

Plaintiff's Exhibit  
**PX 146**

# The (clinical) argument of lightweight mesh in abdominal surgery

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Ethicon

Research & Development

# From Heavyweight to *Lightweight* Meshes

- Two competitive concepts in hernia repair
- Heavyweight Mesh
  - Big mass
  - Small pore size
- Lightweight Mesh
  - Lower mass
  - Big pore size

# Polypropylene Mesh

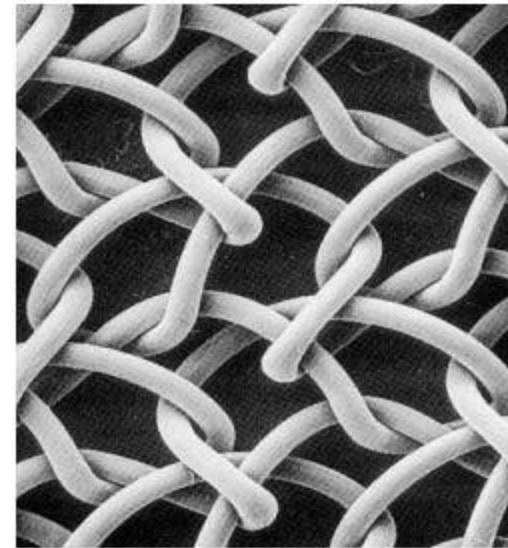


**Monofilament fibers**

**woven - 1958**

**knitted - 1962**

**Marlex**



**Usher F, et al. Am Surg 24:969-974, 1958**

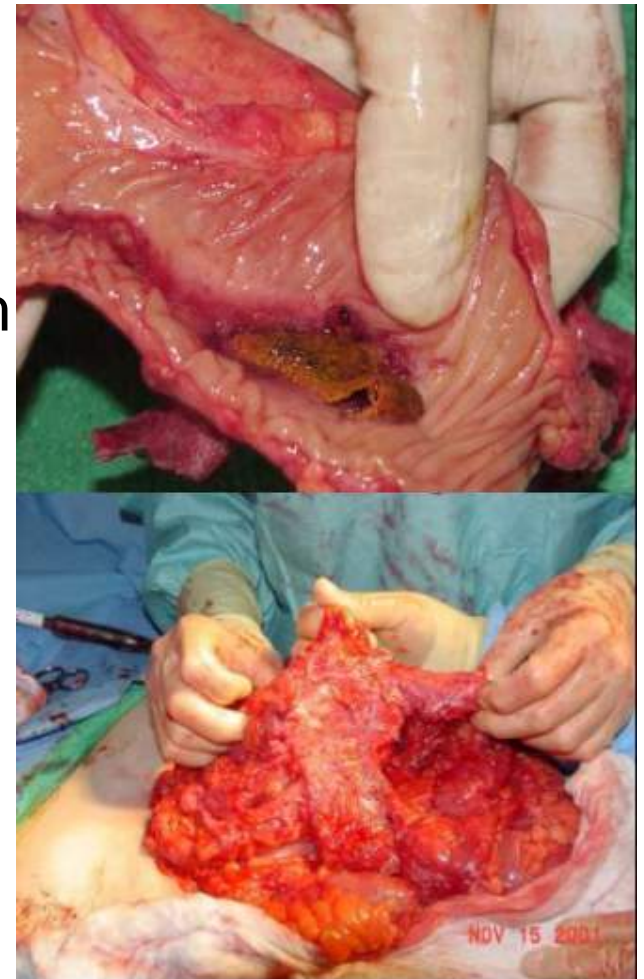
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# Polypropylene Mesh

- Small pore size (< 1mm)
- high tensile strength
- Inert and biocompatible
- Resistant to infection
- Inexpensive
- Long track history
- BUT: Heavyweight: 90 g/m<sup>2</sup>

# Experience with Heavyweight Meshes

- Excessive foreign body reaction
- Chronic inflammation
- Unorganized fibrocollagenous ingrowth
- Scar plate formation
- Shrinkage from bridging fibrosis
- Stiffness – abdominal wall restriction



# What is the ideal mesh for hernia repair?

- Restore abdominal wall functions
- High Biocompatibility (well integrated in abdom. Wall)
- No serious / longterm complications
  - Recurrence
  - Infection
  - Pain
- Optimal handling characteristics
  - Comfortable repair
  - Safe repair

# The truth about Burst Strength

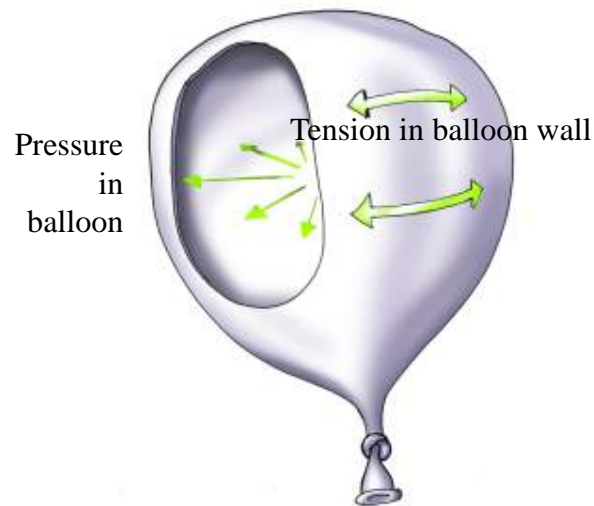
- Studies conducted and showed that meshes are stronger than needed for abdominal tissue support
- A stronger mesh results in:
  - Higher amount of permanent material
  - Usually creates tough scar plate
- Ideal mesh will be:
  - Strong enough to withstand the forces (pressure)
  - Flexible (abdominal wall compliance)
  - Low in mass and thin
  - Open pores for to avoid bridging fibrosis



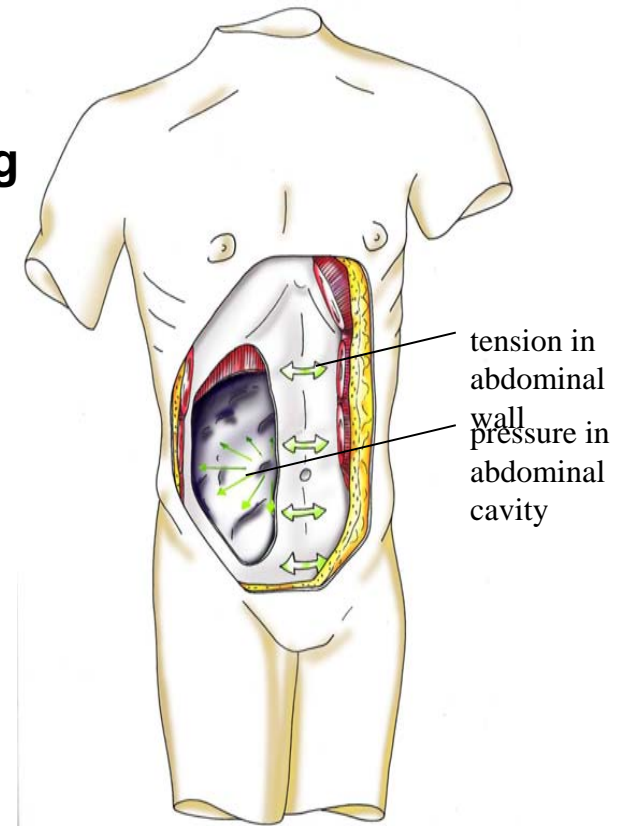
# Forces in Abdominal Wall

**LaPlace's Law:**

**Maximum abdominal pressure < 150mmHg**

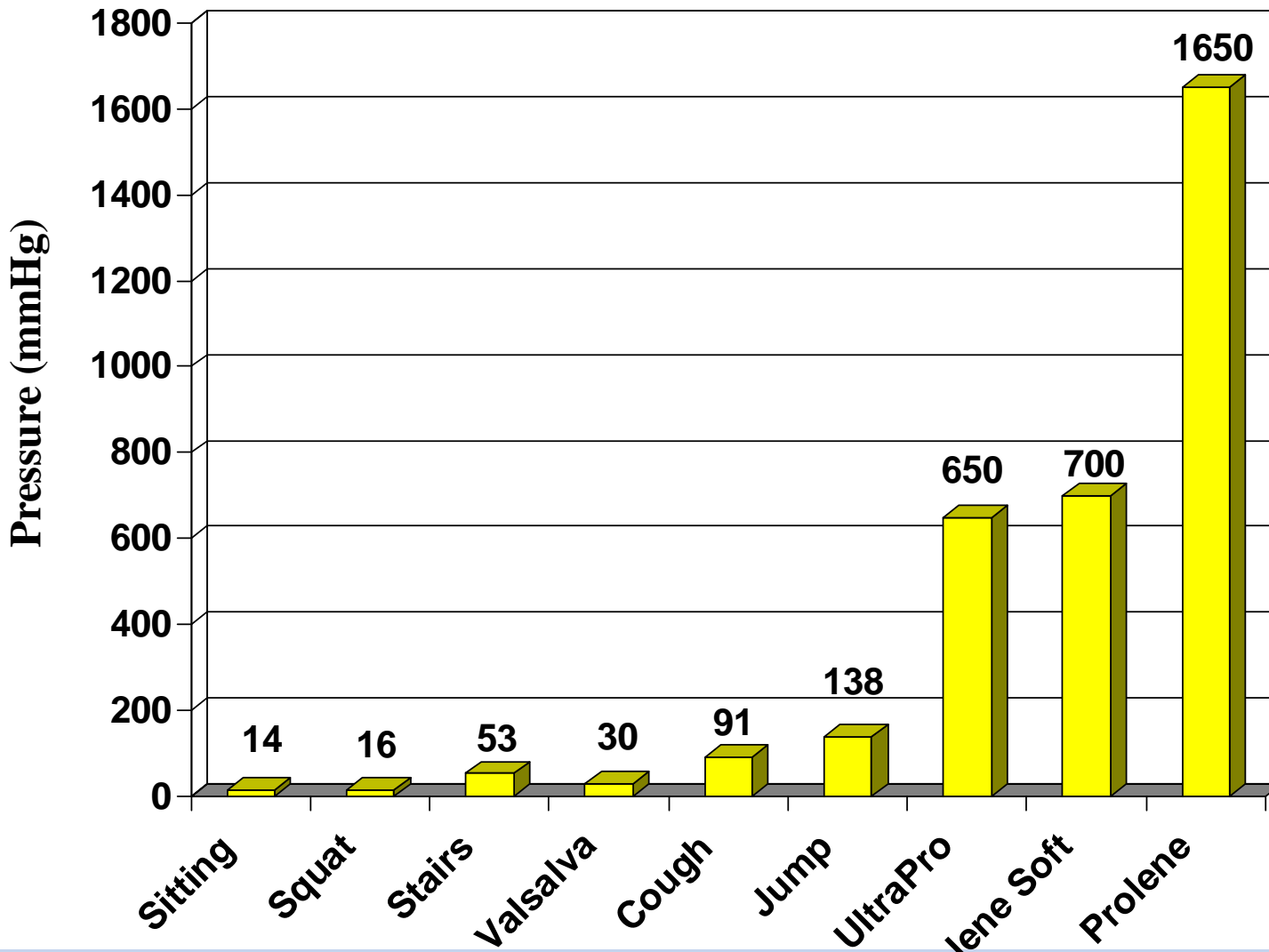


Balloon-model imitating abdominal cavity



**150 mmHg – 16 N/cm**

# Pressure in Abdominal Cavity



# Heavyweight Mesh

- Rupture forces of 40-100 N/cm
- Abdominal wall forces may be as low as 2-26 N/cm
- Restricts mobility of abdominal wall
- May be over-engineered?

**Cobb WS. J Surg Res 2005**

**Klinge U, et al. Chirurg 67:229-233, 1996**

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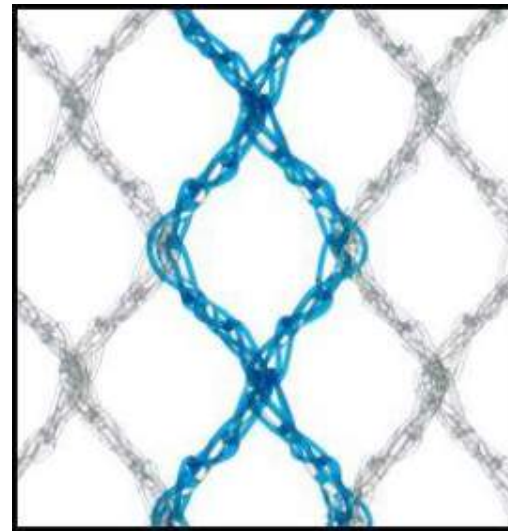
# Lightweight Mesh Requirements

- Alter construction of the mesh in such a way as to allow handling characteristics of a traditional mesh while delivering:
  - A secure repair
  - More natural abdominal wall ability
  - Improved patient comfort
  - Less foreign body implanted over the lifetime of the patient



# What does Lightweight mean?

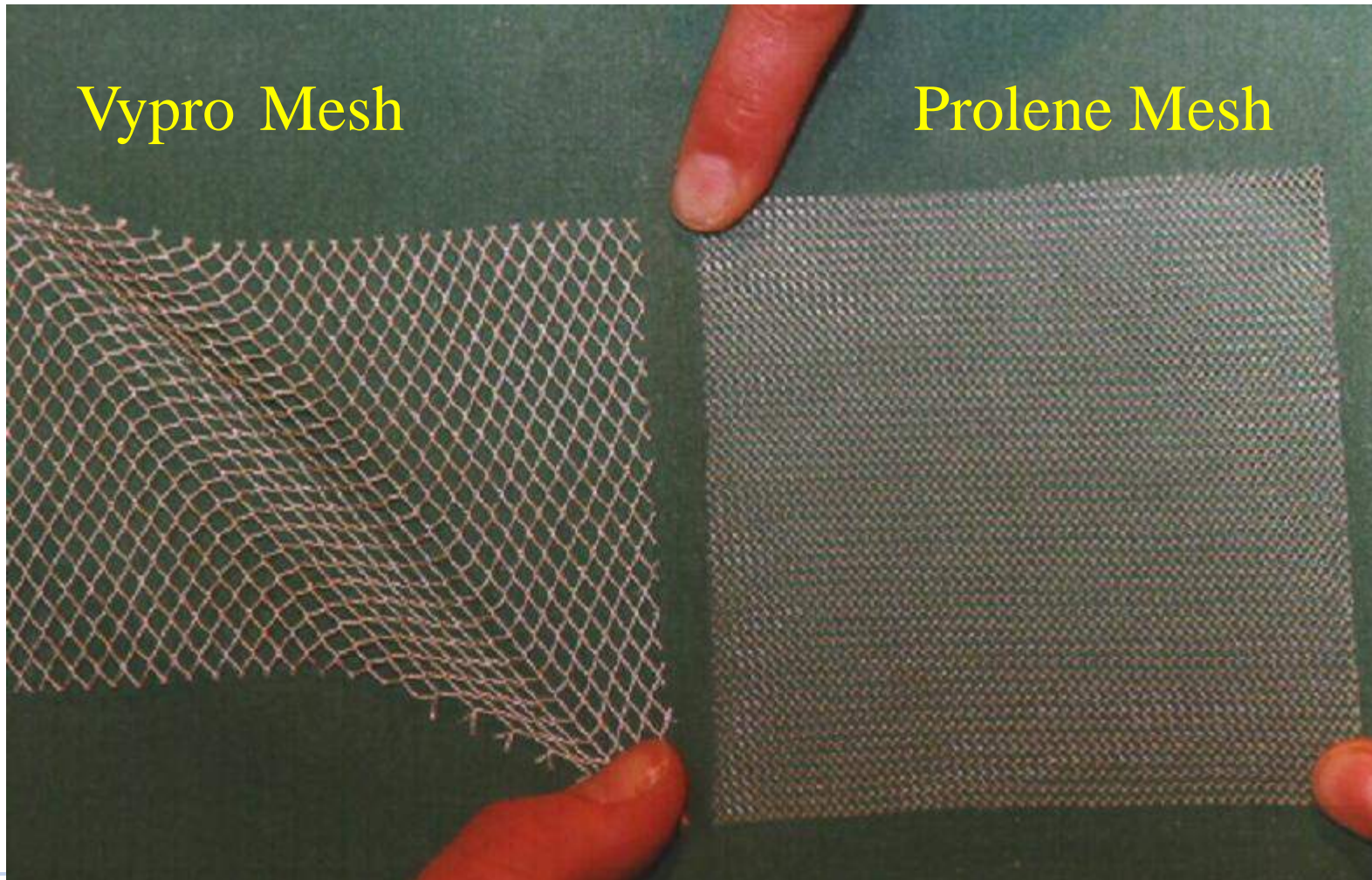
- less remaining foreign body material
- absorbable parts
- large pore size > 2,5 mm
- thin filaments



**All 4 components characterize a Lightweight Mesh !!**



# Flexibility / Compliance

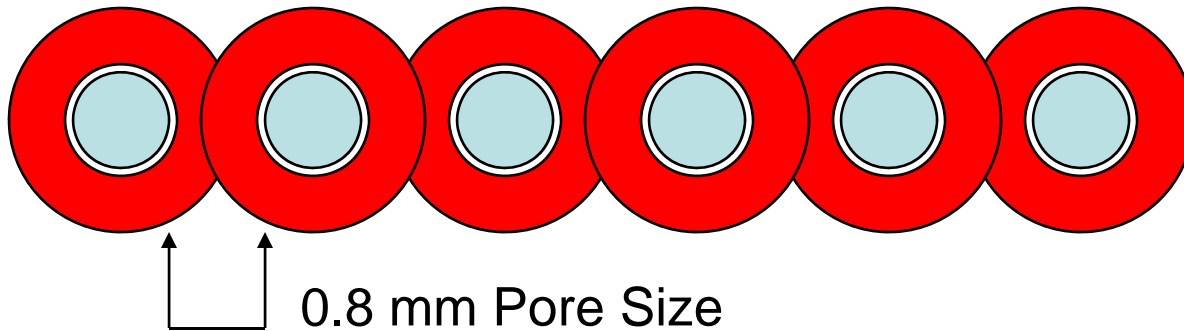


# Fibrotic Bridging

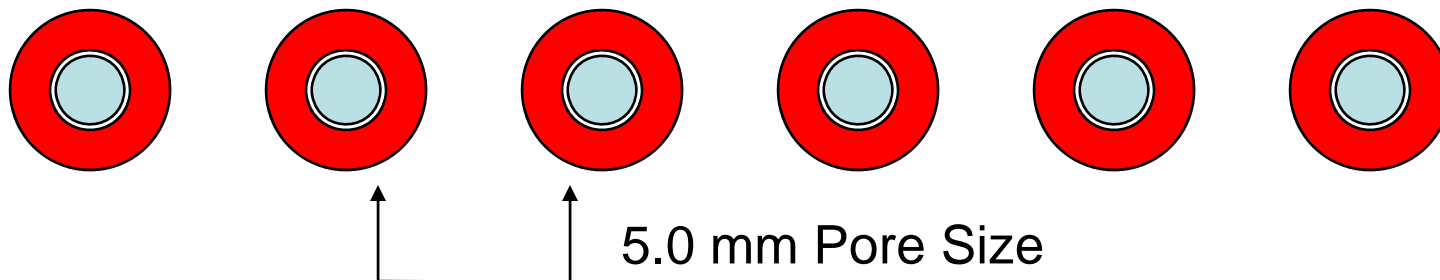
- Fibrotic bridging closely associated with occurrence of bridging
- Bridging is observed in meshes with less than 1mm pore size
- Granula of one fiber starts to become confluent with granuloma formations of adjacent fibers
- Heavyweight Meshes:
  - Scar plate results in stiff and nonflexible scar plate
- Lightweight Mesh
  - No bridging possible
  - Mesh stays flexible and smooth

# Bridging Fibrosis

**Heavyweight**



**Lightweight**

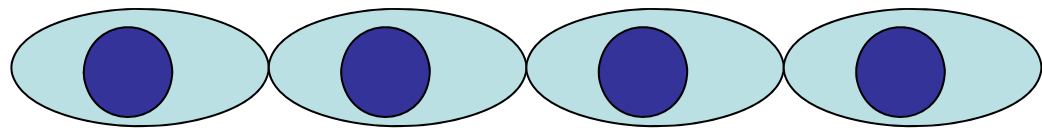




# Optimal Scar Tissue

Lightweight Mesh creates a strong yet flexible scar tissue that mimics the natural abdominal wall versus the rigid, thick scar tissue formed by heavyweight, small pore meshes.

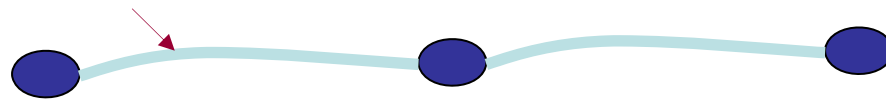
Traditional Mesh



Non elastic, rigid tissue scar plate formed by traditional heavyweight mesh.

Loose connective tissue

Lightweight Mesh



Elastic, compliant scar tissue that mimics natural abdominal wall mobility, created by lightweight construction mesh.

 Foreign Body Mass  
 Scar Tissue

# Shrinking Meshes?

- Mesh implants do not actively shrink, they are passively compressed
- Reduction in area occurs only to the extent to which the tissue contracts
- Key consequence is to ensure that the mesh adequately overlaps the defect and conforms to the anatomical conditions
- Heavyweight Contraction: up to 40%
- Lightweight: 10-20%

# Foreign Body Reaction

- Formation of connective tissue correlates with degree of inflammation, but does not translate to strength
- Increased inflammatory response results in rigid scar plate formation
- Scar plate responsible for shrinkage of mesh up to 40%
- Decreased polypropylene content and larger pore size exhibited reduction in inflammation and fibrosis

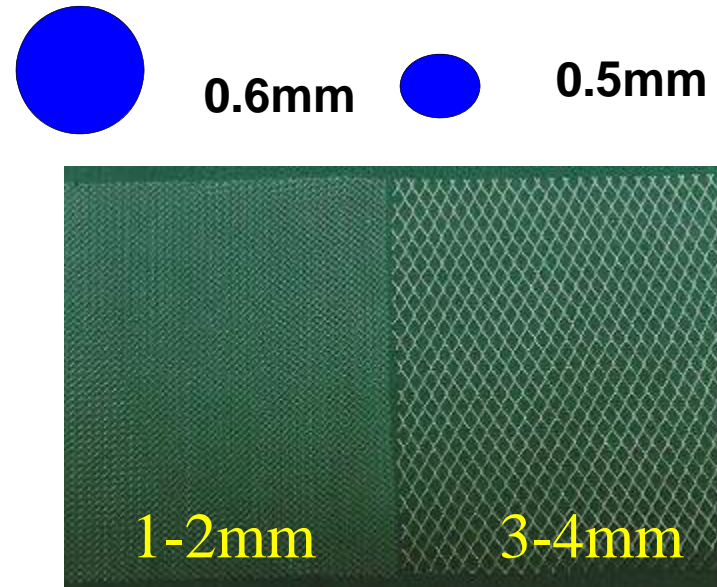
**Klinge U, et al. J Surg Res 2002; 103:208-214**

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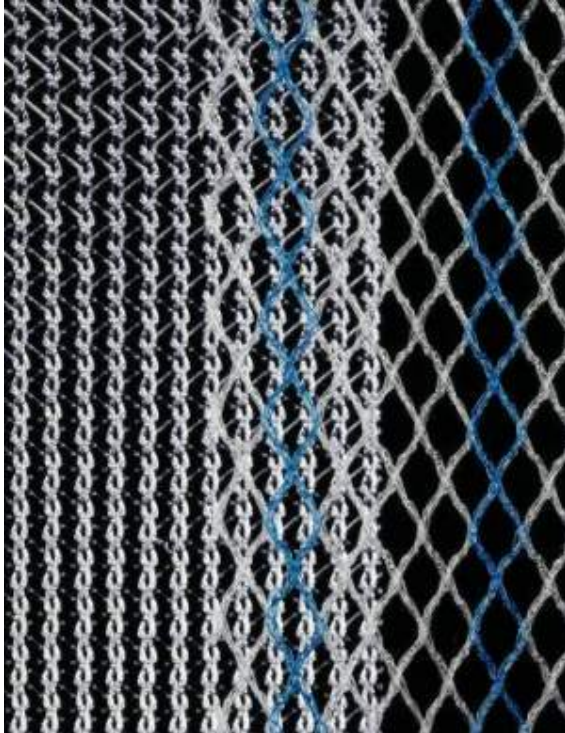
# Patient Comfort

## Reduced mass by

- Constructing a mesh from *thinner filaments*
- Creating a *larger pore size* (more space over a comparable surface area)
- Additional *absorbable component* that will be absorbed slowly after implantation



# Review - What Makes A Mesh?



## Mesh Construction – Variables:

### 1. WEAVE / CONSTRUCTION

Pore size & configuration

### 2. FILAMENT SIZE

Diameter of the fibers used to create the mesh

### 3. COMPONENTS

Choice of absorbable or non-absorbable materials

# Traditional Weight Mesh

- Used for more than 30 years
- Secure repair
- BUT
  - Does it optimize wound healing?
  - Patient complaints
    - Loss of abdominal wall mobility
    - Post-operative discomfort
    - Ability to feel the edge of the mesh

# Lightweight Mesh Hypothesis

- Alter construction of the mesh in such a way as to allow handling characteristics of a traditional mesh while delivering:
  - A secure repair
  - More natural abdominal wall ability
  - Improved patient comfort
  - Less foreign body implanted over the lifetime of the patient

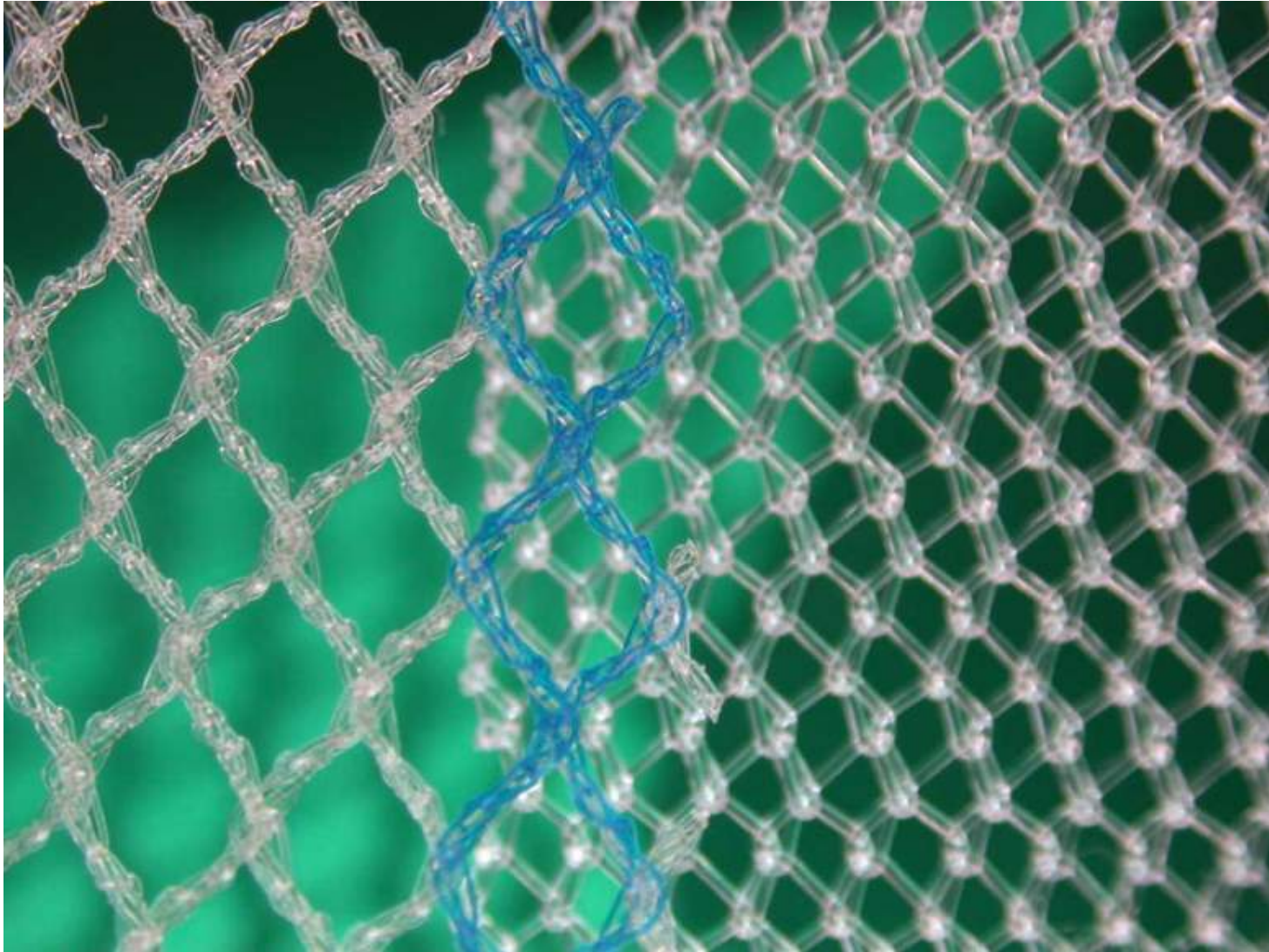
# Advantages of Lightweight Mesh

- less mass over time because of thinner filaments
  - greater patient comfort/ less foreign body implanted
- less permanent mass because of part absorption
  - greater patient comfort/ less foreign body implanted
- less mass due to large pore size (filaments further apart)
  - greater patient comfort, greater elasticity
- larger pore sizes leading to a scar mesh instead of scar plate following tissue incorporation
  - greater patient comfort, greater elasticity



“There is no place for heavyweight polypropylene mesh in modern day hernia repair”

*- BT Heniford, 2004*



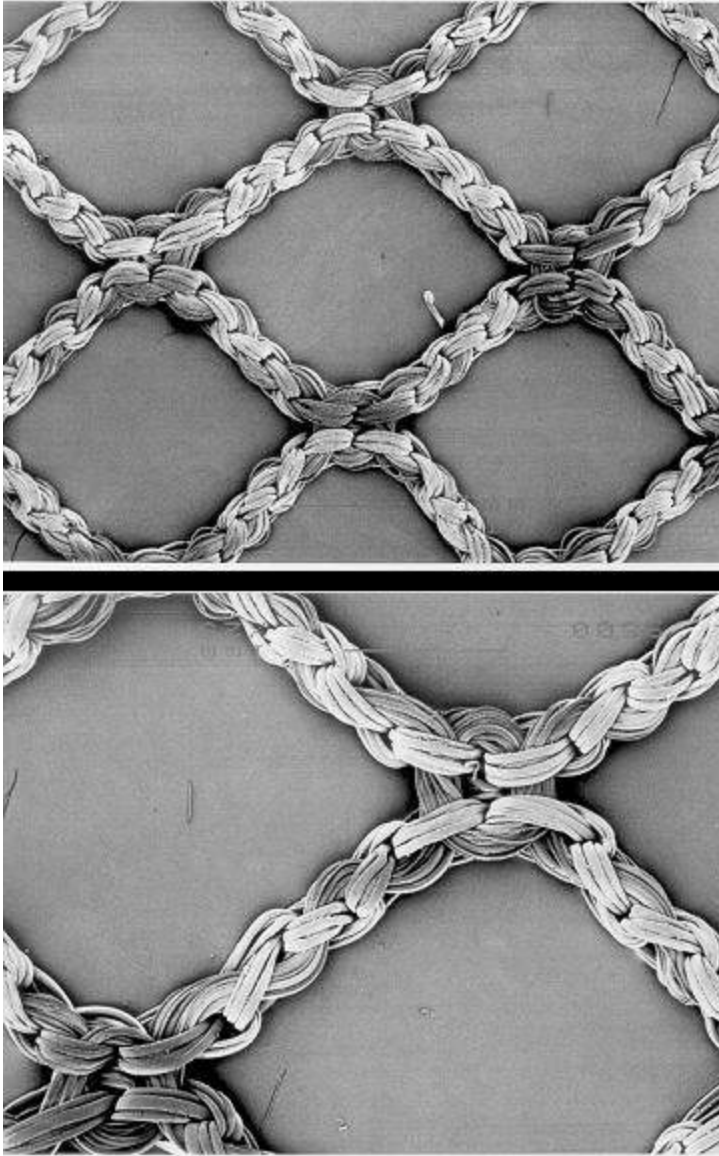
# PRODUCTS

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# VYPRO mesh

# VYPRO



- **Partially-Absorbable**
  - made of c. 50% VICRYL\* and 50% PROLENE\* in mass
  - VICRYL functions to make construction stiffer for better handling
  - absorbed in 56-70 days
- **Macroporous**
  - 5 mm pore size (5000µm)
  - induces orderly ingrowth of collagen fibre network
- **Multifilament**
  - filaments of VICRYL\* and PROLENE\* twisted together to form composite yarns; yarns then knitted to form composite mesh structure
- **Lightweight**
  - 70% less permanently implanted residual mass than PROLENE\*



# VYPRO



- Behaves like abdominal wall after absorption of VICRYL
  - increased patient comfort
- Optimal handling, pliability & cutting characteristics due to exclusive fabric construction
  - appropriate stiffness initially after implantation
- Less foreign mass over time due to partly absorbable construction
- Optimal tissue ingrowth due to macroscopic pore size

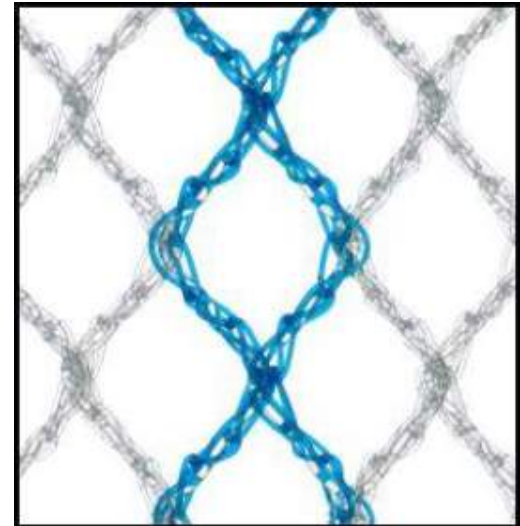
# ULTRAPRO mesh

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# What is ULTRAPRO\* Mesh?

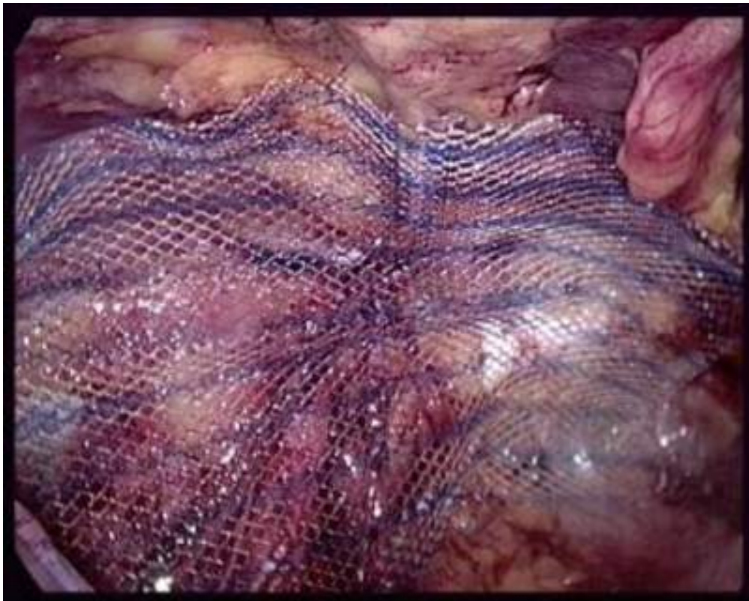
- Composite mesh of PROLENE\* Suture and MONOCRYL\* Suture material
- Partially absorbable (MONOCRYL Suture component is essentially absorbed in 84 days)
- Monofilament
- Thin filament size
- Large pore size
- Over 65% less foreign body implant material compared to traditional polypropylene meshes
- Blue stripes
- Indicated for inguinal and incisional hernia repair



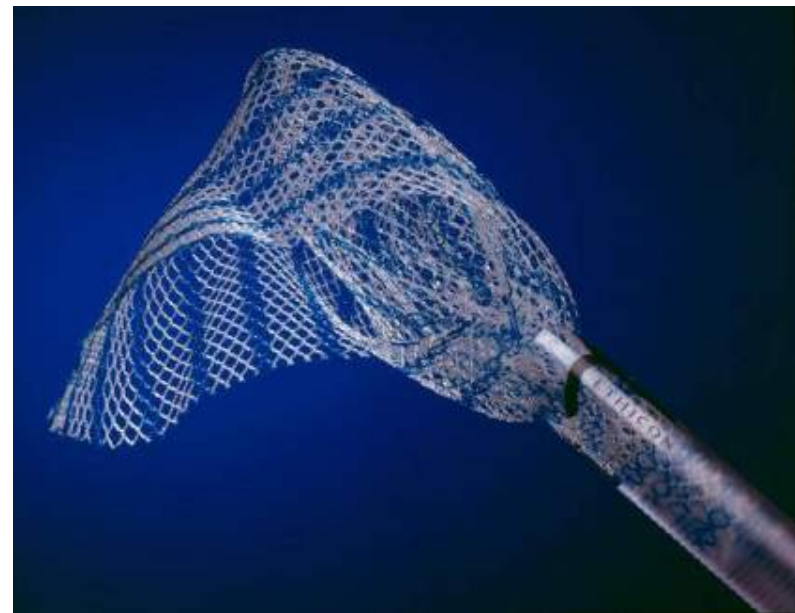


# ULTRAPRO\* Mesh

Excellent intra-operative handling and anatomic visualization



Passes easily through a trocar



# Testimonial

Todd Heniford, MD

Carolinas Medical Center

I was skeptical and thought the strength of the mesh may not be sufficient. Your allowing us to test it in an unbiased manner has paid dividends and should continue to do so for Ethicon in the future. I think the data is clear; the mesh is plenty strong. In fact, I believe that you are on the brink of changing how hernias are performed in North America - indeed the type of mesh utilized should undergo heavy flux in the near future. There is no use for a heavyweight mesh like MARLEX at anytime or anywhere in the human body.

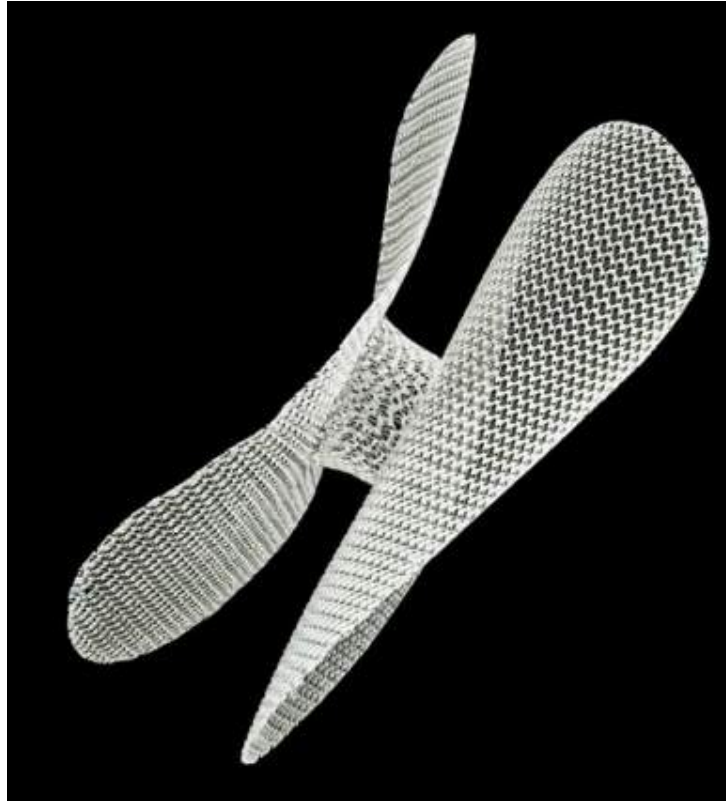
**And, yes, you may quote me.**

What's new?

**U**LTRAPRO **H**ernia **S**ystem

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How can a proven Design get better?

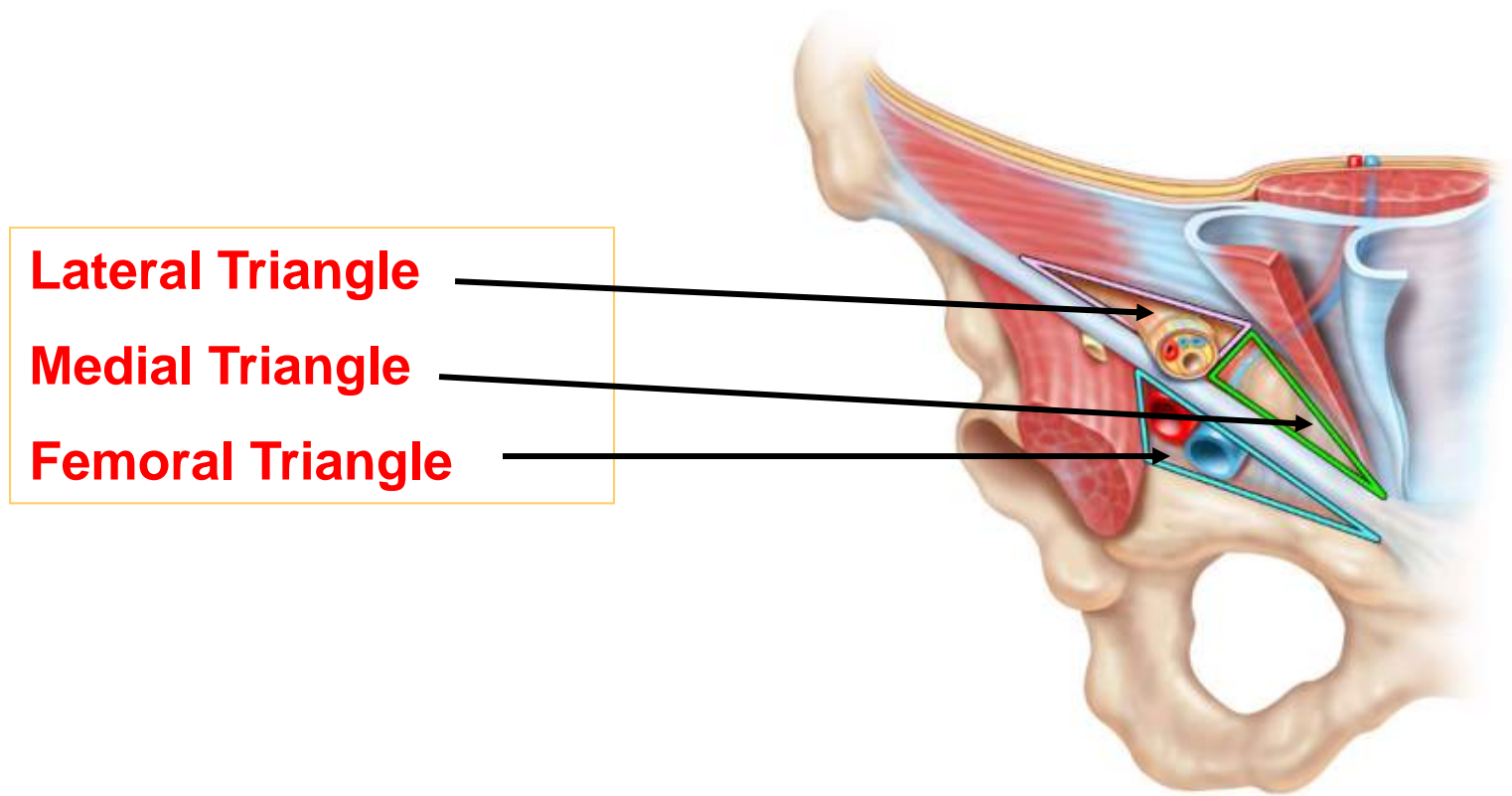
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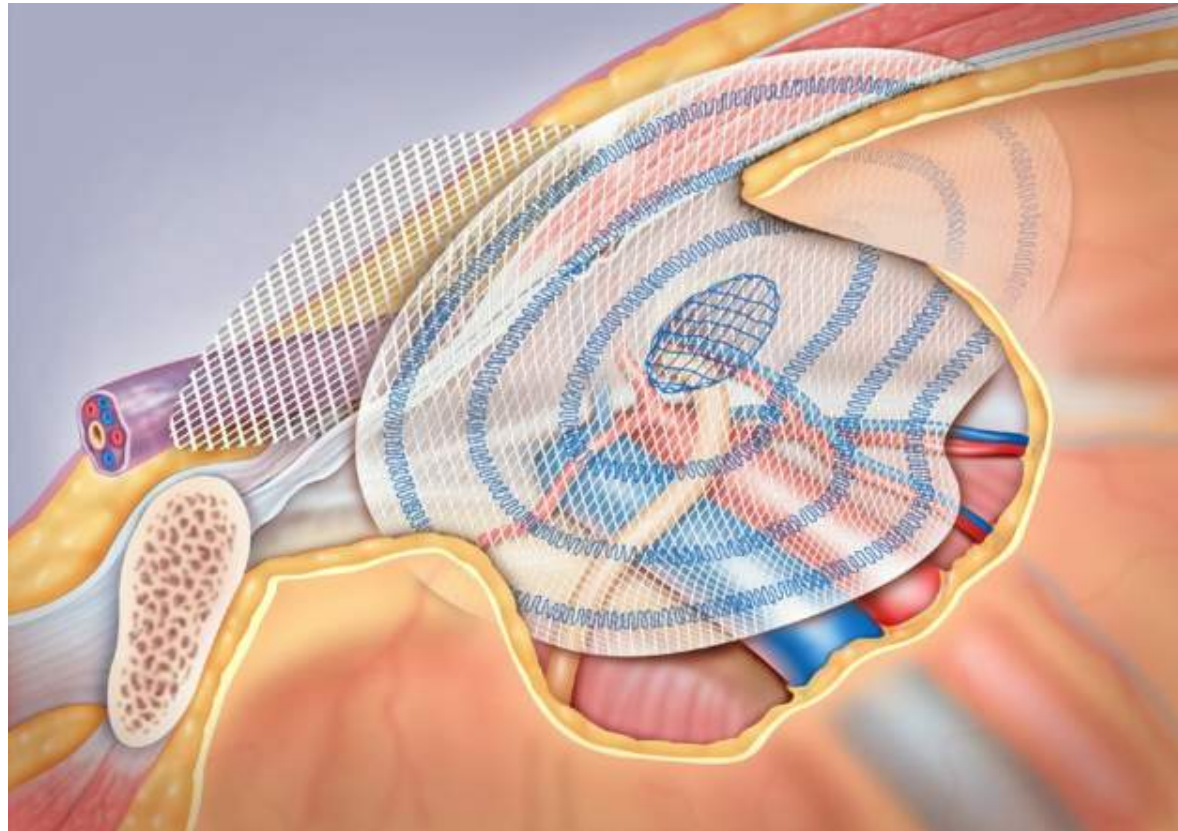
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# Myopectineal Orifice Triple Triangles of the Groin



# UHS in the Posterior Space





# Unmet Customer Needs

- Device with less permanently implanted material
- Reinforced underlay:
  - Easier insertion
  - Easier placement
  - Easier deployment
- Good handling characteristics
- Tactile feedback



**ULTRAPRO\***

HERNIA SYSTEM

A PROVEN DESIGN<sup>1</sup> JUST GOT BETTER

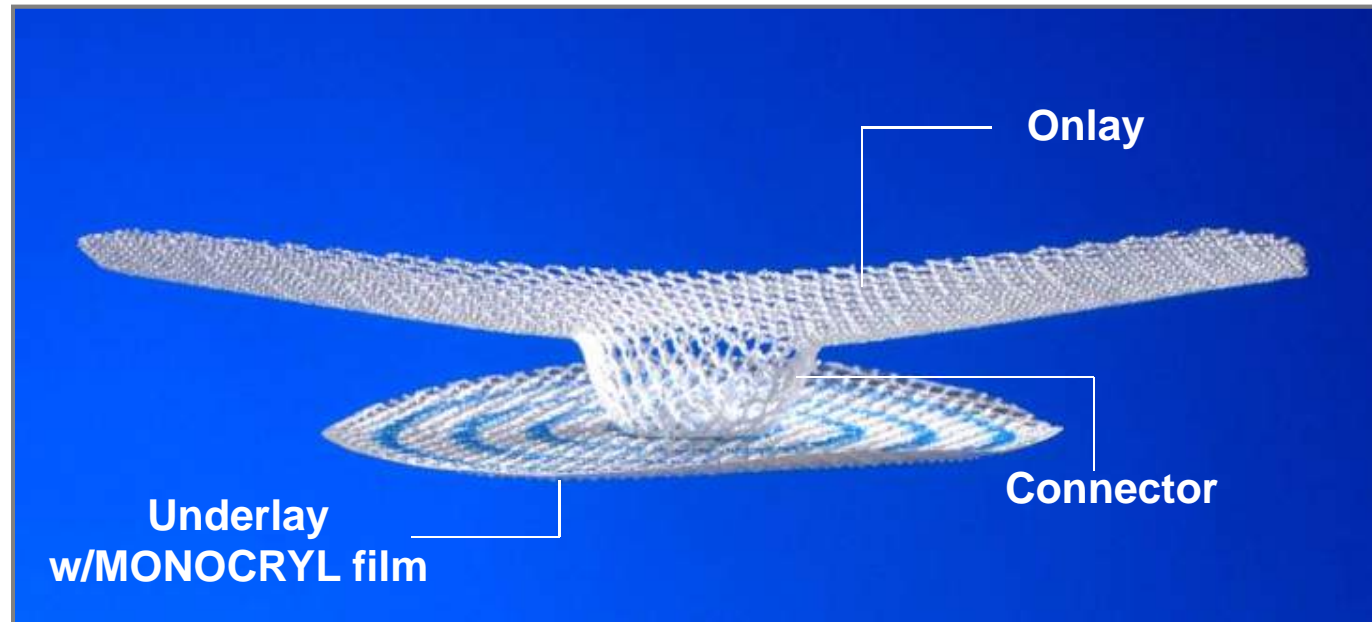
**ETHICON, INC.**  
a Johnson & Johnson company

1. Green IS, Young J, Eckstein WE, Suda CJ, Patel B. Combined anterior and posterior inguinal hernia repair: intermediate-term results with three groups of supports. *Hernia*. 2004;8:294-302. Please see full prescribing information available at the website: [www.ethicon.com](http://www.ethicon.com). ©2006 ETHICON, Inc. \*Trade name

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# ULTRAPRO Hernia System Overview



# Patient Comfort

- Reduced mass by...
  - Constructing a mesh from thinner filaments
  - Creating a larger pore size (more space over a comparable surface area)
  - Additional absorbable component that will be absorbed slowly after implantation

# ULTRAPRO Hernia System Overview

- **Product Function**
  - Used to reinforce abdominal wall hernia defects by providing permanent support of the abdominal wall during and following wound healing.
  - Provides three points of protection in a proven, bilayer design (i.e. PHS)
  - ULTRAPRO mesh construction means a lightweight, partially absorbable material
- **Underlay patch**
  - Placed in the preperitoneal space and covers the entire myopectineal orifice
  - MONOCRYL film & circular PROLENE suture stitching enhance deployment and stabilize the underlay

# ULTRAPRO Hernia System Overview

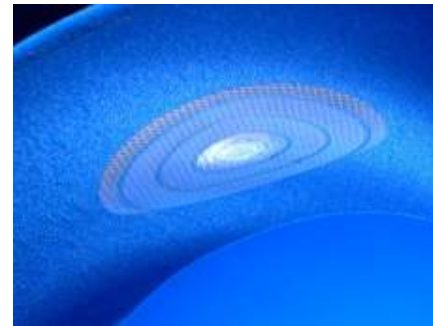
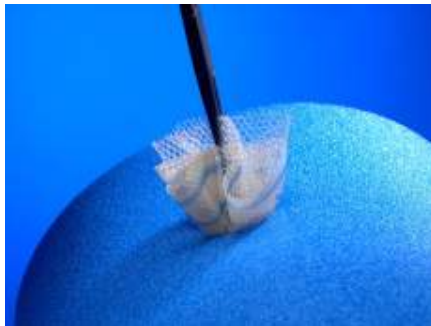
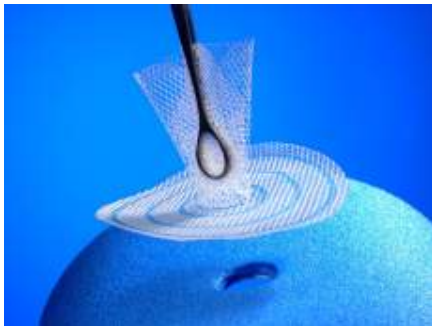
- Onlay patch
  - Reinforces medial and lateral triangles
  - Minimal sutures secure entire device
- Connector
  - Connects both patches, minimizes risk of migration, and provides stability for underlay and onlay



# ULTRAPRO Hernia System

## Key Benefits

- Confidence in preperitoneal deployment
- UHS gives the surgeon confidence that the underlay has been deployed correctly in the preperitoneal space, thus providing full myopectineal orifice (MPO) coverage and protection of the entire groin
  - Ease of deployment – springs open
  - Stays open, flexible mesh conforms to anatomy
  - Confidence that the deployment has taken place

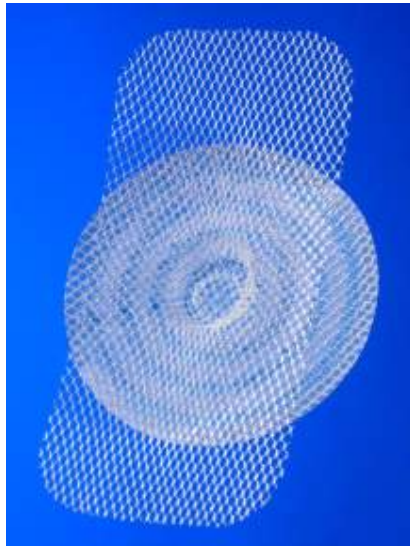


# Tissue Ingrowth

- Tissue ingrowth is same as all macro porous meshes
- Polyglecaprone film is attached to mesh mechanically with stitches (no welding)
- Degradation of film starts couple of days after implantation, fragmented film at early time points is no barrier for tissue ingrowth

# ULTRAPRO Hernia System Product Offering

Medium



Large



Oval



# UHS Key Messages

## ■ Key messages

- Literature supports original PHS design as having the lowest reported recurrence rates (.04%)<sup>1</sup>
- UHS utilizes ULTRAPRO mesh technology of partially absorbable, lightweight, macroporous construction providing a flexible scar plate and abdominal wall compliance
  - less remaining foreign body material
  - thin filament size
  - large pore size
  - absorbable component

1. Gilbert AI Combined anterior and posterior inguinal hernia repair: intermediate recurrence rates with three groups of surgeons. *Hernia*. Aug/2004 8(3):203-7.



**THANK YOU**

**Discussion**

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