A portfolio of natural, perforated allografts designed to meet multiple surgical needs
Designed to support natural fluid flow between planes

Our SimpliDerm™ perforated portfolio provides intraoperative ease of use and optimal plane-to-plane fluid transfer upon implantation, while maintaining the regenerative performance you’ve come to expect from SimpliDerm™.

A unique proprietary process

Aziyo uses a proprietary, patented and gentle process to achieve a sterility assurance level (SAL) of $10^{-6}$, while preserving the key growth factors of native dermis. Due to this unique proprietary process, SimpliDerm™ offers a more pliable, intact matrix membrane that supports the angiogenic process, demonstrating a lower risk of inflammatory response, faster integration and more rapid revascularization.

Proven to maintain key growth factors of native dermis

SimpliDerm™ maintains key growth factors and structural composition of human dermis, supporting robust blood vessel formation and providing similar mechanical strength, collagen integrity, and bioactive components to native dermis.

 Clinically proven results for an optimal immunologic response

SimpliDerm™ demonstrated lower inflammatory response, robust matrix regeneration and integration, greater tissue strength and suture retention, and lower fibrotic response than AlloDerm® RTU in a non-human primate model.

Prior to use, physicians should become familiar with all risk information found in the Instructions for Use, which is available at http://www.aziyo.com/simpliderm/, and included in product packaging.
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.

### 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 $10^{-6}$ 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 a gamma 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™ is supplied as Ellipse™ or rectangular shapes.

### 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 auto-immune 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 appears dull and repels blood. The dermal side appears shiny and absorbs blood. When applied as an implant, it is recommended that the dermal side be placed against the most vascular tissue. The allograft has an additional orientation hole that when oriented in the upper right corner indicates that the basement membrane is facing toward the user.

### 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.