

Closer to Nature. Better Results.

Aziyo is excited to expand its portfolio of *natural*, perforated

allografts.

SimpliDerm® Features¹



Close to native dermis





Prehydrated and protected



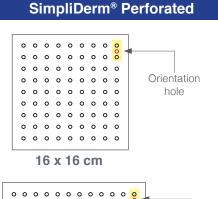
Introducing...

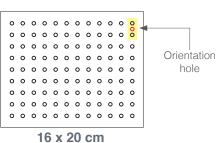
SimpliDerm® Perforated

20x20cm

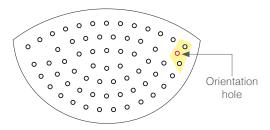
Designed to support natural fluid flow between planes<sup>1</sup>

## SimpliDerm® Perforated Portfolio

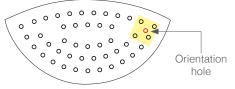




### SimpliDerm Ellipse®



Large: 13 x 21.5 cm



Medium: 10 x 20 cm



<sup>&</sup>lt;sup>1</sup> SimpliDerm® Perforated Instructions for Use



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	

# Customer Service and Ordering 1-800-922-3100 | orders@aziyo.com

SimpliDerm® is an ambient product.
SimpliDerm® is available in a range of sizes.
Storage must be maintained at room temperature, and must not exceed 25°C.

Please see temperature requirements found in the *Instructions for Use.* 

SimpliDerm® Thickness: 0.9 - 1.99 MM		
Order Code	Size	
SD.090.0412	4cm x 12cm	
SD.090.0416	4cm x 16cm	
SD.090.0612	6cm x 12cm	
SD.090.0616	6cm x 16cm	
SD.090.0812	8cm x 12cm	
SD.090.0816	8cm x 16cm	
SD.090.0820	8cm x 20cm	
SD.090.1620	16cm x 20cm	

SimpliDerm® Thickness: 2.00 - 3.50 MM		
Order Code	Size	
SD.200.0412	4cm x 12cm	
SD.200.0416	4cm x 16cm	
SD.200.0612	6cm x 12cm	
SD.200.0616	6cm x 16cm	
SD.200.0812	8cm x 12cm	
SD.200.0816	8cm x 16cm	
SD.200.0820	8cm x 20cm	
SD.200.1620	16cm x 20cm	

#### INSTRUCTIONS FOR USE

DONATED HUMAN TISSUE FROM U.S. TISSUE BANKS. THE RECOVERY AND PROCESSING WAS PERFORMED USING ASEPTIC TECHNIQUES. THE ALLOGRAFT IS TERMINALLY STERILIZED TO A STERILITY ASSURANCE LEVEL OF 10° 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 pre-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.

Our perforated allografts are available in Square, Rectangular, and Ellipse® configurations. Each piece has an additional orientation hole added to help determine basement membrane versus dermal side (see Orientation section of the Instructions for Use for more information).

#### 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.

#### **ALLOGRAFT PRODUCTS**

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#### CORPORATE HEADQUARTERS

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