DISTRIBUTED BY:
Tiger Aesthetics Medical, LLC
555 E North Lane, Ste. 6000, Building A
Conshohocken, PA 19428, USA
support@tigeraestheticsmedical.com
1 (888) 708-0808

DONOR ELIGIBILITY & RELEASE CRITERIA DETERMINED & PROCESSED BY:
RegenTX Partners, LLC
120 Chula Vista Dr.
San Antonio, TX 78232, USA
1 (888) 225-2511

L-032, Rev. 04

alloclæ™

ALLOGRAFT TISSUE INFORMATION & APPLICATION INSTRUCTIONS

Contents

This box contains a Donated Human Tissue Allograft (Human Cellular and Tissue-based Product (HCT/P)) for transplantation that meets all criteria to be compliant with HCT/Ps that are regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271.

The following items are included in addition to this product insert.

Allograft in a container that is packaged in a dual peel-pack.

Patient Label Sheet
Containing supplemental allograft product label for traceability and information transfer.

Product Description & Application for Use

alloClae™ is a sterile, hydrated adipose allograft. It is comprised of non-viable intact adipocytes extracellular matrix (ECM), triglycerides (lipids), and connective tissues. alloClae is intended to be applied subcutaneously in localized areas of the body to provide cushioning and support to the patient's body where adipose tissue naturally exists. alloClae does not contain viable cells, and has no systemic effect, and is not dependent upon the metabolic activity of living cells for its primary function. This allograft is intended for single patient, single use ONLY. Human tissue shall not be offered or dispensed for veterinary use.

Regulatory Classification

alloClae is processed and distributed in accordance with requirements for Human Cellular and Tissue-based Products (HCT/P)(21CFR Part 1271), 361 of the Public Health and Service Act, and State regulations by RegenTX Partners, LLC, and Tiger Aesthetics Medical, LLC respectively.

Federal law restricts this product for sale by or on the order of a licensed medical practitioner, tissue dispensing service, tissue distribution intermediary, end user transplant facility, and/or clinicians only.

Processing

alloClae is derived from cadaveric adipose tissue recovered using aseptic technique from an authorized human donation by qualified and trained personnel using current Good Tissue Practices.

alloClae is processed in a controlled environment using methods to prevent contamination and cross-contamination. Proprietary physiological buffers and surfactants are used during processing. Allograft may contain traces of these processing agents. Final products are sized and packaged according to approved specifications and procedures and are terminally sterilized using gamma irradiation in accordance with ANSI/AAMI/ISO 11137.

alloClae tissue will naturally vary in color with tones/tints of yellow to off-white. Localized areas of discoloration can be a normal occurrence.

Storage & Handling

alloClae is stored at ambient temperature (59-86°F/15- 30°C) until ready for use.

Product has a **3 month** shelf life. Please refer to package label for expiry date (see Expiration section).

The tissue product is for SINGLE patient, **one time use only**.

Once sterile barrier is broken, the tissue **must be used immediately** or disposed of appropriately.

Product usage must be recorded (see HCT/P Tracking section).

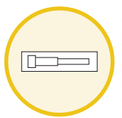
NOTE: It is the responsibility of the tissue dispensing service, tissue distribution intermediary, end user transplant facility, and/or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions and to track expiration date accordingly prior to further distribution or transplant.

Product Preparation

NOTE: alloClae is available in two volumes: 12.5 cc and 25 cc. Product volume and product codes are available on outer packaging labels, patient labels, and product labels. Verify product volume prior to usage.

1. Open product package and remove the dual peel-pack with the container.

2. Using aseptic technique, peel open the outer Poly/Tyvek pouch and present inner Foil/Foil pouch with container onto sterile field.



3. Using aseptic technique, peel open the inner Foil/Foil pouch and remove the allograft container to access the product.

4. Open the container using aseptic technique and transplant the allograft.

NOTE: These recommendations are designed only to serve as general guidelines. They are not intended to supersede any institutional protocols or professional clinical judgement concerning patient care.

Packaging & Labeling

alloClae is packaged in an open bore container, supplied, and stored at ambient temperature. The 12.5 cc product consists of a blister tray and one 12.5 cc container and is sealed in an inner Foil/Foil pouch, then outer Poly/Tyvek pouch. The 25 cc product consists of a blister tray and two containers and is sealed in an inner Foil/Foil pouch, then outer Poly/Tyvek pouch. The inner Foil/Foil pouch protects the product from UV exposure, and in combination with the outer pouch, act as a sterile barrier system. Contents of the package are terminally sterilized using gamma irradiation.

Each allograft is identified using the product labels which contain the allograft ID, product volumes, expiration date, and storage information.

DO NOT USE IF:

- Pouches and/or packaging shows evidence of being opened, damaged, or otherwise compromised.
- The allograft ID and supplemental labels are severely damaged, illegible, or missing.
- Tissue has not been stored in accordance with required storage conditions listed on product label and this IFU.

Expiration

alloClae has a 3-month shelf life. See package label for expiration date. It is the responsibility of the end-user to maintain this allograft in the appropriate storage conditions prior to transplant and to track the expiration date accordingly.

HCT/P Tracking

IMPORTANT NOTICE TO END USER: To comply with HCT/P requirements per 21 CFR Part 1271, recipient records must be maintained for the purpose of tracking tissue post-transplant per The Joint Commission and FDA requirements. A Patient Label Sheet containing supplemental allograft identification labels, which indicate the allograft ID, are contained in this package to aid the tracking process. The allograft ID must be recorded in the operative patient record file.

Donor Testing & Eligibility

Donor eligibility is carefully evaluated as required by the FDA and in accordance with applicable Standards and State guidelines based on screening and testing. Tissue donors are evaluated for considerable risk behaviors and relevant communicable diseases. Screening includes a review of the donor medical and social history, a physical assessment, serological screening, and tissue collection microbiology.

Each donor is tested and shown to be negative or nonreactive for the following:

- Human Immunodeficiency Virus Type 1 Antibody (Anti-HIV-1)
- Human Immunodeficiency Virus Type 2 Antibody (Anti-HIV-2)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Total Antibody (Anti-HBc or HBcAb)
- Hepatitis C Virus Antibody (anti-HCV)
- Syphilis Non-treponemal and/or Treponemal-specific assay
- HIV-1/HCV/HBV ULTRIO Nucleic Acid Test (NAT)

This testing is performed by a laboratory that is registered with FDA as a tissue establishment for testing and is certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493 or that has met equivalent requirements determined by the Centers for Medicare and Medicaid Services (CMS). Test kits used are licensed, approved or cleared by the FDA.

Careful donor screening, laboratory testing and tissue processing have been utilized to minimize the risk of transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, this allograft cannot be guaranteed to be free of all pathogens.

The Medical Director of RegenTX Partners, LLC has determined this donor tissue to be suitable for transplantation. The testing and medical release records are maintained by RegenTX Partners, LLC.

Disposal & Return of Allografts

Disposal: If for any reason the allograft is opened and not used, the reason for non-use should be alerted to Tiger Aesthetics Medical, LLC and tissue should be disposed of in accordance with local, state, and federal regulations for human tissue. Product that cannot be used because it is defective or if it does not meet the specification requirements, should be returned to Tiger Aesthetics Medical, LLC following appropriate return procedures described below.

Returns: alloClae is a single-patient, single-use product. Due to the nature of the product, returns cannot be accepted. Please contact Customer Support with any concerns regarding product integrity or shipment issues. For alloClae issues, the product may be returned with a return authorization obtained from Tiger Aesthetics Medical, LLC prior to shipping the allograft.

Email: support@tigeraestheticsmedical.com
Phone: 1 (888) 708-0808

Adverse Events

All adverse outcomes potentially attributed to this allograft must be promptly reported to RegenTX Partners LLC.

Potential complications may include cystic formations, nodule formation, pain, infection, hematoma, anaphylaxis, or other allergic response, specific or non-specific immune response to components, some component of the allograft, or discoloration of the skin at the procedure site.

Disease screening methods are limited; therefore, certain diseases may not be detected. The following complications of tissue transplantation may occur: Transmission of diseases of unknown etiology; transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi.

NOTE: No claims are being made concerning the biological properties of the tissue allograft. All tissues have been recovered, processed, stored, and distributed in compliance with FDA regulations governing HCT/Ps. Although every effort has been made to ensure the allografts' safety, current technologies may not preclude the transmission of disease.

Precautions

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

Do not re-sterilize. Dispose of all open and unused portions of the product.

Warnings

alloClae must not be transplanted in the presence of an active infection.

alloClae should not be transplanted into an area where native adipose does not exist.

The use of alloClae combined with local anesthetic agents, (e.g., lidocaine), has not been evaluated.

alloClae is contraindicated for patients with significant allergies manifested by a history of anaphylaxis or severe allergen sensitivity.