

# ALLOPATCH HD® ACELLULAR HUMAN DERMIS



## RAISING THE STANDARD FOR Biologic scaffolds

ALLOPATCH HD<sup>®</sup>, from ConMed Linvatec, was developed to meet the need for a safe, high-quality extracellular matrix (ECM) scaffold. Allopatch HD is derived from human allograft skin that is processed using proprietary procedures to preserve and maintain the natural biomechanical, biochemical and matrix properties of the collagen graft. Comparative studies and testing show that Allopatch HD possesses the desired properties for the selection and utilization of a biologic scaffold.



ALLOPATCH HD<sup>®</sup> is available in meshed and non-meshed versions.

## ACELLULAR HUMAN COLLAGEN MATRIX

- Preserved collagen I, collagen III, elastin, hyaluronan and vitronectin responsible for promoting cell attachment and growth
- Natural biologic scaffold for cell infiltration and neovascularization
- Non-immunogenic
- Non-crosslinked

## BIOMECHANICAL PROPERTIES<sup>2</sup>

- Superior tensile strength
- Equivalent suture retention strength
- Greater resistance to stretching and deformation

(Note: Biomechanical properties of Allopatch HD were tested against a comparative human collagen matrix graft.)

## HYDRATED

- Stored at ambient temperature; does not require refrigeration
- Ready to use out of the package
- Reduces OR time; lowers operative costs
- Also available in dehydrated form

### TISSUE SAFETY

- Partnered with MTF, the nation's largest tissue bank with more than 5.0 million grafts transplanted from over 90,000 donors and an exemplary safety record
- MTF has strict acceptance criteria and accepts only 3% of the donors referred each year

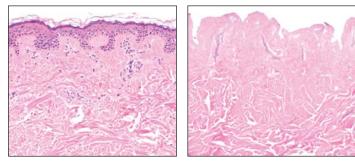
#### ACELLULAR SCAFFOLD

Extracellular matrices (ECMs) are typically marketed as "decellularized" biomaterials since they undergo processing treatments to remove cellular elements, minimizing the potential for an immunogenic response. The resulting acellular matrix is a natural collagen scaffold for the promotion of host cell proliferation and eventual matrix synthesis.3 Allopatch HD is processed to remove the epidermal layer and other cellular elements while maintaining histomorphological integrity. Hematoxylin and eosin (H&E) staining of normal skin and Allopatch HD show that the dermal matrix structure is preserved during processing.1 H&E staining also demonstrates the absence of the epidermis and cells in the human collagen matrix graft (Figures 1a & 1b).

In an animal model, Roth et. al. compared hydrated vs. freeze-dried human collagen matrix grafts for hernia repair and found fewer white blood cells (WBC) and eosinophils (EOS) in the hydrated graft at 4 and 8 weeks vs. the freeze-dried graft. At 20 weeks there was no difference in WBC or EOS in either graft material.<sup>4</sup> In conclusion, the hydrated graft demonstrated a reduced inflammatory response at 4 and 8 weeks compared to the freeze-dried graft.<sup>4</sup> Both collagen matrix grafts demonstrated similar amounts of vascular ingrowth at each time point.4

#### NORMAL SKIN

#### ALLOPATCH HD



Figures 1a and 1b: Hematoxylin and eosin staining of normal skin (left) and ALLOPATCH HD (right) from the same donor. Note absence of cells and preservation of collagen matrix structure after processing.

#### ORDERING INFORMATION

| HYDRATED | DEHYDRATED | SIZE      | DESCRIPTION                            |
|----------|------------|-----------|--|
| 470505   | 370505     | 5cm x 5cm | Allopatch HD Thin 0.4–0.7              |
| 471505   | 371505     | 5cm x 5cm | Allopatch HD Thick 0.8–1.7             |
| 472505   |            | 5cm x 5cm | Allopatch HD Ultra Thick 1.8–3.9       |
| 473505   |            | 5cm x 5cm | Allopatch HD Extra Ultra Thick 4.0–5.0 |
| 470408   | 370408     | 4cm x 8cm | Allopatch HD Thin 0.4–0.7              |
| 471408   | 371408     | 4cm x 8cm | Allopatch HD Thick 0.8–1.7             |
| 472408   |            | 4cm x 8cm | Allopatch HD Ultra Thick 1.8–3.9       |
|          | 371404     | 4cm x 4cm | Allopatch HD Thin 0.4–0.7              |
|          | 372404     | 4cm x 4cm | Allopatch HD Thick 0.8–1.7             |
|          |            |           |  |

1 Histology courtesy of Premier Laboratory, LLC, data on file at MTF.

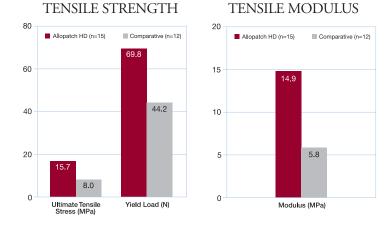
<sup>2</sup> ASTM (D638) International Standards for Mechanical Strength – data on file at MTF.

<sup>3</sup> Valentin JE, Badylak JS et. al., Extracellular Matrix Bioscaffolds for Orthopaedic Applications, JBJS. 2006; 88:2673-2686.

#### **BIOMECHANICAL PROPERTIES**

In a recent biomechanical study evaluating commercially available soft-tissue augmentation devices, acellular human collagen matrix grafts were found to be stronger after cyclic loading with greater stiffness than comparative xenograft and synthetic grafts. Suture retention strength was also greatest in the acellular human collagen matrix grafts compared to all other grafts tested.5

In a side-by-side test, Allopatch HD (hydrated) human collagen matrix graft exhibited greater biomechanical strength and tensile modulus than a comparative (freeze-dried) human collagen matrix graft. Allopatch HD exhibits an average ultimate tensile stress of 15.7MPa, withstanding an average maximum load of 69.8N prior to yielding. The comparative freeze-dried graft, when subjected to the same testing, exhibits an average ultimate stress of 8.0MPa and a maximum load before yield of 44.2N (P<0.05). The tensile modulus of Allopatch HD was also significantly higher at 14.9MPa vs. the comparative freeze-dried graft, which has an average tensile modulus of 5.8MPa (P<0.05).2



#### HYDRATED DEHYDRATED SIZE

|        | DENTERIO | OILL       |                                  |
|--------|----------|------------|----------------------------------|
| 470205 | 370205   | 2cm x 5cm  | Allopatch HD Thin 0.4–0.7        |
| 471205 | 371205   | 2cm x 5cm  | Allopatch HD Thick 0.8–1.7       |
| 470112 |          | 1cm x 12cm | Allopatch HD Thin 0.4–0.7        |
| 471112 |          | 1cm x 12cm | Allopatch HD Thick 0.8–1.7       |
| 474505 |          | 5cm x 5cm  | Allopatch HD Meshed Thin 0.4–0.7 |
| 474408 |          | 4cm x 8cm  | Allopatch HD Meshed Thin 0.4–0.7 |
| 474404 |          | 4cm x 4cm  | Allopatch HD Meshed Thin 0.4–0.7 |
| 474205 |          | 2cm x 5cm  | Allopatch HD Meshed Thin 0.4–0.7 |
|        |          |            |                                  |

DESCRIPTION

<sup>4</sup> Roth JS, Dexter DD, Hydrated vs. Freeze-Dried Human Acellular Dermal Matrix for Hernia Repair: A Comparison in a Rabbit Model. Hernia. 2008.

Barber AF, Aziz-Jacob J, Biomechanical Testing of Commercially Available Soft-Tissue Augmentation Materials. Arthroscopy: The J. of Arthro and Related Sur. 2009: Vol.25; No.11, pp. 1233-1239.

Available through:



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