

### Best In Class Biomaterials Manufacturing Facility:

The Process is the Product

## A fully integrated, purpose-built manufacturing and research center

- \$80M investment in platform-based cGMP/cGTP manufacturing
- Optimized, product-specific CMC, QA/QC and manufacturing processes accelerate product development, production and commercialization
- Rapidly scalable, end-to-end supply chain
- Greater efficiency and economy than can be achieved through outsourcing to contract manufacturing organizations (CMOs) alone.

Interf

**PURPOSE BUILT FACILITY** Staffed by highly specialized scientists, engineers & technicians.

**150,000 SQ FT** Including laboratory and advanced manufacturing space for biomaterials.

CLINICAL SCALE (9) Grade C/ISO 7 GMP suites and (6) Grade D/ISO 8 GMP labs

Interfyl is a decellularized human placental connective tissue matrix (CTM) to be used for the replacement or supplementation of damaged or inadequate integumental tissue.

- · Can be used with acute injuries and/or chronic conditions
- Intended for homologous use

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- Ready to use with room temperature storage
- · Contains only the key components of connective tissue matrix
- 10-year shelf life

Available in **flowable** and **particulate** form in units of weight ranging from 45mg to 275mg to meet a variety of application needs

1.5 mL 1 mL 100 mg 0.6 mL 0.3 ml

1.5 mL 1 mL	Flowable (275mg) Flowable (170mg)
100 mg	Flowable
0.6 mL	Flowable (75mg)
0.3 mL	Flowable (45mg)

00mg	Particulate
0mg	Particulate

#### Interfyl 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).

#### Interfyl Contraindications, Warnings, and Precautions

Interfyl should not be used in clinically infected sites. If a recipient had an adverse reaction related to previous use of Interfyl, do not re-apply. Do not use Interfyl for intravenous, intra-arterial, intra-ocular, or intrathecal applications. 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. The contents are sterile if the vial/syringe (container) is unopened and undamaged. Do not sterilize.

For product information, product complaints, or adverse reaction reporting, call 1-844-963-2273. Please refer to the Interfyl Package Insert for complete product information.

Interfyl

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## BIOVANCE

BIOVANCE INDICATIONS FOR USE BIOVANCE is an allograft intended for use as a biological membrane covering that provides the extracellular matrix. As a barrier membrane, BIOVANCE is intended to protect the underlying tissue and preserve tissue plane boundaries. Indications include, but are not limited to, surgical covering, wrap or barrier, application to partial- and full-thickness, acute and chronic wounds (such as, traumatic and complex wounds, burns, surgical and Mohs surgery sites; and diabetic, venous, arterial, pressure and other ulcers), including wounds with exposed tendon, muscle, bone or other vital structures.

- BIOVANCE is completely decellularized devoid of cells, hormones, growth factors, cytokines, and other substances.
- BIOVANCE is designed for ease of use in both surgical and nonsurgical settings. It requires no preparation, can be applied in any orientation, conforms easily to irregular surfaces, and requires no sutures.



#### **3L INDICATIONS FOR USE**

3L is an allograft intended for use as a biological membrane covering that provides the extracellular matrix while supporting the repair of damaged tissue. As a barrier membrane, 3L is intended to protect the underlying tissue and create a barrier between the tissue plane boundaries. Indications include, but are not limited to, surgical covering, wrap or barrier, application to partial- and full-thickness, acute and chronic wounds (such as, traumatic and complex wounds, burns, surgical and Mohs surgery sites; and diabetic, venous, arterial, pressure and other ulcers), including wounds with exposed tendon, muscle, bone or other vital structures.

- Easy to handle three layer design is thicker than other single layer amnion
- Tri-layer design allows for suturing if needed
- 10-year shelf life stored at ambient room temperature



### Biovance.3L OCULAR

BIOVANCE-3L OCULAR INDICATIONS FOR USE BIOVANCE 3L Ocular is an allograft intended for use as a biological membrane covering that provides an extracellular matrix. As a barrier membrane, BIOVANCE 3L Ocular is intended to protect the underlying tissue and preserve tissue plane boundaries. Applications include, but are not limited to, corneal and conjunctival related injuries or defects such as corneal epithelial defects, pterygium repair, fornix reconstruction, and other procedures



- Easy to use no preparation required. Shaped for ophthalmology procedures -conforms easily to irregular surfaces
- Designed for patient comfort no outer ring or ridge
- Not side-specific stromal side interfaces with ocular surface regardless of orientation



# CentaFlex

### CENTAFLEX INDICATIONS FOR USE

CentaFlex® is an allograft used as a barrier or wrap to cushion and protect surgical site and support wound management during healing. It is intended for use as a biological membrane covering that provides the extracellular matrix while supporting the repair of damaged tissue. As a barrier membrane, CentaFlex® is intended to protect the underlying tissue. Indication include, but are not limited to, surgical covering, wrap or barrier.

- Derived from the human placental umbilical cord
- Strength to support tissue repair without the trade- off of an overly thick tissue
- Extracellular matrix of this allograft provides a natural scaffold and protective barrier



#### CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS:

The contraindications, warnings, and precautions for Biovance, 3L, Biovance 3L Ocular, and CentaFlex are identical. BIOVANCE, 3L BIOVANCE, BIOVANCE 3L Ocular, and CentaFlex are contraindicated in patients with a known hyper-sensitivity to BIOVANCE, 3L BIOVANCE, BIOVANCE 3L Ocular, and CentaFlex. If a patient has an adverse reaction related to the use of BIOVANCE, 3L BIOVANCE, BIOVANCE 3L Ocular, or CentaFlex, immediately discontinue its use. BIOVANCE, 3L BIOVANCE, 3L Ocular, and CentaFlex should not be used on clinically infected wounds.

The pouch contents are sterile if the pouch is unopened and undamaged. Do not use if package seal is broken. Discard material if mishandling has caused possible damage or contamination. Do not resterilize. BIOVANCE, 3L BIOVANCE, BIOVANCE 3L Ocular, or CentaFlex must be used prior to the expiration date on the product pouch. BIOVANCE, 3L BIOVANCE, BIOVANCE 3L Ocular, and CentaFlex should not be used together with a collagenase product on the wound. For product information or adverse reaction reporting, telephone 1-844-963-2273. ase refer to the BIOVANCE, 3L BIOVANCE, BIOVANCE 3L Ocular, or CentaFlex Package Insert for complete product information

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