NATURAL. HEALING.

FlexHD®

ACELLULAR HYDRATED DERMIS

FlexHD® Acellular Hydrated Dermis

Natural

like native tissue^{1,2,3}

Unique

minimally processed4

Innovative

both strong and flexible⁵



NATURAL. HEALING. UNIQUE PROCESS

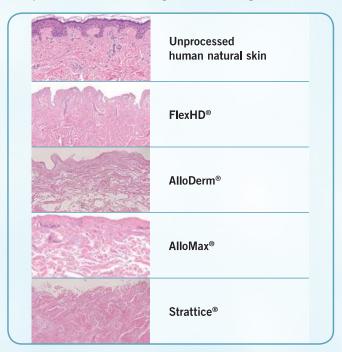
Process protected by US Patent 7,723,108.

FlexHD® has unique processing that does not impact human skin properties.

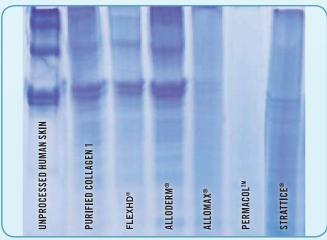
FlexHD ^{®6}	Other Matrices7-11	
high concentration sodium chloridenon-ionic detergentperacetic acid	acetonelyophilizationgamma irradiatione-beam sterilization	

MATRIX THAT IS CLOSEST TO NATURAL HUMAN TISSUE

FlexHD® retains the architectural elements of human unprocessed skin, allowing natural healing.^{3,12}

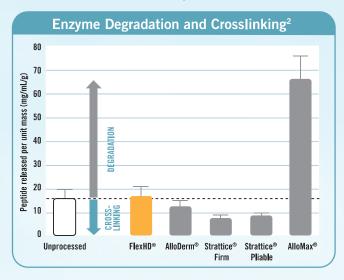


Minimal processing of FlexHD® maintains the natural characteristics of collagen.¹



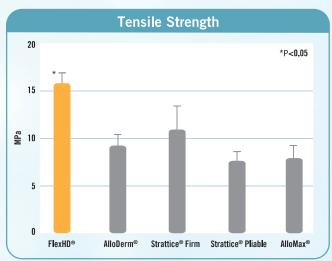
Collagen proteins separated by molecular weight through sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE). Smaller, degraded proteins migrate lower in the gel, whereas larger, crosslinked proteins remain higher in the gel. Collagen in FlexHD® is similar to unprocessed human skin.

FlexHD® is most similar to unprocessed human tissue.2

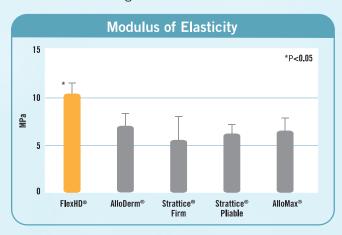


INNOVATIVE: STRONG AND FLEXIBLE

FlexHD® has the greatest tensile strength of all leading matrices.⁵



FlexHD® stands out with natural memory to resist excessive stretching.⁵



NATURAL. HEALING.

INTEGRATION WITH NATIVE TISSUE

FlexHD® has natural components and architecture that support cellular infiltration and revascularization.

Hyaluronan is present in all living organisms and provides matrix structure, osmotic balance and assists with cell migration and differentiation. Vitronectin, an adhesive glycoprotein, binds to collagen and promotes cell attachment, proliferation and differentiation. Both hyaluronan and vitronectin are found in FlexHD®.3



Left: Immunohistochemical staining using Alcian Blue/PAS shows the presence of hyaluronan in FlexHD® as indicated by indigo staining.

Right: Immunohistochemical staining shows vitronectin in FlexHD® as indicated by brown staining. Histology courtesy of Premier Laboratory, LLC.

FlexHD® shows healthy revascularization after 8 weeks, without adhesions to internal organs. 13



Rabbit abdominal wall

Clinical evidence of FlexHD® integration.

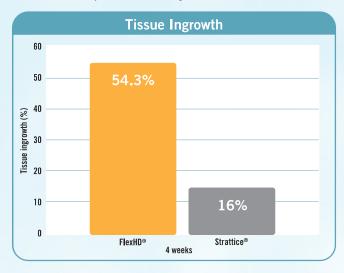
Shown here at 3 months after placement in patient.



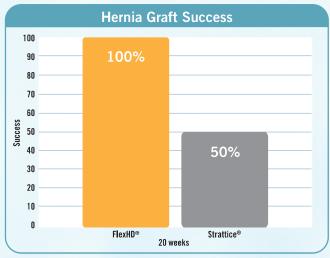
FlexHD® is visibly (40× magnification) populated with fibroblasts, indicating integration of the dermal matrix into soft tissues. Numerous red blood cells are also apparent in blood vessels within FlexHD®, demonstrating neovascularization. Images courtesy of Dr. John Y.S. Kim.

PROVEN PERFORMANCE

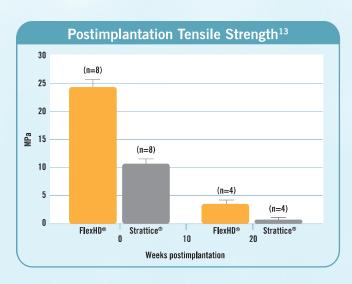
FlexHD® shows 3× greater tissue ingrowth than Strattice® in preclinical study. 13



FlexHD® outperforms Strattice® in preclinical study.13



Preclinical studies indicate 50% graft resorption and thinning resulting in hernia defect or recurrence with Strattice®.13



NATURAL. HEALING.

STRINGENT QUALITY AND SAFETY STANDARDS.

FlexHD® is available through the Musculoskeletal Transplant Foundation (MTF).

- MTF adheres to quality and safety standards developed by leading physicians, transplant surgeons, and specialists in the fields of science and medicine
- Donor screening criteria are among the most stringent of any tissue bank
- MTF meets and exceeds the standards and regulations of the American Association of Tissue Banks (AATB) and the Food and Drug Administration (FDA)

References

- 1. Choi B. (Report) LE-284: Characterization of Acellular Dermis via SDS-PAGE. February 20, 2010.
- Choi B. (Report) LE-282: Analysis of Extracellular Matrix (ECM) Characteristics via Enzyme Degradation Assay. February 20, 2010.
- 3. Ngo, MD. (Report) LE-268: Extracellular Matrix Components in Acellular Dermis. December 22, 2009.
- 4. Vaynshteyn E, Ngo MD, Munoz M, et al. Process Validation Report, PV-147, Sterilization of Acellular Dermis: July 19, 2005:1-16.
- 5. Choi B. (Report) LE-271: Analysis of Tensile Testing Data of Acellular Dermis. February 20, 2010.
- 6. Musculoskeletal Transplant Foundation. Processing Dermis (Skin).
- Ramshaw B and Bachman S. Surgical materials for ventral hernia repair, Biologic mesh, Part 2 of 3. *General Surgery News*, February 2007:1-14.
- 8. Livesey SA, del Campo AA, Nag A, et al. United States Patent Number 5,336,616. August 9, 1994.
- Hammond TM, Chin-Aleong J, Navsaria H, Williams NS. Human in vivo cellular response to a cross-linked acellular collagen implant. Br J Surg. 2008;95(4):438-446.
- 10. Freytes DO, Badylak SF. Sterilization of biologic scaffold materials. In: Webster JG, ed. Encyclopedia of Medical Devices and Instrumentation, 2nd ed. John Wiley & Sons, Inc; 2006:1-13.
- Grimes M, Pembroke JT, McGloughlin T. The effect of choice of sterilization method on the biocompatibility and biodegradability of SIS (small intestinal submucosa). Biomed Mater Eng. 2005;15(1-2):65-71.

12. Data on file.

13. Ngo MD, Aberman HM, Fanfan D. Comparative effectiveness of human and porcine acellular dermal matrices for incisional hernia repair in the rabbit. Data on file.

Other Clinical and Preclinical References

Bachman S, Ramshaw B. Prosthetic material in ventral hernia repair: how do I choose? Surg Clin North Am. 2008-88(1):101-112

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.

 $Eberli\,D,\,Rodriguez\,S,\,Atala\,A,\,Yoo\,JJ.\,In\,vivo\,evaluation\,of\,acellular\,human\,dermis\,for\,abdominal\,wall\,repair.\,\textit{J\,Biomed\,Mater\,Res}\,A,\,2010;93(4):1527-1538.$

Gocke DJ. Tissue donor selection and safety. Clin Orthop Relat Res. 2005;(435):17-21.

Louie L. The use of ALLODERM versus FLEXHD in implant based breast reconstruction. *Plast and Reconstr Surg.* June 2010 Supplement.

Maxwell GP, Gabriel A. Use of the acellular dermal matrix in revisionary aesthetic breast surgery. Aesthet Surg J. 2009;29(6):485-493.

Ngo M, Gertzman A. Acellular dermis for use in reconstructive surgery. Presented at: Biologic Scaffolds for Regenerative Medicine 5th Symposium, Phoenix, Arizona, February 15-16, 2008.

Roth JS, Dexter DD, Lumpkins K, Bochicchio GV. Hydrated vs. freeze-dried human acellular dermal matrix for hernia

Topol BM, Dalton EF, Ponn T, Campbell CJ. Immediate single-stage breast reconstruction using implants and human accellular dermal tissue matrix with adjustment of the lower pole of the breast to reduce unwanted lift. *Ann Plast Surg.* 2008;61(5):494-499.

Tissue Code	Description	Thickness
	Ultra Thin	
479102	FlexHD® 1 cm x 2 cm	0.2 mm - 0.4 mm thick
479204	FlexHD® 2 cm x 4 cm	0.2 mm — 0.4 mm thick
479307	FlexHD® 3 cm x 7 cm	0.2 mm — 0.4 mm thick
479407	FlexHD® 4 cm x 7 cm	0.2 mm — 0.4 mm thick
	Thin	
470102	FlexHD® 1 cm x 2 cm	0.4 mm - 0.8 mm thick
470204	FlexHD® 2 cm x 4 cm	0.4 mm — 0.8 mm thick
470307	FlexHD® 3 cm x 7 cm	0.4 mm — 0.8 mm thick
470407	FlexHD® 4 cm x 7 cm	0.4 mm – 0.8 mm thick
470412	FlexHD® 4 cm x 12 cm	0.4 mm – 0.8 mm thick
	Thick	
471102	FlexHD® 1 cm x 2 cm	0.8 mm – 1.7 mm thick
471104	FlexHD® 1 cm x 4 cm	0.8 mm — 1.7 mm thick
471204 471207	FlexHD® 2 cm x 4 cm	0.8 mm – 1.7 mm thick 0.8 mm – 1.7 mm thick
471212	FlexHD® 2 cm x 7 cm FlexHD® 2 cm x 12 cm	0.8 mm – 1.7 mm thick
471307	FlexHD® 3 cm x 7 cm	0.8 mm — 1.7 mm thick
471312	FlexHD® 3 cm x 12 cm	0.8 mm – 1.7 mm thick
471407	FlexHD® 4 cm x 7 cm	0.8 mm — 1.7 mm thick
471412	FlexHD® 4 cm x 12 cm	0.8 mm - 1.7 mm thick
471416	FlexHD® 4 cm x 16 cm	0.8 mm — 1.7 mm thick
471510	FlexHD® 5 cm x 10 cm	$0.8 \; \text{mm} - 1.7 \; \text{mm} \; \text{thick}$
471512	FlexHD® 5 cm x 12 cm	0.8 mm — 1.7 mm thick
471608	FlexHD® 6 cm x 8 cm	0.8 mm – 1.7 mm thick
471612	FlexHD® 6 cm x 12 cm	0.8 mm — 1.7 mm thick
471616 471206	FlexHD® 6 cm x 16 cm FlexHD® 6 cm x 20 cm	0.8 mm – 1.7 mm thick 0.8 mm – 1.7 mm thick
471812	FlexHD® 8 cm x 12 cm	0.8 mm – 1.7 mm thick
471816	FlexHD® 8 cm x 16 cm	0.8 mm — 1.7 mm thick
471208	FlexHD® 8 cm x 20 cm	0.8 mm - 1.7 mm thick
471016	FlexHD® 10 cm x 16 cm	0.8 mm — 1.7 mm thick
471122	FlexHD® 12 cm x 12 cm	$0.8 \; \text{mm} - 1.7 \; \text{mm} \; \text{thick}$
471216	FlexHD® 12 cm x 16 cm	0.8 mm — 1.7 mm thick
471220	FlexHD® 12 cm x 20 cm	0.8 mm – 1.7 mm thick
471224	FlexHD® 12 cm x 24 cm	0.8 mm — 1.7 mm thick
471620 471202	FlexHD® 16 cm x 20 cm FlexHD® 20 cm x 20 cm	0.8 mm – 1.7 mm thick 0.8 mm – 1.7 mm thick
471225	FlexHD® 20 cm x 25 cm	0.8 mm – 1.7 mm thick
472312	Ultra Thick FlexHD® 3 cm x 12 cm	≥1.8 mm thick
472412	FlexHD® 4 cm x 12 cm	≥1.8 mm thick
472416	FlexHD® 4 cm x 16 cm	≥1.8 mm thick
472510	FlexHD® 5 cm x 10 cm	≥1.8 mm thick
472512	FlexHD® 5 cm x 12 cm	≥1.8 mm thick
472612	FlexHD® 6 cm x 12 cm	≥1.8 mm thick
472616	FlexHD® 6 cm x 16 cm	≥1.8 mm thick
472206	FlexHD® 6 cm x 20 cm	≥1.8 mm thick
472812 472816	FlexHD® 8 cm x 12 cm FlexHD® 8 cm x 16 cm	≥1.8 mm thick ≥1.8 mm thick
472208	FlexHD® 8 cm x 20 cm	≥1.8 mm thick
472016	FlexHD® 10 cm x 16 cm	≥1.8 mm thick
472122	FlexHD® 12 cm x 12 cm	≥1.8 mm thick
472216	FlexHD® 12 cm x 16 cm	≥1.8 mm thick
472220	FlexHD® 12 cm x 20 cm	≥1.8 mm thick
472224	FlexHD® 12 cm x 24 cm	≥1.8 mm thick
472620	FlexHD® 16 cm x 20 cm	≥1.8 mm thick
472202	FlexHD® 20 cm x 20 cm	≥1.8 mm thick
472225	FlexHD® 20 cm x 25 cm	≥1.8 mm thick
	Breast Kit, Thick	
4B1416	FlexHD® 4 cm x 16 cm	0.8 mm – 1.7 mm thick
4B1612	FlexHD® 6 cm x 12 cm	0.8 mm — 1.7 mm thick
4B1616	FlexHD® 6 cm x 16 cm FlexHD® 8 cm x 16 cm	0.8 mm - 1.7 mm thick
4B1816		0.8 mm — 1.7 mm thick
	Breast Kit, Ultra Thick	
4B1416	FlexHD® 4 cm x 16 cm	≥1.8 mm thick
4B1612	FlexHD® 6 cm x 12 cm	≥1.8 mm thick
4B1616 4B1816	FlexHD® 6 cm x 16 cm FlexHD® 8 cm x 16 cm	≥1.8 mm thick ≥1.8 mm thick
401010	LICKLID O CHILY TO CHI	≥1.0 mm untK
THE RESERVE OF THE PARTY OF THE	The second secon	The second secon

The Musculoskeletal Transplant Foundation maintains an unrivaled safety record with over 4.2 million grafts distributed since 1987.12

Contact MTF Customer Service at 1-800-433-6576.



