare the patient, and layout the above supplies in an aseptic field.

- a. In an aseptic field open the outer package to expose and remove the first inner peel pouch.
- b. Open the first inner peel pouch in the aseptic field and deliver the innermost sterile sealed pouch containing the ReGen® allograft product to the sterile field.
- c. Remove cryogenically preserved vial from the packaging. use caution when removing the allograFT from the pouch as the allograPH vial is small AND extremely lightweight.
- d. Thaw by holding the vial in a hand or roll vial gently between the hands until crystal is thawed. **(Approximately 2 to 3 minutes)**

Do not rapid thaw or use a high heat device during the thawing process. Over heating or significant agitation of the product during or after thaw may significantly impair cell viability. It is best to pass the -40C to 0C stage as quickly as possible via body temperature thawing.

2. Prepare for the injection

- Place 18ga needle on syringe.
- Remove screw top cap from product vial and place needle into vial at a 45-degree angle to draw the product into the syringe. (If you choose you may add 2-3ml of 0.9% NS or PRP into the syringe, which may improve cell viability due to minimizing the hyperosmolar affect)
- Remove all air from the syringe.

3. Perform the injection as per your preferred technique.

- Use on a single occasion for a single patient only
- Do not use past the specific expiration date on the label
- Do not use ReGen® if it is thawed upon receipt
- ReGen® is to be handled under aseptic conditions

If for any reason the product is opened and not used, it should be disposed of properly or returned to Genetech Inc., by contacting Customer Services and following the appropriate return procedures. Document the reason for the non-use of the product and indicate the disposition of the tissue on the enclosed transplantation record.

Returns

The Liveyon ReGen® product is shipped with dry ice and may not be returned after the seal has been broken on the Styrofoam cooler. Any return of an unopened container must be completed within 24 hours of receipt. Please contact **Genetech Inc.** for a return authorization and shipping instructions. The Liveyon ReGen® product is to be stored at – 80 °C or colder at all times.

Patient Records

Recipient records must be maintained for the purpose of tracking tissue post-transplants. Important notice to the end user: Please record the distinct identification codes on the records of the patient's medical record. It is also recommended that the following information be recorded in the patient's medical record.

Description of Tissue
Product Code
Expiration Date
Description of Procedure
Date and Time of Procedure
Physicians Name and any other Pertinent Information

Please record the following information on the Transplantation record:

Patients Name
Patients Date of Birth
Patient Sex
Name and Address of the Healthcare Facility
Patient I.D.
Physicians NPI Number
Physicians Name
Date of Procedure
Type of Procedure
Name of Person Providing Information
Distinct product identification code (sticker provided with info)

Once completed, the bottom copy of the transportation record should be returned to Liveyon LLC. Copies of this form should be retained by the transportation facility for future reference.

Return the record to:

7700 Irvine Center Dr.
Suite 800
Irvine, California, 92618

Potential Complications

Allografts are composed of proteins as a component so the potential for hypersensitivity, allergic reaction or other immune response may exist. All adverse outcomes potentially attributed to this allograft must be properly reported to Liveyon LLC.

Possible complications can occur as with any surgical procedure including, but not limited to pain, infection, hematoma, and/or immune rejection of the introduced tissue.

Disease screening methods are limited; therefore, certain diseases may not be detected.

The following complications of the tissue transplantation may occur:

- Transmission of disease of unknown etiology.
- Transmission of known infectious agents including but not limited to viruses, bacteria, and fungi.

Disposal

Allograft disposal shall be in accordance with the local, state, and federal regulations for human tissue.

Warranty Statement

The Liveyon ReGen® allograft products are processed and packaged for Intra Articular Joint Injections. They are exclusive and do not constitute a product under liability laws for them in most states. No impact warranties of merchantability or suitability for particular purpose are applicable. No implied warranties exist as to the defects in Biologics which cannot be identified, removed, or prevented by reasonable use of obtainable 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 particular purpose. In addition, all consequential damages, or expenses, directly or indirectly arising from the use of these allografts are hereby disclaimed.

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