

# AmnioFlo™

## Your Direct Connection to Regenerative Healing

- AmnioFlo is a non-surgical option for patients.
- AmnioFlo is a minimally-manipulated acellular amniotic fluid that is loaded with naturally occurring proteins that are known to stimulate angiogenesis, epithelial activity, and modulate various inflammatory processes.
- AmnioFlo is produced from the amniotic fluid that is collected during a scheduled cesarean section. AmnioFlo is derived solely from full-term pregnancies.
- AmnioFlo is derived only from a healthy baby and a healthy mother.
- AmnioFlo is comprised of 200+ different growth factors.
- AmnioFlo is intended for homologous use in various applications.

PRODUCT	SIZE	REF. NO.
AmnioFlo	0.5cc	AF-0050
AmnioFlo	1.0cc	AF-0100
AmnioFlo	2.0cc	AF-0200

**Direct Biologics is an innovative technology company focused on developing and providing regenerative biologic products for the medical market.**

DIRECT



BIOLOGICS™

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## Prescribing Summary

**Important:** For complete prescribing summary contact Direct Biologics.

## Safety Information

### CONTRAINDICATIONS

- Do not administer to patients that are immuno-compromised or taking immuno-suppressive drugs.
- **AmnioFlo** injections are contraindicated in cases of present infections or skin diseases in the area of the injection site to reduce the potential for developing septic arthritis.

### WARNINGS

- **DO NOT USE FOR INTRAVENOUS INJECTION.**
- Do not use if solution has a turbid appearance upon thaw.
- Once product is thawed, use immediately, store at 4-8°C until injection. Do not maintain a thawed vial at room temperature for more than 24 hours.

### PRECAUTIONS

#### General

- Strict aseptic administration technique must be followed to avoid infections in the injection site.
- **STERILE CONTENTS.** The vial is intended for single use. The contents of the vial must be used immediately once the container has been opened. Discard the unused solution.
- **VIAL MUST REMAIN FROZEN UNTIL USE. Thaw at room to body temperature (20-33°C).**

### INFORMATION FOR PATIENTS

- Provide patients with a copy of the Patient information prior to use.
- Transient pain and/or swelling of an injected joint may occur after intra-articular injection of **AmnioFlo**.
- When used intra-articularly, it is recommended that the patient avoid any strenuous activities or prolonged (i.e. more than 1 hour) weight-bearing activities such as jogging or tennis within 48 hours following intra-articular injection.

### ADVERSE EVENTS

- Adverse events include injection site pain and transient swelling.
- Adverse events should be communicated to Direct Biologics.

### HOW SUPPLIED

**AmnioFlo** is supplied in 0.5cc, 1.0cc, and 2.0 cc vials.

## Patient Selection

**AmnioFlo** is intended for homologous use in the treatment of acute or chronic inflammatory environments commonly associated with pain.

## Administration

**AmnioFlo** is a purified amniotic fluid derived product. By removing whole cells and cell debris, a product with twice the volume can be manufactured. This product must remain frozen but does not require cryo-preservation for a period of up to six months.

### RECOMMENDED INSTRUCTIONS FOR USE

- Remove vial from freezer 15 minutes prior to use to thaw.
- Product may be thawed at room temperature and maintained refrigerated for up to 24 hours if needed.
- Use in tissues as needed to suppress inflammation and instantiate growth.
- **Not for intravenous administration.**

### SCREENING & TESTING

Prior to processing, serological and microbial testing is performed. All products have been tested for the following diseases by an industry standard FDA and CLIA registered laboratory for the following communicable diseases:

- HIV 1 & 2
- Nucleic Acid Test for HIV-1 RNA
- Hepatitis B Virus (HBV) Surface Antigen
- Hepatitis B (HBV) Core Antibody (Total)
- Nucleic Acid Test for HBV RNA
- Antibody to Hepatitis C Virus (HCV)
- Nucleic Acid Test for HCV RNA
- Antibody to Human T Cell Lymphotropic Virus 1 & 2 (HTLV 1 & 2)

### PRODUCT OFFERING

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