



ACUTE SURGICAL WOUND ANIMAL STUDY

HELIOPEN[®] vs. MariGen Micro[®] (Kerecis)

Objective: Evaluate the host response to scaffold products^{1,2}

Methods: Subcutaneous implant of scaffold products in athymic nude mice* with acute wounds

Test Articles: Scaffold Products

HELIOPEN

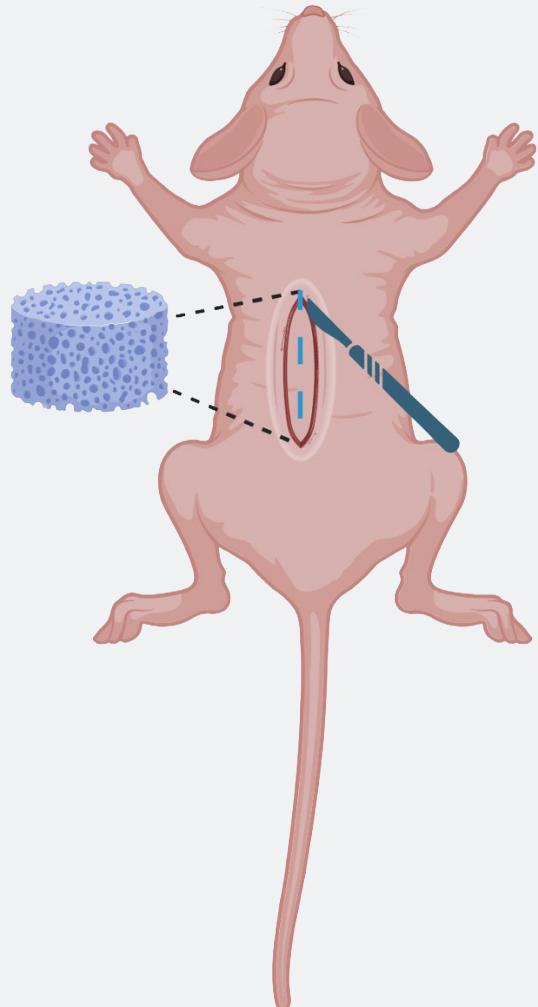
- Type I and III bovine dermis particulate
- n=8 to 10 animals per time point[^]

MariGen Micro (Kerecis)

- Fish skin particulate
- n=5 to 6 animals per time point[^]

Timepoints Evaluated:

- 1 week and 4 weeks
- Tissue sample section processed and evaluated microscopically

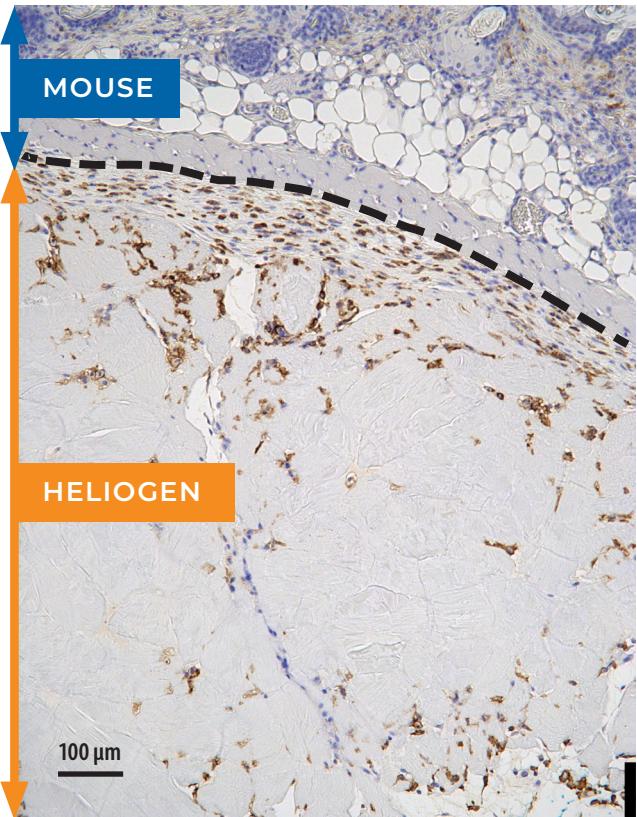


* Athymic nude mice lack T cells. Therefore, they do not reject foreign tissue. This model eliminates confounding results from a xenogenic response.

[^] One site per animal.

Results: Week 1 Post-Implantation¹

HELIOPEN is **well-tolerated** as evident by **fewer inflammatory macrophages** infiltrating into the implant site compared to MariGen Micro (Kerecis).



HELIOPEN[®]
FIBRILLAR COLLAGEN MATRIX



MariGen Micro (Kerecis)

Staining Guide



Macrophages (brown staining) are inflammatory cells responsible for clearing damaged tissue and foreign objects³



All nucleated cells (blue/purple staining)



Neocollagenesis (red staining) is the process by which new collagen fibers are synthesized and deposited

Results: Week 4 Post-Implantation²

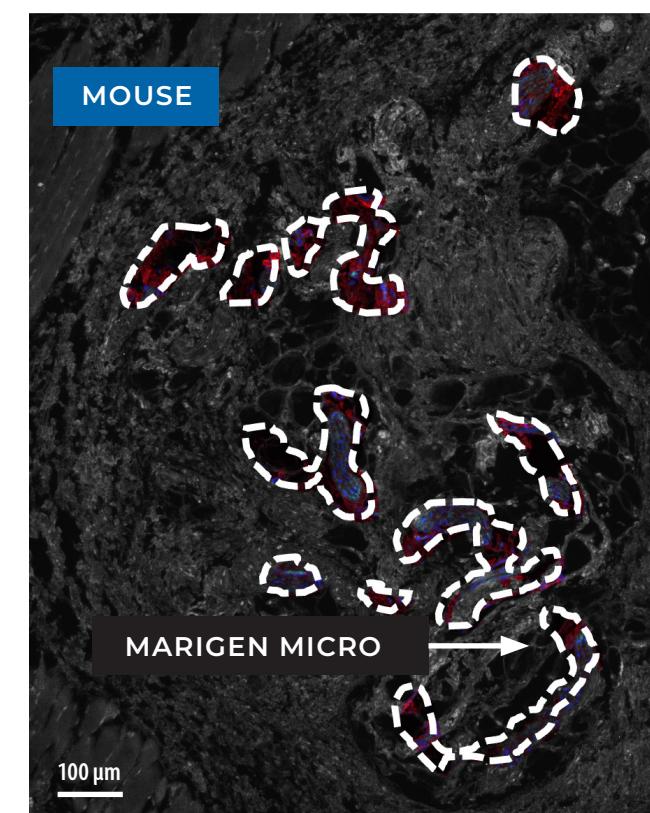
New collagen was deposited into the **HELIOPEN** implant site because the scaffold was **well-tolerated** and **supported cellular ingrowth**.

MariGen Micro (Kerecis) was largely degraded; therefore, minimal collagen deposition was apparent within the implant.



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Existing subcutaneous mouse collagen has been subtracted to highlight new collagen formation into the remaining implant.



MariGen Micro (Kerecis)

Conclusion^{1,2}

Week 1: HELIOGEN exhibited a lesser inflammatory response than MariGen Micro (Kerecis).

Week 4: HELIOGEN persisted and exhibited scaffold properties like supporting new collagen production. MariGen Micro was degraded due to early inflammation.



Overall, HELIOGEN collagen matrix provided an optimal scaffold in an acute surgical wound.[†]

HELIOGEN[®]
FIBRILLAR COLLAGEN MATRIX



Product	Product Compatibility With Host [‡]	Product Persistence Post-Implantation
HELIOGEN	++++	++++
MariGen Micro (Kerecis)	++	++

⁺Ratings are based upon histopathological analysis. Higher ratings (+) are indicative of improved performance.



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Please Call: 866.477.4219 **Email: customerservice@mimedx.com**

[†]Results were demonstrated in animal only. Correlation to clinical results in humans is unknown.

[‡]Biocompatibility was determined by the macrophage response because nude mice lack an adaptive immune system.

1. MIMEDX Internal Report. MM-RD-00183, Immunofluorescence and Immunohistochemical Analysis of Xenograft ECM Particulates in a Mouse Subcutaneous Implant Model. 2. MIMEDX Internal Report. MM-RD-00178, Non-GLP Evaluation of Xenograft Scaffolds for Cellular Response in a Mouse Subcutaneous Implant Model. 3. Aitcheson SM, Frentiu FD, Hurn SE, Edwards K, Murray RZ. Skin Wound Healing: Normal Macrophage Function and Macrophage Dysfunction in Diabetic Wounds. *Molecules*. 2021;26(16):4917.

Note: Mouse and stain guide images created using BioRender.

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