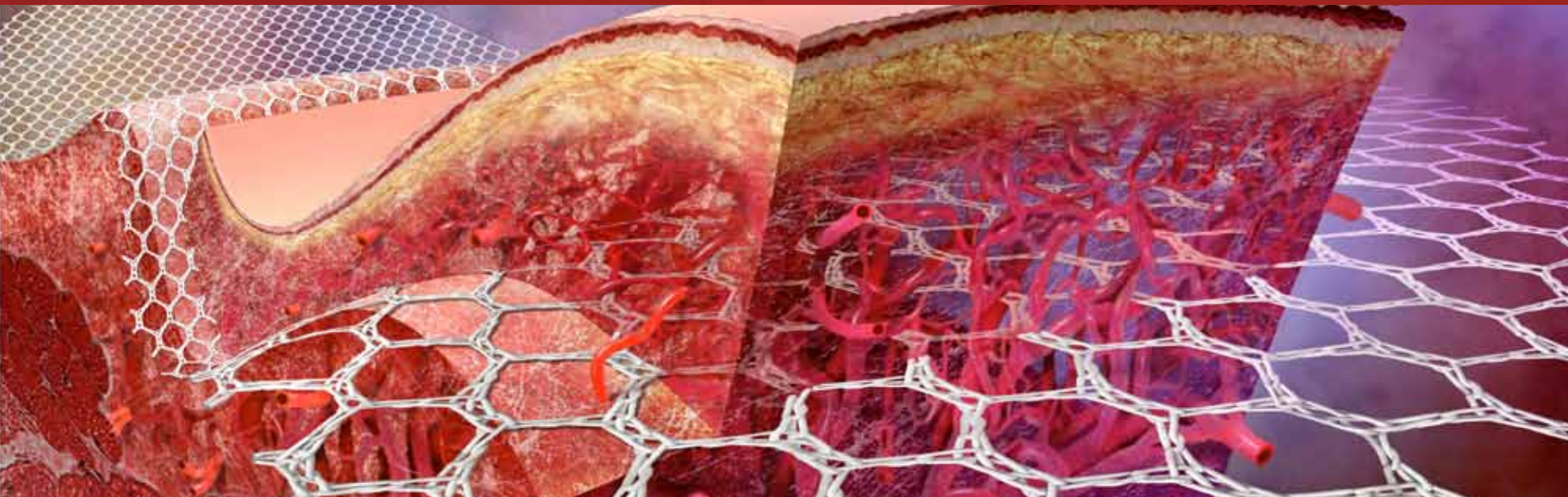


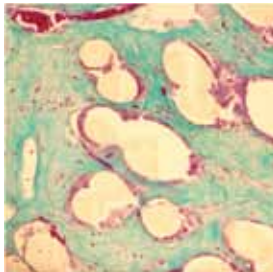
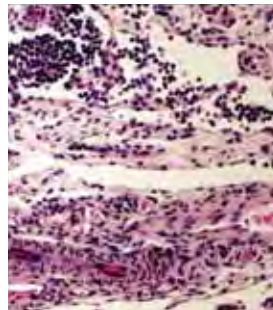
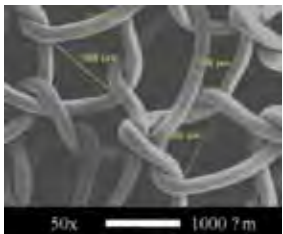
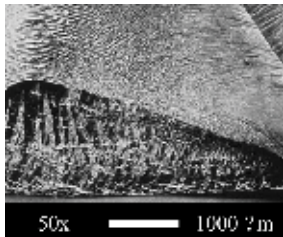
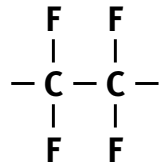
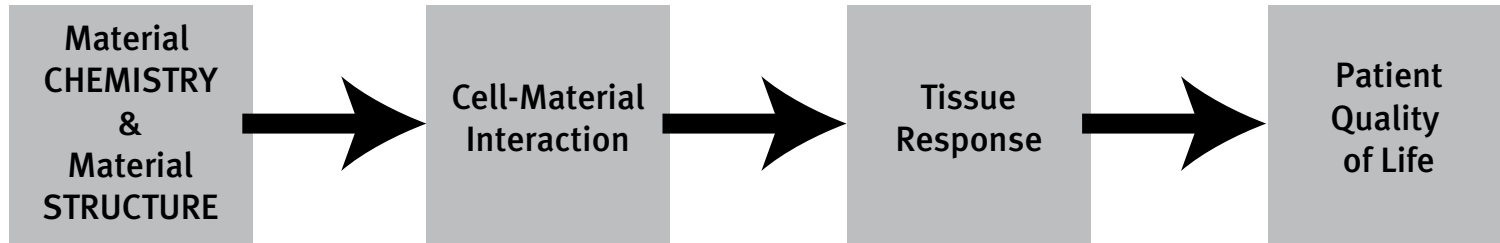
▶ GORE INFINIT MESH



PERFORMANCE by design



GORE INFINIT MESH



CLINICAL SIGNIFICANCE OF CHRONIC FOREIGN BODY REACTION

- “...understood as a chronic wound persisting over many years at the interface of the mesh and recipient tissues.”
- Responsible for “..the fibrotic reaction around the mesh in total as well as around each single mesh fiber.”
- Leads to a ‘scar plate’ that can “appreciatively manipulate the abdominal wall function and quality of life.”
- “..the onset of chronic pain as a consequence of FBR is typically more than one year after hernia repair.”
- “All experimental evidence and first clinical data indicate the superiority of the lightweight and large porous mesh concept with regard to a reduced number of long-term complications and particularly, increased comfort and quality of life after hernia repair.”

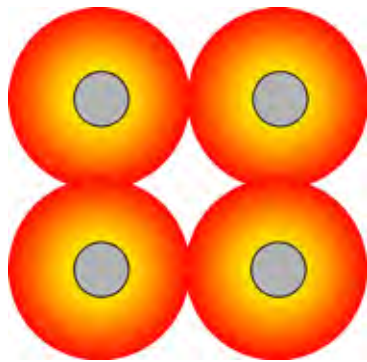
Klosterhalfen B, Junge K, Klinge U. The lightweight and large porous mesh concept for hernia repair. *Expert Reviews in Medical Devices* 2005;2(1):103-117.



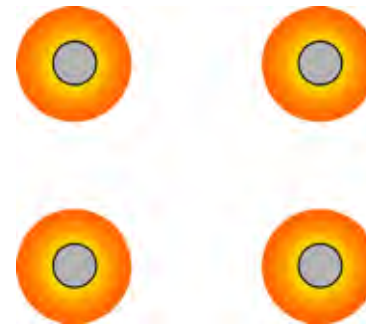
MINIMIZING CHRONIC FOREIGN BODY REACTION

- ▶ “Chronic Foreign Body Reaction (FBR) depends not only on the polymer, but also the surface area in contact with the host tissue”
-Klosterhalfen et al

Chemistry + Fiber Size + Pore Size



Highest CFBR
– Reactive chemistry
– Large fiber
– Small pore



Lowest CFBR
– Inert chemistry
– Small fiber
– Large pore

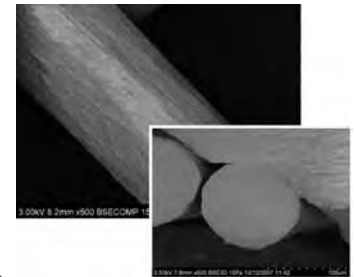
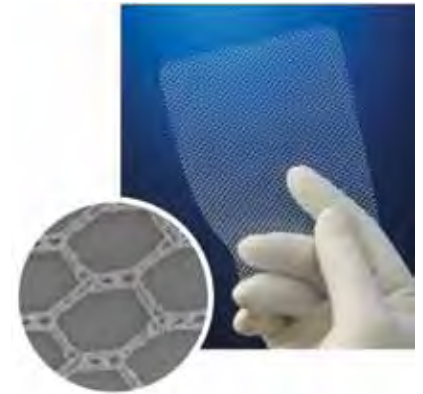
Klosterhalfen B, Junge K, Klinge U. The lightweight and large porous mesh concept for hernia repair. *Expert Reviews in Medical Devices* 2005;2(1):103-117.



GORE INFINIT MESH

PERFORMANCE THAT LASTS.

- The only 100% solid monofilament PTFE large-pore, knitted surgical mesh
 - Naturally low chronic foreign body reaction
 - Complete tissue ingrowth
 - Soft, conformable yet strong
 - Engineered to improve long-term patient comfort and quality of life
- Chemically and mechanically stable
 - Will not degrade in the body over time
- Intended for use in the reconstruction of hernias and other soft tissue deficiencies.
Typical applications include:
 - Inguinal: Lichtenstein, Plug & Patch, Laparoscopic TEP/TAPP
 - Ventral: Preperitoneal, Rives-Stoppa (retrorectus)
 - Repair when no adhesion barrier or ventral fascial bridging is required



MESH

SUPPORTING DATA

- Rabbit Dorsum Model
 - Comparative study with reduced weight polypropylene
 - Gross observation and histological evaluation at 30 & 90 days
- Rabbit Dorsum Model
 - Study of commercial polyester mesh
 - Gross observation and histological evaluation at 90 days
- Porcine Model of Ventral Incisional Hernia Repair
 - Brent D. Matthews, MD, FACS
 - Department of Surgery, Section of Minimally Invasive Surgery, Washington University School of Medicine, Saint Louis, MO
 - Presented at ACS, San Francisco, 2008
 - Histologic evaluation of a novel macroporous PTFE Knit Mesh compared to lightweight and heavyweight polypropylene meshes
 - Gross observation and histological analysis at 3 months



NATURALLY LOW CHRONIC FOREIGN BODY REACTION

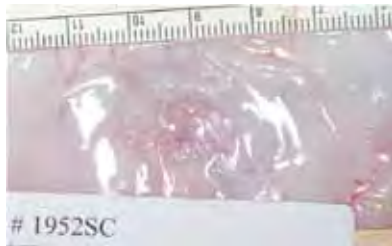
▶ Rabbit Dorsum - Gross Observations

Reduced-Weight
Polypropylene
Mesh



Polypropylene mesh explants associated with visual irritation and bleeding (30 day)

GORE
INFINIT
Mesh



GORE INFINIT Mesh explants associated with bland looking tissue response similar to surrounding tissues (30 day)

Polyester
Mesh



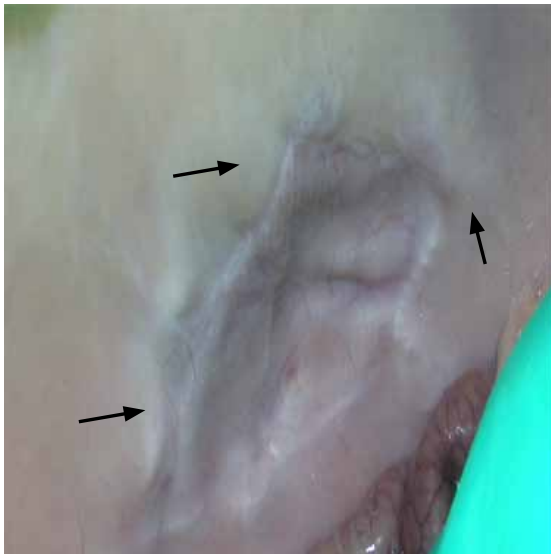
Polyester mesh is covered extensively with blood vessels at this time with focal coverage of the mesh with fibrosis (arrow) (90 day)



NATURALLY LOW CHRONIC FOREIGN BODY REACTION

Chronic FBR: Porcine Model of Ventral Incisional Hernia Repair - 3 Month Explants
Brent D. Matthews, MD, FACS - Washington University School of Medicine

Heavyweight Polypropylene



Extensive wrinkling and buckling from original shape (rectangular), edges nodular and fibrotic with tension lines (arrows) at the margins

Lightweight Polypropylene



Wrinkling and buckling of mesh with fibrosis at margins. Focal vascularity and distortion of peritoneum

GORE INFINIT Mesh



Mesh is vascularized and well incorporated with native tissue, compliant with abdominal wall and maintains normal architecture of peritoneum

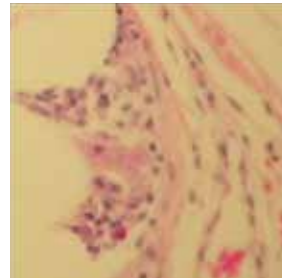
Initial Experience with GORE INFINIT Mesh
American College of Surgeons, San Francisco, CA, October 12-16, 2008



NATURALLY LOW CHRONIC FOREIGN BODY REACTION

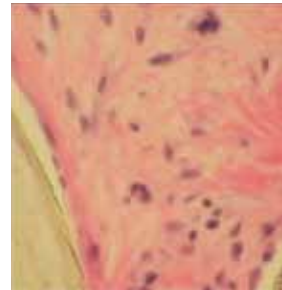
▶ Rabbit Dorsum - 30 Day H&E Stain, 20x

Reduced-Weight
Polypropylene
Mesh



Polypropylene fibers are surrounded by inflammatory cells at the tissue interface.

GORE
INFINIT
Mesh



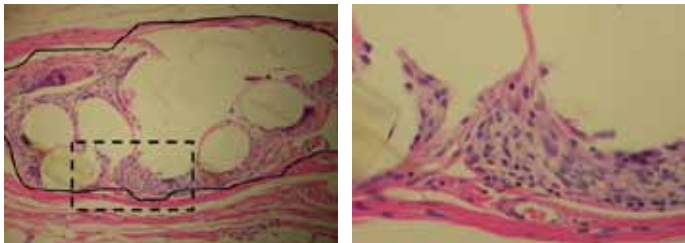
Inflammatory cells are sparse around and at the PTFE fiber interface.



NATURALLY LOW CHRONIC FOREIGN BODY REACTION

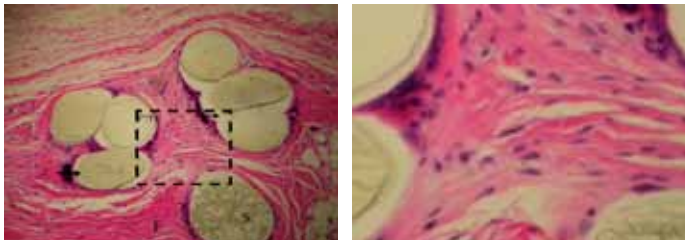
▶ Rabbit Dorsum - 90 Day H&E Stain, 20x

Reduced-Weight
Polypropylene
Mesh



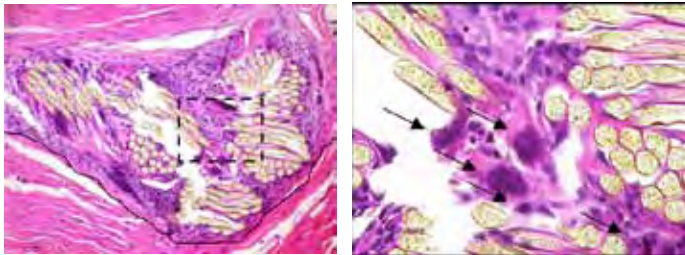
Polypropylene fibers are surrounded by persistent inflammatory cells at the tissue interface.

GORE
INFINIT
Mesh



Minimal inflammatory cells are present around and at the PTFE fiber interface.

Polyester
Mesh

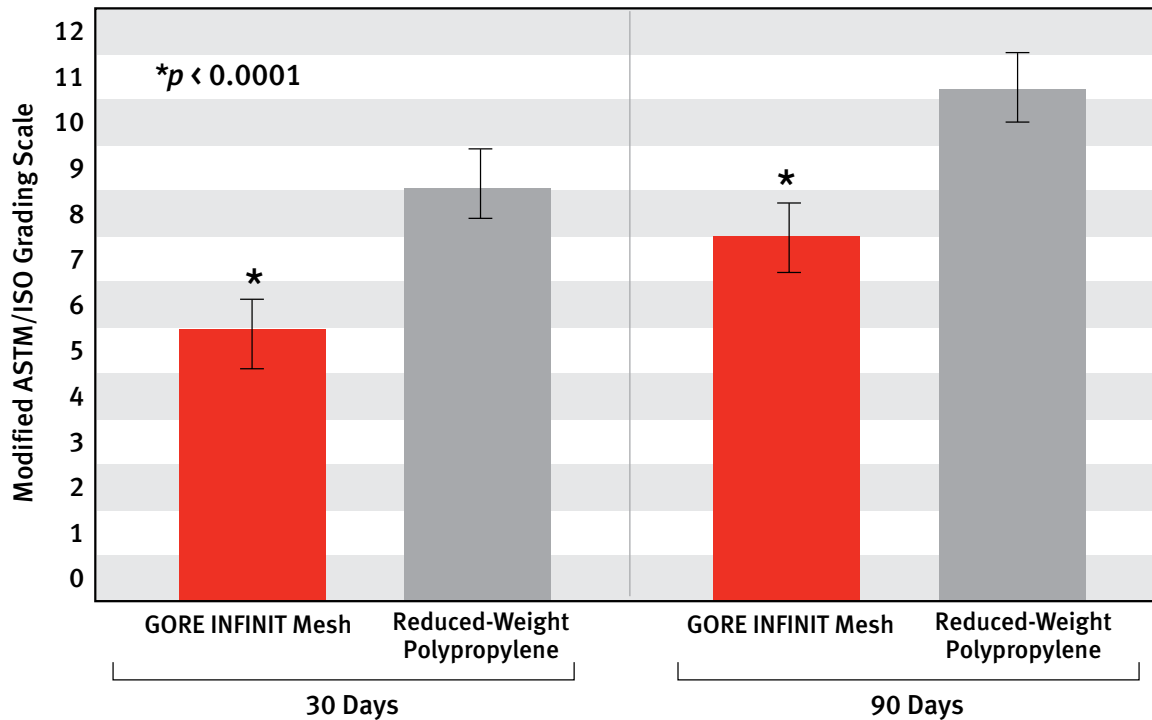


Inflammatory cells are observed around the polyester fibers with numerous foreign body giant cells (arrows).



NATURALLY LOW CHRONIC FOREIGN BODY REACTION

▶ Rabbit Dorsum - 30 and 90 Day Inflammation Scores

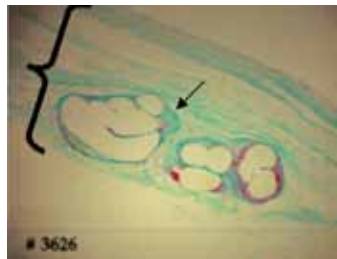


GORE INFINIT Mesh has a significantly lower chronic foreign body reaction than reduced-weight polypropylene.

COMPLETE TISSUE INGROWTH

▶ Rabbit Dorsum – Trichrome, 10x

Reduced-Weight
Polypropylene
Mesh



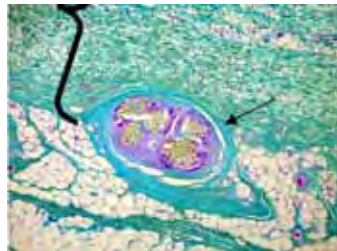
Polypropylene mesh fibers are completely incorporated and have a thick fibrous capsule forming at interface (arrow).

GORE
INFINIT
Mesh



PTFE mesh fibers are completely incorporated and have a bland fibrous capsule forming at the interface.

Polyester
Mesh

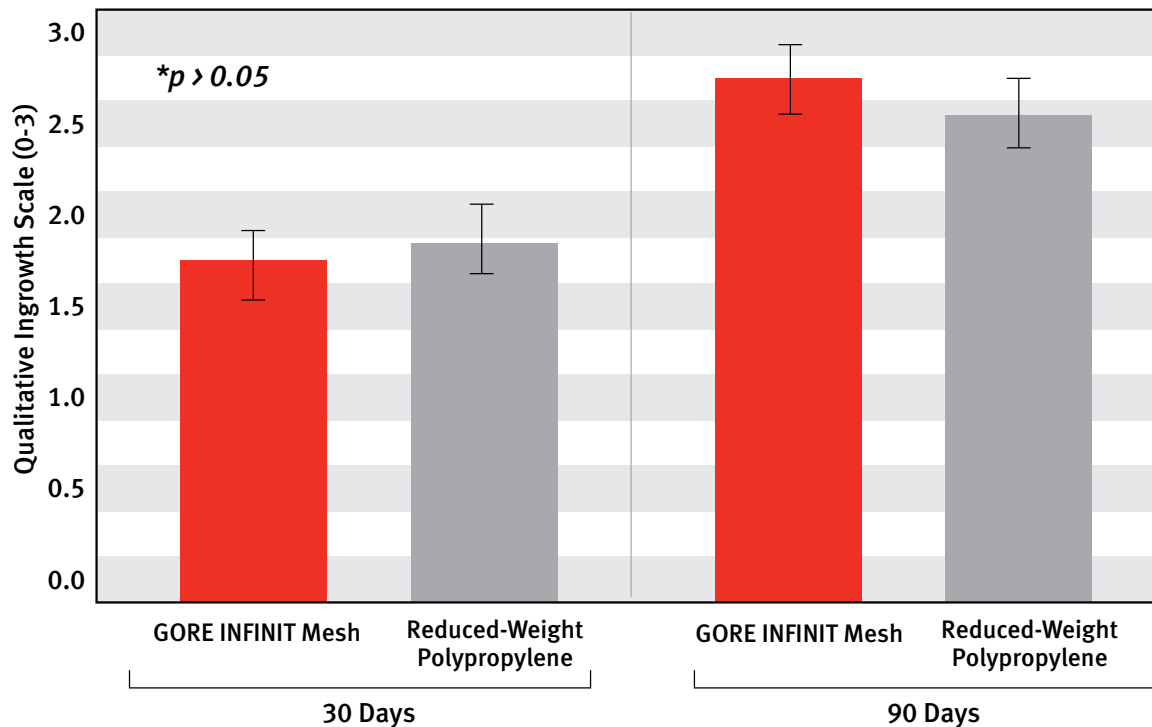


Polyester mesh fiber bundles are completely incorporated and have a thick fibrous capsule forming at the interface which intrudes into adjacent tissues (arrow).



COMPLETE TISSUE INGROWTH

▶ Rabbit Dorsum - 30 and 90 Day Tissue Ingrowth



No significant differences at 30 and 90 days. GORE INFINIT Mesh has complete tissue ingrowth, comparable to polypropylene.



SOFT, CONFORMABLE, YET STRONG

- GORE INFINIT Mesh has been engineered to meet or exceed 16 N/cm, the tensile strength necessary for the repair of inguinal defects and when abdominal fascial defects can be closed¹.
- Intended for use in the reconstruction of hernias and other soft tissue deficiencies. Applications include:
 - Inguinal: Lichtenstein, Plug & Patch, Laparoscopic TEP/TAPP
 - Ventral: Preperitoneal, Rives-Stoppa (retrorectus)
 - Repair when no adhesion barrier or ventral fascial bridging is required

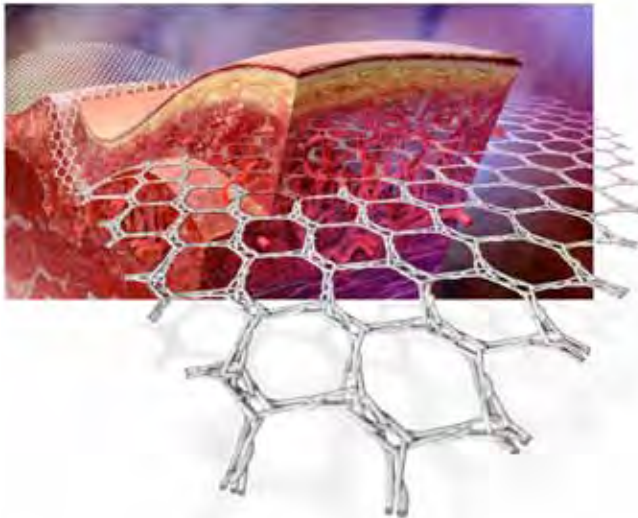
¹ Klosterhalfen B, Junge K, Klinge U. The lightweight and large porous mesh concept for hernia repair. *Expert Reviews in Medical Devices* 2005;2(1):103-117.”



GORE INFINIT MESH

PERFORMANCE THAT LASTS.

- ▶ Naturally low chronic foreign body reaction
- ▶ Complete tissue ingrowth
- ▶ Soft, conformable, yet strong
- ▶ Engineered to improve long term patient comfort and quality of life





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