# INTERFYL®

Human Connective Tissue Matrix

## DESCRIPTION

**INTERFYL®** Human Connective Tissue Matrix is an allogeneic decellularized particulate human placental connective tissue matrix consisting of natural human structural and biochemical extracellular matrix components. The transplanted matrix retains its fundamental structural and functional characteristics of connective tissue extracellular matrix, providing mechanical/structural support and elasticity. **Interfyl** provides a framework for incorporation by the recipient's tissues and cells. The common functions of extracellular matrix in connective tissues that are part of the integument (dermis and fascia) are structural support and mechanical support for cell adherence and growth and tissue repair.

## INDICATIONS FOR USE

(For surgical indications)

**Interfyl** is intended for use as the replacement or supplementation of damaged or inadequate integumental tissue. Indications include, but are not limited to, treatment of soft tissue voids, correction of soft tissue defects, soft tissue augmentation during repair of dehisced or complicated surgical closures and repair of small surgical defects resulting from either medical or surgical conditions including those with exposed vital structures (bone, tendon, ligament, or nerve).

(For wound indications)

**Interfyl** is intended for use as the replacement or supplementation of damaged or inadequate integumental tissue. Indications include, but are not limited to: augmentation of deficient/inadequate soft tissue and treatment of deep dermal wounds; surgical wounds; soft tissue voids as a result of tunneling wounds, fistula tracts, or dermal undermining-including those with exposed vital structures (bone, tendon, ligament, or nerve).

## REGULATORY CLASSIFICATION

**Interfyl** is regulated by the US Food and Drug Administration (FDA) under Section 361 of the Public Health Service Act as a human cell, tissue, and cellular and tissue-based product (HCT/P, 21 CFR, Part 1271.10(a). **Interfyl** is minimally manipulated during processing and is marketed in accordance with the FDA's requirements for HCT/Ps. This product is distributed only to licensed health care practitioners.

## QUALITY ASSURANCE

**Interfyl** is produced from donated human placentas after normal, healthy, full-term pregnancies. Each donor is carefully screened. Comprehensive medical and social histories of the donors are obtained and tissues are procured, processed, and tested in accordance with standards established by the AABB and FDA to minimize potential risks of disease transmission to recipients. Infectious disease testing is performed at a CLIA-certified laboratory. Current testing cannot provide absolute assurance that the tissue will not transmit infectious disease to the recipient.

The following tests are performed on donor samples and the infectious disease markers are interpreted as negative or non-reactive for release of product with the exception of CMV and Antibody Screen. Maternal blood is tested for CMV Antibody and Antibody Screen but a placenta is not discarded due to maternal CMV and Antibody Screen status.

## MATERNAL BLOOD TESTING

- HIV 1/2 Antibodies
- HIV NAT
- HTLV I/II Antibodies
- West Nile Virus NAT
- CMV Antibodies
- Hepatitis C Antibody
- Hepatitis C NAT
- Hepatitis B Core Antibody
- Hepatitis B Surface Antigen
- Hepatitis B NAT
- Antibody Screen
- Syphilis Screening Assay
- Trypanosoma cruzi – (Chagas) Antibody

The process used to manufacture **Interfyl** has been confirmed to produce product that is absent of bacterial and fungal pathogens. Testing for endotoxins is conducted to assure levels are below 20 EU/dose, non-pyrogenic.

## PRECAUTIONS

- **Interfyl** should not be used in clinically infected sites.
- Do not use **Interfyl** for intravenous, intra-arterial, intra-ocular or intrathecal applications.
- The contents are sterile if the vial/syringe (container) is unopened and undamaged.
- Do not resterilize.
- **Interfyl** must be used prior to the expiration date on the product pouch.
- Once opened, **Interfyl** must be used within two hours or discarded per institutional procedures.

## CONTRAINDICATIONS AND WARNINGS

If a recipient had an adverse reaction related to previous use of **Interfyl**, do not re-apply.

## ADVERSE EFFECTS

Adverse reactions or outcomes that potentially involve the use of **Interfyl** must promptly be reported to the Celularity, Inc. Customer Service at 1-844-963-2273.

## HOW SUPPLIED

**Interfyl** is supplied in 50 mg and 100 mg particulate and in 40 mg, 0.3 mL, 0.6 mL, 1 mL, and 1.5 mL flowable. Included in the packaging is this insert, a Tissue Tracking Letter and patient labels with the tissue identification number.

## STORAGE

Store **Interfyl** in its original packaging in a clean, dry environment at an ambient room temperature.

## STERILIZATION

**Interfyl** is an aseptically processed product and is terminally sterilized with e-beam irradiation.

## RECIPIENT TRACKING

The FDA requires a system of record keeping that enables the tracking of human tissue-based products from donor to consignee and vice versa. It is the responsibility of the practitioner to maintain sufficient records to permit prompt identification of the recipient. Tracking labels are enclosed in the **Interfyl** packaging to facilitate this process and should be affixed to the patient medical records. The enclosed Tracking Letter provides more detailed instructions.

## INSTRUCTIONS FOR USE

- These recommendations are designed to serve only as general guidelines. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.
- **Interfyl** should not be applied until excessive exudate or bleeding, acute swelling, and infection are controlled.
- Each syringe/vial of **Interfyl** is intended for use on a single patient on one occasion. Discard any unused material remaining after each treatment as per institutional procedures.
- Always handle **Interfyl** using aseptic techniques. Inspect all packaging integrity. Do not use if package seal is broken or the container has been violated. Discard material if mishandling has caused possible damage or contamination.

## APPLICATION GUIDE FLOWABLE

Note: The product is supplied in a double-pouch configuration; the inner pouch and its contents are sterile. Always handle **Interfyl** using aseptic technique. Once opened, use within two hours.

After proper preparation of the treatment area site:

- Open product package and remove inner pouch containing the syringes and accessories.
- Using aseptic technique, peel open the inner pouch and present the syringes and accessories onto the sterile field.

### Interfyl® 40 mg Flowable

Package Contains: **Interfyl** (dry) product syringe with 40 mg;
(1) empty syringe; (1) syringe adapter with double female luer locks;
(1) flexible 1.5 inch cannula

- Fill the empty syringe with 0.3-0.4 mL sterile saline or other sterile non-viscous fluid. 0.3-0.4 mL of liquid will achieve a toothpaste-like consistency. Based on physician preference and/or clinical application, the consistency can be altered by adding more or less liquid.
- Remove the needle from the syringe and attach the provided double female luer lock connection. Set syringe aside.

### Interfyl® 0.3 mL, 0.6 mL, 1 mL, and 1.5mL Flowable

Package Contains: **Interfyl** (dry) product syringe;
(1) empty syringe; (1) syringe adapter with double female luer locks;
(1) flexible 1.5 inch cannula

- Fill the empty syringe with equal parts sterile saline or other sterile non-viscous fluid. The 1:1 product to liquid ratio will achieve a toothpaste-like consistency. Based on physician preference and/or clinical application, the consistency can be altered by adding more or less liquid.
- Remove the needle from the syringe and attach the provided double female luer lock connection. Set syringe aside.

Notes on MIXING (Aseptic Technique):

- **Interfyl®** product syringe: Do not remove the cap. Pull back on the plunger slightly to create space and hold. Tap the syringe until the product particles are loosened.
- Connect the two syringes with the luer lock.
- Holding the connected syringes vertically (with the syringe containing the sterile fluid on top), push down on the plunger to release sterile fluid into the **Interfyl** product syringe.
- Holding the two connected syringes horizontally, push both plungers back and forth a minimum of 15 times to create a homogeneous mix.
- Can use 18 gauge needle if desired.

## APPLICATION GUIDE PARTICULATE

### Interfyl® Particulate 50 mg and 100 mg

Package contains one (1) product vial.

Note: The product is supplied in a double-pouch configuration; the inner pouch and its contents are sterile. Always handle **Interfyl®** using aseptic technique. Once opened, use within two hours.

After proper preparation of the treatment area site:

- Open product package and remove inner pouch containing the product vial.
- Unscrew the cap to open the vial.

Notes on MIXING (Aseptic Technique):

- The product may be used 'dry.' Placement of the product can be achieved by either tapping/sprinkling the contents out directly from the vial or by utilizing a non-traumatic forceps to pick-up the particulate for placement to the desired area.
- Sterile saline or other sterile fluid may be added to the particulate for a wet application. To achieve a paste-like consistency, add 0.6 mL sterile fluid for the 100mg vial, and 0.3mL sterile fluid for the 50mg vial.
- The consistency can be altered by adding more or less liquid. The resulting wet particulate may be placed as desired.

NOTE: NOT to be used as an injectable.

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For product information or adverse reaction reporting, telephone 1-844-963-2273