

# GF-7®

# Allograft Tissue Information and Product Preparation Insert



## DONATED EQUINE TISSUE

### RESTRICTED TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN

The **Donated Tissue** has been determined eligible for transplantation by a licensed Medical Director according to the criteria listed in the Donor Selection section below.

## Product Description

GF-7® is derived from donated equine amniotic fluid. Birth tissue is obtained with consent from owner with delivery at approved foaling center. GF-7® is processed using aseptic techniques. The allograft is aseptically aliquoted in a sterile vial and frozen. The allograft has been sterilized using a proprietary sterilization process and secured in an outer container. Included in the packaging along with this insert are a Tracing Record and a set of patient labels.

- GF-7® is intended for single patient, one time use only.
- Once opened, GF-7® must be used immediately or discarded.

## Introduction

Sefton Biologics, LLC is registered with the Food and Drug Administration (FDA) as a processor and as the distributor of ACT/P 21 CFR 511.1(b)(4)(ii). All donor recoveries are performed by Sefton Biologics, LLC, and adhere to the regulations regarding ACT/P recovery and the screening and testing of the tissue donor as verified through supplier audits.

## Donor Selection

The Medical Director of the recovery agency has determined that the donor of the tissue contained in this product is eligible to donate tissue for transplantation based on meeting the following criteria:

1. The results of donor screening indicated that the donor was free from risk factors for and clinical evidence of infection due to relevant communicable disease agents and diseases.
2. The results of donor testing for the following relevant communicable disease agents are negative or non reactive:

- Equine Adenovirus
- Equine Encephalomyelitis Viruses
- Equine Herpes Virus (EHV-1, EHV-4)
- Equine Infectious Anemia Virus
- Equine Influenza Virus
- Equine Rhinitis Virus A and B
- Equine Rotavirus
- Equine Viral Arteritis Virus
- Equine Parvovirus
- Rabies Virus
- Vesicular Stomatitis Virus
- West Nile Virus
- Anaplasma phagocytophilum
- Babesia caballi
- Borrelia spp
- Neorickettsia risticii
- Theileria equi

At the time of recovery, the donor's medical history of the Mare is obtained prior to donation. Discussions with veterinarian and/or the owner/trainer are conducted to identify circumstances that may lead to the exclusion of the donor or donated tissue. The blood sample test results, donor medical history, behavior risk assessment, physical assessment, and information from other sources or records, which may pertain to donor suitability, have been evaluated by a Medical Director. The Medical Director is a licensed veterinarian who completes a comprehensive review of every donor record. The results are used to determine that the donor suitability criteria at the time of tissue recovery have been met, and that the tissue is acceptable for transplantation.

The names and addresses of the testing laboratories, the interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records and all pertinent donor medical information can be quickly retrieved upon request for any allograft tissue recovered on the behalf of Sefton Biologics, LLC.

## Recovery

Tissue recovery is aseptically performed by Licensed Veterinarian with Peterson & Smith Equine Reproduction Center. At the time of recovery, medical records are collected and reviewed as part of donor eligibility.

## Processing

GF-7® is processed by Sefton Biologics, LLC, in a controlled environment under aseptic conditions using methods designed to prevent contamination and cross-contamination of the products. Technical quality assurance standards are rigorously maintained.

## Tissue Distribution

GF-7® is distributed by Sefton Biologics, LLC

## Tissue Storage

GF-7® must be transferred to a monitored freezer which maintains the temperature at -20°C or colder for short term storage (less than 6 months) or at -40°C or colder for long term storage (until expiration date on graft). It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain the GF-7® in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

## ACT/P Tracking

**Important notice to end-user:** Recipient records must be maintained for the purpose of tracing tissue post-transplant per FDA requirements. The allograft ID number must be recorded in the operative record. The Tracing Record must be completed and returned to Sefton Biologics, LLC.

## General Usage

GF-7<sup>®</sup> is intended to provide cushioning within joint capsules and also intended for homologous use for the repair, reconstruction of soft tissue when a Veterinarian concludes that such function is medically indicated.

## Precautions

1. GF-7<sup>®</sup> has been processed and packaged using aseptic techniques and sterilized. The allograft must be handled in an aseptic manner to prevent contamination.
2. This product should not be used for intravenous or intrathecal applications.
3. Although donor tissue is evaluated and processed following strict FDA guidelines, the donor screening methods are limited and may not detect all diseases. As with any allograft, complications at the graft site may occur post-operatively that are not readily apparent. These include, but are not limited to:

- Transmission of communicable diseases, including those of unknown etiology
- Transmission of infectious agents such as viruses, bacteria and fungi
- Immune rejection of, or allergic reaction to, implanted ACT/P.

## Adverse Reactions

**Adverse reactions or outcomes that potentially involve the use of GF-7<sup>®</sup> should be reported immediately to Sefton Biologics, LLC. Customer Service Department at 1-800-000-0000.**

### Recommended instructions for use of

#### GF-7<sup>®</sup>

These recommendations are designed only to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

## Preparation Instructions

1. Carefully open the outer box containing the vials and aseptically transfer onto the sterile field.
2. Allow to thaw completely (approximately 5-10 minutes).
3. Once thawed, pull the GF-7<sup>®</sup> into a syringe and apply the allograft to the appropriate areas.

## Return Policy

Due to the delicate biological nature of a processed allograft, it **cannot** be returned for credit. If for any reason the allograft must be returned, a return authorization is required from Sefton Biologics, LLC. prior to shipping. It is the responsibility of the Veterinarian/institution returning the allograft to adequately package and label it for return shipment.

## WARNINGS



Do not sterilize. Discard all open and unused portions of the product.



Once the expiration date on the label has been reached, the allograft must be discarded.



Do not use if the vial integrity has been violated, is opened or damaged, or if mishandling has caused possible damage or contamination.



Each allograft is intended for single patient use, on a single occasion only.



Not made with natural rubber latex.

**Store at -20 C or colder. Do not re-freeze once thawed!**

**Rx Only. Use is limited to specific health professionals (e.g. Veterinarian).**

**After use, handle and dispose of all unused product and packaging in accordance with accepted local practice and applicable local, state and federal laws and regulations.**

**Donor Procurement and Eligibility Determined by:**  
Hydra Consultants, LLC

11374 Majestic Acres Ter  
Boynton Beach, Florida 33473  
1-800-000-0000

**Processed by:**  
Sefton Biologics, LLC

12413 Equine Lane  
Wellington, Florida 33414  
1-800-000-0000

**Distributed by:**  
Sefton Biologics, LLC

12413 Equine Lane  
Wellington, Florida 33414  
1-800-000-0000

GF-7 <sup>®</sup> Equine Amniotic Allograft		
Product Code	Description	UPC
#####	8 x 1ml	#####
#####	4 x 1ml	#####
#####	2 x 1ml	#####
#####	1ml	#####
#####	2ml	#####

Sefton Biologics, LLC

12413 Equine Lane  
Wellington, Florida 33414

Toll Free - 1-800-000-0000  
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