BIOLAB Fluid GF™

ambient liquid human tissue

Instructions for Use

PRODUCT DESCRIPTION

BioLab Fluid GF™ is liquid human tissue derived from the amniotic fluid within the amniotic sac and is intended for use to cushion, lubricate, and protect human joint areas.

PACKAGE CONTENTS

The product package contains the following items:

- One vial containing liquid human tissue, packaged in one peelable pouch
- Instructions for Use insert (this document)
- One set of supplemental Tracking Labels
- One Tissue Tracking Record (TTR) card

If any of these items are missing, please contact BioLab Sciences.

PREPARATION & APPLICATION

1 

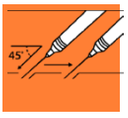
Using aseptic technique, peel open the product pouch; place the vial onto a sterile field.

2 

Remove the vial cap.

3 

Draw contents into sterile syringe with an 18G or smaller needle. Change to a 21G – 23G needle for injection.

4 

Inject at 45-degree angle, injecting clockwise throughout the site to provide maximum coverage.

5 

Inject fluid slowly to allow the product to settle into the patient's joint area.

Product can also be applied externally onto the area of damaged or inadequate soft tissue.

STORAGE AND HANDLING

- Store at ambient temperature (15-25°C, 59-77°F).
- Handle using aseptic techniques.

WARNINGS

- For single patient use only.
- To be used under the supervision of a qualified healthcare provider.
- Do not use if the product sterile barrier system or its packaging is compromised.
- Cannot be re-sterilized.

PRECAUTIONS

- The tissue should not be injected in the presence of a live infection.
- BioLab Sciences makes no claims concerning the biological properties of this liquid human tissue. All tissues have been collected, processed, stored, and distributed in compliance with US Food and Drug Administration (FDA) regulations governing human cells, tissues, and cellular and tissue-based products (HCT/Ps) to prevent the transmission of communicable diseases listed on page two. Current technologies may not preclude the transmission of all communicable diseases.

HCTP RECORD TRACKING

Recipient records are maintained for the purpose of tracking tissue post-transplant in accordance with The Joint Commission standards and the FDA requirements under 21 CFR Part 1271. Supplemental labels, which indicate the tissue ID number, are contained in this package for tracking process. The allograft ID number must be recorded in the operative record. The provided Tissue Tracking Record must be completed and returned to BioLab Sciences.

PROCESSING

The HCT/Ps are processed in accordance with FDA's Good Tissue Practice regulations in a controlled cleanroom environment, using processes designed to prevent contamination of the tissue, and to prevent the introduction, transmission, and spread of communicable diseases.

The tissue products are sterilized using electron-beam irradiation for a SAL $^{10\text{-}6}$.

DONOR SCREENING, TESTING AND ELIGIBILITY

The donated human birth tissue has been determined to be eligible for transplantation by a licensed physician, the Medical Director of BioLab Sciences. In accordance with FDA regulations under 21 CFR Part 1271, the donor has been determined to be free from risk factors for, and clinical evidence of, infection due to relevant communicable diseases and other exclusionary disease conditions through review of donor records, including medical/behavior risk assessment, medical records, and a recent physical examination. Additionally, testing of a qualified blood sample indicates that the donor is nonreactive or negative for the following communicable disease markers:

- Antibody to human immunodeficiency virus (HIV) types 1 & 2
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core (HBc total)
- Antibody to hepatitis C (HCV)
- Treponema pallidum - Syphilis (RPR)*
- WNV NAT
- HCV NAT
- HIV NAT
- HBV NAT

* Tissues from a donor whose blood specimen is initially reactive for the non-treponemal screening assay, are cleared for transplantation use **only** when the confirmatory result from the treponemal specific assay is non-reactive.

All laboratories performing donor screening tests for this product are registered with the FDA and certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments Act of 1988 (CLIA) and 42 CFR Part 493, or equivalent requirements. Test kits used are approved and cleared by the FDA for screening blood specimens collected from living donors. A copy of the relevant medical records can be obtained from BioLab Sciences upon request.

ADVERSE REACTIONS

Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to BioLab Sciences at QA@biolabsciences.net or by calling 480-656-5746, ext. 200.

ALLOGRAFT TISSUE PROCESSED BY:

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FDA FEI (FDA Establishment Identifier)#: 3014573577

IFU-GF Revision 1.0, June 2021