GF-7®

Allograft Tissue Information and Product Preparation Insert

INSTRUCTIONS FOR USE

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.

- 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. All donor recoveries are performed by Sefton Biologics, LLC, and adheres to the regulations regarding ACT/P recovery and the screening and testing of the tissue donor as verified through supplier audits. GF-7® 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® 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® should be reported immediately to Sefton Biologics, LLC. Customer Service Department at 1-800-000-0000.

Recommended instructions for use of GF-7®

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.

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.

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 Storage

GF-7® must be transferred to a monitored freezer which maintains the temperature at 0° C or colder for short term storage (less than 6 months) or at - 20°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-injection. The allograft ID number must be recorded in the operative record. The Tracing Record must be completed and returned to Sefton Biologics, LLC.

Preparation Instructions

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- Ĺ≠≠∫¸ Î∫ Î£[¸ s∫±…≠áÎá≠¸ (Approximately 5-10 minutes)
- Once thawed, pull the GF-7 ® into a syringe and apply the allograft to the appropriate areas (Please try to use
- Dilute with Saline if necessary

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.

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 medical 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

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Wellington, Florida 33414
1-800-000-0000

Distributed by:
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