RRG EXM

RRG EXM Flowable Placental Tissue Extacellular Matrix Allograft

Regenerative
Research
GROUP LLC

TISSUE MODULATION FACTORS

RRG EXM includes growth factors, fibronectin, laminin, hyaluronic acid, proteoglycans, and other proteins. Placental Extracellular Matrix (ECM) can modulate correct tissue reconstruction rather than the formation of scar tissue.

REGENERATION POTENTIAL

RRG EXM is a structural allograft that contains collagens I, III, IV, V, VI, VII, and fibrous proteins that provide a structural scaffold. Fibronectin, integrins, laminin, and hyaluronan also play a key role in proliferation, differentiation, and adherence to the scaffold.

HEALTHY ENVIRONMENT

RRG EXM Flowable Placental Tissue Extacellular Matrix Allograft contains components that help to create a healthy environment by potentially reducing bacteria counts. In published literature, these antibacterial effects have been demonstrated against a wide range of bacteria.

INFLAMMATION & FIBROSIS REGULATION

Anti-inflammatory and anti-fibrotic proteins in placental tissue ECMs may reduce inflammation, fibrous tissue growth, and potential scar tissue formation as they upregulate TGF-B, suppress pro-inflammatory cytokines, and inhibit MMPs and fibroblast formation.

NON-IMMUNOGENIC

Placental tissues possess little risk of foreign body reactions in the Patient. Placental tissues perform help prevent a response between baby and mother during pregnancy.

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PRODUCT DESCRIPTION

RRG EXM Flowable Placental Tissue Extacellular Matrix Allograft are unique, pre-mixed, tissue matrix allografts, processed from human placental tissues. This tissue matrix contains collagens, growth factors, and other key biologic components.*

- Two cryopreserved configurations available
  RRG EXM A
  RRG EXM B (DMSO free)
- 3-year shelf life at -40o C
- Flowable through a 23G needle
- Injectable to target structural defects quickly and precisely
- Easily mixable with autologous fluids*

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PERINATAL STEM CELLS AND FDA REGULATIONS

Several articles concerning the use of perinatal human cell and tissue products (HCT/P) and the governing regulations of the FDA have been published recently. The FDA has acknowledged that HCT/P products have the potential to benefit patients, but have put strict regulatory restrictions in place. The FDA often reviews manufacturers' processes and procedures for compliance.

As part of the FDA review, investigators must show how each product will be manufactured so the FDA can make sure appropriate steps are being taken to help ensure the product's safety, purity, and quality.

Through very meticulous processes, numerous precautions are taken to ensure that all products are safe, in their purest form, and maintain the highest quality.

We are proud of this product's 15-year history of remaining FDA compliant.

Eligibility
Our proprietary process begins with meticulous screening of the donor mother and father as well as family members for several generations.

Collection
A recovery specialist, once given the donation information, will collect the postnatal donation at the designated hospital. The recovery specialist will then return the donation to the lab for processing.

Testing
Our lots are quarantined for 14 days and thoroughly tested for bacterial and disease contamination by a CLIA-certified lab.

Processing
Our proprietary process meets the FDA requirements of minimal manipulation.

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RRG EMPHASIZES A 100 PERCENT CHAIN OF CUSTODY

DONOR ELIGIBILITY REQUIREMENT:

Our proprietary process begins with meticulous screening of the donor mother and father, as well as family members for several generations. In addition to routine industry screens for bloodborne pathogens, we also screen for heritable and non-heritable conditions, and environmental contaminants from medications, alcohol, drugs, tobacco, and electronic vaping. Only healthy families who meet or exceed these criteria are considered. Postnatal tissue donations are promptly collected from local hospitals by our recovery specialists following a healthy cesarean birth. After processing, allografts are tested again to ensure they are free of contaminants or infection and contain healthy, viable cells prior to cryopreservation.

TESTING PROCEDURES:

Our lots are quarantined for 14 days and thoroughly tested for bacterial, communicable, and other disease contamination by a CLIA-certified lab. Additional testing is conducted in multiple phases of the process to ensure zero contamination.

Diseases that are tested prior to donation eligibility:

Hepatitis Bs Ag	HIV 1&2 Plus O Ab
Hepatitis Bc Ab	CMV ab
HTLV I/II Ab	RPR (Non-treponemal syphilis)
Hepatitis C Ab	HIV-1/HCV/HBV NAT (Ultrio)
	WNV NAT

FDA REQUIREMENTS OF MINIMAL MANIPULATION:

For structural tissue, the process does not alter the original relevant characteristics of the tissue related to the tissue's utility for reconstruction, repair, or replacement. For cells or nonstructural tissues, the process does not alter the relevant biological characteristics of the source material.

CRYOPRESERVATION:

We use a unique cryopreservation technique that includes using the source's natural components preserved with a natural cryoprotectant to help ensure maximum functionality at ime of use.

SHIPPING:

All orders are carefully packed in specially insulated overnight containers to maintain the integrity of our products. Products are shipped only to licensed medical professionals.

RRG EXM

PRODUCT DESCRIPTION

Product	Size	Description
RRG EXM (DMSO)	1cc	
RRG EXM (DMSO Free)	1cc	
RRG EXM (DMSO)	2cc	
RRG EXM (DMSO Free)	2cc	

Note: To learn more about the full line of Placental Tissue & Amniotic Membrane allograft solutions, please visit ww.regenerativeresearchgroup.org

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