

SimpliDerm® Perforated

Hydrated Acellular Dermal Matrix

Closer to Nature. Better Results.

SimpliDerm Features

Engineered to facilitate natural healing processes and enhance regenerative tissue remodeling.

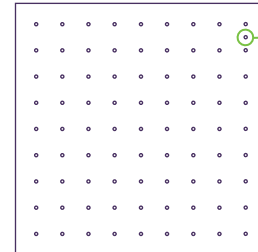
- Designed to support natural fluid flow between planes
- Advanced tissue processing for a more pliable and intact hydrated ADM
- Uniform thickness
- Excellent tissue handling

Close to native dermis

SAL 10^{-6}

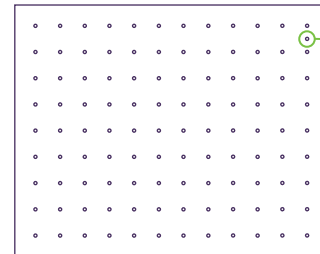
Prehydrated and protected

Orientation markings



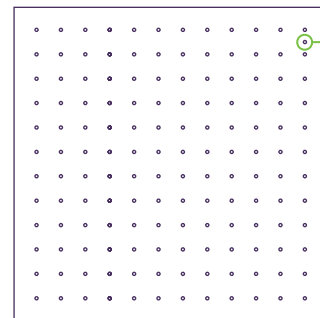
16 x 16cm

Orientation hole*



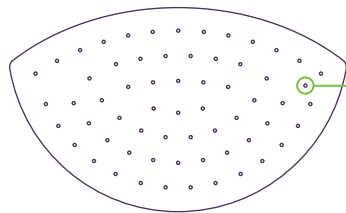
16 x 20cm

Orientation hole*



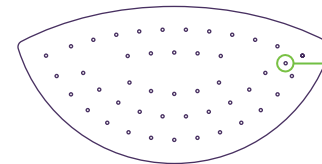
20 x 20cm

Orientation hole*



Large Ellipse® 13 x 21.5cm

Orientation hole*



Medium Ellipse® 10 x 20cm

Orientation hole*

* Orientation hole in upper right corner of tissue indicates dermal side

SIMPLIDERM PERFORATED

| Order Code | Size | |
|----------------|-----------------|---------------|
| SD.090.1616P | 16cm x 16cm | |
| SD.090.1620P | 16cm x 20cm | |
| SD.090.2020P | 20cm x 20cm | |
| SD.090.1020ELP | Ellipse™ Medium | 10cm x 20cm |
| SD.090.1321ELP | Ellipse™ Large | 13cm x 21.5cm |

SIMPLIDERM NON-PERFORATED

| Order Code | Size |
|-------------|-------------|
| SD.090.0616 | 6cm x 16cm |
| SD.090.0816 | 8cm x 16cm |
| SD.090.0820 | 8cm x 20cm |
| SD.090.1620 | 16cm x 20cm |

SimpliDerm is available in a thickness range of 0.90 – 1.99mm

INSTRUCTIONS FOR USE (ABBREVIATED)

DONATED HUMAN TISSUE FROM U.S. TISSUE BANKS. THE ALLOGRAFT IS TERMINALLY STERILIZED TO A STERILITY ASSURANCE LEVEL OF 10^{-6} IN ITS FINAL PACKAGING.

DESCRIPTION

SimpliDerm Perforated Hydrated Acellular Dermal Matrix (HADM) is a human skin allograft minimally processed to remove epidermal and dermal cells and then preserved in an irradiation protection solution. The process utilizes a proprietary and patented technology to preserve the remaining bioactive components and extracellular matrix of the dermis. The resulting acellular matrix is hydrated without damage to the matrix components and is designed to be rinsed quickly in a sterile isotonic solution. The resulting allograft functions as a framework to support cellular repopulation and vascularization at the surgical site. SimpliDerm perforated HADM is supplied as Square, Rectangle or Ellipse configurations.

INDICATIONS FOR USE

SimpliDerm is to be used for the repair or replacement of damaged or insufficient integumental tissue. It may also be used for the repair, reinforcement or supplemental support

of soft tissue defects or any other homologous use of human integument. Each package of SimpliDerm is intended for use in one patient on a single occasion by a licensed physician.

CONTRAINDICATIONS

Use of SimpliDerm in patients exhibiting autoimmune connective tissue disease is not recommended. SimpliDerm should not be used in patients with sensitivities to processing agents (see WARNINGS).

ORIENTATION

SimpliDerm has two (2) distinct sides: a basement membrane and a dermal side. The basement membrane repels blood. The dermal side absorbs blood. When applied as an implant, it is recommended that the dermal side be placed against the most vascular tissue. Each piece has an orientation hole to determine basement membrane versus dermal side. See Orientation section in full Instructions for Use.

SimpliDerm®

Hydrated Acellular Dermal Matrix

Customer Service and Ordering

877-651-2628

customerservice@elutia.com

Storage must be maintained at room temperature, not to exceed 25°C.

For the full Instructions for Use visit:

<https://elutia.com/products/soft-tissue-repair/simpliDerm/>

WARNINGS

Potential adverse effects that may result from placement of SimpliDerm include, but are not limited to wound or systemic infection; seroma; dehiscence; hypersensitivity; allergic or other immune response; sloughing or failure of the graft; and disease transmission.

- Trace amounts of processing agents include, but are not limited to: gentamicin, maltodextrin and trehalose.
- Do not re-sterilize or reuse.

Extensive medical screening procedures have been used in the selection of all tissue donors (see Donor Screening and Testing). Due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human source material may transmit infectious agents or diseases.

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