

FlexHD®

ACELLULAR HYDRATED DERMIS

FlexHD® Acellular Hydrated Dermis

AN ADVANCEMENT IN BREAST
RECONSTRUCTION PROCEDURES



The acellular allograft

A BREAKTHROUGH FOR SURGEONS AND PATIENTS

Acellular dermal allografts are donated human dermis that has been processed to remove the components that could result in any immune/inflammatory response and trigger rejection. What remains is an undamaged tissue matrix, capable of natural, full regeneration after implant.¹

OPERATIVE BENEFITS OF FlexHD® Acellular Hydrated Dermis

- Hydrated and ready-to-use off the shelf
 - Hydration of some freeze-dried grafts can require 40 minutes²
- Does not require refrigeration
- Provided sterile*
- Minimizes handling in the OR by people other than surgeons for less chance of contamination
- Quality and safety assurance from the Musculoskeletal Transplant Foundation (MTF)^{3,4} with over 4 million grafts distributed since 1987



The annual number of musculoskeletal tissue transplants increased from approximately 350,000 in 1990 to over 1.6 million in 2006.⁵

—CENTER FOR BIOLOGICS
EVALUATION AND RESEARCH

*Passes USP <71> sterility tests.

FlexHD®

THE ACELLULAR HUMAN DERMIS OF CHOICE

FlexHD® is a unique hydrated acellular human dermis. It provides an acellular (nonimmunogenic) tissue matrix with excellent biomechanical strength.^{1,6,7}

OPERATIVE BENEFITS OF FlexHD® WHEN USED IN BREAST RECONSTRUCTION

- Demonstrates revascularization after 8 weeks^{8,9}
- Demonstrates minimal inflammatory response⁹
- Available in matched pairs for consistent bilateral breast reconstruction
- Allows for an immediate breast pocket and helps to define the inframammary fold¹⁰
- Comes from Mentor, the name you already trust in breast reconstruction surgery

PROVIDING STRENGTH, VERSATILITY, AND NEW POSSIBILITIES IN BREAST RECONSTRUCTION

Reconstruction with implants has proven to be easier, quicker, and less traumatic than the use of autologous tissue, while offering acceptable aesthetic outcomes.¹¹

FlexHD®, when used to accomplish complete coverage of a tissue expander or implant, enables the surgeon to create a larger submuscular pocket with durable lateral and lower pole support.¹¹

FlexHD® can help create the ideal inframammary fold (IMF) and lateral mammary fold (LMF) during breast reconstruction. Additionally, the rectus abdominis and anterior rectus fascia, and/or muscles that otherwise would have been harvested in a TRAM procedure, are spared.^{12,13}

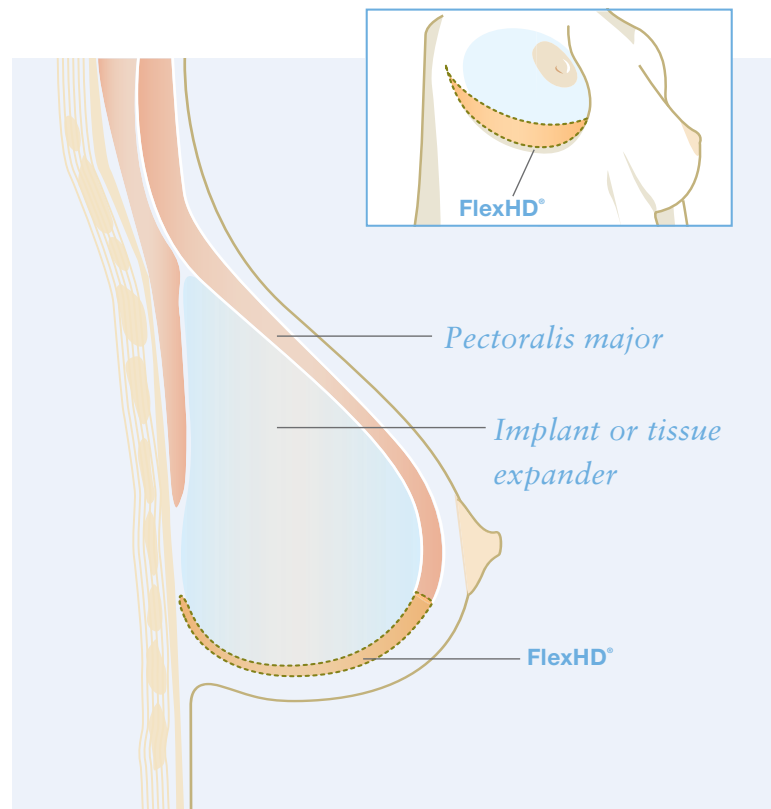
Implant procedures with FlexHD® Acellular Hydrated Dermis

SUPPLEMENT MUSCLE WITH REINFORCING SLING

The interposition of **FlexHD®** between the inferior border of the pectoralis major muscle and the IMF-LMF span provides secure support in the form of a sling.

BENEFITS OF ACELLULAR ALLOGRAFTS LIKE FlexHD®

- Supports and holds prosthesis in place, helping define shape and contour of reconstructed breast¹²
- Provides a biologic interface between mastectomy skin flaps and prosthesis, potentially reducing the risk of necrosis and/or extrusion¹²
- Obviates the need to create muscle or fascial defects to restore breast shape and contour¹²
- In breast reconstruction surgery, **FlexHD®** has been shown to provide implant support, prevent bottoming out, and prevent extrusion of the implant through the skin^{14,15}



An extended **FlexHD®** flap helps create a secure pocket that defines the inframammary fold, and provides an additional layer of coverage for the implant/expander.

NIPPLE RECONSTRUCTION USING FlexHD®

Often the last stage in the procedure, successful nipple reconstruction can be one of the most important and challenging. When achieved, it can restore a patient's sense of completeness and familiar body shape.

Long-term success has been achieved using acellular allografts such as **FlexHD®** as a central strut within a modified star flap. The dimensions of the flap width should be designed so that a projection overcorrection of 50% can be achieved to allow for postoperative projection loss.

FlexHD® Acellular Hydrated Dermis use in TRAM flap procedures

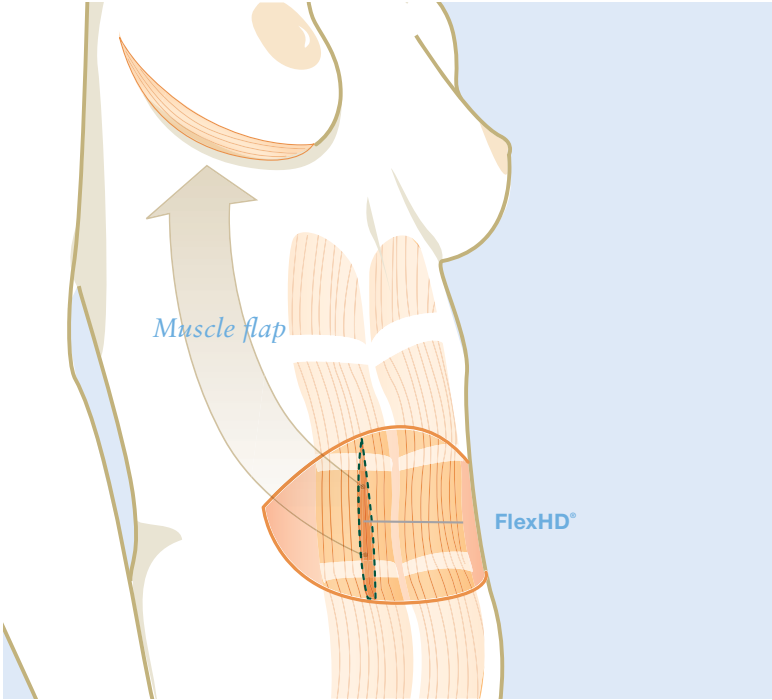
CLOSURE OF ABDOMINAL FASCIAL DEFECT

Since the introduction of the TRAM flap technique for breast reconstruction, the closure of abdominal donor site defects has posed a challenge.

Numerous studies have shown the improved outcomes that result from the use of acellular human dermis—such as **FlexHD®**—to provide an option for the repair of abdominal fascial defects after TRAM flap harvesting for breast reconstruction.¹⁷

BENEFITS OF ACELLULAR ALLOGRAFTS LIKE FlexHD®

- **FlexHD®** integrates into the surrounding tissue with less chance of rejection or inflammation¹³
- May avoid the need to perform a submuscular dissection¹³
- Obviates the need for alternative techniques such as:
 - The surgical incision or transection of the external oblique muscle to facilitate closure¹³
 - The use of synthetic mesh and the potential risk of infection which could lead to contracture or encapsulation¹³



After the transposition of abdominal wall muscle during a TRAM procedure, **FlexHD®** can be used as an underlay to provide strong, nonimmunological support tissue for the repair of resulting abdominal wall defects.

FlexHD® Implant Product Specifications		
Tissue Code	Size (cm)	Thickness (mm)
1 Unit, Thick		
471412	4 x 12	0.8 - 1.7
471612	6 x 12	0.8 - 1.7
471416	4 x 16	0.8 - 1.7
471616	6 x 16	0.8 - 1.7
471816	8 x 16	0.8 - 1.7
471206	6 x 20	0.8 - 1.7
471208	8 x 20	0.8 - 1.7
Breast Kits—2 Units, Thick		
4B1612	6 x 12	0.8 - 1.7
4B1416	4 x 16	0.8 - 1.7
4B1616	6 x 16	0.8 - 1.7
4B1816	8 x 16	0.8 - 1.7
Breast Kits—2 Units, Ultra Thick		
4B2612	6 x 12	≥1.8
4B2416	4 x 16	≥1.8
4B2616	6 x 16	≥1.8
4B2816	8 x 16	≥1.8

Additional sizes available.

Mentor and MTF

AN ALLIANCE FOR EXCELLENCE AND INNOVATION

The alliance with the Musculoskeletal Transplant Foundation (MTF), the largest tissue bank in the US, is another example of Mentor's commitment to advancing the standard of care in tissue repair.

FOR MTF, QUALITY AND SAFETY ARE IN THE DETAILS

- **FlexHD® Acellular Hydrated Dermis** passes rigorous safety testing using the latest technology
- Demonstrates all desired biomaterial properties before being made available for implantation
- Over 4 million grafts distributed since its inception in 1987

RESULT: A versatile, ready-to-use dermal matrix with an excellent safety record for the best outcomes in plastic surgery

FlexHD® is used for the replacement of damaged or inadequate integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects.

Before use, physicians should review all risk information, which can be found in the Instructions for Use attached to the packaging of each FlexHD® Acellular Dermal Matrix.

References: 1. Ramshaw B, Bachman S. Surgical materials for ventral hernia repair. Part 2: Biologic Mesh. *Gen Surg News*. Feb 2007;1-14. 2. Alloderm® Directions for Use. LifeCell Corporation Web site. <http://tissuepartners.lifecell.com/healthcare/dfus/alloderm.cfm>. Accessed January 21, 2008. 3. FlexHD® Acellular Dermal Matrix. Tissue safety analysis. Musculoskeletal Transplant Foundation. Edison, NJ; 2007. 4. MTF signs marketing agreement with Ethicon, Inc., for FlexHD® Acellular Dermal Matrix. [April 30, 2007, press release]. Musculoskeletal Transplant Foundation Web site. http://www.mtf.org/pdf/mtf_ethicon_press.pdf. Accessed January 21, 2008. 5. *Center for Biologics Evaluation and Research* (CBER) FY 2006 Annual Report. US Dept of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research. 2007;1-64. 6. FlexHD® Acellular Dermal Matrix. Biomechanical properties. Musculoskeletal Transplant Foundation. Edison, NJ; 2007. 7. FlexHD® Acellular Dermal Matrix. Histology: in vitro and in vivo studies. Musculoskeletal Transplant Foundation. Edison, NJ; 2007. 8. Roth JS, Dexter DD, Lumpkins K, Bochicchio GV. Hydrated vs. freeze-dried human acellular dermal matrix for hernia repair: a comparison in a rabbit model. *Hernia*. 2009;13(2):201-207. 9. Eberli D, Rodriguez S, Atala A, Yoo JJ. In vivo evaluation of acellular human dermis for abdominal wall repair. *J Biomed Mater Res A*. 2010;93(4):1527-1538. 10. Buck DW 2nd, Heyer K, DiBardino D, Bethke K, Kim JY. Acellular dermis-assisted breast reconstruction with the use of crescentric tissue expansion: a functional cosmetic analysis of 40 consecutive patients. *Aesthet Surg J*. 2010;30(2):194-200. 11. Zienowicz RJ, Karacaoglu E. Implant-based breast reconstruction with allograft. *Plast Reconstr Surg*. 2007;120(2):373-381. 12. Spear SL, Mesbahi AN. Implant-based reconstruction. *Clin Plast Surg*. 2007;34(1):63-73. 13. Glasberg SB, D'Amico RA. Use of regenerative human acellular tissue (AlloDerm) to reconstruct the abdominal wall following pedicle TRAM flap breast reconstruction surgery. *Plast Reconstr Surg*. 2006;118(1):8-15. 14. Choi. LE-284 characterization of acellular dermis via SDS-PAGE. February 20, 2010:1-5. 15. Ngo. LE-268 extracellular matrix components in acellular dermis. December 2009. 16. Garramone CE, Lam B. Use of AlloDerm in primary nipple reconstruction to improve long-term nipple projection. *Plast Reconstr Surg*. 2007;119(6):1663-1668. 17. Holton LH III, Kim D, Silverman RP, Rodriguez ED, Singh N, Goldberg NH. Human acellular dermal matrix for repair of abdominal wall defects: review of clinical experience and experimental data. *J Long Term Eff Med Implants*. 2005;15(5):547-558.

Contact your Mentor Sales Representative for more information on FlexHD® in breast reconstruction procedures.

