



U.S. Patent No. 8,153,162; 8,182,840; 8,182,841; 8,440,235; 8,455,009; 8,460,714; 9,161,955; 9,161,956; 9,198,939; 9,682,044; 9,724,370; 9,750,771; 10,272,119; 10,426,731; 10,632,155

Product Insert

Description

Clarix Flo is a sterile, micronized human amniotic membrane and umbilical cord product. **Clarix Flo** is aseptically processed, devascularized, cell devitalized and lyophilized. **Clarix Flo** is manufactured from donated human birth tissue according to Current Good Tissue Practice (CGTP) and Current Good Manufacturing Practice (CGMP) regulations established by the U.S. Food & Drug Administration (FDA). **Clarix Flo** is terminally sterilized via gamma irradiation with a Sterility Assurance Level (SAL) of 10^{-6} . **Clarix Flo** is for single use only in one patient by a qualified medical professional. **Clarix Flo** is intended for use as a barrier or cushion in acute and chronic wounds.

Precautions

- Do not use **Clarix Flo** if the packaging is damaged – Immediately report if there is any abnormality observed (e.g., labeling, packaging, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- Once the outer foil pouch is opened, **Clarix Flo** shall either be transplanted or otherwise discarded.
- Open and prepare **Clarix Flo** only at the time of use.
- Only rehydrate the **Clarix Flo** within the vial container. Do not remove **Clarix Flo** for rehydration into another vessel or container.
- Do not re-sterilize the product. Do not autoclave before use.
- Transient pain and/or swelling at the injection site is possible.

Warnings

As with the use of any human tissue, the possibility of infectious agent transmission cannot be completely eliminated although all screening and microbial testing results for this donor were satisfactory for transplantation.

Storage

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

Upon receipt, remove the product from the shipper and store accordingly until use.

Location & Temperature	Use After Receipt
Ambient Room Temperature 0°C → 38.0°C (32.0°F → 100.4°F)	Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)

Instructions

1. Open the pouch to retrieve the **Clarix Flo** vial. Vial can be delivered to a sterile field.
2. To use in suspension for topical application, remove the red plastic cap from the vial to reveal the rubber stopper held in place by the aluminum crimp seal.
3. Wipe the rubber stopper with an alcohol swab and allow to air dry.
4. Remove the stopper and add a minimum of 3 drops (~75-150 µL) of sterile saline to the vial. Do not exceed 2.0 mL of saline.
5. Gently tap the vial with fingers from the outside for ~30 seconds and allow 15 minutes for rehydration. Then aspirate the resultant solution from the vial with a sterile applicator and deliver **Clarix Flo**.



See Reverse



Donor Eligibility and Summary of Records

- This tissue was procured from a donor determined to be eligible based on the results of donor screening and testing. Donor eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, has been performed and documented by BioTissue Holdings Inc.
- A blood specimen, drawn within $\pm$ 7 days of donation, has undergone serological testing by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with 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). The donor has been tested for the following infectious diseases and results were non-reactive:

— HIV-1 & HIV-2 Antibody	— Hepatitis B Virus (HBV, DNA-NAT)
— HIV-1 (RNA-NAT)	— Hepatitis C Antibody (HCVAb)
— Hepatitis B Surface Antigen (HBsAg)	— Hepatitis C Virus (HCV, RNA-NAT)
— Hepatitis B Core Antibody (HBcAb)	— Syphilis (RPR)
	— HTLV I & II Antibody (HTLV I/II Ab)
	— West Nile Virus (WNV, RNA-NAT)

- This tissue has been deemed eligible for transplantation based on acceptable screening, serological and microbial test results.
- A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls is available upon request.

Recipient Records

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain records for the purpose of tracing tissue post-transplantation. The transplanting entity should document the disposition (transplanted or discarded) on the Donor and Recipient Information Card (DRI), attach one of the provided product tracking labels to the DRI and mail to the manufacturer. Attach the remaining labels in patient and hospital records.

Customer Feedback

Report any customer feedback, including complaint, error or accident notification promptly to BioStem at:

Phone: +1 (954)-380-8342 ext. 4

Email: quality@biostemtech.com.

Adverse Events

The FDA requires that information be supplied to the product manufacturer for mandatory reporting of adverse events. Possible significant adverse events include, but are not limited to microbial infection and transmission of viral disease. **The doctor is responsible for immediately reporting any adverse event potentially attributable to the use of Clarix Flo to BioStem.**

For Adverse Events and/or Complaints, notify via:

Phone: +1 (954)-380-8342 ext. 4

Email: quality@biostemtech.com



Manufactured and Distributed by BioTissue Holdings Inc.
for BioStem Technologies Inc.

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