

RENOVO BIOSCIENCE



INTRA-SITE®

- Sterile Allograft
- Ambient Temperature
- 2-Year Shelf Life

THE SCIENCE

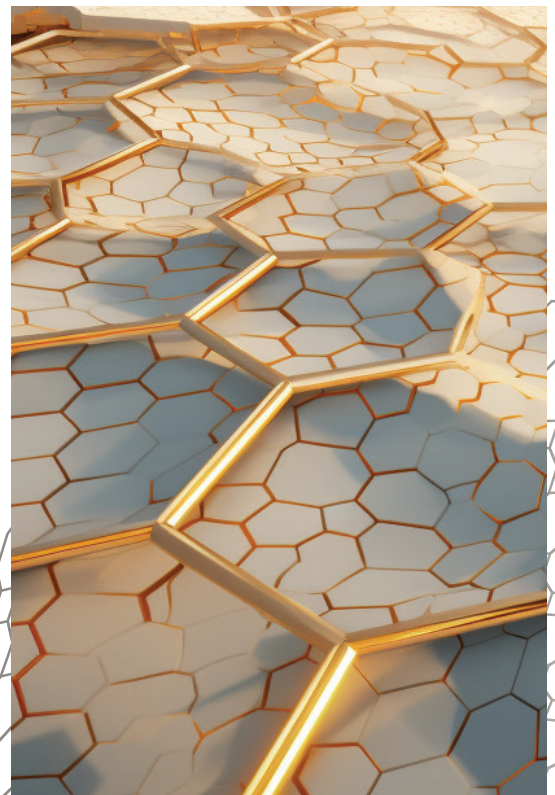
Damaged skin, tissue, muscle and bone can cause acute and chronic pain, impacting the ability to complete daily activities. Activities as simple as walking, running, or working can feel impossible to do with tissue and bone damage. From tendonitis to joint damage and arthritis, these conditions can lower the quality of life and lead to severe pain.



Injuries can also lead to significant tissue damage, and even after surgical repair these sites often lack adequate functional tissue to remodel successfully. This can result in post-operative complications, failure, or re-injury.

In order to augment the tissue damage, surgeons look to the most native tissue options to increase the likelihood of successful repair.

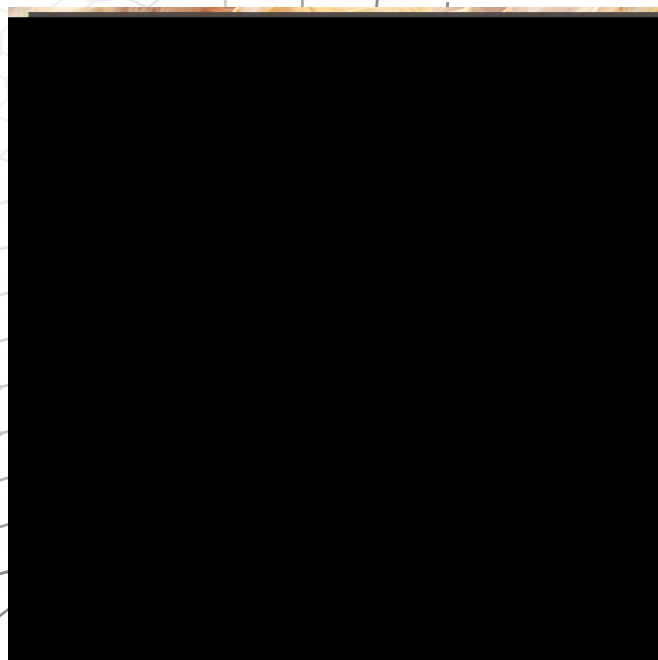
Connective tissue is the most prolific tissue type and is common throughout the body. This allows us to create an ideal extra-cellular matrix implant option to augment tissue damage and support constructive remodeling in a diverse range of surgical sites.



THE SCIENCE (CONT.)

Renovo Bioscience has developed a line of immune-privileged connective tissue matrix products including: **Intra-Site, Derma-Site and Wound-Site**. These products come in convenience kits that allow clinicians to customize how to best administer the product to the most appropriate location.








Our products are designed to cover or protect tissues and to augment or replace damaged or inadequate tissue. The extra-cellular matrix is a combination of both structural and functional components including **collagens, glycoproteins, proteoglycans, mucins, elastic fibers, and growth factors that form a three-dimensional matrix**, providing structural support to the body's tissues and cells. Unlike other fibers of the human body, these connective tissue products are also rich in a variety of cells scattered through fibrous proteins and glycoproteins.



These connective tissues products may aid in the repair of damage to all types of structural tissues, including skin, bone, cartilage, tendon, ligament, and muscle tissues of the body.

WHAT IS INTRA-SITE®?

Intra-Site® is a human cell and tissue product (HCT/P). It is a connective tissue allograft derived from perinatal tissue. The product is regulated by the U.S. FDA under 21 CFR 1271.

						
BMP-2	BMP-7	PDGF-BB	FGF-1	IGF-1	TGF-B	VEGF
Differentiation of MSCs into osteoprogenitor cells, chondrocytes and osteoblasts	Differentiation of osteoprogenitor cells into osteoblasts	Mitogenic for MSCs and osteoblasts and responsible for macrophage chemotaxis	Mitogenic for MSC, chondrocytes, and osteoblasts. Promotes vascularization	Promotes proliferation and differentiation of osteoprogenitor cells	Pleiotropic growth factor responsible for stimulation of undifferentiated MSCs	Promotes migration and proliferation of osteoblasts. Promotes angiogenesis

INTENDED USE

Intra-Site® is derived from placental connective tissue and is intended for homologous use to supplement or support damaged or inadequate connective tissue in the recipient.

STORAGE

Intra-Site® has been terminally sterilized and the vial of allograft material is sealed and packaged in a double Tyvek™ pouch providing a 2-year shelf life. The product should be stored between -4 degrees and +40 degrees Celsius. It is the responsibility of the distributors, tissue dispensing services, and/or clinicians to safely store the allograft in an appropriate location to maintain the shelf-life of the allograft. The allograft is marked with an expiration date and should be used before the end of the shelf-life date.

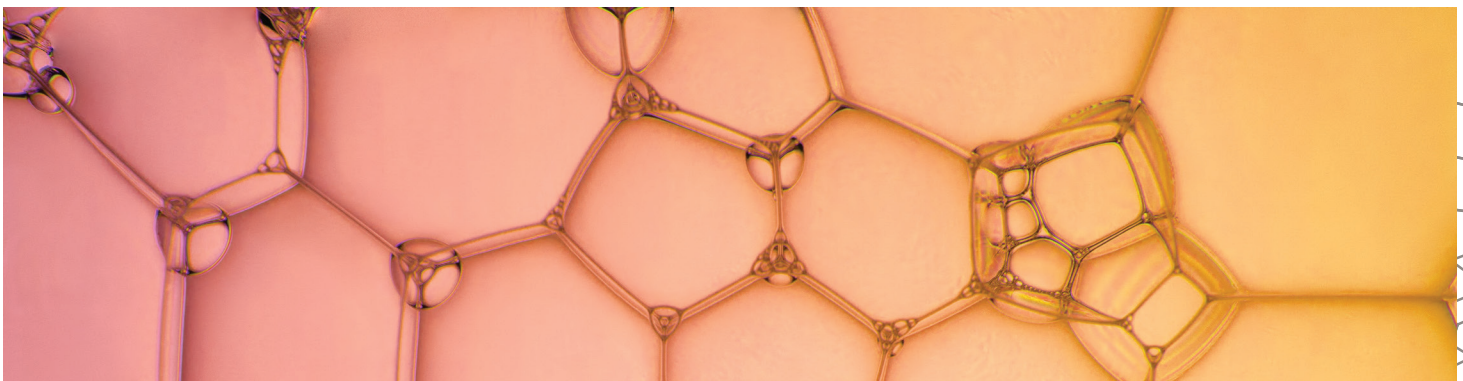
DONOR SCREENING

The allograft material in the Intra-Site® product is derived from donated tissue from healthy human donors. The allograft has been determined eligible for transplant by the manufacturer's Medical Director after review of medical and social history, hospital records, infectious disease screening and testing. The donor was tested and found negative or non-reactive to all standard infectious diseases and contaminations. Testing has been completed by an FDA registered third-party laboratory in accordance with the Clinical Laboratory Improvement Amendment (CLIA) of 1988 and 42 CFR part 493 or has met the equivalent requirements as determined by the Centers of Medicare and Medicaid Services (CMS).

DONOR TRACKING FORM

Renovo Bioscience has created an online Allograft Tracking System to assist in the post-implantation tracking. To utilize this system, please go to <https://renovotrackingform.com> and follow the instruction for tracking recipients. The end-user can access this information at any time and is easier than filling out a Donor Tracking Form and returning it to the manufacturer. Please feel free to call Renovo Bioscience at 800-440-9314 if you have any additional questions.

Note: Federal regulations (21 CFR 1271 and Joint Commission Standards) require proper tracking of all allograft material distributed in the U.S. It is the responsibility of the end-user to maintain the records for the purpose of appropriate tracking and reporting.



PRICING



INTRA-SITE®
Connective Tissue Allograft

SIZE	PRICE	SKU
3.0 cc	\$799.00	RB-IS-3CC



Distributed by:

ReNovo Bioscience, LLC
30 North Gould Street, Suite N
Sheridan, Wyoming 82801

Processed exclusively by:

Altair Bioscience, LLC
7533 South Center View Court, Suite R
West Jordan, Utah 84084



Sterile Processed Allograft



Physician Order



One time use Only



Store at ambient temperature



Minimize exposure and heat



Consult instructions for use

This brochure, and the information contained, is intended solely to inform and educate medical professionals and their patients about ongoing developments and innovations in the field of "Regenerative Medicine". Patients should not rely on any information in this brochure solely to make medical decisions. This information is not intended to make any claims or representations about the availability, effectiveness, or appropriateness of these products in medical treatment. The product depicted in the brochure as been determined to comply with the U.S. Food and Drug Administration's (FDA) regulations contained in Title 21 Part 1271 of the Code of Federal Regulations, Section 361 of the Public Health Service Act, as a Human Cell and Tissue Product (HCT/P).

Any provider administering an HCT/P therapy shall have sole discretion and responsibility to determine in accordance with applicable law and professional standards if the product is usable and suitable for any and all intended uses and situations. Any user of the products accepts and shall have full responsibility and liability with respect to such use. Consult with your provider, scientific literature, and governmental agency databases and websites, including those of the Food and Drug Administration (FDA), and your state Medical Authorities for more information about HCT/Ps and to evaluate current information from clinical trials.

Note: These products have not been evaluated by the Food and Drug Administration, and are not intended to diagnose, treat, cure, or prevent any disease. Individuals were not paid or given free product in exchange for their testimony.

Caution: Federal law restricts the use of the product to sale by or on the order of a physician.

"Renovo Bioscience" and "Intra-Site" are registered trademarks.

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