genr8 WITHIN

Flow

2mL vial

Storage: 2°C - 22°C

Away from sunlight

Read this entire package insert carefully prior to use.

Restricted to sale by or on the order of a licensed physician.
Single patient use, on a single visit.
Only qualified licensed professionals should transplant this tissue.

Description

Genr8 within Flow is aseptically processed human birth tissue and is preserved using a proprietary, minimally manipulated system that retains the naturally occurring proteins. This implant is restricted to homologous use to supplement the recipient's tissue and assist in the body's natural regenerative functions.

Genr8 within, LTD assumes no responsibility for the clinical use of this tissue, the administering licensed professional solely determines the route and method of its use.

Donor Screening and Testing

This product contains human tissue. The mother's consent to its collection was obtained prior to recovery by elective cesarean section. The donor mother's blood was tested for relevant disease agents using FDA approved kits by an independent laboratory who complies with CLIA standards, is registered with US FDA, certified by CMS, and accredited by CAP, AATB, and AABB. The donor returned negative or non-reactive results for the following:

- HIV I&2 antibody
- Hepatitis C virus antibody
- Hepatitis B surface antigen
- HBV NAT
- Hepatitis B Core Antibody (total)
- Ultrio NAT
- Syphilis, I-ITLV1/11
- West Nile/NAT
- Cytomegalovirus CMV (IgG/IgM)
- Zika screen per CDC zone exclusion
- Epstein Barr (IgG/IgM)
- Lyme Disease.
- Donor is screened for information pertaining to COVID-19, Chlamydia trachomatis, Neisseria gonorrhoeae, & Creutzfeldt-Jacob disease (CID)

Tissue cultures were taken at the time of procurement and evaluated. Donor tissue testing positive for the following microorganisms are deferred:

- Clostridium
- Streptococcus pyogenes (group A strep)
- Enterococcus
- Fungi (mold or yeast phase)

As additional screening tools, pertinent medical history and a behavioral risk assessment were obtained. A licensed medical doctor has reviewed the results of testing along with other available, relevant information (which may have included, but was not limited to; medical records, donor physical assessment, infectious disease test results, radiology/pathology, etc.) and determined the donor has met all eligibility requirements.

Processing

The donor tissue was recovered using the safest techniques and sterile equipment to minimize any bioburden contamination. The donor tissue was procured via a network of qualified and trained recovery partners, using the most stringent screening and recovery protocols. This graft was meticulously processed from a single donor in an aseptic environment within an FDA registered facility operating to cGMP standards followed by terminal sterilization to an SAL of 10^{-6}. No donor pooling was conducted. Microbiological testing was performed, where appropriate, and results met documented acceptance criteria. The graft implant was released for transplantation based on the donor eligibility determination and review of processing records against established release criteria.

Shipping and Storage

This product is shipped in a validated shipping container with wet ice or equivalent ice packs and must arrive within the validated expiration time and date for the container. The product should be transferred to an appropriate storage location prior to the expiration of the shipping container.

Store away from sunlight in a clean, controlled environment ranging from **2°C - 22°C** (36°F - 72°F) until use.

Once reconstituted, this product must be used within 30 minutes or discarded.

Tissue Tracking

A Tissue Tracking/Transplant Record (TTR) QR Code and Link along with pre-printed labels are provided with every graft to properly track the tissue from donor to final use. Recipient records must be maintained for the purpose of tracing tissue post-transplant. Even if the tissue has been discarded for any reason, a completed TTR with the graft identification must be submitted online to Genr8 within, LTD.

Precautions

Prior to use, the physician must become familiar with the implant and the surgical procedure.

The implant should be used with considerable caution in surgical sites where an active infection is present, in necrotic sites or in sites with poor perfusion.

The implant should NOT be used under high tension or high pressure. Use in the spinal canal, disc, or epidural space is **NOT** recommended.

Appropriate placement of the graft is critical for successful outcomes.

Warnings

Same and similar potential medical/surgical, conditions or complications that apply to any surgical procedure may occur during or following implantation of this graft. The physician is responsible for informing clients of the risks associated with this treatment and the possibility of complications or adverse reactions. As with any birth tissue implant, the potential for transmission of infectious agents may exist.

A small number of patients may experience localized immunological reactions to the implant.

Warranty

This biologic graft, processed and packaged for surgical implantation, is unique and does not constitute a product under liability laws. No implied warranty of merchantability or fitness for a particular purpose are applicable. No implied warranties exist as to defects in biologics, which cannot be

detected, removed, or prevented by reasonable use of available scientific procedures or techniques. Furthermore, all warranties are disclaimed, whether expressed or implied by operation of law or otherwise including all implied warranties of merchantability or fitness for a particular purpose.

Instructions for use

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties.

General instructions

1. For use on a single visit/surgery/episode for a single patient, the tissue cannot be shared.
2. After reconstitution, the tissue must be used within 30 minutes or discarded. It cannot be stored for later use.
3. Open the box, remove the vial, and inspect the packaging and labeling materials carefully.
4. Do not use past expiration date specified on the product label.
    a. Do not use if the implant or packaging is damaged.
    b. Do not use if there are discrepancies in label information.
    c. Contact genr8within for packages with flaws, lacking graft, wrong size, or wrong labeling.
    d. Take photographs to document any concerns.
    e. To prevent contamination of the implant, use sterile technique for preparation and implantation.
    f. Do not re-sterilize or freeze.
    g. Use standard practices for handling and disposal of human tissue.
5. **Packaging and outer surfaces of the vial are not sterile**. The contents of the vial are **sterile**, the vial was prepared in an aseptic environment and has been terminally sterilized.
6. Using gloved hands, wipe down the vial with IPA or EtOH.
7. Hold the vial upright and pry off the cap exposing the stopper.
8. Using a sterile syringe and 18g needle, reconstitute by injecting at least 1mL of sterile saline or other appropriate diluent (PRP, 1% Lidocaine) through the exposed area of the stopper.
9. Gently swirl the contents to mix thoroughly.
10. Using a new, sterile syringe and a sterile, 22g needle, withdraw the graft from the vial into the syringe and utilize pre physician direction.
11. Physician experience and knowledge are key to proper application and usage.
12. If unsure as to appropriate application, do not use until fully informed as to protocol and technique from an experienced user.
13. Fill out the online Tissue Tracking Record (even if the graft is discarded). Record the patient information on the link provided, the practice name and address, the graft information and comments regarding tissue use on the TTR. Submit the completed TTR online and retain a copy in the patient's medical record. This information is kept confidential and used only for implant tracking.
14. Follow your patient and inform Genr8 within, LTD of any adverse events, concerns, or questions immediately.

Customer Returns

Genr8 within, LTD does not accept returns. If product is unusable, document the reason, take photographs of any damage, defects, or deficiencies and forward this information to info@genr8within.com

Disclaimer: It is the responsibility of the End-User clinician to maintain tissue intended for transplant in appropriate storage containers and temperatures. Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Genr8 within, LTD will not be liable for any damages, whether direct or indirect, special, incidental, or consequential, resulting from improper use of this graft. The instructions for use are specific, and Genr8 within, LTD waives all responsibility associated with mishandling, inappropriately storing, and/or not taking proper precautions with the graft tissue included with this insert.

Questions or concerns contact:

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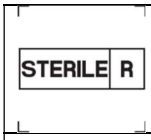
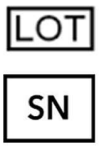
Manufactured by: Thrivell, LLC, Miami, FL
FDA Registration is on file
Trademarks are on file.

	Sterilized by E-beam Irradiation
	Read attached information on product use
	To be used with prescription only
	One time use on one recipient
	Lot number and serial number in barcode and product label
	Manufacturing date and expiration date in barcode and on product label
	Temperature Sensitive
	Store away from sunlight