



## TECHNICAL DATA REPORT

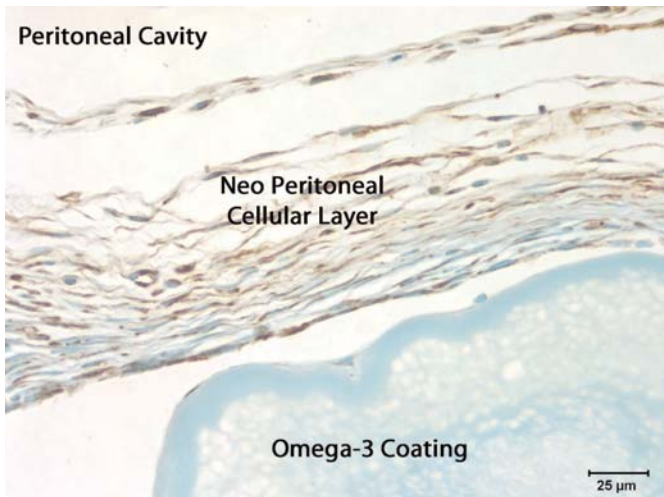
# What is Atrium's Omega 3 Coated Mesh and What Happens Following Implantation?



# What is Atrium's Omega 3 Coated Mesh and What Happens Following Implantation?

## Coating Technology

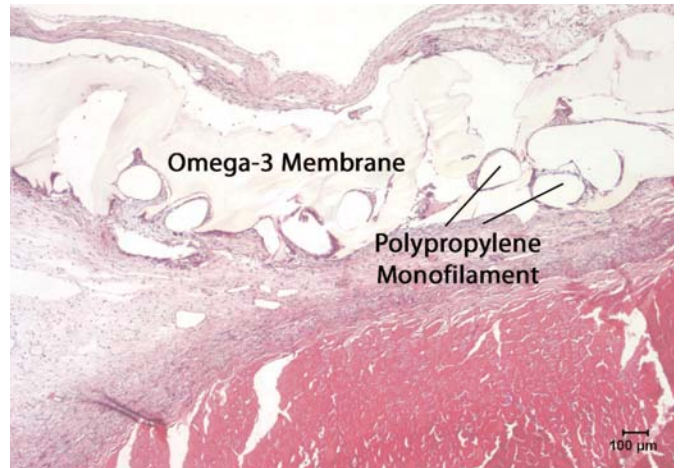
Atrium Medical Corporation has developed a novel coated mesh for intraperitoneal soft tissue repair. C-QUR™ Coated Mesh consists of a lightweight polypropylene mesh material coated with a bioabsorbable Omega 3 fatty acid cross-linked gel. The Omega 3 fatty acid material consists of a blend of mono-, di-, and triglycerides and fatty acids of various chain lengths. The fatty acid material is a highly



**Vimentin Stain**

purified pharmaceutical grade, free of contaminants and heavy metals. The Omega 3 fatty acid material is also free from all allergenic materials, such as proteins.

The Omega 3 fatty acid material is formed into the gel coating through a low temperature thermal cross-linking process that uses no



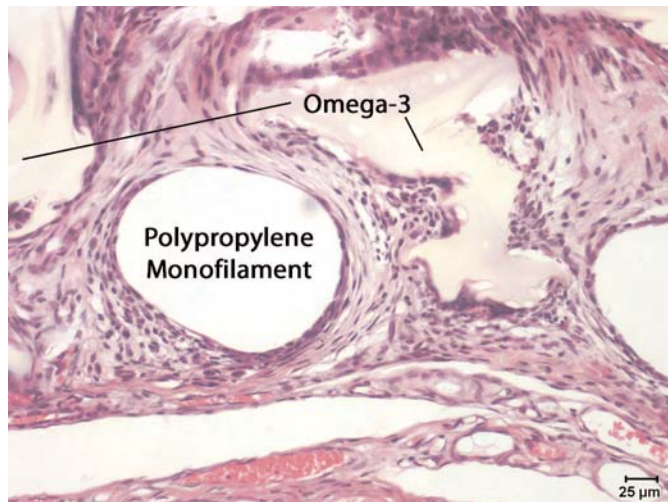
**H&E Stain**

chemical cross-linking agents. The coating completely covers the polypropylene monofilaments and creates a smooth film surface on one side of the mesh, providing a tissue separating layer between the polypropylene mesh and visceral cavity. The cross-linked fatty acid gel coating undergoes hydrolysis by body fluids and lipase enzymes in vivo, slowly cleaving the cross-linked bonds. The hydrolysis process converts the cross-linked gel material into naturally occurring fatty acids, fatty alcohols, and glycerides. These smaller components are readily absorbed by local tissue, and are consumed by normal lipid metabolism in the mitochondria of the cell for use in energy production. The bioabsorption of the coating material leaves lightweight polypropylene mesh behind as a permanent repair for the defect.

## What Happens to the Coating?

The semi-solid coating is carefully formulated to provide controlled incorporation and penetration of cellular remodeling as a soft tissue repair material. Animal studies have shown resorption of the coating occurring upon implantation and continuing over a 3 to 6 month period. The animal studies indicate that bio-resorption occurs with decreased inflammation as evidenced by decreased presence of mononuclear cells (morphologically characterized by macrophages and foreign body giant cells) and was consistently less intense when compared with other commercially available non-coated polypropylene mesh.

Excellent tissue incorporation was evident at all comparable time points to uncoated controls of Atrium ProLite™ and ProLite Ultra™ Mesh. In three different animal models (rabbit, pig and rat, hernia patch model, a subcutaneous implant model, an adipose implant model, a peritoneal wall implant model), C-QUR mesh has shown fibrotic tissue incorporation, specifically on the abdominal wall side of the implant. The same degree of incorporation and penetration in and around the polypropylene monofilaments was demonstrated by detailed histological evaluation and testing. This evidence of encapsulation and reinforcement, i.e. not retardation or lack of fibrotic attachment was advantageous in the animal model because it promoted wound defect buttressing and healing to the same degree as other commercially available products. At the same time there was consistent evidence of excellent tissue incorporation when placed as a patch, spanning an abdominal wall defect. Evidence of extensive mesothelial cell coverage was observed with concomitant reduction in peritoneal attachments. The promotion of a mesothelial lining is intended to act as a neo-peritoneum to minimize attachment of tissues and organs. This was adequately demonstrated in all ani-



***Lack of Inflammatory Response and Incorporation of Monofilament***

mal tests compared to non-coated controls.

The thin semi-solid layer of Omega 3 oil did not impede normal healing or incorporation in and around the individual polypropylene fibers. At the same time, it demonstrated a membrane or layering effect reducing inflammation and promoting a slip layer that formed on the peritoneal cavity side minimizing attachment of the organs and underlying viscera in the peritoneum.

There was no evidence demonstrating adverse events in these animal studies. It is expected that the C-QUR mesh will not impact adverse events which can occur in the human condition, such as malignancies, obstructions, abscess, fistulas, or other abdominopelvic conditions.

The enclosed histopathology pictures are incorporated by reference into this description to demonstrate the tissue attachment minimizing layer or membrane effect of the product as observed in preclinical studies.



## TECHNICAL DATA REPORT No. 010



**C·QUR™**  
MESH PRODUCTS

**ATRIUM MEDICAL CORPORATION**  
5 Wentworth Drive  
Hudson, New Hampshire 03051 U.S.A.  
☎ 603-880-1433 📠 603-880-6718

**ATRIUM EUROPE B.V.**  
Rendementsweg 20 B  
3641 SL Mijdrecht, The Netherlands  
☎ +31-297-230-420 📠 +31-297-282-653

**ATRIUM AUSTRALIA-PACIFIC RIM PTY. LTD.**  
L 1 Bridgepoint, 3 Brady Street  
Mosman NSW 2088 Australia  
☎ +61-2-9960-0169 📠 +61-2-8969-2735