

# C-QUR Science Day

Oct 27<sup>th</sup>, 2017



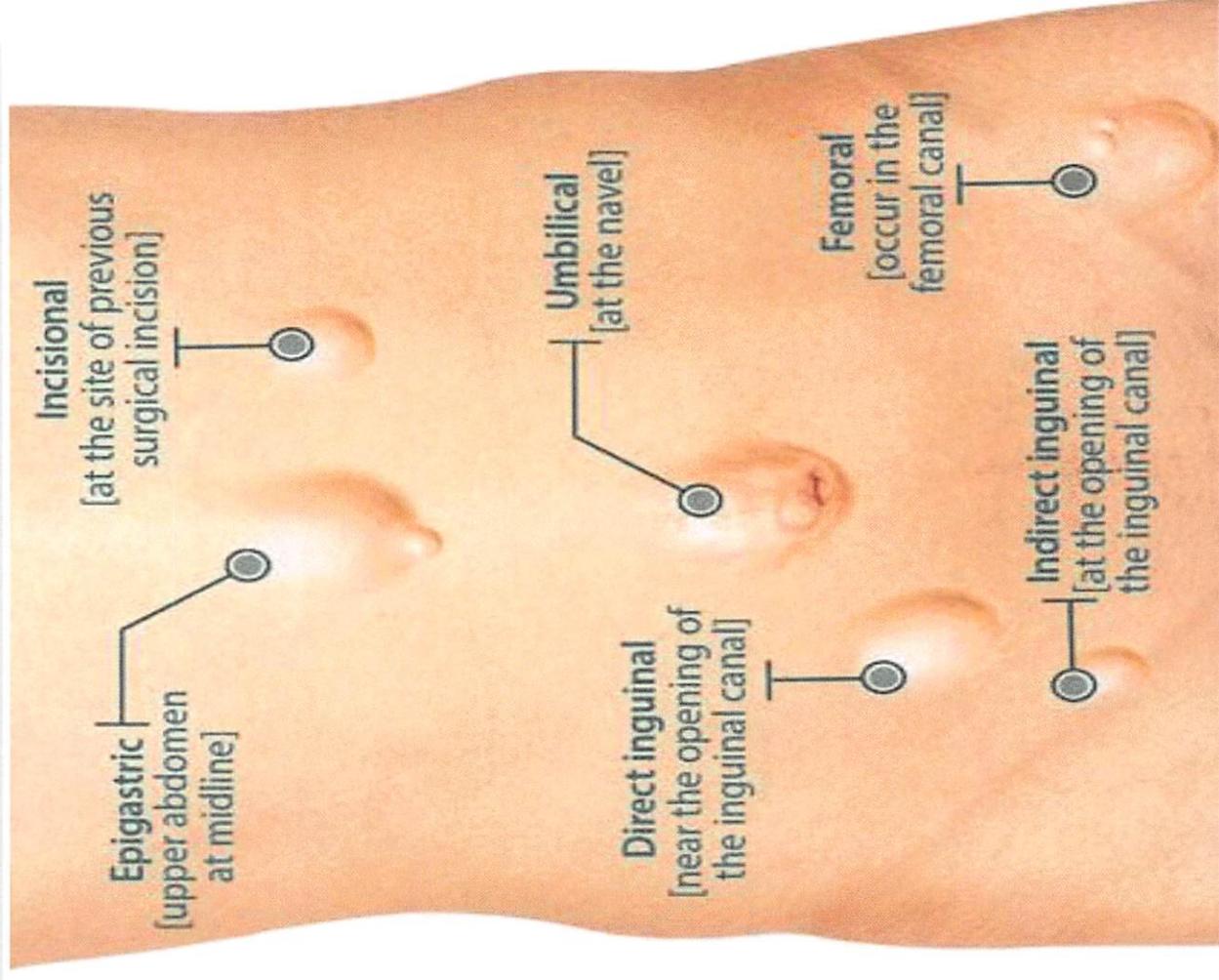
# Facts about Hernias

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- It is estimated that **5%** of the population will develop an abdominal wall hernia and of these, about **70%** are inguinal hernias
- **900,000+** - Number of Americans who have surgery to correct hernias in the U.S. every year.

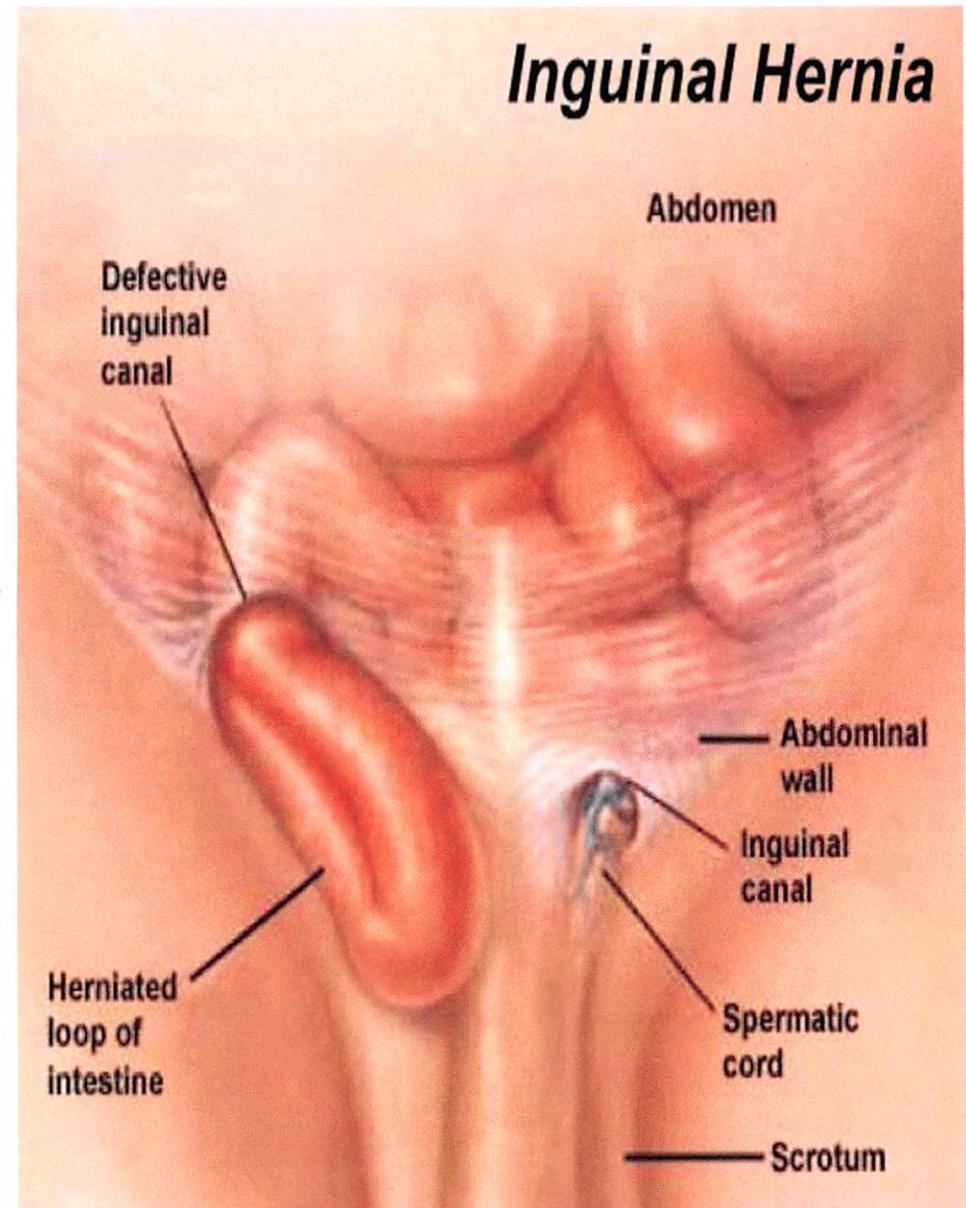
# Types of Hernias

There are several types of hernias:



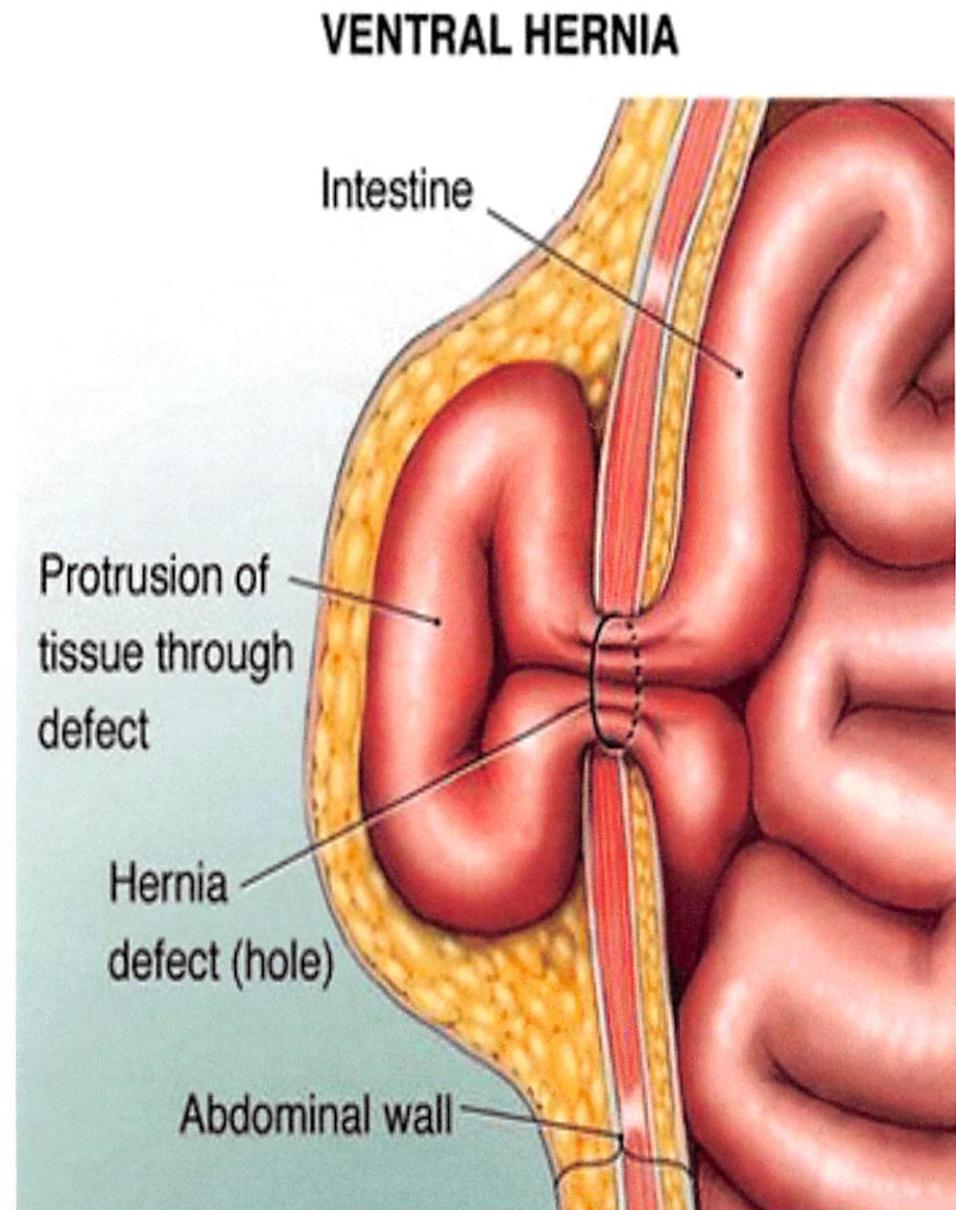
# Inguinal Hernia

Inguinal hernias are the most common type of hernia. They make up about 70% of all hernias, according to the British Hernia Centre (BHC). These hernias occur when the intestines push through a weak spot or tear in the lower abdominal wall, often in the inguinal canal.

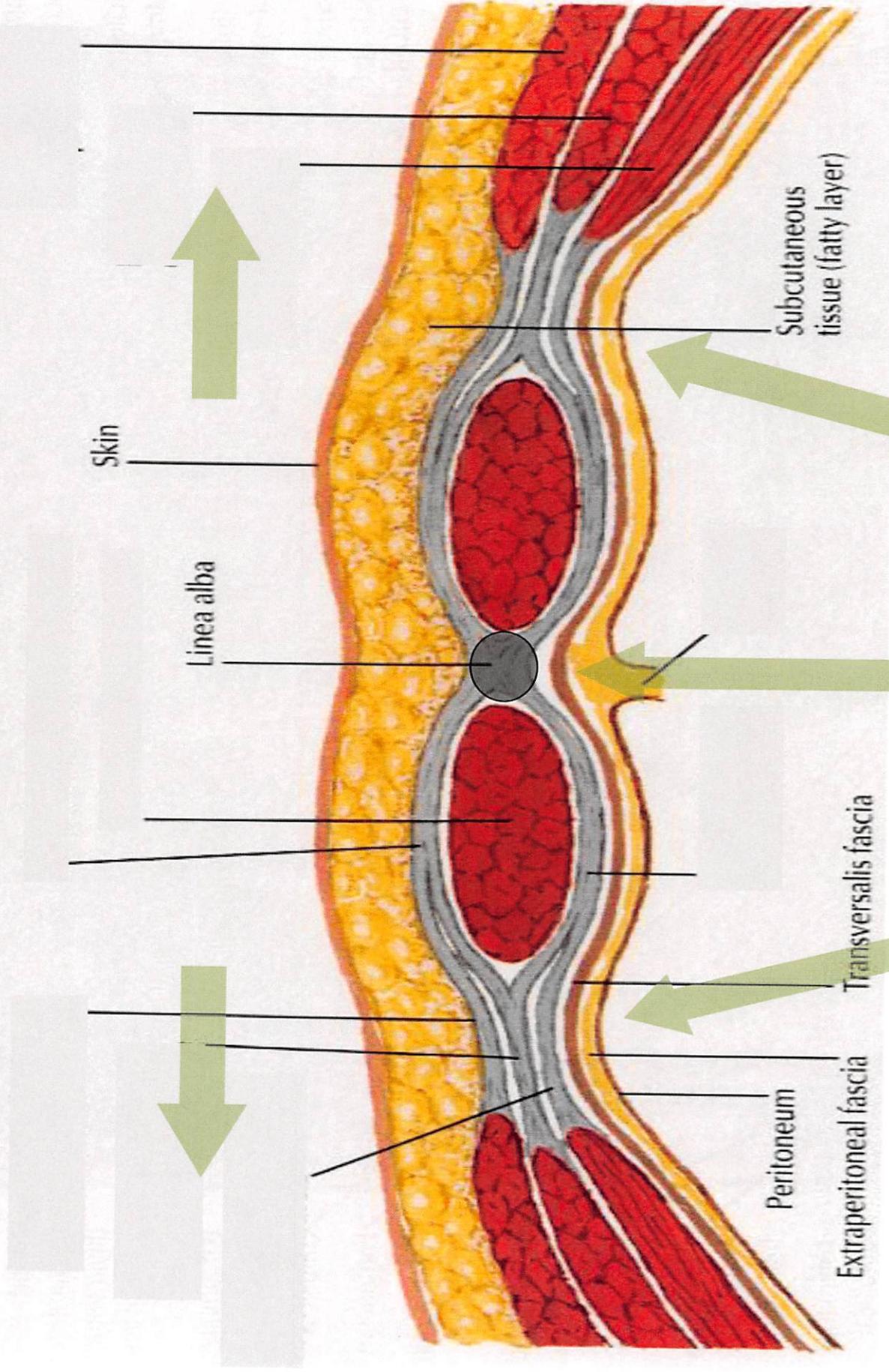


# Ventral Hernia

A **ventral hernia** is a bulge through an opening in the muscles on the abdomen. The **hernia** can occur at a past incision site (incisional), above the navel (epigastric), or other weak muscle sites (primary abdominal)



Section above arcuate line



**Pressure**

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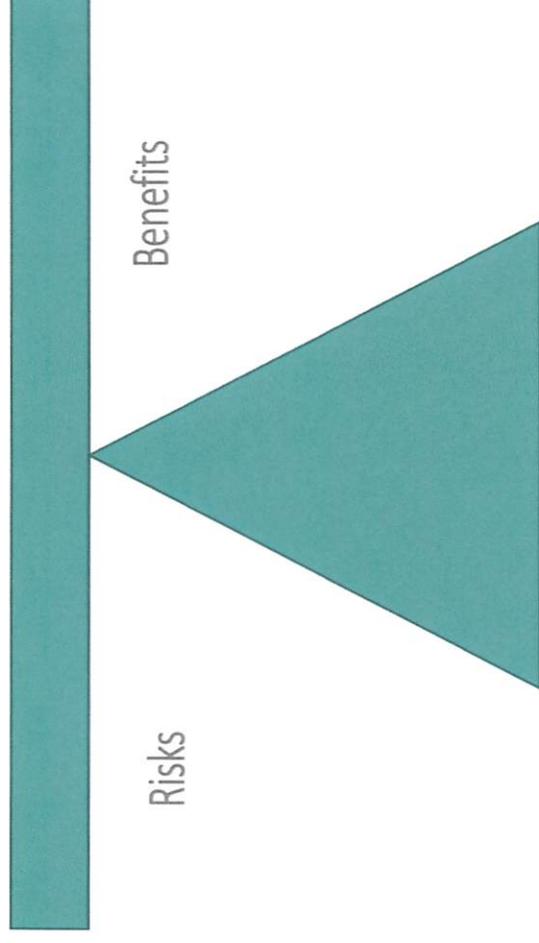
# Treatments Modalities

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# Surgical Options

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- Primary Suture Repair
- Mesh Repair
  - Synthetic permanent mesh
  - Biologic mesh
  - Synthetic absorbable mesh
  - Composite Mesh



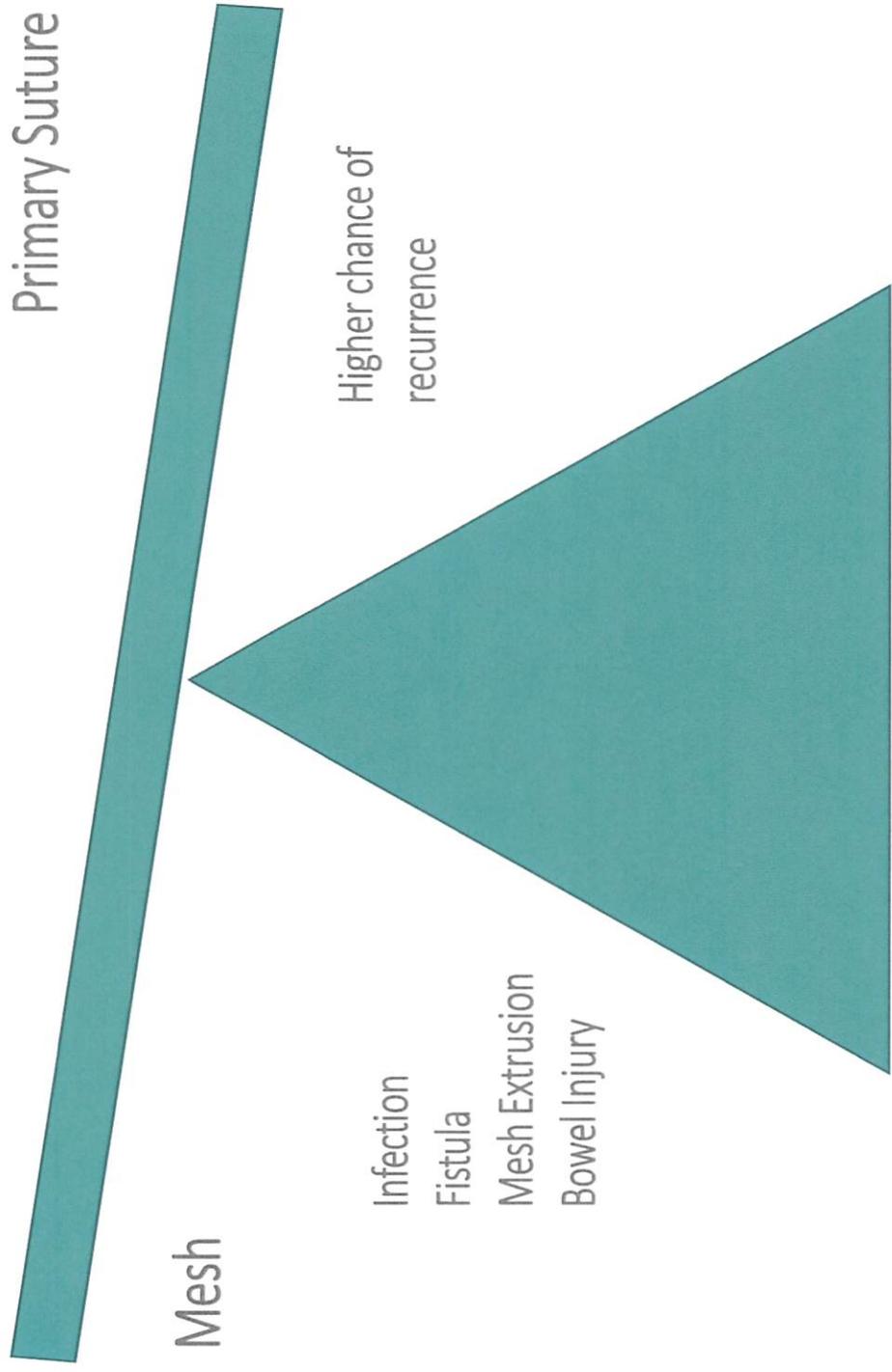
# Primary Suture Repair

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- Today primary suture repair is most often used for small defects (<2–3 cm). The technique of overlapping abdominal wall fascia in a “vest-over-pants” manner was described by William Mayo and remained the most renowned surgical technique for a long time.
- Some studies have noted high recurrence rates in hernia repair without graft augmentation. Newer studies indicate that surgeries involving the use of grafts may have a smaller reduction in recurrence than previously believed.

# Surgical Options

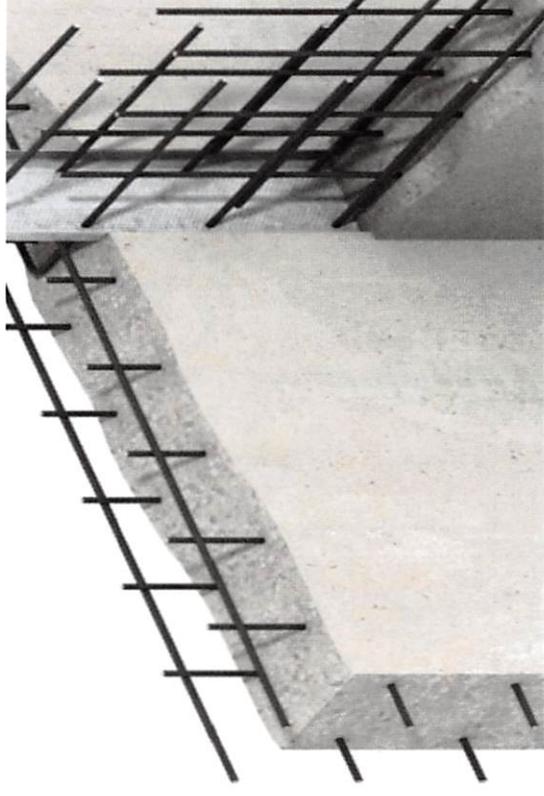
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# Surgical Grafts

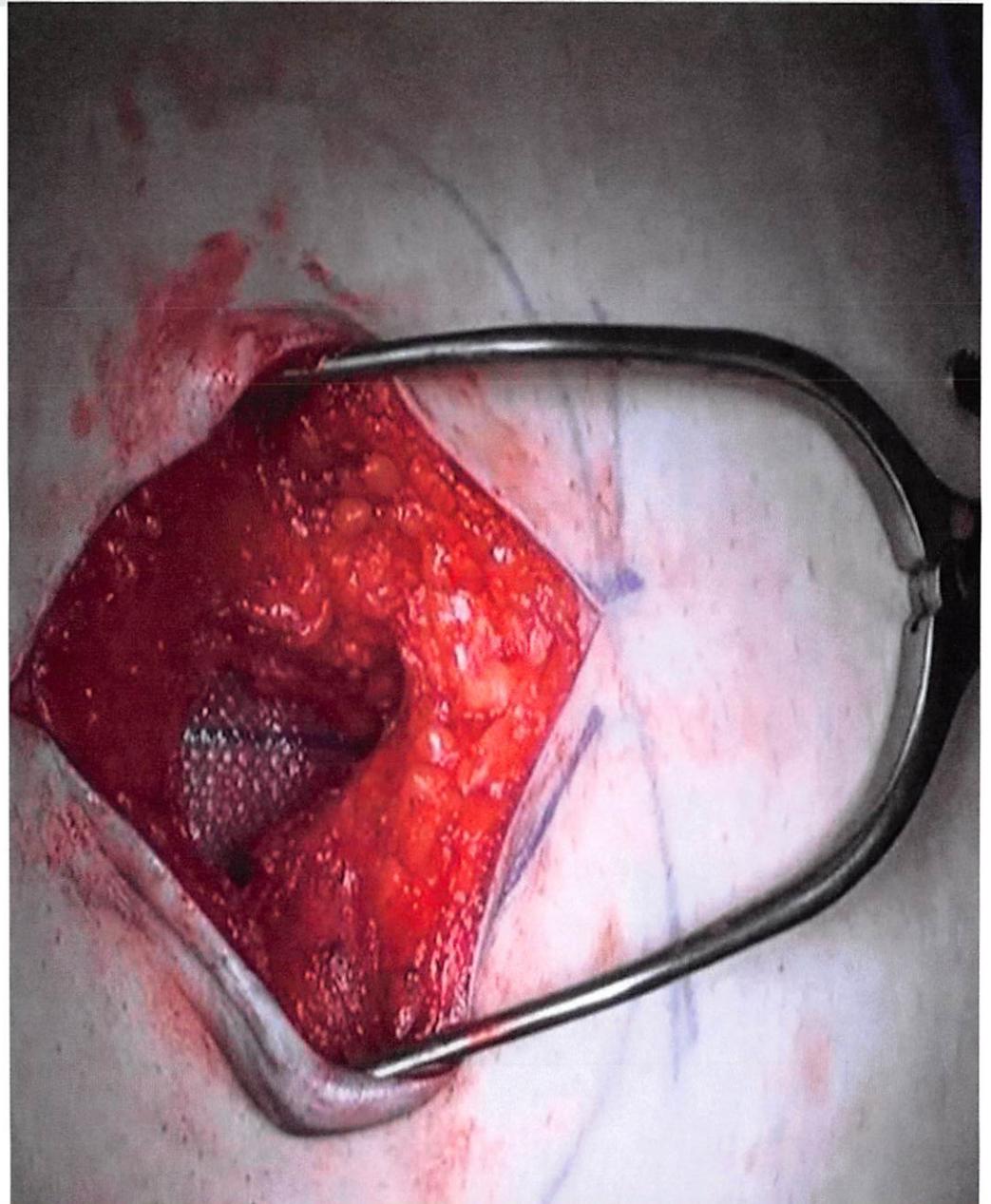
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- Connective tissue does not regenerate except at fetal stages.
- Mesh or other graft materials provide scaffolding and act like rebar for the repair of soft tissue.
- This additional structural support minimizes the chance of recurrence.



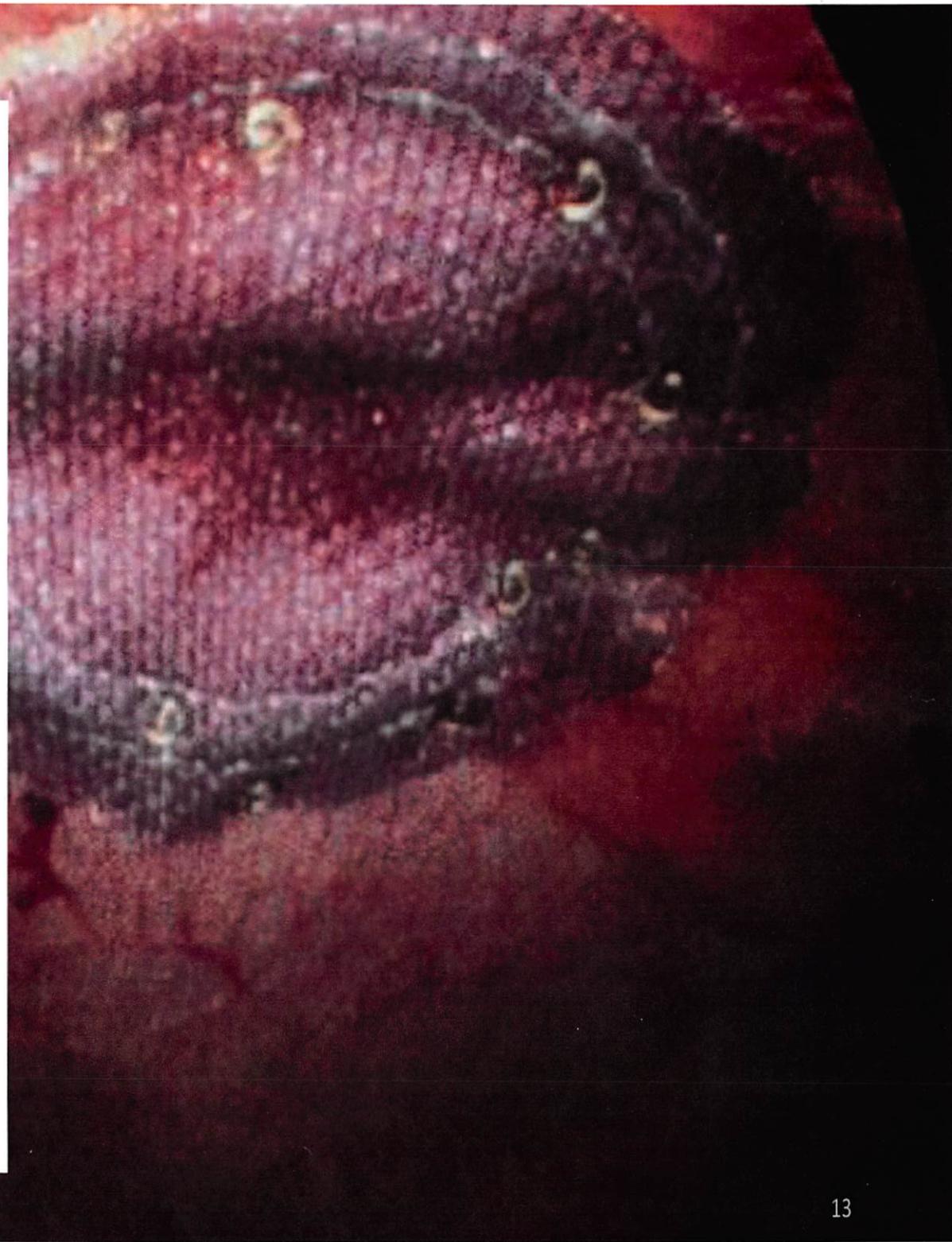
# Open Hernia Repair with Mesh

- An incision is made in the abdomen directly over the hernia
- Surgeon identifies hernia sac, reducing the contents into the abdominal cavity and revealing the defect in the fascia
- Mesh is placed over the entire defect, overlapping the edges, and sewn in place with sutures
- Skin covering the mesh is then sewn together



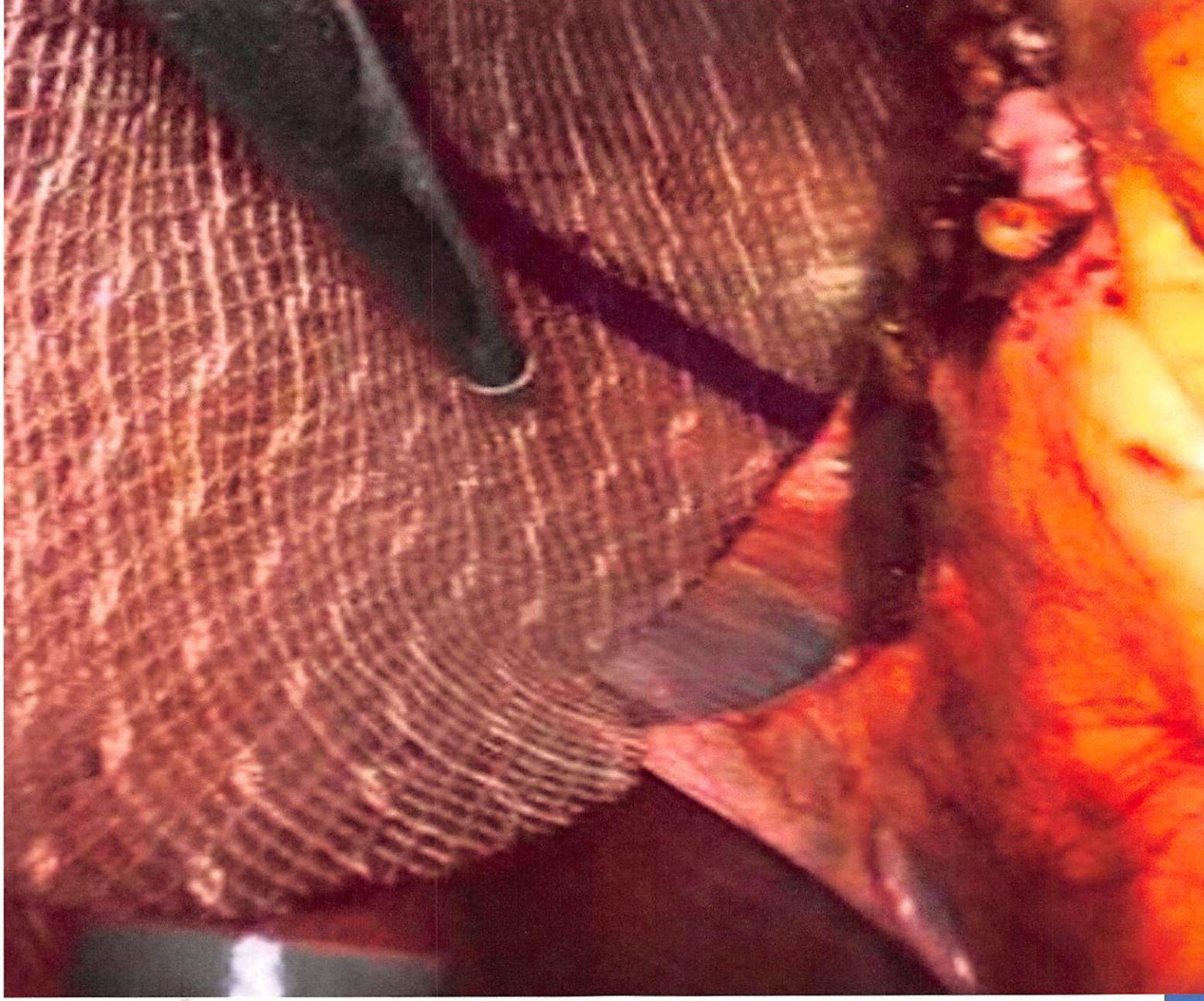
## Laparoscopic Hernia Repair

- Begins with three to five incisions, each measuring less than an inch, around the hernia
- A laparoscope and other instruments are used to place the mesh device
- The scope allows the surgeon to see inside the abdomen
- Contents of hernia sac are reduced, mesh is placed and secured with sutures
- Advantages:
  - reduced pain
  - quicker recovery
  - fewer wound complications
  - reduced chance of recurrent hernia
- Pictured: Intraoperative view of umbilical hernia patch and laparoscopic fixation sites



# History of IPOM Procedure

- First discussed in early 1990's
- **Highly controversial** in medical community
- Gained popularity despite higher complication rates than traditional repair
- Sparked creation of **tissue separating meshes**



# Different Options for Mesh Placement

- a) Intraperitoneal Sublay/Onlay (IPOM)
- b) Extraperitoneal Sublay
- c) Extraperitoneal Inlay
- d) Extraperitoneal Onlay

●●●●● = mesh placement

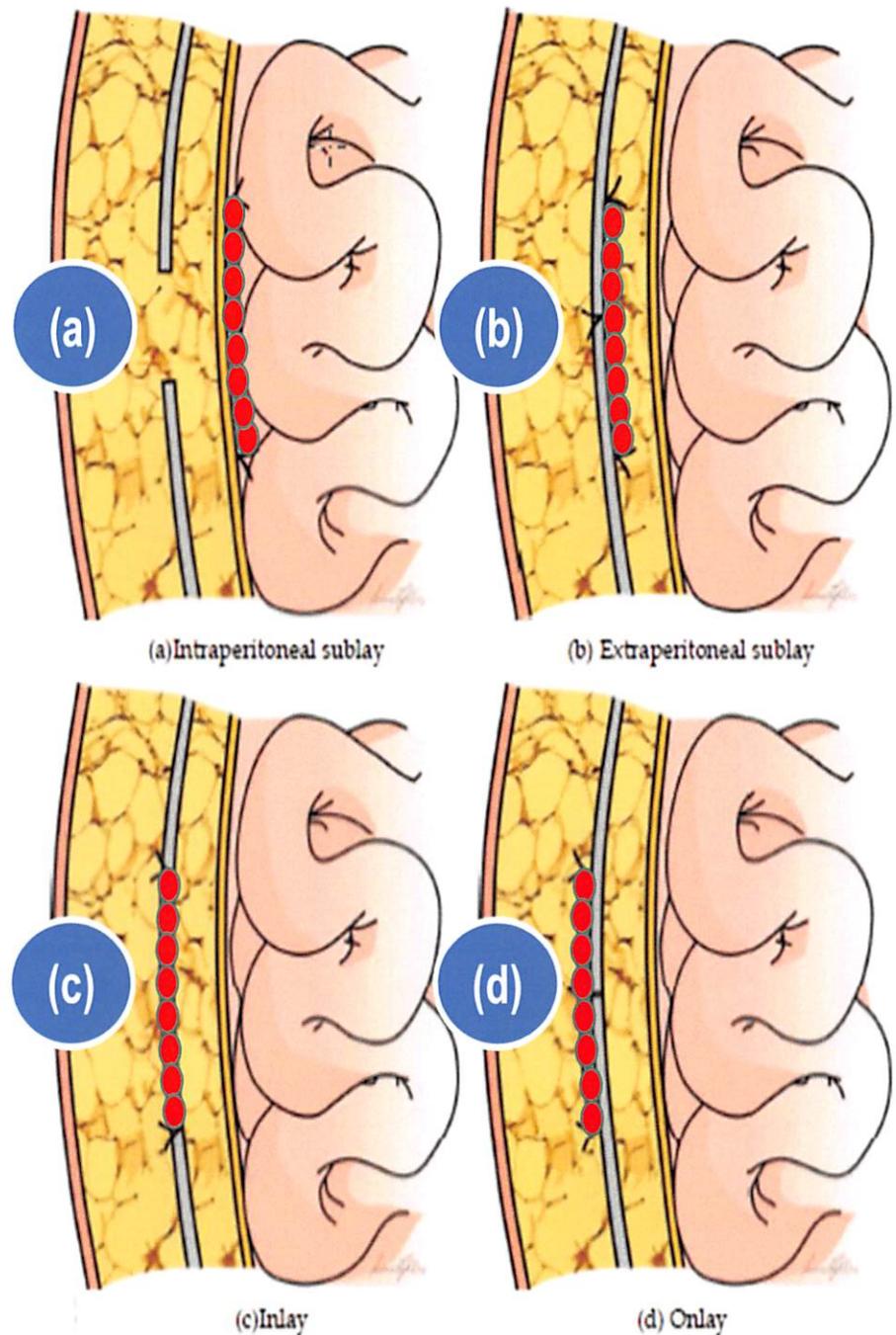
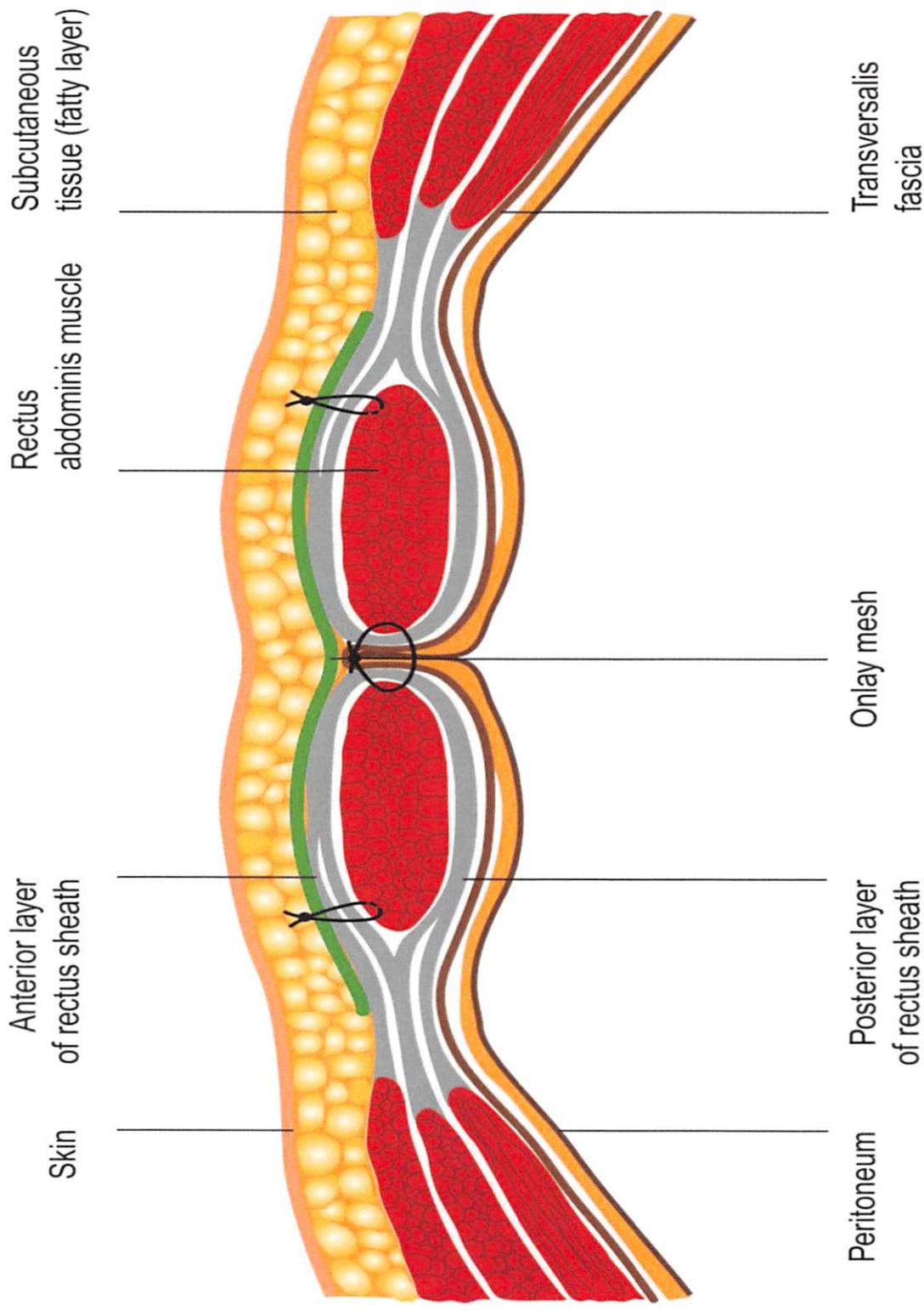
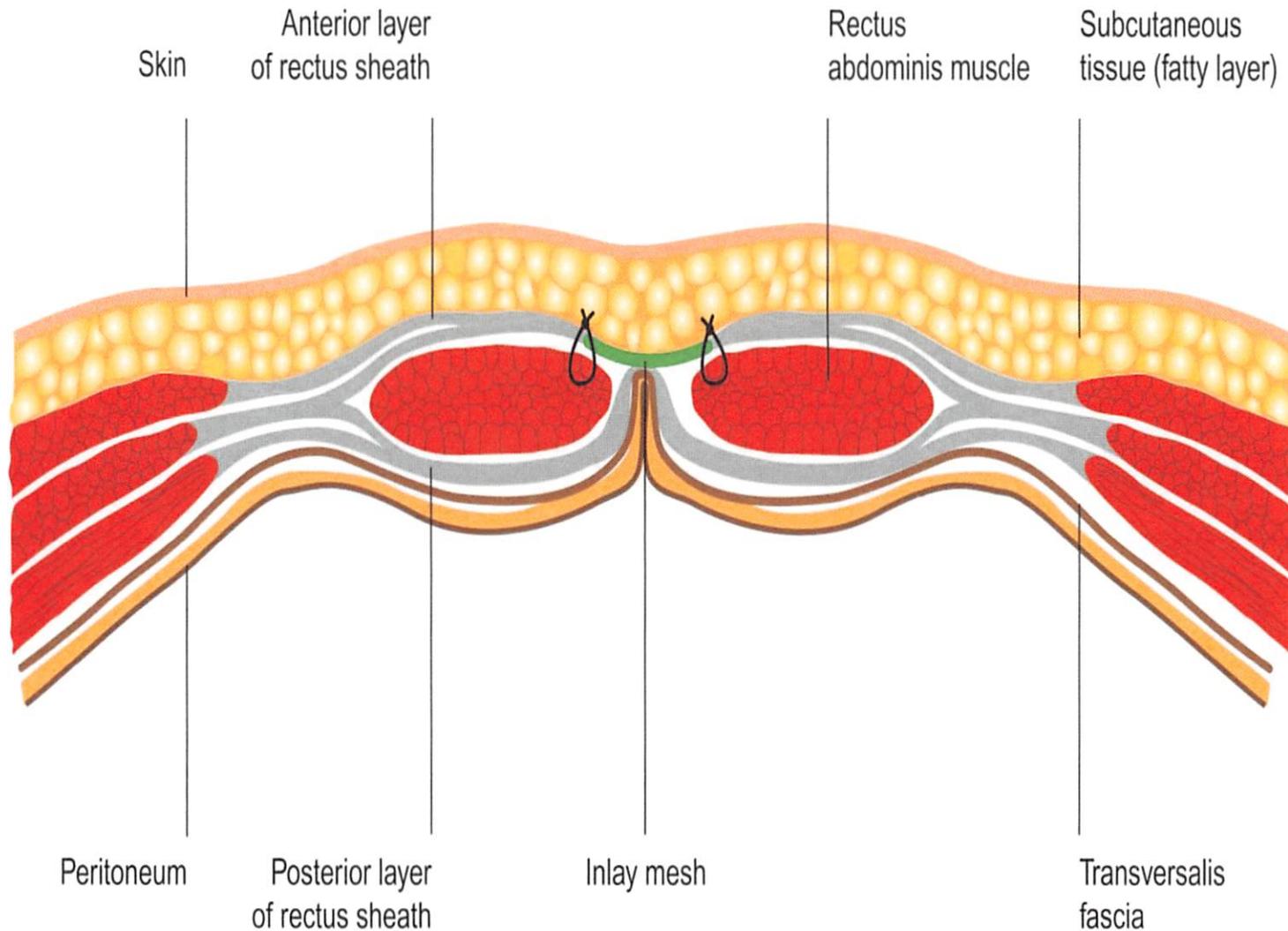


Fig. 6. Possible plans of the abdominal wall to insert the prosthesis.

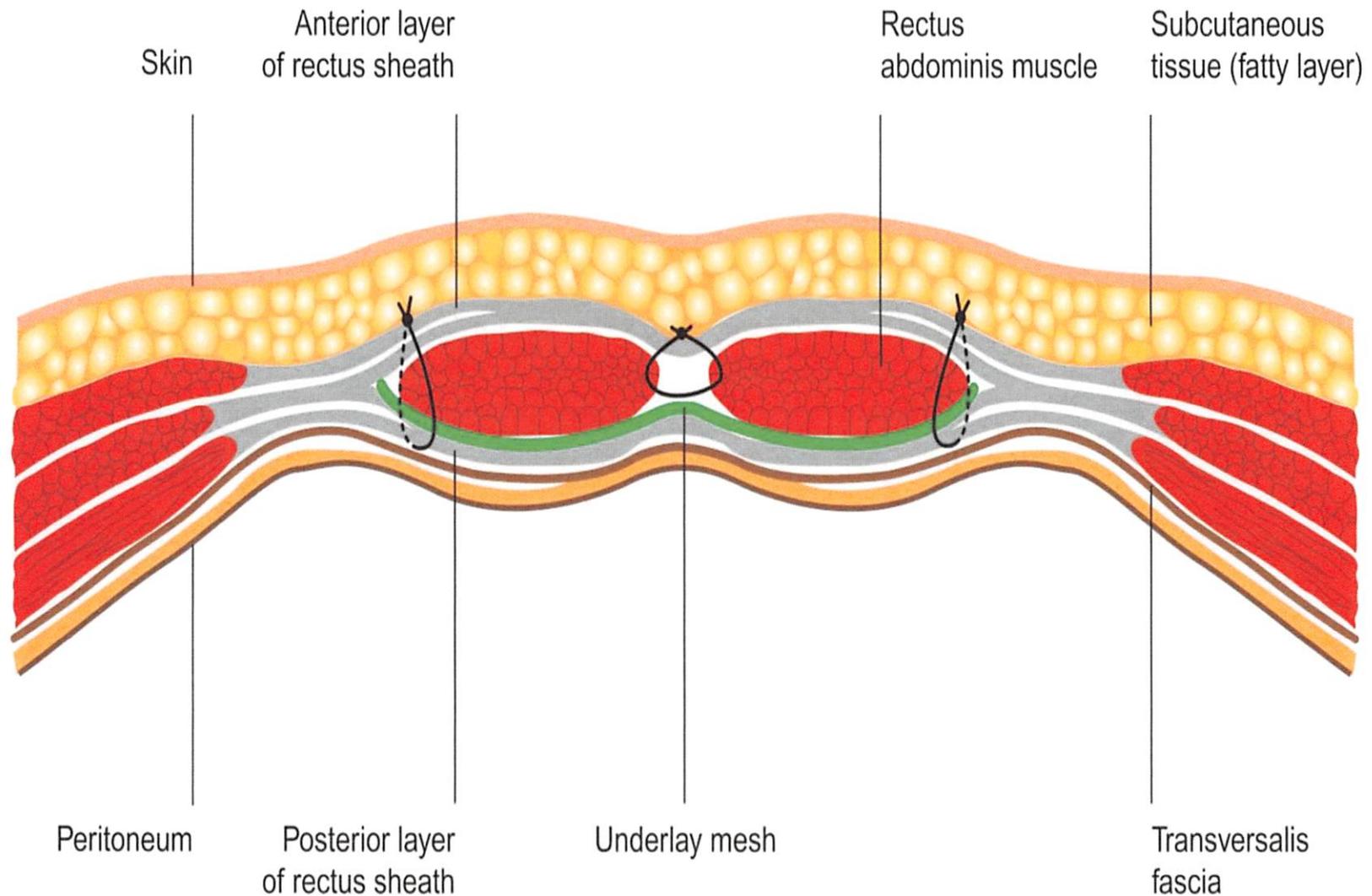
# Ventral Hernia Mesh Positioning: Onlay



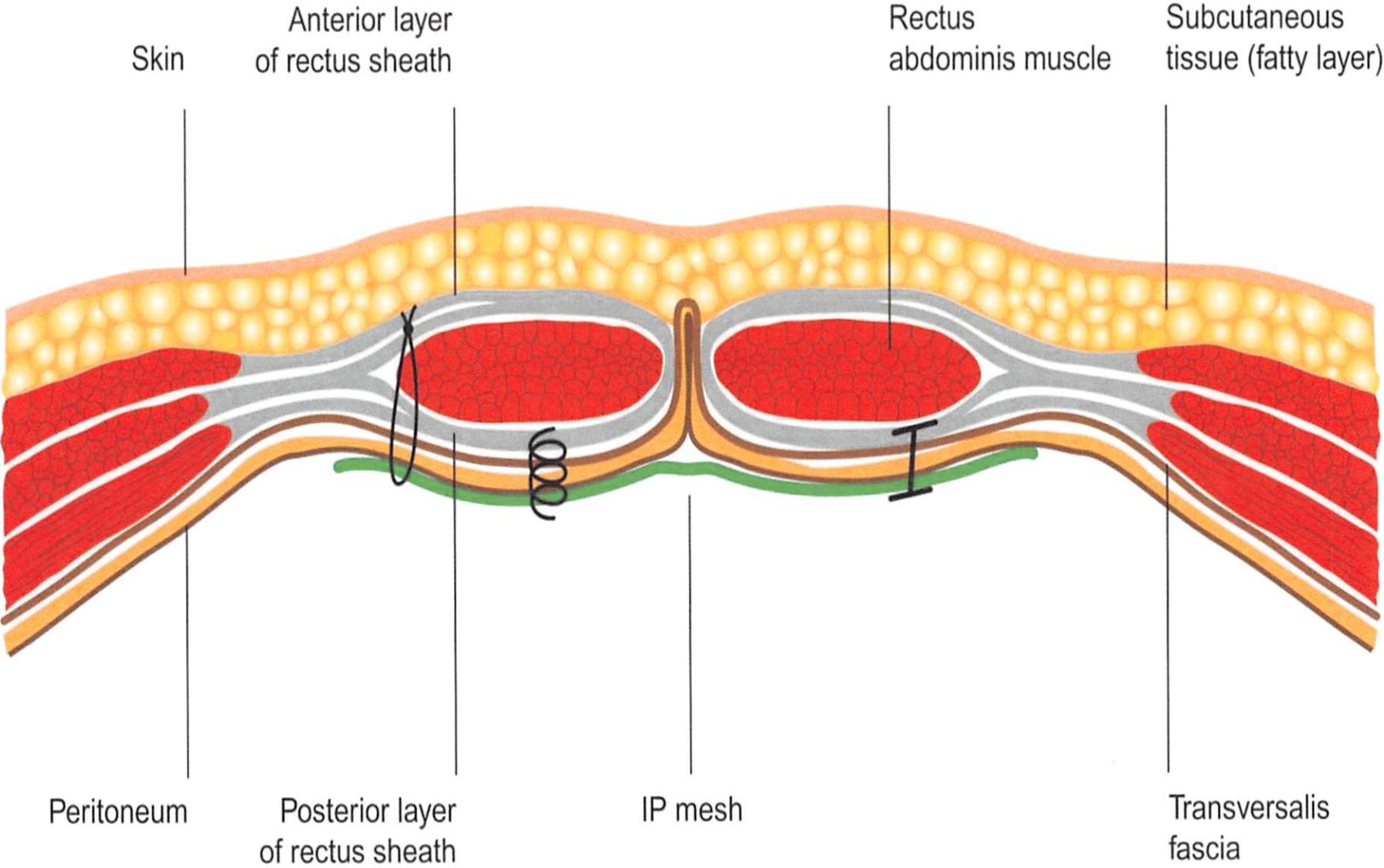
# Ventral Hernia Mesh Positioning: Inlay



# Ventral Hernia Mesh Positioning: Underlay



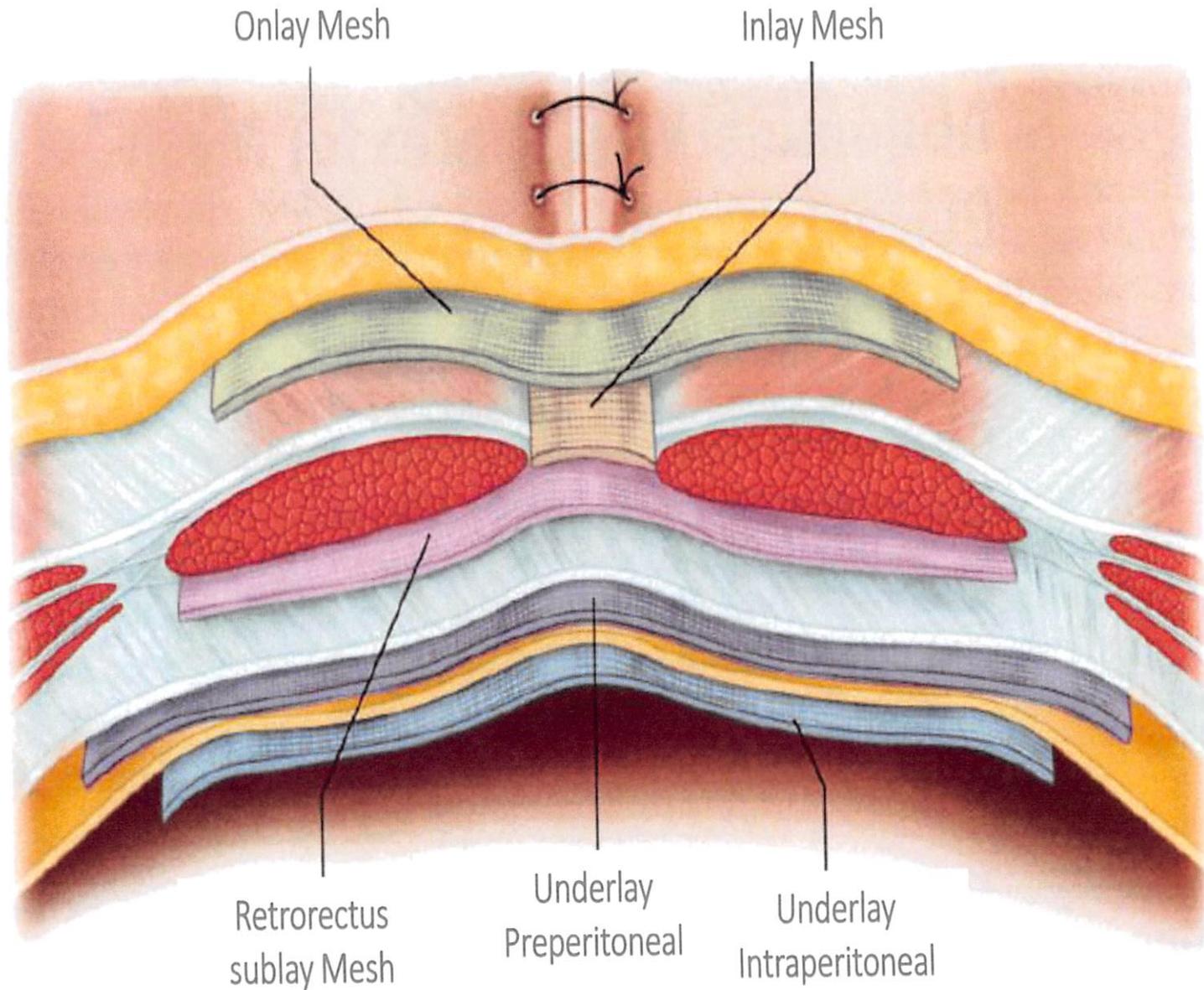
# Ventral Hernia Mesh Positioning: Intraperitoneal



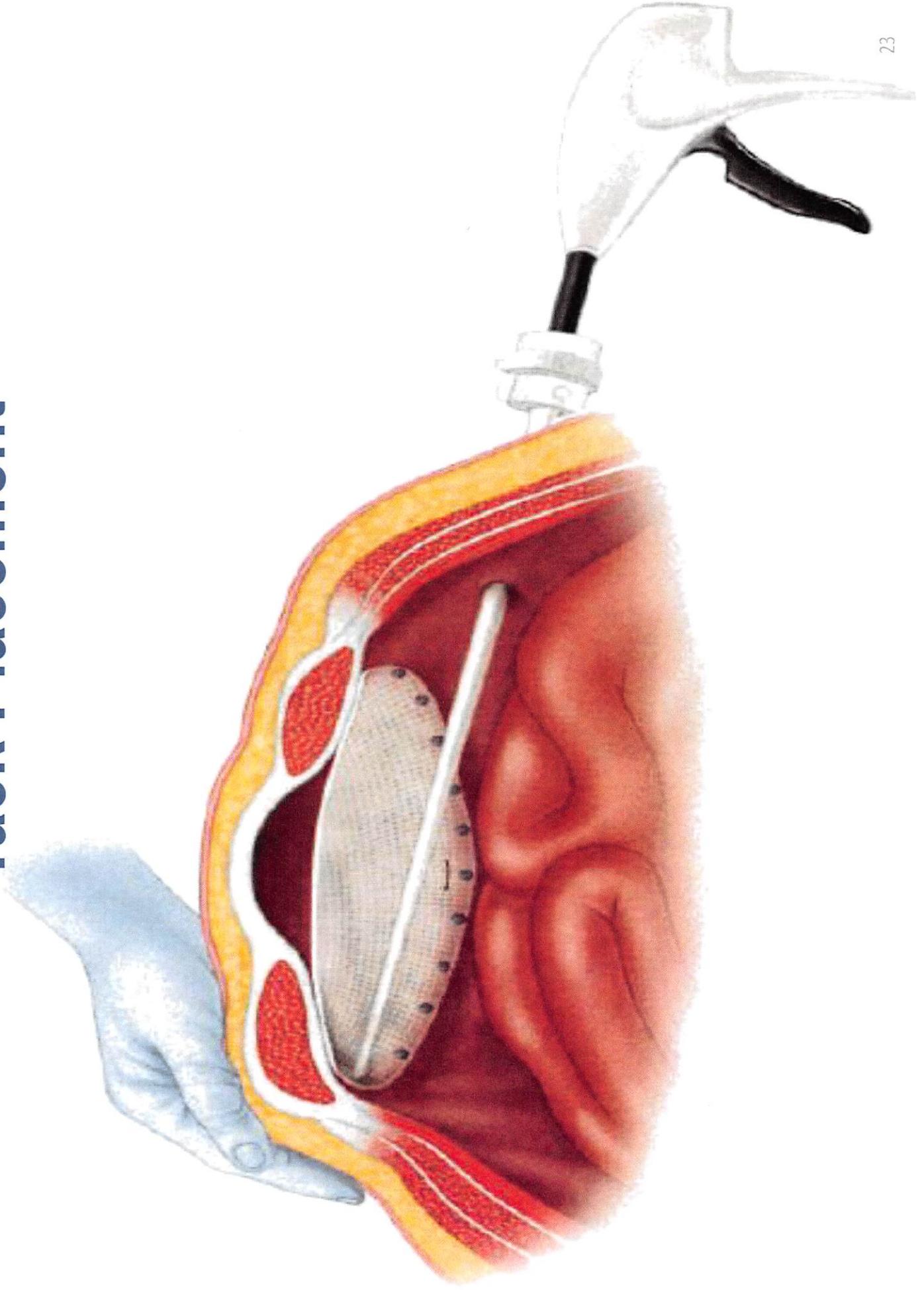
# Totally Extraperitoneal (TEP) Laparoscopic Inguinal Hernia Repair

# Laparoscopic Repair of Ventral Incisional Hernia

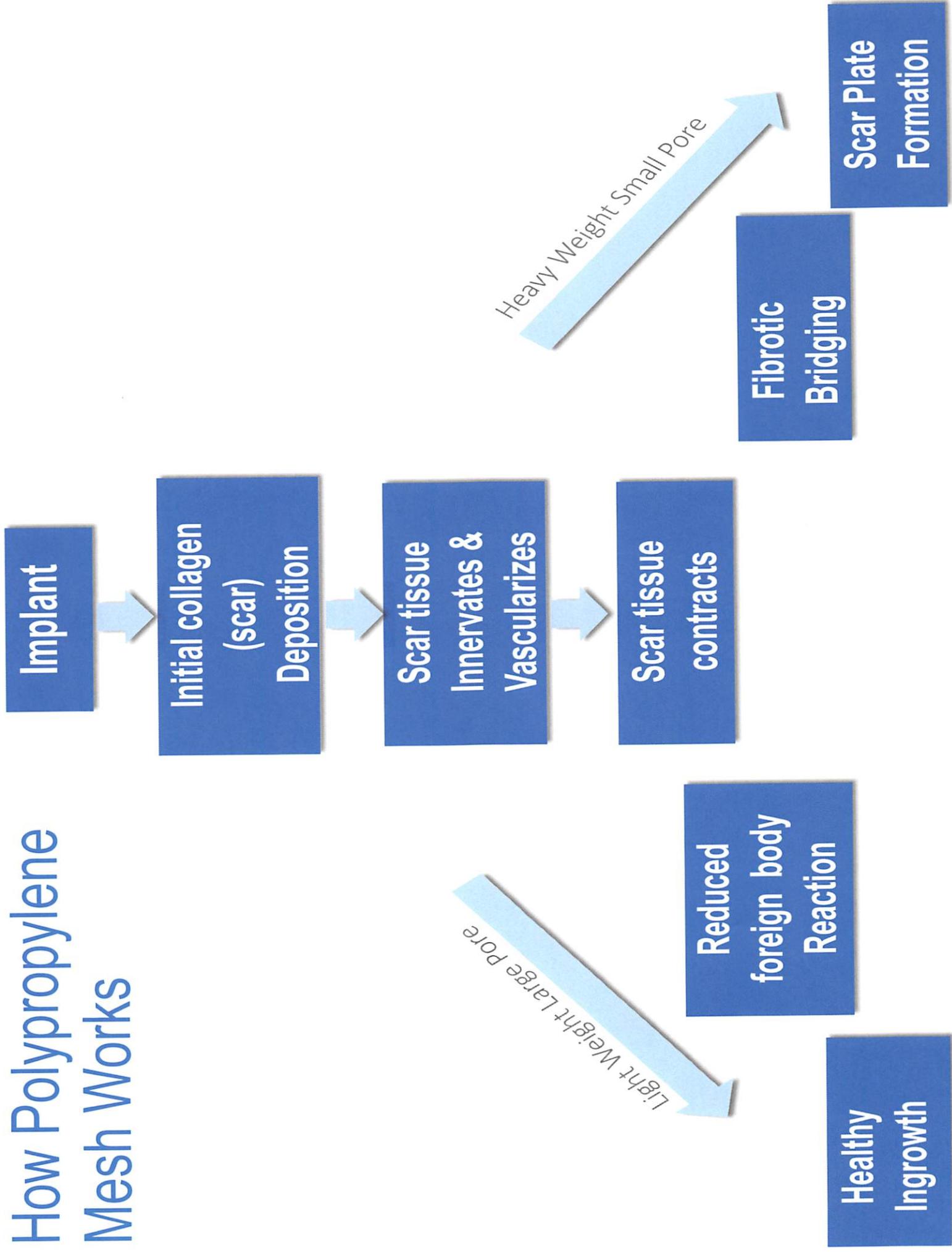
# Ventral Hernia and Mesh Positioning



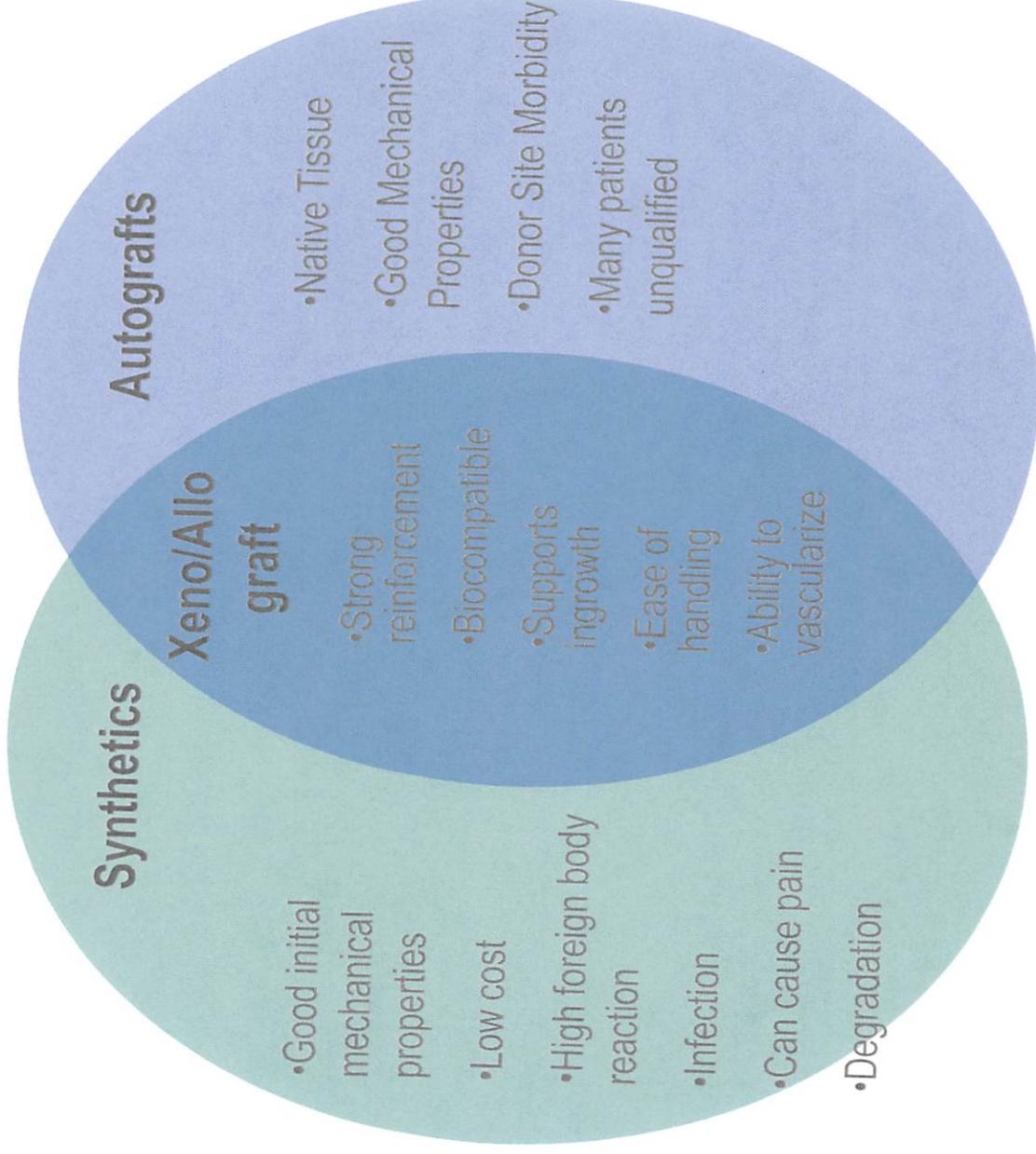
# Tack Placement



# How Polypropylene Mesh Works



# Material Considerations for Soft Tissue Repair



# Knowledge of Implants

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**1953**

Any implanted device must not be physically altered by tissue fluids

**1973**

Granulation formation related to friction between tissue and implant

**1979**

Bacteria are protected in interstices of material

**1980**

Pore size is important for tissue incorporation

# Knowledge of Implants

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**1984**

Heat exposed polypropylene releases biologically active degradation products affecting normal metabolic events

**1987**

Immediately upon insertion of a mesh there is a race to the mesh surface between bacteria and host defense cells

**1993**

Bacteria migrate along synthetic polymeric fibers

**1998**

Bacteria adhere to biomaterials using a biofilm

# Knowledge of Implants

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**1998**



Polypropylene  
mesh shrinks  
30–50% after  
4 weeks

**1999**



Surface  
toughness  
promotes  
wicking of  
bacteria

**2000**



Bacterial  
colonization  
found in 33% of  
explanted  
meshes



# Mesh Device Factors to Consider

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- ✓ Tensile strength
- ✓ Pliability
- ✓ Biocompatibility
- ✓ Ease of manipulation
- ✓ Durability
- ✓ Degree of tissue in-growth
- ✓ Infection rate
- ✓ Inflammatory response / adhesion formation
- ✓ Seroma formation

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# History of C-QUR



Congressional  
Research  
Service

## FDA Regulation of Medical Devices

Judith A. Johnson  
Specialist in Biomedical Policy

June 25, 2012

Congressional Research Service  
7-5700  
www.crs.gov  
R42130

CRS Report for Congress  
Prepared for Members and Committees of Congress

FDA Regulation of Medical Devices - June 25, 2012

Congressional Research Service - 7-5700

R42130

P.3

malfunctions, and 2,830 deaths; a more recent independent analysis claims there were 4,556 device-related deaths in 2009.<sup>13</sup> Consequences such as these have raised questions as to whether adequate enforcement tools, resources, and processes are in place to ensure that marketed devices are safe. Reports by the Government Accountability Office (GAO), the Department of Health and

## PMA vs. 510(k)

There is a fundamental difference between the PMA and 510(k) pathways. In a PMA review, FDA determines if the device is reasonably safe and effective for its intended use. In a 510(k) review, FDA determines if the device is substantially equivalent to another device whose safety and effectiveness may never have been assessed.

<sup>13</sup> GAO regularly reports on government operations that it identifies as high risk due to their greater vulnerability to fraud, waste, abuse, mismanagement or the need for transformation to address economy, efficiency or effectiveness challenges. See GAO, *High-Risk Series: An Update*, GAO-09-271, January 2009, and GAO, *High-Risk Series: An Update*, GAO-11-278, February 2011.

<sup>14</sup> (21 CFR 862-892).

<sup>15</sup> The term *manufacturer* is used throughout this report for simplicity, but regulations also apply to any person, organization, or sponsor that submits an application to FDA to market a device.

<sup>16</sup> *In vitro* diagnostic products (IVDs, or laboratory tests) have their own unique premarket requirements and are not (continued...)



## FDA Regulation of Medical Devices

Judith A. Johnson  
Specialist in Biomedical Policy

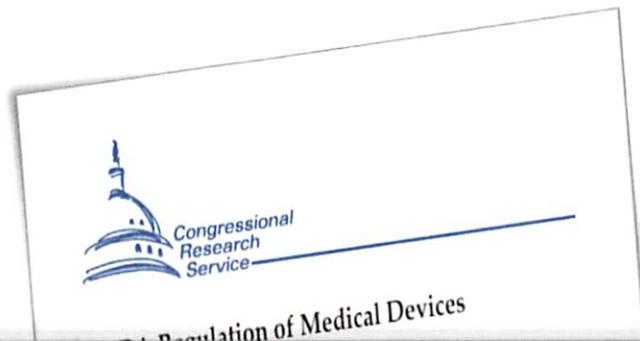
June 25, 2012

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R42130

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Prepared for Members and Committees of Congress

## 2011 IOM Report on 510(k) Substantial Equivalence

“In practice, the assessment of substantial equivalence generally does not require evidence of safety or effectiveness of a device. Unlike the premarket approval (PMA) process, by law the 510(k) process, with some exceptions [see SMDA 1990], focuses solely on the determination of a device’s substantial equivalence to a predicate device. According to the FDA and the Supreme Court, when the FDA finds a device substantially equivalent to a predicate device, it has done no more than find that the new device is as safe and effective as the predicate. It is important to note that devices on the market before the enactment of the 1976 Medical Device Amendments (MDA)—the origin of all predicate devices for the 510(k) process—have never been systematically assessed to determine their safety and effectiveness. Because the preamendment device to which equivalence was established was not itself reviewed for safety or effectiveness, the committee found that clearance of a 510(k) submission was not a determination that the cleared device was safe or effective.” See p. 154.



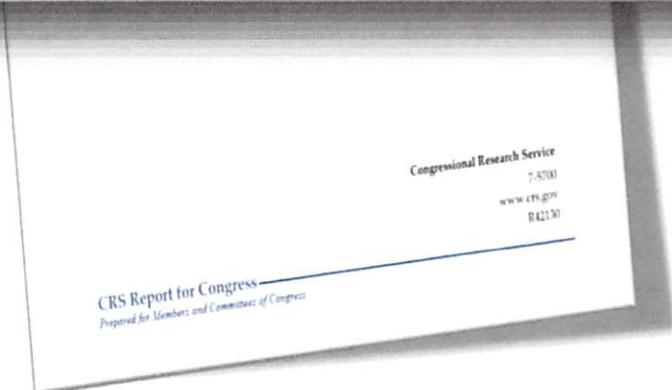
were either implantable, life sustaining or presented significant risk to the health, safety, or welfare of the patient.<sup>47</sup> The agency cleared about 90% of 510(k) submissions reviewed during FY2003 through FY2007.<sup>48</sup>

As noted previously, the standard for clearance of a traditional 510(k) is substantial equivalence with a predicate device. A predicate device can be one of two things. It can be a previously cleared Class I or II device that does not require a PMA. It can also be preamendment Class III for which the agency has not issued regulations requiring a PMA. (PMAs, which are more rigorous submissions than 510(k)s, are discussed in the "Pre-market Approval (PMA)" section.)

A manufacturer may choose one of three types of 510(k)

2011 IOM Report on 510(k) Substantial Equivalence

Most of the studies supporting a 510(k) submission are not clinical studies. Substantial equivalence, in many cases, means only that the device performs in a similar fashion to the predicate under a similar set of circumstances. As a result, many devices never have to demonstrate safety and effectiveness through clinical studies.



the quality of the device, and information about any computer software or additional or special equipment needed. Several administrative forms are also required.<sup>49</sup>

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<sup>47</sup> U.S. Government Accountability Office, *Medical Devices: FDA should take steps to ensure that high-risk device types are approved through the most stringent premarket review process*, GAO-09-190, January 2009, p. 18.

<sup>48</sup> *Ibid.*, p. 27.

<sup>49</sup> FDA, *Medical Devices, 510(k) Submission Methods*, at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>

<sup>50</sup> IOM, *Public Health Effectiveness of the FDA 510(k) Clearance Process: Measuring Postmarket Performance and Other Select Topics*, Workshop Report, Washington, DC, 2011, pp. 12 and 79.

<sup>51</sup> FDA, *How to Prepare a Traditional 510(k)*, September 14, 2009, [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134572.htm#link\\_4](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134572.htm#link_4)



## FDA Regulation of Medical Devices

### FDA Regulation of Medical Devices

In addition to not requiring clinical studies, three other characteristics of the 510(k) process make it much less rigorous than the PMA process: (1) premarket inspections of how devices were manufactured are generally not required by FDA; (2) postmarket studies are not required by FDA as a condition of clearance; and (3) FDA has limited authority to rescind or withdraw clearance if a 510(k) device is found to be unsafe or ineffective.<sup>52</sup>

FDA may take any of the following actions on a 510(k) after conducting its review:

- find the device substantially equivalent to the predicate and issue a clearance letter;
- find the device not substantially equivalent (NSE) and issue an NSE letter prohibiting marketing;
- determine that the device is exempt from a 510(k) submission;

In addition to not requiring clinical studies, three other characteristics of the 510(k) process make it much less rigorous than the PMA process: (1) premarket inspections of how devices were manufactured are generally not required by FDA; (2) postmarket studies are not required by FDA as a condition of clearance; and, (3) FDA has limited authority to rescind or withdraw clearance if a 510(k) device is found to be unsafe or ineffective.<sup>52</sup>

abbreviated 510(k) in 60 days.

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CRS Report for Congress  
Prepared for Members and Committee of Congress

<sup>52</sup> Diana M. Zuckerman, Paul Brown, and Steven Nissen, "Medical Device recalls and the FDA approval process," *Archives of Internal Medicine*, Online publication 2011, p. 24.

<sup>53</sup> 21 CFR 807.100(a).

<sup>54</sup> 21 CFR 807.870.

<sup>55</sup> The FDA time clock (i.e., review cycle) begins when FDA receives the 510(k) and ends with the date that FDA issues either a request for additional information or a decision. More than one cycle may occur before FDA issues its final decision.

<sup>56</sup> 21 CFR 10.115. FDA occasionally accepts public comment on any draft or final guidance document.

<sup>57</sup> 21 CFR 861.

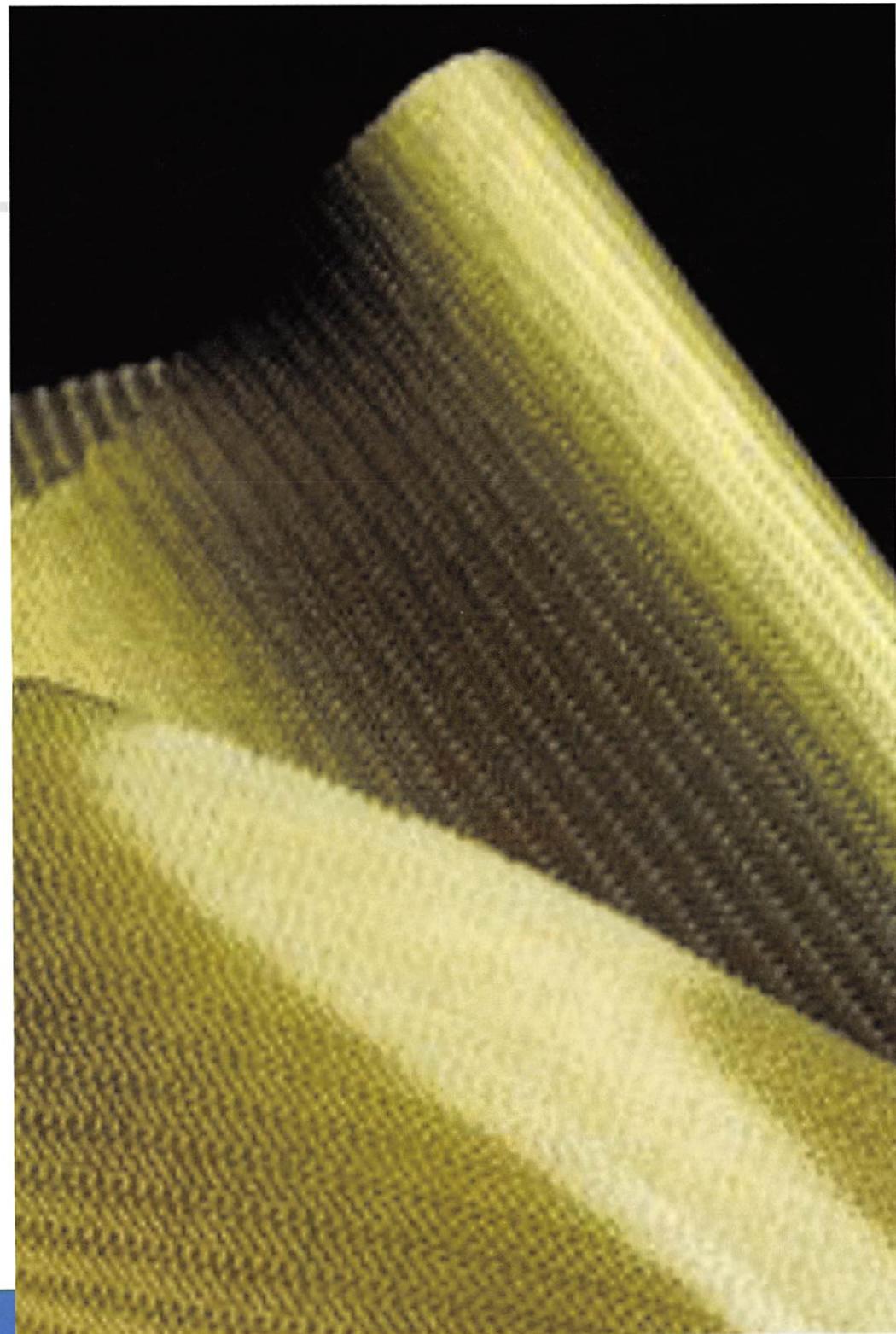
Congressional Research Service

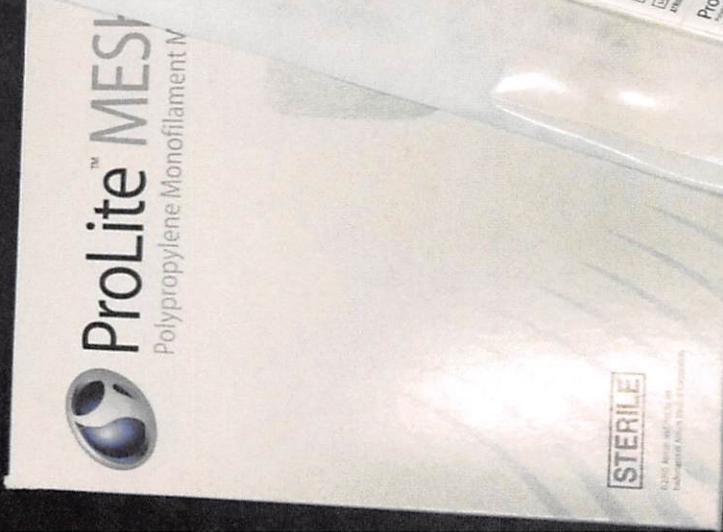
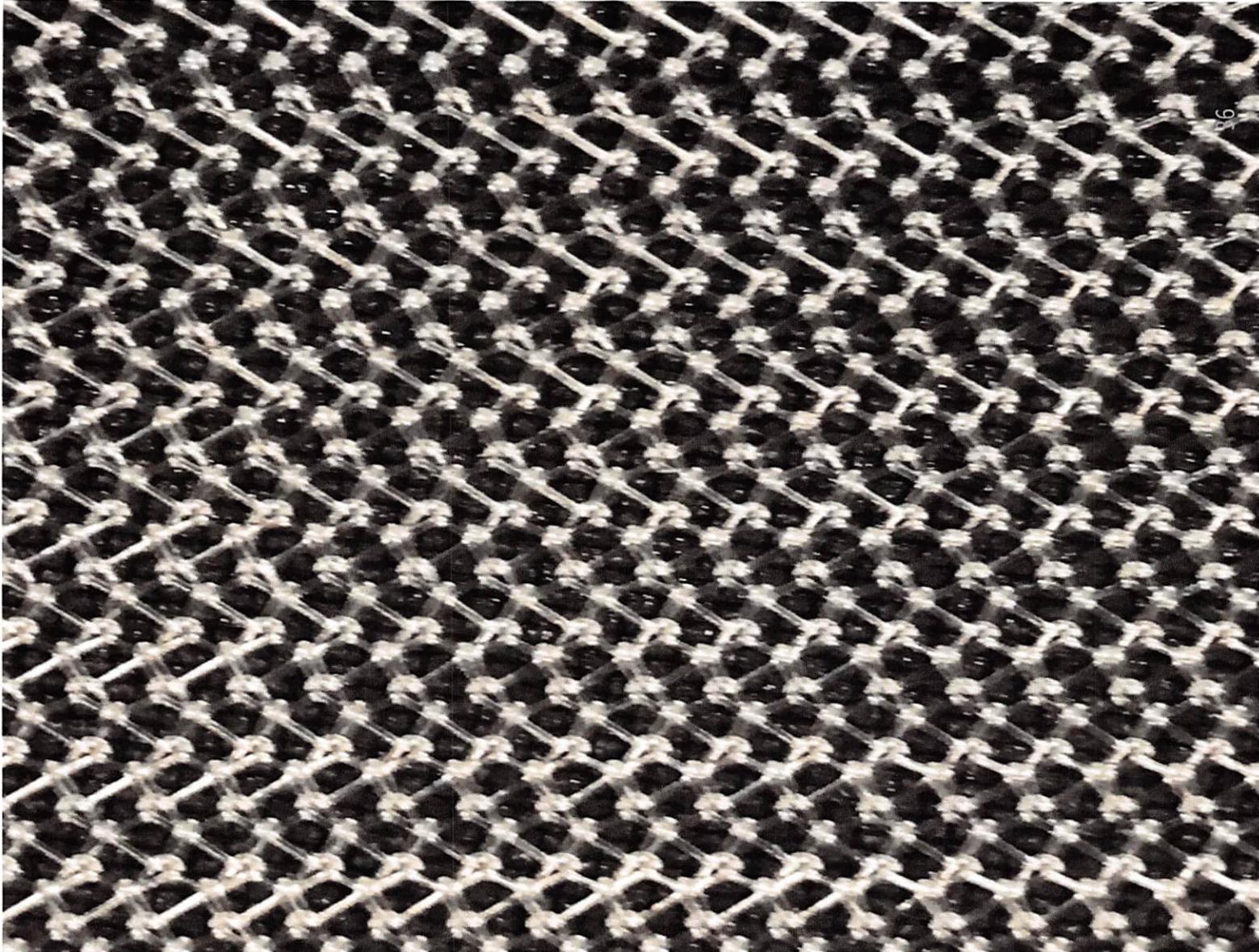
10

# C-QUR

## Components

- Base mesh is Atrium ProLite polypropylene mesh with .8 mm pores
- Coated in a thick film made of crosslinked glycerides and omega 3 fatty acids (O3FA)
- Coating forms a solid gel after being heated or 'cured'
- Fatty acids come from fish oil





# Tissue Separating Meshes

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- Coated with one or more permanent or bioabsorbable films
- Intended to:
  - Separate mesh from internal organs
  - Prevent adhesions to the mesh device
  - Yet promote mesh ingrowth into abdominal wall
  - Provide permanent repair





REF 31528  
 C-QUR | MESH  
 COFA COATED POLYPROPYLENE MESH  
 10 cm x 15 cm  
 4" x 6"

REF 31528  
 C-QUR | MESH  
 COFA COATED POLYPROPYLENE MESH  
 10 cm x 15 cm  
 4 in. x 6 in.

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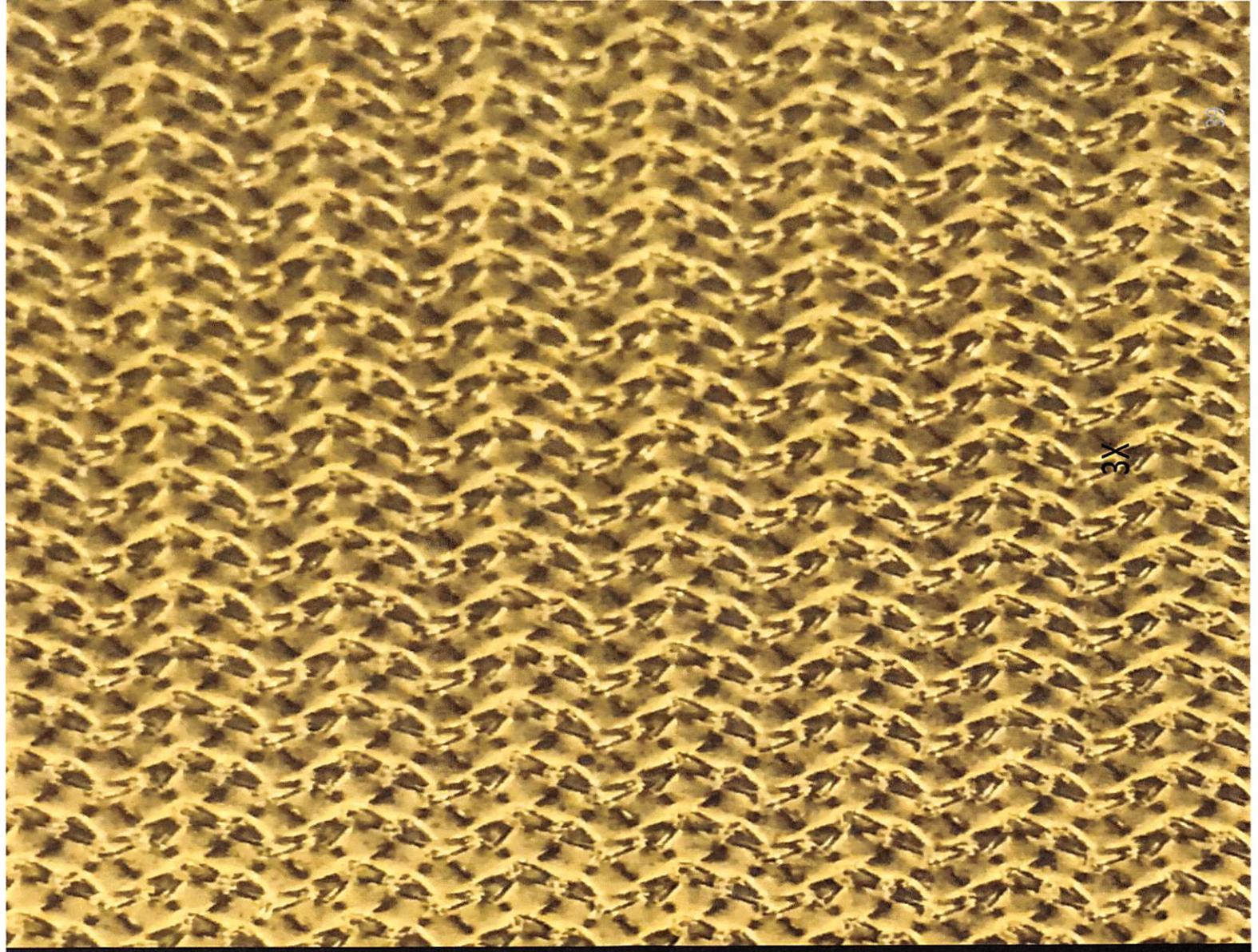
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C-QUR | MESH  
 COFA COATED POLYPROPYLENE MESH

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3X



GETINGE GROUP  
Passion for life



When it comes to  
natural integration...

Nature and C-QUR™ 03FA  
do it best!

C-QUR™ Mesh is the only hernia mesh on the market with a bio-absorbable, Omega-3 fatty acid (O3FA) coating. The O3FA coating is composed of fatty acids, lipids and glycerides.

- O3FA coating provides a tissue separating layer resulting in minimal tissue attachment to the mesh<sup>1</sup>
- Base material is a mid-weight monofilament polypropylene with a strong knit construction



<sup>1</sup> Pineda SA, Penne BJ, Newell, et al. *Augustine*. 2009;16(1):40-44.

C-QUR O3FA coated mesh family—  
the natural choice in hernia repair.

MAQUET  
GETINGE GROUP



Laparoscopic ventral repair using C-QUR 03FA mesh  
Mesh Mesh

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# GENERAL SURGERY NEWS

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GENERAL

The Independent Monthly Newspaper for the General Surgeon

## Opinion

### The Employed Surgeon

Walking a Fine Line on the Edge of a Scalpel

By F. PAUL BUCKLEY III, MD, FACS



Full disclosure: I have never been in private practice. Upon finishing residency, I served four years in the US Air Force (the ultimate in employed practice), and then joined the Scott

& White Clinic, now Baylor Scott & White Health (BS&WH) in Round Rock, Texas. BS&WH is an \$8 billion integrated health system with more than 1,000 employed physicians and 6,000 physicians in a quality alliance.

I have good friends who believe that physicians who practice in a hospital-based or employed setting have gone to the dark side. By giving up autonomy and heading for the safety of employment within a hospital, you are somehow abandoning your professional and ethical duty to patients. While not necessarily true, there is certainly the potential for professional, ethical and financial tensions/conflicts of interest. Working through a few of these issues is the focus here.

What does the ideal employment model look like?

see *Employed Surgeon* page 22

## Guidelines Target SSIs: Focus on Glucose, Antibiotics

New Glucose Range, Antibiotic Cessation at End of Procedure, Skullcaps Given Green Light

SSI

By CHRISTINA FRANGOU

Two leading surgical societies are calling for changes to the way surgeons manage blood glucose control and provide antibiotics to patients in an effort to reduce rates of surgical site infections.

The recommendations are part of a set of new guidelines for the prevention and treatment of SSIs, and were created by the American College of Surgeons and the Surgical Infection Society (SIS).

The guidelines, which are based on a review of best available research and clinical practice experience, set target blood

see *Guidelines for SSIs* page 28



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olde as oile 50 years, est other factor). During th Cancer Syng inge from a i oncogenes o leages deve that age was factor for ke tant factors w required and was negative.

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## Open Approach to Small Umbilical Hernias May Cut Time, Cost

Patch Appears to Achieve Same Results as Lap Approach

By MUNICA J. SMITH

NEW YORK—Before the availability of a relatively small patch initially designed for mesh closure, Guy Voelker, MD, and his colleagues were satisfied with laparoscopic repair for small umbilical and epigastric hernias.

“With laparoscopy, you could put a big patch behind the hole, and that’s

see *Umbilical Hernia* page 4

## INSIDE

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OBESITY CARE

15 A Parade of New Endoscopic Devices Emerges for Obesity Control

In the News

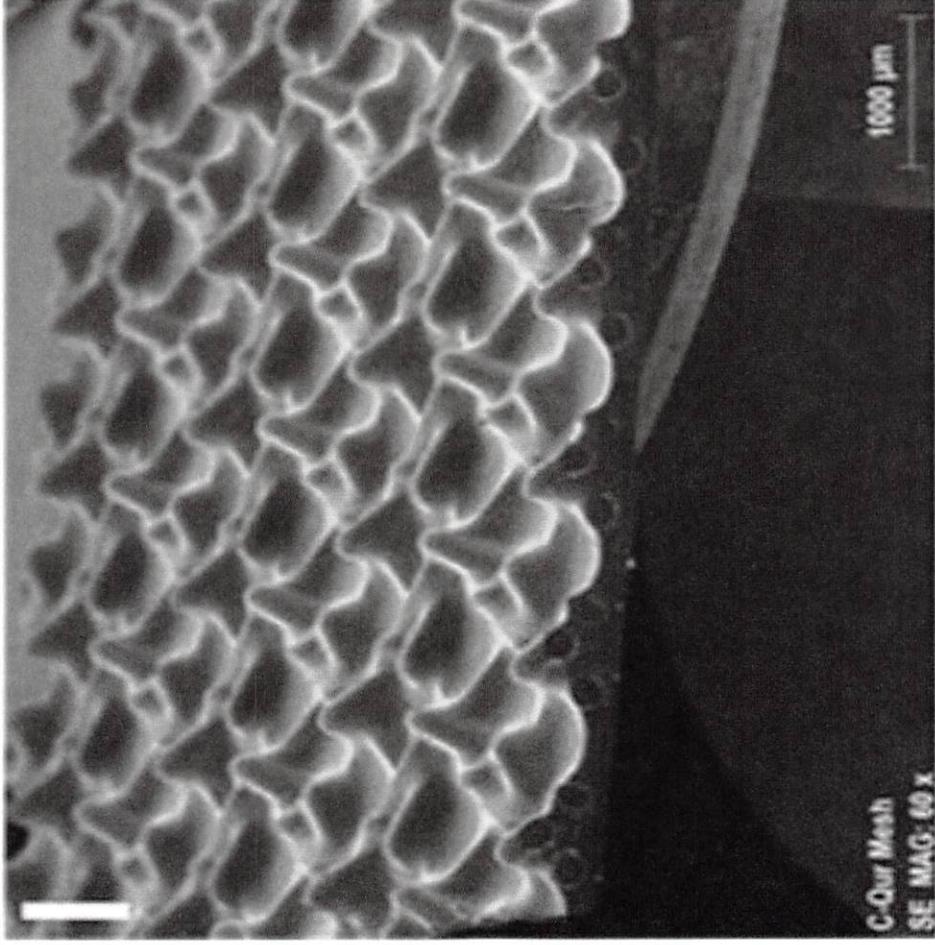
17 Surveillance for Breast Cancer Survivors Found to Be Falling Short

# Atrium C-Qur Mesh

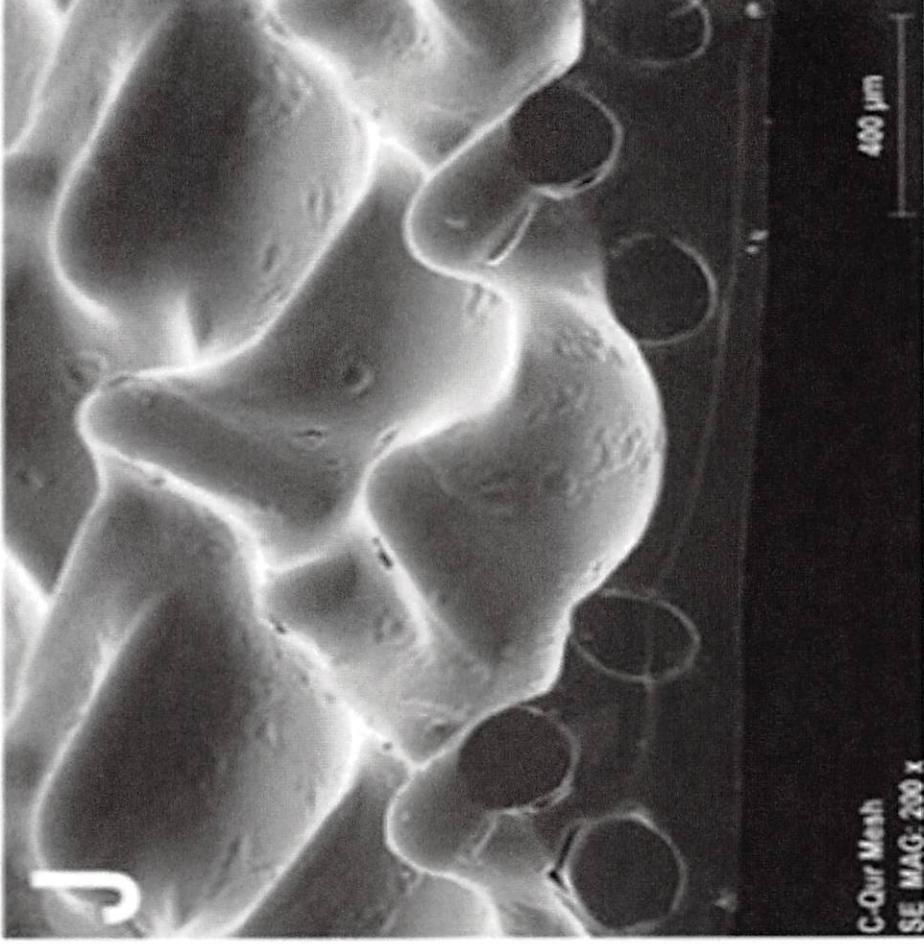
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- Limited market launch in 2006, and then full market release around mid-2007
- Mesh is Atrium Prolite polypropylene mesh
- Mesh is then coated on both sides with fish oil (03FA).
- Heat cured to crosslink into a gel
- A number of additional C-QUR brand mesh devices added to product line from 2008 to 2015

# C-QUR Under a Microscope



At 60x Magnification

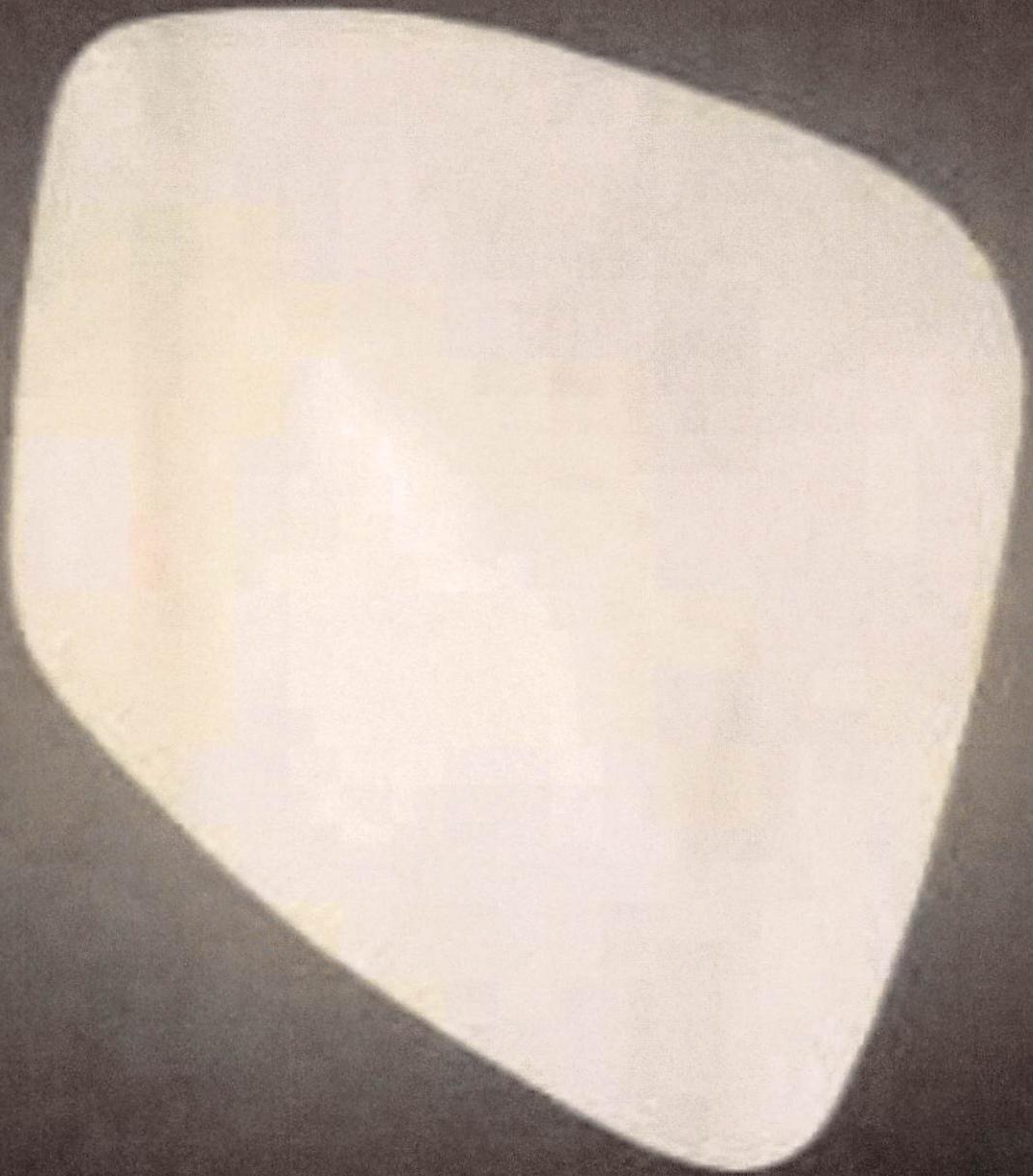


At 200x Magnification

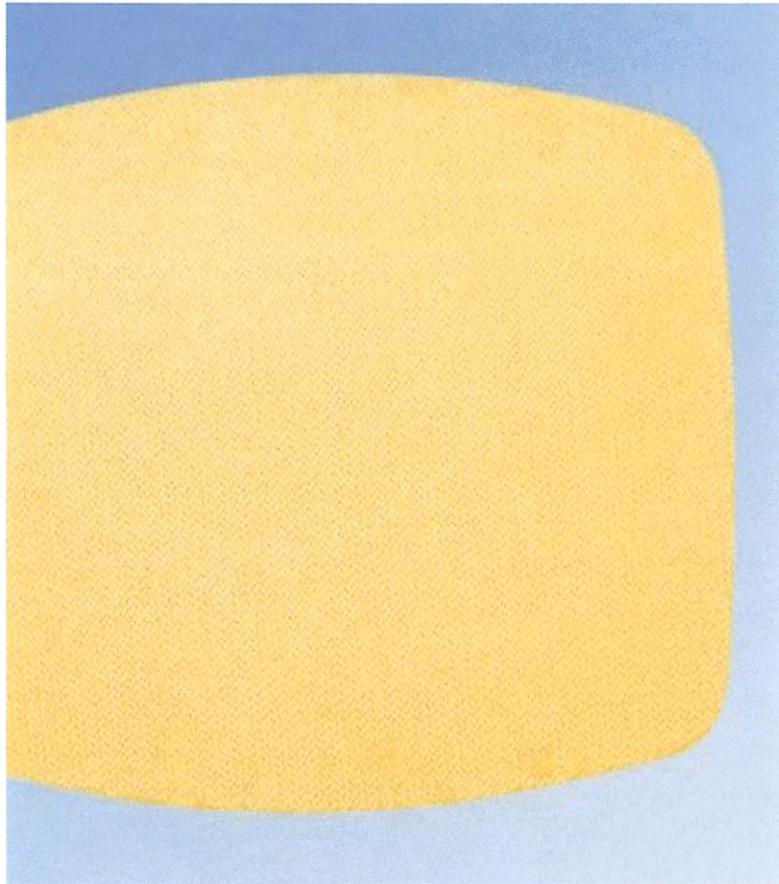
# Types of C-QUR Mesh



U·QUJR™  
MESH



# C-QUR – 1<sup>st</sup> Generation -2006



Indication Statement	Indication(s) Alt Sources	Materials/ Composition
Intended for use in soft tissue deficiencies including hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a supportive material.	Open and lap hernia repair	Mesh: ProLite Ultra, .75mm pore size, Polypropylene monofilaments Coating: O3FA fish oil coating (C-Qur Brochure)



**U·QUJR™** **EDGE™**  
MESH

# C-QUR Edge - 2007



## Indication Statement

Intended for use in soft tissue deficiencies including but not limited to hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a supportive material.

## Indication(s) Alt Sources

Hernia repair, chest wall reconstruction, traumatic or surgical wounds, other fascial surg. Intervention procedures

## Materials/ Composition

Base: Polypropylene monofilament (Prolite Ultra)  
Edge: Polypropylene monofilament strip of mesh welded on top of monofilament mesh base  
Coating: O3FA fish oil coating.

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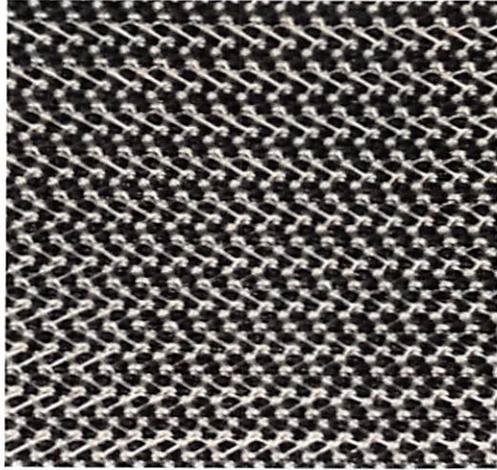
**C·o·qur**<sup>™</sup> | **MESH**

**O3FA COATED MESH**



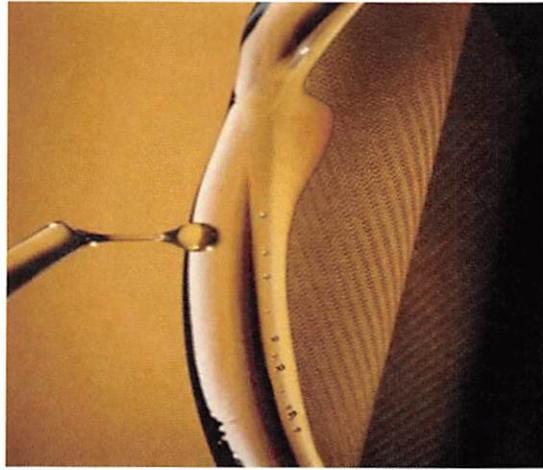
# C-QUR - 2009

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## Prolite polypropylene mesh

- .8mm pore size
- 85 g/m<sup>2</sup>



## Fish oil coating

- 53% less coating than Edge

# C-QUR V-Patch Mesh -2009



## Indication Statement

Indicated for use in hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a nonabsorbable supportive material

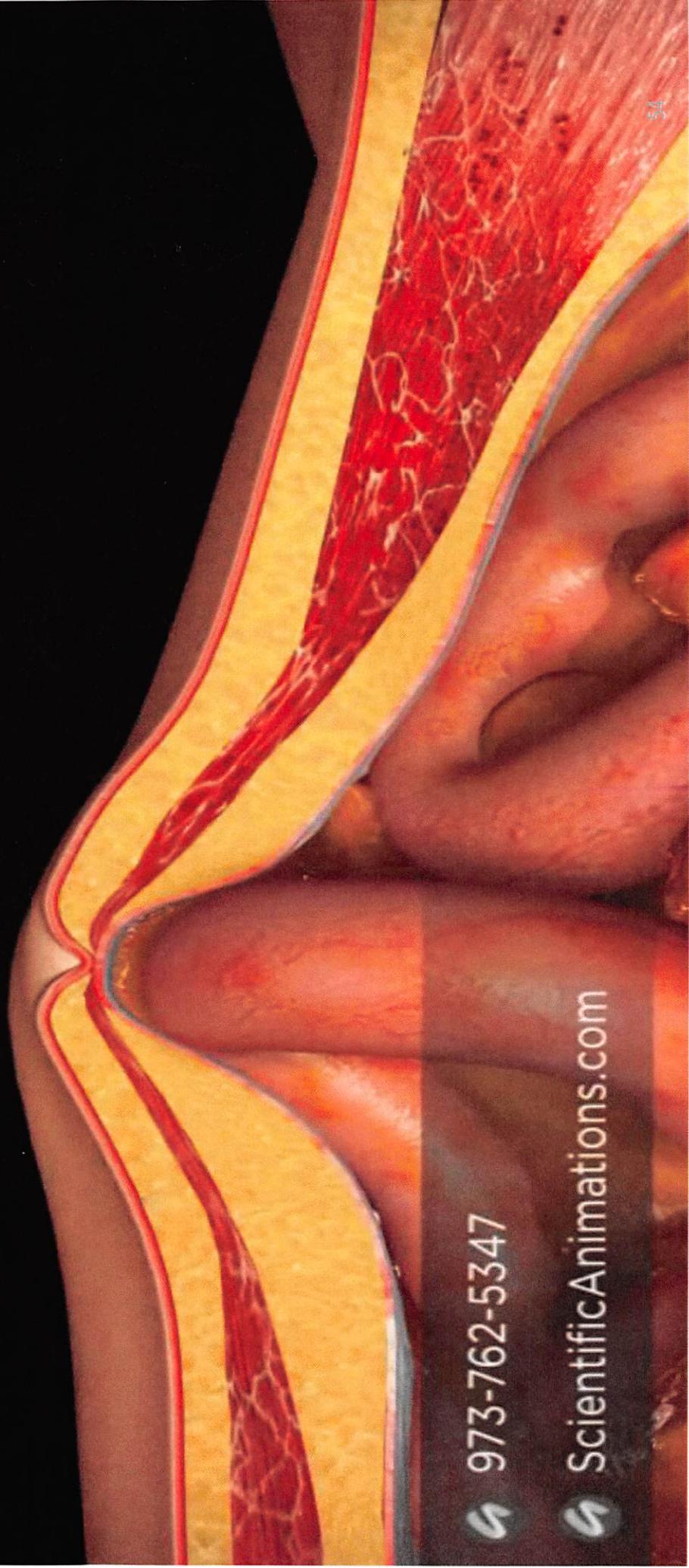
## Indication(s) Alt Sources

Small hernias (umbilical, epigastric, trocar site defects) and other small abdominal wall defects (V-Patch Brochure)

## Materials/ Composition

Mesh: One layer of C-QUR and one layer of C-QUR Lite mesh with two positioning straps  
Coating: O3FA fish oil coating

# Umbilical Hernia Repair with **C-QUR™ V-Patch Mesh**



☞ 973-762-5347

☞ [ScientificAnimations.com](http://ScientificAnimations.com)

# C-Qur TacShield -2010



Indication Statement	Indication(s) Alt Sources	Materials/ Composition
Intended for use in soft tissue deficiencies including hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a supportive material.	Repair of medium to large size open ventral hernias (TacShield Brochure)	Center Mesh: Polypropylene monofilament mesh; Mesh Apron: Polypropylene monofilaments lightweight Mesh Coating: O3FA fish oil coating

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mosaic<sup>TM</sup>

C-QUR 03FA COATED MESH

# C-QUR Mosaic -2012



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## Indication Statement

Intended for use in soft tissue deficiencies including hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a supportive material

## Indication(s) Alt Sources

Open and lap hernia repair (Mosaic Brochure)

## Materials/ Composition

Mesh: ProLite, polypropylene monofilaments  
Coating: Non-continuous coating barrier made of O3FA fish oil. (Coating greatly reduced).

# C-QUR FX – 2015 (formerly C-QUR Lite)



Indication Statement	Indication(s) Alt Sources	Materials/ Composition
Intended for use in hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a non-absorbable supportive material.	Open and lap hernia repair	Mesh: Polypropylene monofilaments mesh Coating: O3FA fish oil coating.

FX = “filament coated”

# C-QUR CentriFX - 2015



Indication Statement	Indication(s) Alt Sources	Materials/ Composition
Intended for use in hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a non-absorbable supportive material.	3D Lap inguinal hernia repair (CentriFX Brochure)	Mesh: Polypropylene monofilaments Coating: O3FA fish oil coating (CentriFX Brochure)

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# Most Common Adverse Events Associated with Hernia Mesh Repair

**C•OQUR™** | **MESH**

**O3FA COATED MESH**

**INSTRUCTIONS FOR USE**

## Instructions For Use

### Device Tracking Labels

The enclosed Device Tracking Labels should be read and followed.

### Description

Atrium C-QUR™ Mesh products are sterile, non-absorbable material for tissue reinforcement with a coating of fatty acids, lipids and glycerides (BAO - Bioactive Adhesive Overlay).

### Indications for Use

Atrium C-QUR Mesh products are intended for hernia repair, chest wall reconstruction, trauma and other surgical intervention procedures requiring tissue reinforcement.

### Contraindications

Atrium C-QUR Mesh products are contraindicated in children or pregnancy where future growth is expected.

### Warnings

1. Federal Law (U.S.A.) restricts this device to single use only. Do not reuse, re-sterilize or reuse after sterilization. Sterilization may compromise the structural integrity which, in turn, may result in patient failure. Adequate mesh fixation is required to prevent recurrence. The fixation technique, method (sutures, staples or other means) is left to the discretion of the surgeon.
2. This device is supplied sterile. Please do not use if damaged prior to use.
3. Do not use a C-QUR Mesh that has been used on patients where tissue separation is of concern.

### Precautions

1. Please read all instructions prior to use.
2. Handling of mesh should be with clean hands.
3. Careful attention to surgical mesh handling is required in the presence of nerves and vessels.

### Adverse Reactions

Complications that may occur with the use of Atrium C-QUR Mesh include, but are not limited to, inflammation, infection, seroma, hematoma, possible adhesions when placed in direct contact with the viscera (intestines) and organs.

### Preclinical Studies

Pre-clinical in-vivo small animal studies were conducted to evaluate the tissue ingrowth of Atrium C-QUR Mesh. The C-QUR mesh material was evaluated at 4, 7, 14, 21 and 28 days and compared histologically and morphometrically to uncoated polypropylene mesh samples implanted in the same manner. Results of these studies show that the duration of the inhibition of tissue ingrowth is 10 days or less. Less visceral tissue attachment at all time points was demonstrated on the BAO coated mesh compared to uncoated polypropylene mesh.

### Open Sterile Package

Peel open the package and remove the Atrium C-QUR Mesh product using sterile technique.

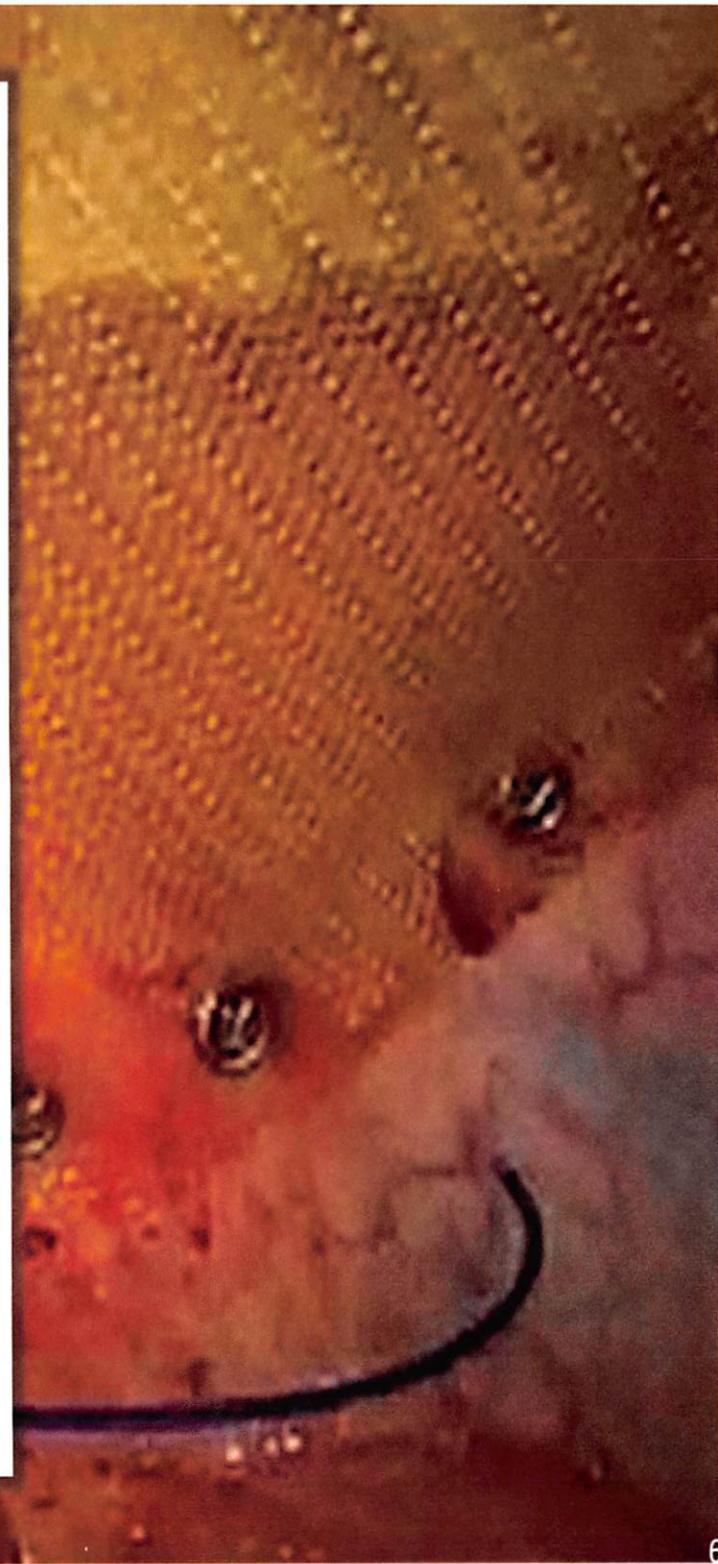
# Adverse Reactions

Complications that may occur with the use of any surgical mesh include, but are not limited to, inflammation, infection, seroma, hematoma, fistula formation or mechanical disruption of the tissue and/or mesh material, possible adhesions when placed in direct contact with the viscera (intestines) and organs.

## “Adverse Events” - C-QUR

- Chronic Infection
- Abscess
- Skin rash
- Dense Adhesions
- Meshoma
- Bowel entrapment/  
obstruction/resection
- Recurrence
- Pain

Frequency  
Severity



# Mechanisms of Injuries

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- “O3FA” Fish Oil volume and properties
- Non-porous 2-sided coating
- Polypropylene Degradation
- Place on intestines
- Lack of Uniformity, Contamination and Impurity

# Atrium C-QUR – Infection Cases

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## FISH OIL COATING

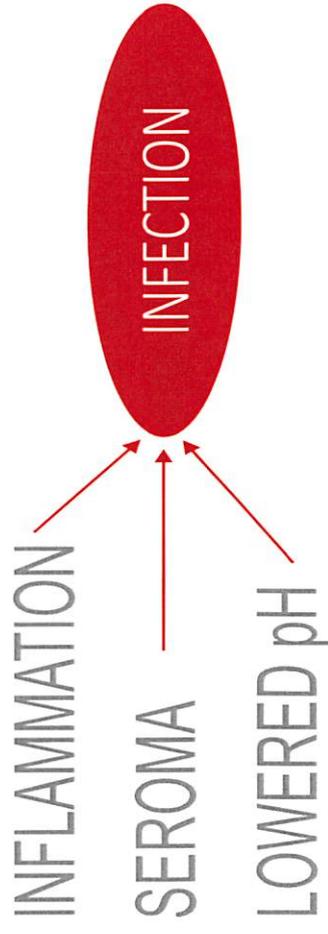
- Incites Profound Inflammatory Response
- Film Prevents Fluid-flowthru ➡ Seroma
- Acidic - Reduces pH At Implant Site And Within Peritoneum (Lowers Concentration of Proteins that Suppress Bacterial Growth)
- Cytotoxicity

INFLAMMATION

SEROMA

LOWERED pH

INFECTION

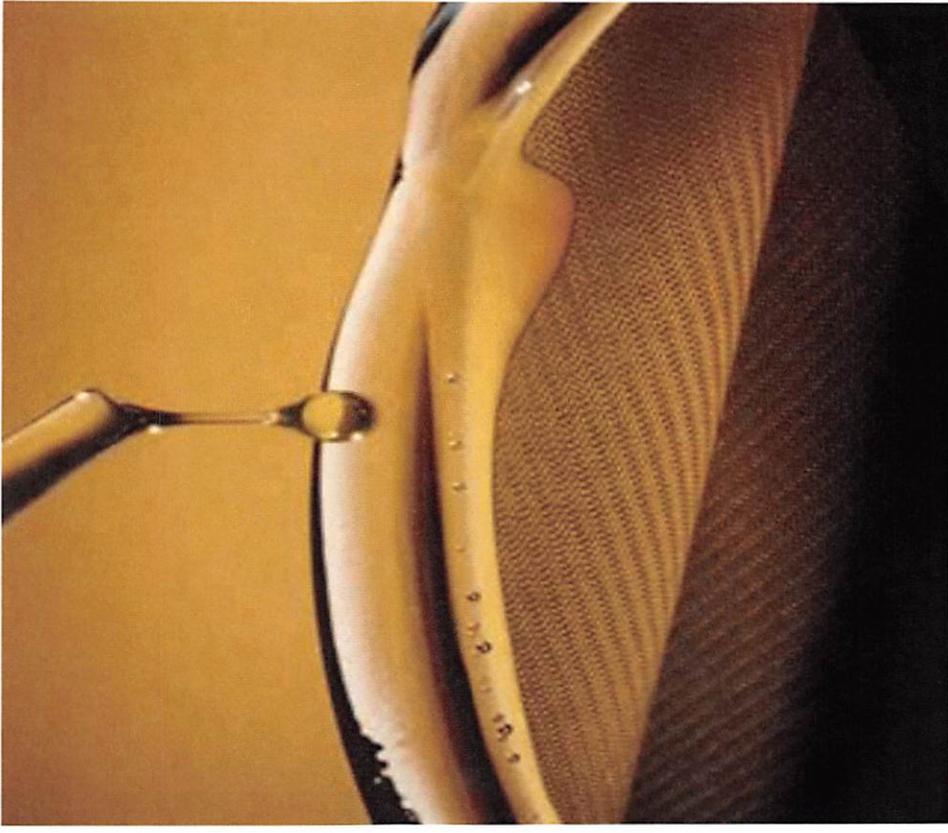


*Any One of These Factors Raise the Risk of Infection*

# Density of Gel Coating

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C-QUR when originally launched had more than 3 times the amount of “fish oil” gel coating than later iterations.



# Atrium C-QUR - Dehiscence Cases

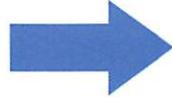
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- Infection Precipitated by Properties of Fish Oil Film
- The Different Phases of Wound Healing Require Different pH Ranges
  - Lowered pH Inhibits Formation of Healthy Granulation Tissue
  - Implant site Never Fully "Heals"
  - Cyclical Injury (Patients' Wounds Reopen As Long As C-QUR Mesh Is Present)

# Atrium C-QUR – Adhesion/Failed Incorporation

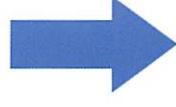
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- Higher Volume of Fish Oil
- Present on Both Sides of Mesh
- Small Pores

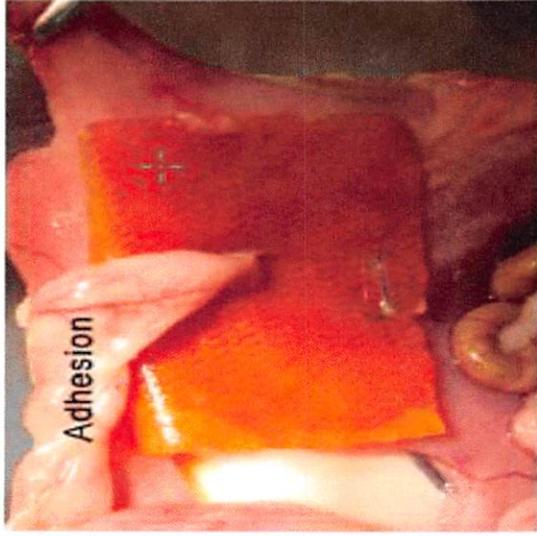


Failed Incorporation,  
migration, meshoma,  
encapsulation and  
contraction

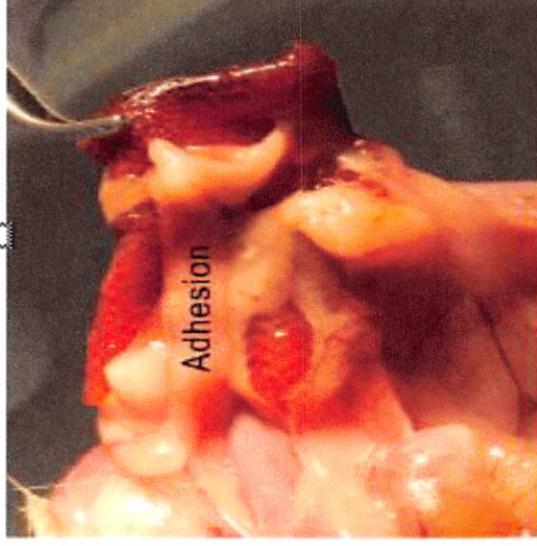
- Oil sloughs off after implantation
- PP Exposed to Bowel/Degradation
- Augmented Inflammatory Response  
From Fish Oil



Tenacious Dense  
Adhesions

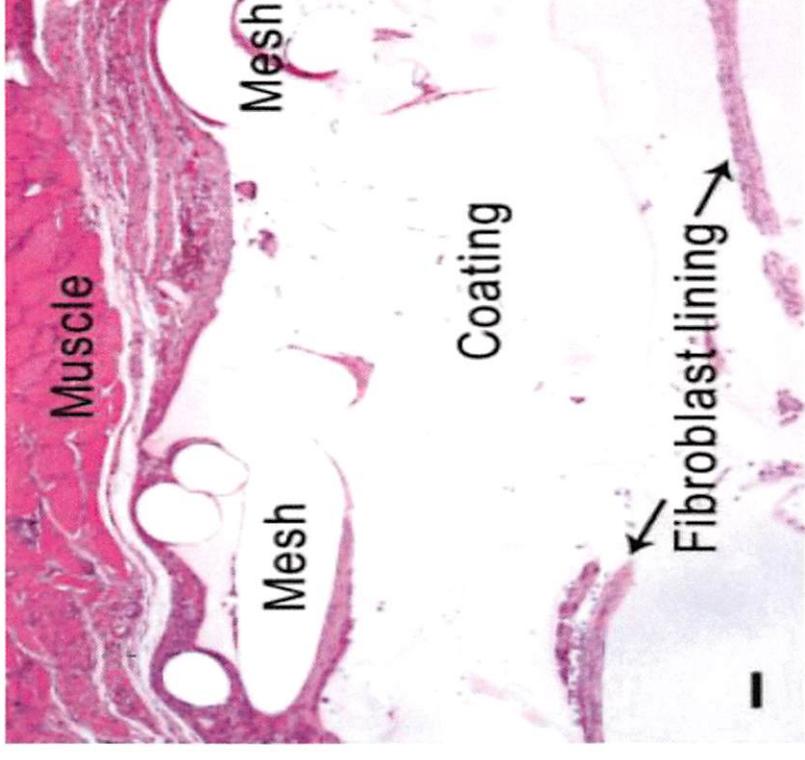


**a** 7 days



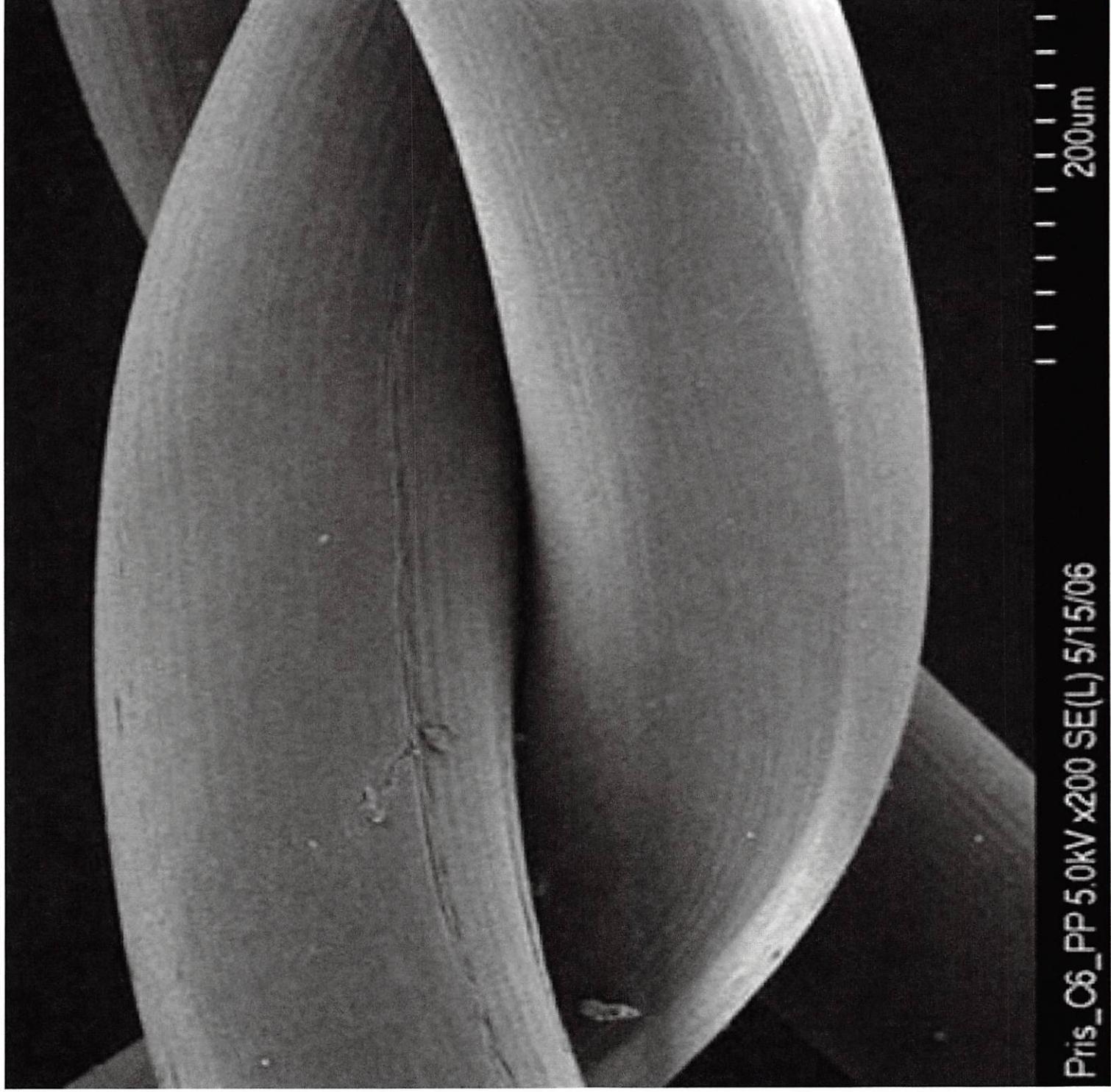
**b** 30 days

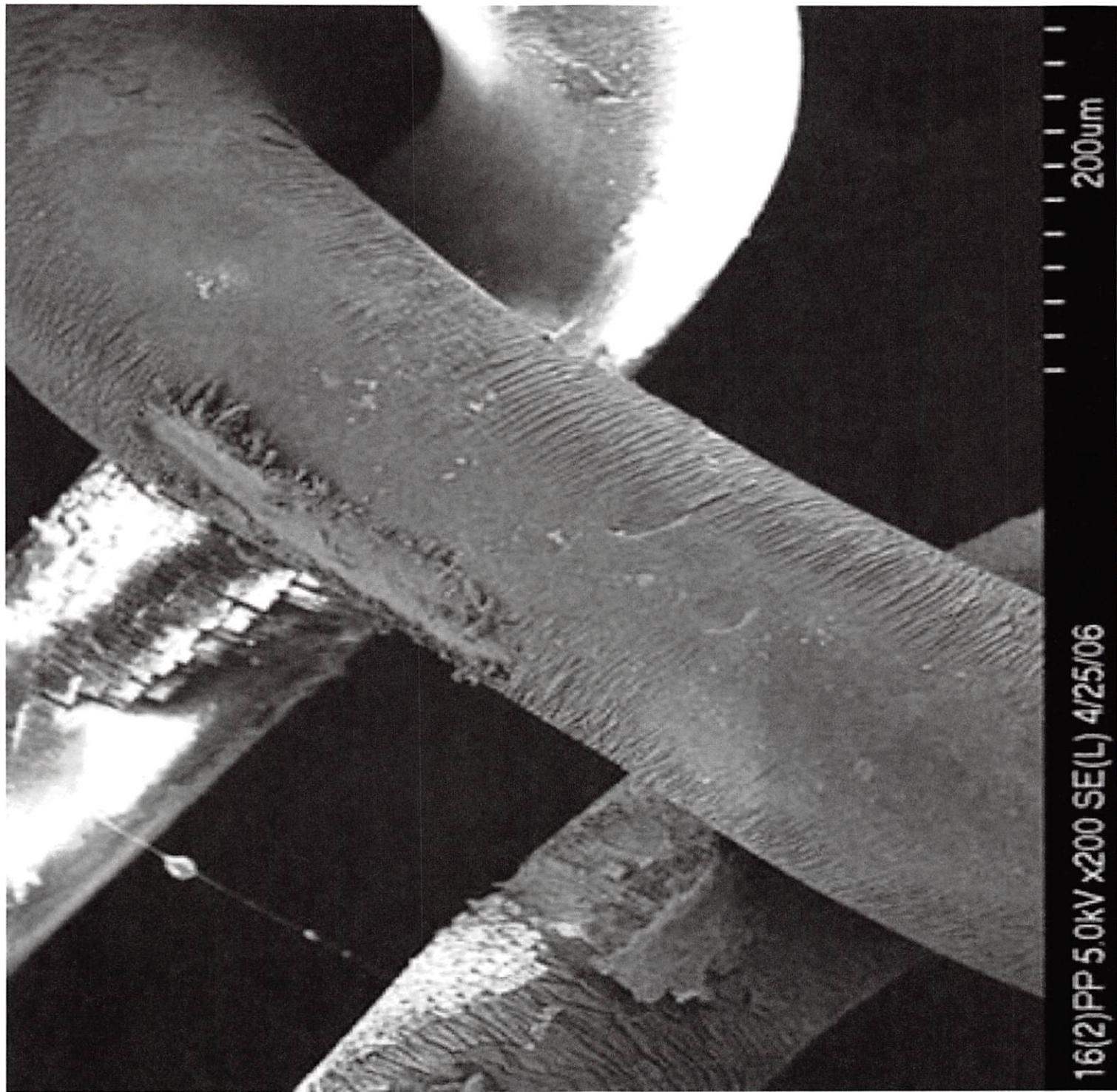
photographs of C-Qur<sup>®</sup> mesh at a 7 days' and b 30 days' follow-up. In a adhesion related to the polypropylene suture underneath it is visible. Note shrinkage of the mesh between a and b



**a** C-Qur<sup>®</sup> at 30 days

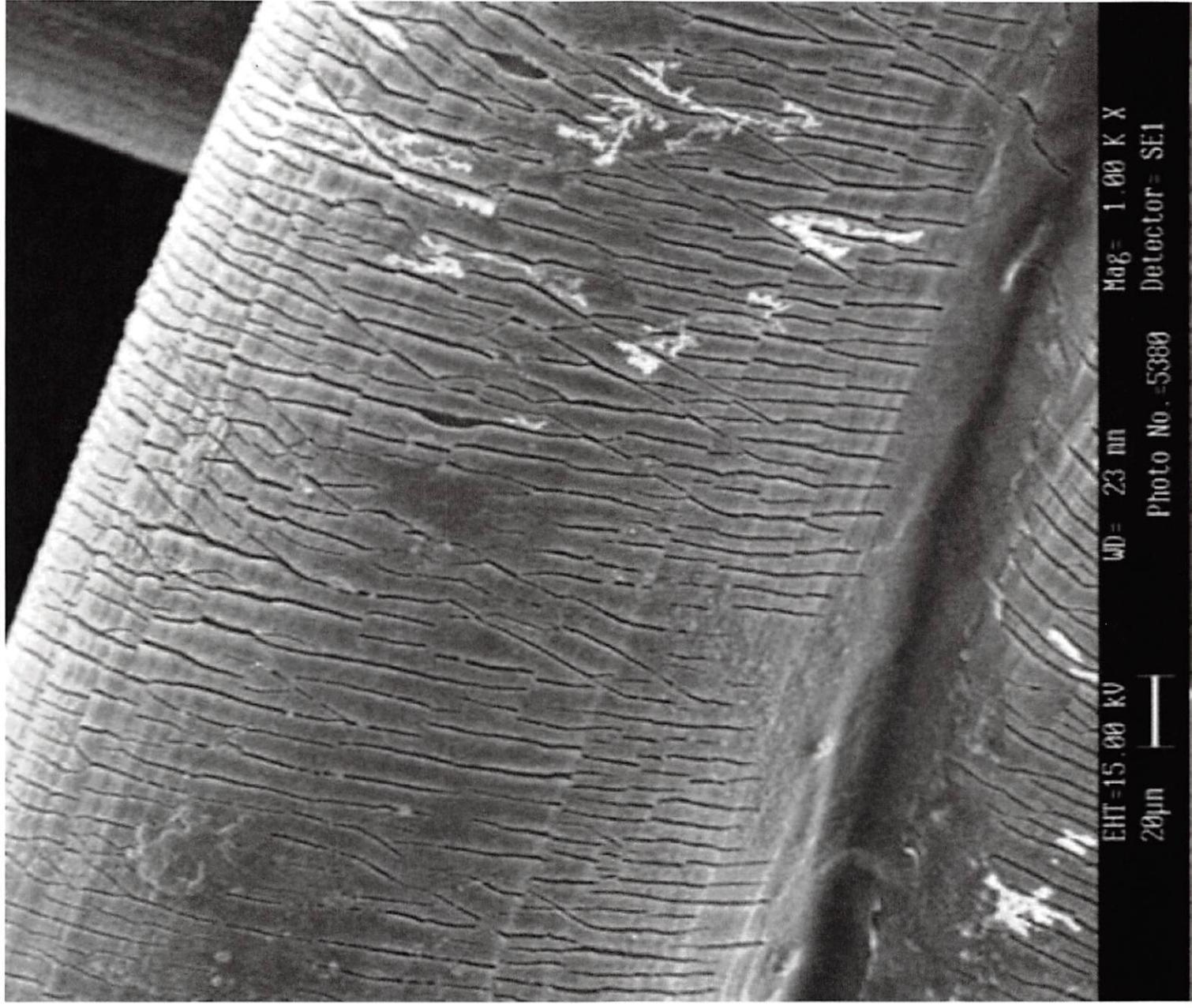
histological samples. a C-Qur<sup>®</sup> at 30 days' follow-up (40 × original magnification). There is no ingrowth of muscle as peritoneum separates mesh and muscle.





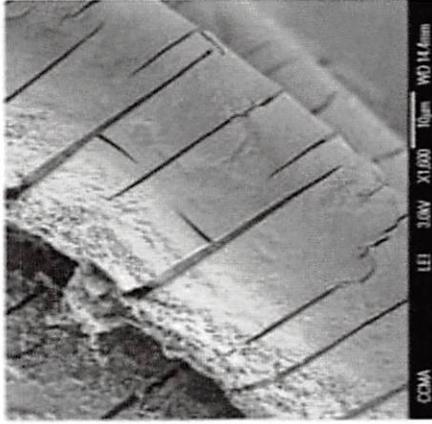
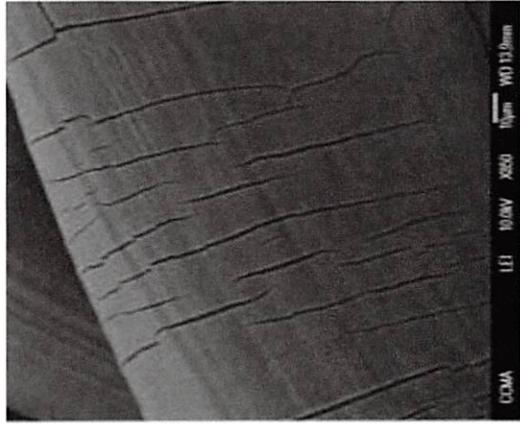
16(2)PP 5.0kV x200 SE(L) 4/25/06

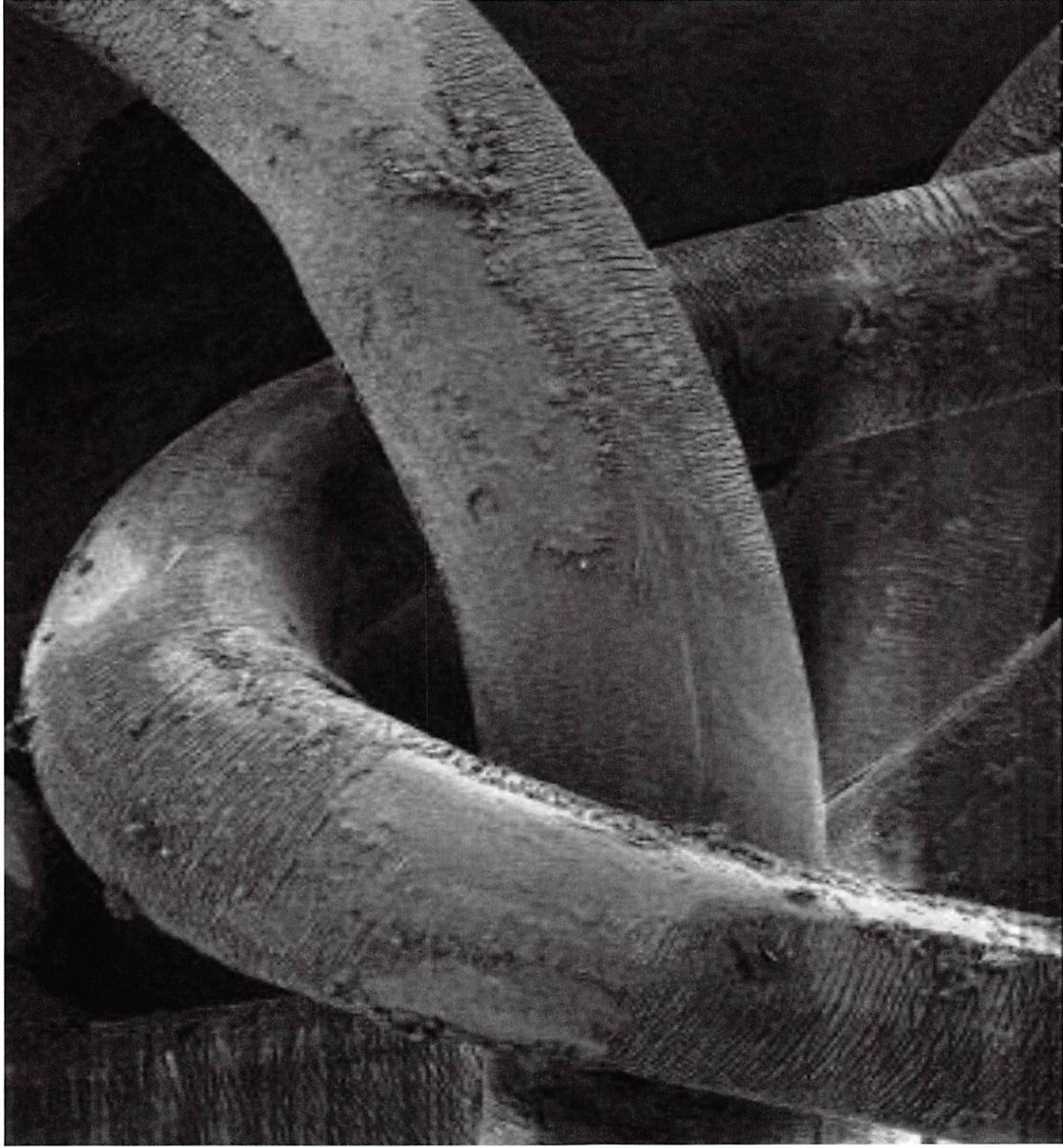
200µm



Bracco [2005] Comparison of polypropylene and polyethylene terephthalate - Figure 3

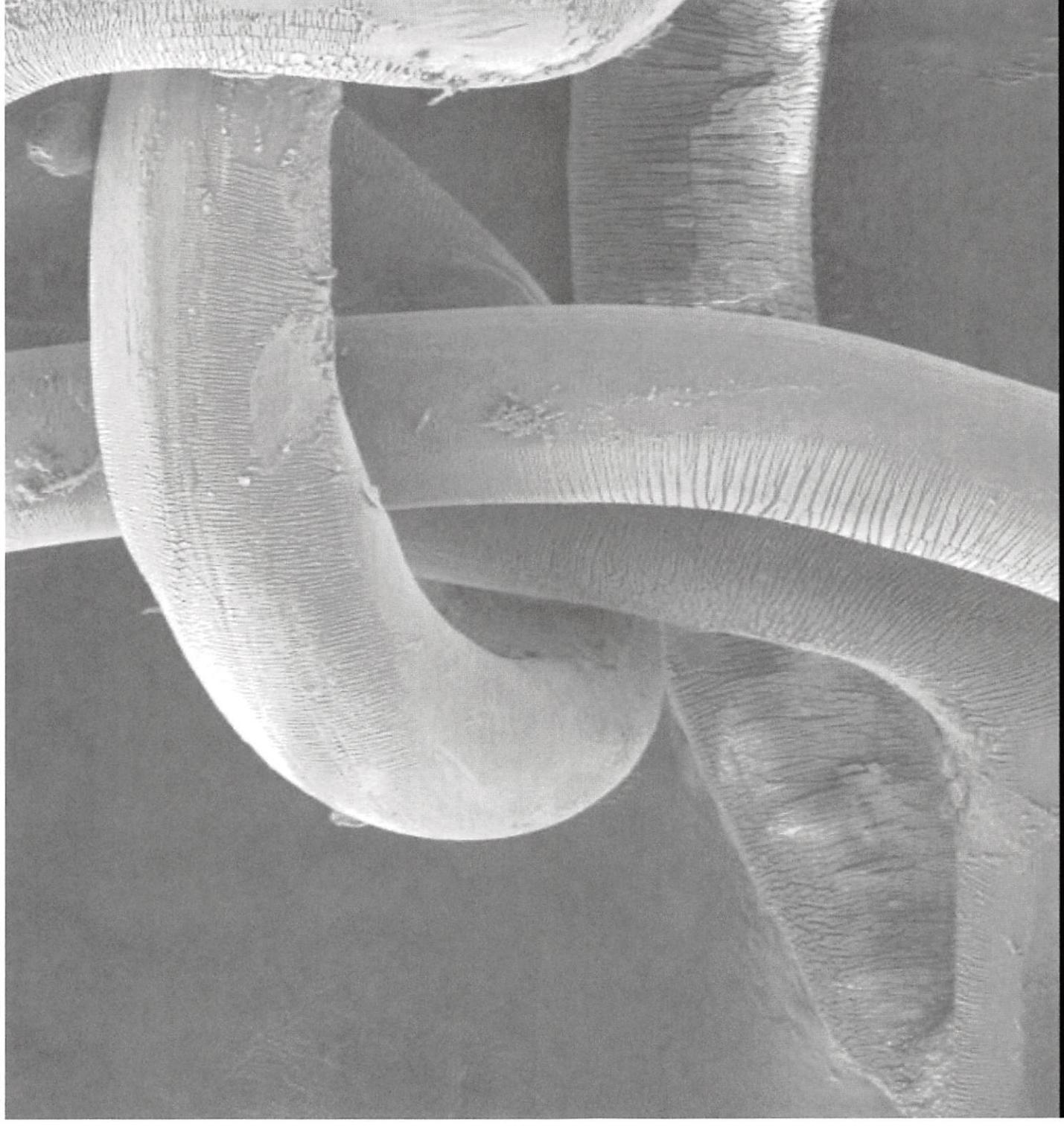




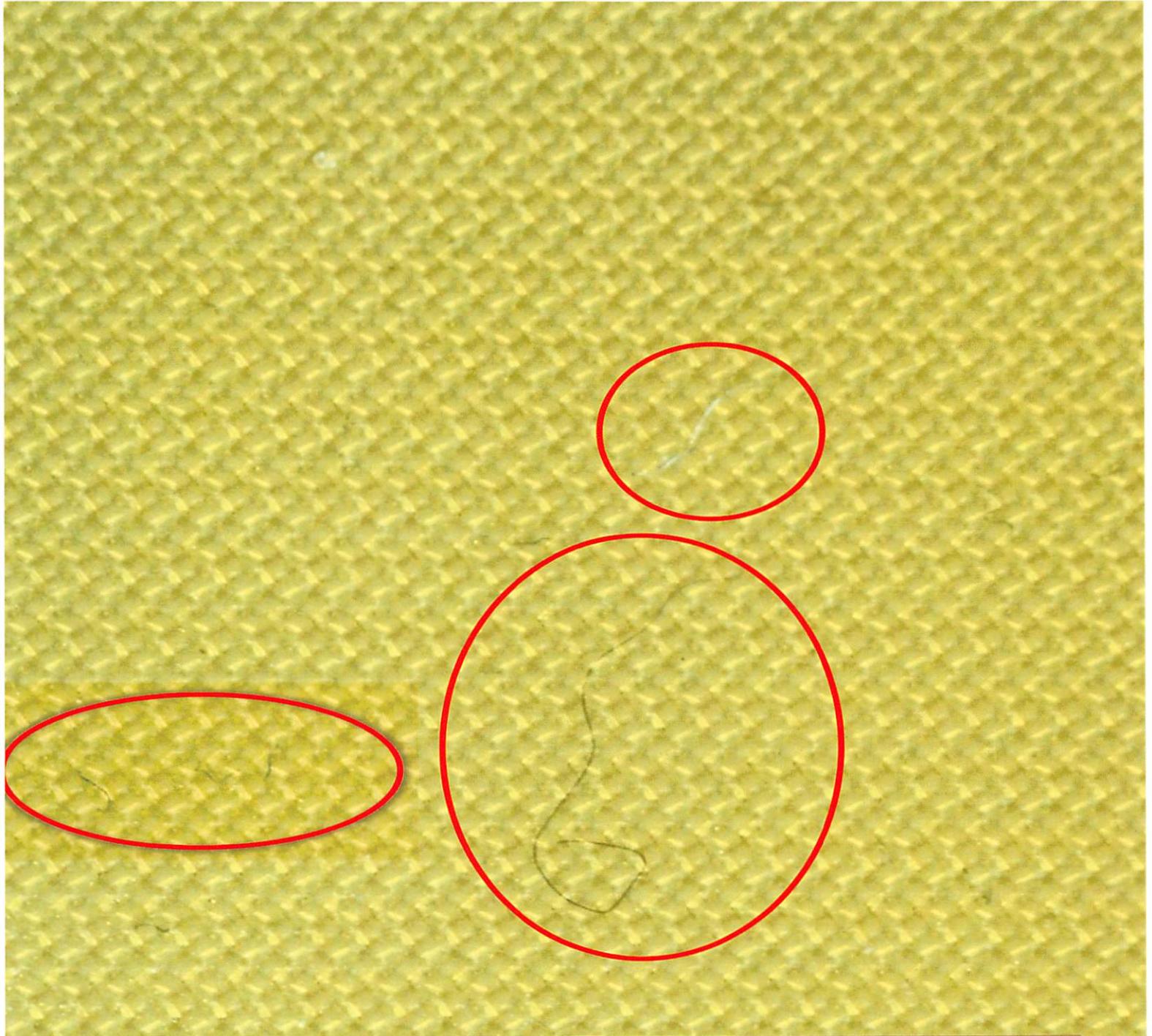


30(2)mesh 0.5kV 24.1 mm x150 SE(L) 7/19/06

300um



LEI 5.0kV X250 100µm WD 14.8mm



REF 31528 QTY 1  
 410445015  
 1719120821410445015

REF 31528  
 0100050862315288  
 (2)410445015  
 17191208

**C-QUR | MESH**  
 COATED POLYPROPYLENE MESH  
 10 cm x 15 cm  
 (4" x 6")

**C-QUR | MESH**  
 COATED POLYPROPYLENE MESH  
 10 cm x 15 cm  
 4 in. x 6 in.

**REF 31528**  
 15 cm x 11 cm  
 5" x 4 1/4"  
 0100050862315288  
 (2)410445015  
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# C-QUR Science Day

## Questions?

