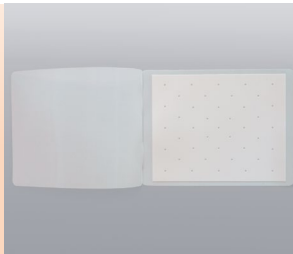


NEW ALLODERM SELECT™ RTM PACKAGING

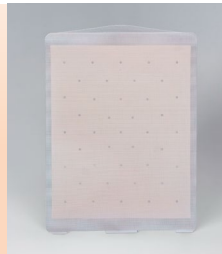


New packaging features



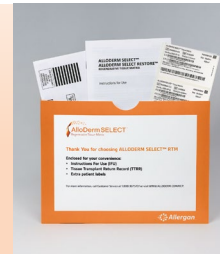
MESH HOLDER

Prevents movement in package and allows fluid flow



POUCH

Offers visibility of tissue shape prior to opening sterile layer



DOCUMENT ENVELOPE

Contains patient labels, Instructions for Use (IFU), and Tissue Transplant Return Record (TTRR) cards

For general product information, please call Customer Service at 1.800.367.5737.

IN-SERVICE INSTRUCTIONS

STEP 1



Open the carton and pull out the paper tray.

STEP 2



Flip up the TagAlert holder. Then, flip open the paper tray side and bottom panels.

STEP 3



Follow the "PEEL HERE" instructions on the pouch to open and slide out the holder.

NOTE:

- The foil pouch is not sterile and should not be placed into the sterile field
- Be careful as there is fluid within the pouch

STEP 4



Using aseptic technique, remove the holder and place into the sterile field.

IMPORTANT:

- The mesh holder provided is sterile
- The tissue is exposed through the mesh material
- Only sterile technicians should handle the inner mesh holder
- A trace amount of fluid may seep out during transfer

STEP 5



Open the holder that contains ALLODERM SELECT™ RTM. Using aseptic technique, remove the ALLODERM SELECT™ RTM from the holder and place it into a sterile basin for rinsing.

INDICATIONS

ALLODERM SELECT™ Regenerative Tissue Matrix (ALLODERM SELECT™ RTM refers to both ALLODERM SELECT™ RTM and ALLODERM SELECT RESTORE™ RTM products) is intended to be used for repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument. This product is intended for single patient one-time use only. ALLODERM SELECT™ RTM is not indicated for use as a dural substitute or intended for use in veterinary applications.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ALLODERM SELECT™ RTM should not be used in patients with a known sensitivity to any of the antibiotics listed on the package and/or Polysorbate 20.

WARNINGS

Processing of the tissue, laboratory testing, and careful donor screening minimize the risk of the donor tissue transmitting disease to the recipient patient. As with any processed donor tissue, ALLODERM SELECT™ RTM is not guaranteed to be free of all pathogens. No long-term studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of ALLODERM SELECT™ RTM.

DO NOT re-sterilize ALLODERM SELECT™ RTM. **DO NOT** reuse once the tissue graft has been removed from the packaging and/or is in contact with a patient. Discard all open and unused portions of the product in accordance with standard medical practice and institutional protocols for disposal of human tissue. Once a package or container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded. **DO NOT** use if the foil pouch is opened or damaged. **DO NOT** use if the seal is broken or compromised. **DO NOT** use if the temperature monitoring device does not display "OK." **DO NOT** use after the expiration date noted on the label. Transfer ALLODERM SELECT™ RTM from the foil pouch aseptically. **DO NOT** place the foil pouch in the sterile field.

PRECAUTIONS

Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for implanting ALLODERM SELECT™ RTM as such conditions may compromise successful clinical outcome. Whenever clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken.

ALLODERM SELECT™ RTM has a distinct basement membrane (upper) and dermal surface (lower). When applied as an implant, it is recommended that the dermal side be placed against the most vascular tissue. Soak the tissue for a minimum of 2 minutes using a sterile basin and room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the tissue. If any hair is visible, remove using aseptic technique before implantation.

ALLODERM SELECT™ RTM should be hydrated and moist when the package is opened. **DO NOT** use if this product is dry. Use of this product is limited to specific health professionals (e.g., physicians, dentists, and/or podiatrists). Certain considerations should be made to reduce the risk of adverse events when performing surgical procedures using a tissue graft. Please see the Instructions for Use (IFU) for more information on patient/product selection and surgical procedures involving tissue implantation before using ALLODERM SELECT™ RTM.

ADVERSE EVENTS

The most commonly reported adverse events associated with the implant of a tissue graft include, but are not limited to the following: wound or systemic infection; seroma; dehiscence; hypersensitive, allergic or other immune response; and sloughing or failure of the graft.

ALLODERM SELECT™ RTM is available by prescription only.

For more information, please see the [Instructions for Use \(IFU\)](#) for ALLODERM SELECT™ RTM available at www.allergan.com/AlloDermIFU or call 1.800.678.1605.

To report an adverse reaction, please call Allergan at 1.800.433.8871.

Allergan
Aesthetics
an AbbVie company

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