TETROUS™

# INSTRUCTIONS FOR USE
# EnFix RC™

This package contains an HCT/P as defined by US Food and Drug Administration (FDA) 21 CFR Part 1271. All tissue has been collected, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (AATB) and the US FDA regulations.

## DESCRIPTION / USE

EnFix RC™ is derived from voluntarily DONATED HUMAN TISSUES. It is intended for single patient, single use only and is restricted to use by a licensed clinician only. The tissue was aseptically collected from a donor determined to be suitable for transplant by a qualified Medical Director in accordance with US FDA regulations and AATB Standards. The allograft is processed, packaged and lyophilized in a controlled, aseptic environment and terminally sterilized using a validated electron beam irradiation process.

## DONOR SUITABILITY

Donor suitability determination was made by a qualified Medical Director who has reviewed pertinent donor records, including medical and social history, hospital records, infectious disease screening, autopsy report (if performed), physical assessment, microbial testing results and serological testing results.

## SEROLOGICAL TESTING

Communicable disease testing was performed in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493 using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens, where applicable. The following required testing was performed and found to be negative or non-reactive:

- Antibody to Human Immunodeficiency Virus 1 & 2 (HIV 1 & 2)
- Nucleic Acid Testing for Human Immunodeficiency Virus Type 1 (HIV-1 NAT)
- Antibody to Hepatitis C Virus (HCV)
- Nucleic Acid Testing for Hepatitis C Virus (HCV NAT)
- Antibody to Hepatitis B Core IgG/IgM (HBcAb)
- Hepatitis B Surface Antigen (HBsAg)
- Nucleic Acid Testing for Hepatitis B Virus (HBV NAT) testing may have been performed, if applicable.
- Rapid Plasma Reagin or Serologic Test for Syphilis (RPR or STS)
- Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II) testing may have been performed, if applicable.

## MICROBIAL TESTING

Tissue was subjected to microbiological testing at recovery and during processing and was found to be free of specific aerobic and anaerobic microorganisms and fungal contaminants whose presence would preclude tissue from processing or transplantation.

## CONTRAINDICATIONS

Contraindications include:

- The presence of infection at the implantation site.
- A patient with a known or suspected allergy to any of the processing reagents listed in this package insert.

## WARNINGS / PRECAUTIONS

- HUMAN TISSUE HAS THE POTENTIAL TO TRANSMIT INFECTIOUS AGENTS. Stringent donor screening, processing treatments and laboratory testing are employed to reduce the risk of infectious agent transmission.
- Trace amounts of processing reagents (hydrochloric acid, hydrogen peroxide, Dulbecco's phosphate buffered saline) may be present and caution should be exercised if the patient has specific sensitivities or allergies.
- Do not use if the expiration date has been exceeded or if there is evidence of defects in the package or label integrity
- Do not use if the allograft is damaged or the packaging integrity is compromised.
- Do not use if the product has not been stored according to the recommended storage instructions.
- Do not sterilize or re-sterilize.
- Use aseptic technique at all times
- It is the responsibility of the hospital or clinician to inform the patient of the potential risks associated with the use of this allograft.

## COMPLICATIONS / POSSIBLE ADVERSE EVENTS

Inherent uncertainty exists in medical and social histories and laboratory testing which may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation:

- Immune response to transplanted tissue.
- Transmission of known infectious agents including viruses and bacteria.
- Transmission of diseases of unknown etiology.
- Loss of function and/or integrity of implanted tissue due to resorption, fragmentation or disintegration.

Adverse outcomes potentially attributable to the product must be reported promptly to Origin Biologics.

## RECORD KEEPING / TRACEABILITY

The US FDA CFR 1271.290(e) requires that allograft tissue be traceable from the donor to the recipient. The tissue bank (source establishment) is responsible for traceability from the donor to the consignee (transplantation facility, clinician or hospital), and the transplantation facility is responsible for traceability to the recipient. Joint Commission standard QC.5.310.7 requires that "the organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities". To comply with these requirements, an Allograft Implant Record and preprinted labels are provided with every allograft. Record the patient identifier, the transplantation facility name and address, the allograft tissue identification information (using the preprinted labels) and comments regarding the use of the tissue on the Allograft Implant Record. Return the completed form to Origin Biologics and retain a copy in the patient medical record. If the tissue has been discarded, please return the Allograft Implant Record with graft identification information and reason for discard.

## COMPLAINTS AND RETURNS

For information on returns or to report a complaint or potential adverse event, please contact your authorized distributor or Origin Biologics at 702-790-7015.

## HANDLING AND PREPARATION

THESE PREPARATION INSTRUCTIONS ARE INTENDED AS GUIDELINES AS PART OF ESTABLISHED SURGICAL TECHNIQUES. THEY ARE NOT INTENDED TO REPLACE OR CHANGE STANDARD PROCEDURES OR INSTITUTIONAL PROTOCOLS.

**All preparation should be performed using aseptic technique.**
Once the packaging has been opened, the tissue must either be implanted or discarded.

Preparation:
This allograft is provided in a two-pouch packaging configuration with a sterile inner pouch.

1. Peel open the outer pouch.
2. Introduce the inner pouch into the sterile field.
3. Peel open or cut the inner pouch.
4. After preparing the implant site, insert the non-hydrated graft fully so the top of the device is flush with the cortical surface.
5. Following the manufacturer's instructions, insert a suture anchor into the lumen of the graft so that it advances into the graft maintaining central alignment.

## STORAGE

- Store freeze dried grafts at ambient temperature (15-30°C) in a clean, dry location.
- Do not freeze or expose to excessive temperatures.
- Do not use if the expiration date has been exceeded.
- Tissue shelf life is indicated on the product label.

## SYMBOLS GLOSSARY

The following symbols may appear in labeling:

| Symbol | Meaning |
|---|---|
|  | Single Use Only |
|  | Caution |
|  | See Instructions for Use |
|   | Sterilized by irradiation |
|  | Expiration Date |
|  | Manufacturer |
|  | Restricted to use by a licensed clinician |
|  | Store in a dry, ambient environment |
|  | Protect from light and excessive heat |



Donor Assessment, Manufactured, and
Released for Distribution By:

ORIGIN BIOLOGICS
Life Enhancing Allografts

6635 S. Eastern Avenue Suite 100
Las Vegas, NV 89119 USA
702-790-7015

Distributed By:

TETROUS™

14930 Ventura Blvd. Suite 325
Sherman Oaks, CA 91403
331-307-7499