ReBellaC™
RETURNING LIFE

UMBILICAL CORD FLOWABLE SUSPENSION INFORMATION & PREPARATION INSTRUCTIONS

ReBellaC™ contains Umbilical Cord Flowable Suspension in sterile normal saline. Each vial contains numerous growth factors and cytokines present at physiological levels in the umbilical cord tissue. These include: Growth factors including IGFBP 1, 2, 3, 4, and 6, TGF-α, and PDGF-AA; immunomodulatory cytokines, such as RANTES, IL-6R, and IL-16; proinflammatory cytokines MCSFR, MIP-1a; anti-inflammatory cytokines TNF-RI, TNF-RII, and IL-1RA; and homeostatic cytokines TIMP-1 and TIMP-2; cytokines associated with wound healing, ICAM-1, G-CSF, GDF-15; among others.

RebellaC™ is derived from the Wharton's Jelly of the umbilical cord and processed to preserve its structural integrity. No animal products or DMSO are used to produce or store RebellaC™. RebellaC™ is produced under ISO7 certified clean rooms utilizing cGMP guidelines. All batches of RebellaC™ were tested for sterility at an independent CLIA accredited laboratory following United States Pharmacopia Ch 71-Sterility testing guidelines. RebellaC™ is provided in a sterile vial.

USAGE

This product is distributed ONLY to licensed practitioners and is intended FOR TOPICAL USE ONLY.

QUALITY ASSURANCE

RebellaC™ is collected from umbilical cord tissue collected during c-section delivery from donors with normal, full-term pregnancies. Each donor is carefully screened including for COVID-19. Comprehensive medical and social histories of the donors are obtained and tissues are procured, processed, and tested in accordance with FDA requirements to minimize potential risks of disease transmission to recipients. Infectious disease testing is performed at a certified laboratory in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493. Current testing cannot provide absolute assurance that the tissue will not transmit infectious disease to the recipient. Each donor is tested for HBsAg (Hepatitis B Surface Antigen), HBcAb (hepatitis B core Antibody), HCV (hepatitis C Antibody), HIV I/II-Ab (Antibody to Human Immunodeficiency Virus Types 1 and Syphilis detection test, HIV NAT (HIV Nucleic Acid Test), CMV and HCV NAT (HCV Nucleic Acid Test), Lyme and Zika. RebellaC™ is also subjected to additional testing. All testing results are reviewed by the Medical Director of the manufacturing lab, which is BioIntegrate INC (2505 Newpoint Pkwy, Lawrenceville, GA 30043)

CONTRAINDICATIONS

Contraindications for the use of RebellaC™ shall be determined by a licensed practitioner.

WARNINGS AND PRECAUTIONS

If the patient experiences any adverse events or severe adverse events, they should consult their treating licensed practitioner as to how to get appropriate medical care. If any of these events happen, it must immediately be reported to Regen Suppliers.

- Do not use if package seal is broken. Discard material if mishandling has caused possible damage or contamination.
- Do not resterilize.
- RebellaC™ must be used prior to the expiration date on the product.
- Do not use if product has been thawed for more than 4 hours.
- Each package of RebellaC™ is intended for use on a single patient on one occasion.
- Discard any unused portions of RebellaC™ and empty vials per institutional procedures.

HOW SUPPLIED

This package contains a human tissue allograft. In addition to this product insert, the following items should be included in the product package:

1 Sterile Vial of Allograft Material

1 Product Label on Vial

1 Instructions for use

1 Tissue Tracking Form

STORAGE CONDITION REQUIREMENTS

RebellaC™ is supplied/shipped frozen (-80°C, on dry ice) until package is opened. It is the responsibility of the licensed practitioner to store RebellaC™. RebellaC™ may be stored frozen at -20°C or colder for up to 120 days or until expiration date, whichever comes first. For longer storage, RebellaC™ must be stored at -80°C up to the expiration date, as long as the package has not been breached, and temperature is maintained. Refer to product ID label for applicable expiration date information. If you find package has been breached in any way or that temperature has not been maintained at -80°C, dispose of appropriately and DO NOT USE.

ReBella C™
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The tissue product is for a single patient, one time use only. Once opened, the tissue must be used immediately or disposed of appropriately. Proper storage is the responsibility of the end user.

RECIPIENT TRACKING

The FDA requires that records are maintained and tracked for human tissue-based products from donor to consignee and vice versa. It is the responsibility of the practitioner to maintain sufficient records to permit prompt identification of the recipient. Product use must be documented by filling out and returning the enclosed Donor Registration Form for each product used. Affix the pre-printed label to the Donor Registration Form and fill out all applicable sections and return to the manufacturer lab: BioIntegrate INC, 2505 Newpoint Pkwy, Suite 100, Lawrenceville GA 30043. If RebellaC™ is not used (for any reason) after opening, complete the Donor Registration Form and indicate the method of disposal.

INSTRUCTIONS FOR USE

1. Remove the vial from the dry ice or -80°C or -20°C freezer 15 minutes prior to use to thaw.
2. Thaw the vial at room temperature.
3. Allow product to thaw (room temperature for 5-10 minutes), until ice completely melts and invert tube several times to mix completely.
4. After contents in vial is completely thawed, place the vial in an upright position so that the contents distribute and flow to the bottom. You can tap the vial on a hard surface.
5. Prepare the procedure site using institutions standard operating protocol.
6. Use sterile technique. Remove cap of sterile vial by unscrewing lid.
7. Apply topically to procedure site as determined by the licensed practitioner.

For product information or to report an adverse event, telephone 1-800-568-6909

The Health Care Practitioner receiving this human tissue shall have sole discretion and responsibility to determine in accordance with applicable law and professional standards if the allograft is usable and suitable for any and all uses to which the Health Care Practitioner shall apply the allograft, and upon delivery of the human tissue by BioIntegrate to the Health Care Practitioner and thereafter the Health Care Practitioner accepts and shall have full responsibility and liability with respect to such allograft. The TISSUE ALLOGRAFT IS INTENDED FOR TOPICAL USE ONLY. ALL HUMAN TISSUE FURNISHED BY REGEN SUPPLIERS. TO THE HEALTH CARE PRACTITIONER IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NON INFRINGEMENT OF THIRD PARTY PROPRIETARY RIGHTS UNLESS DISCLAIMING SUCH WARRANTIES IS PROHIBITED BY LAW.