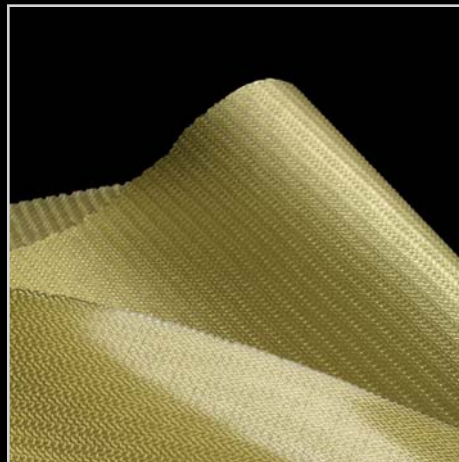


TECHNICAL DATA REPORT

**C-QUR™ Coated Mesh Products Pre-Clinical
Implant Studies Summary**



C-QUR™ Coated Mesh Products Pre-Clinical Implant Studies Summary

C-QUR™ Coated Mesh consists of a light-weight polypropylene mesh material coated with a bioabsorbable Omega 3 fatty acid cross-linked gel. The coating completely covers and encapsulates 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 thermally cross-linked fatty acid gel coating undergoes hydrolysis in-vivo, and is converted 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. C-QUR™ Coated Mesh received FDA approval in March 2006 with the following indications for use, and is currently in clinical use in the US:

"Atrium C-QUR™ Mesh is indicated 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."

C-QUR™ Coated Mesh is available in a wide range of sizes, configurations and preferred anatomical shapes to accommodate the needs of even the most challenging operating conditions.

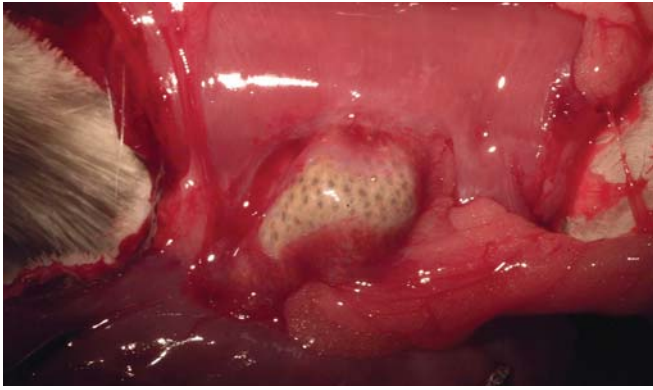
C-QUR™ Coated Mesh has been evaluated in several preclinical models prior to clinical use, with direct comparison to currently marketed

soft tissue reinforcement products, in addition to extensive testing to FDA and ISO 10993 standards for safety and biocompatibility. These models include two small animal full muscle wall defect repair models, as well as a rabbit open intact peritoneum placement. In all models, visceral tissue attachment and histopathology was assessed.

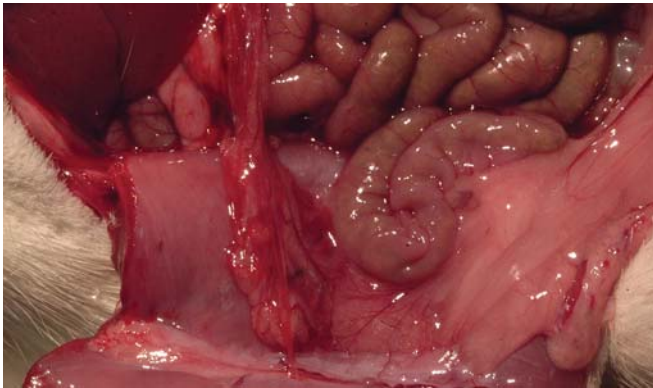
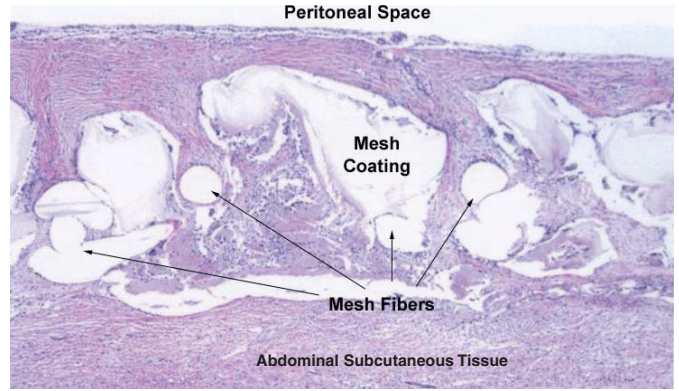
Small Animal Study #1

The first preclinical evaluation was performed using the well accepted rat model in an open surgical procedure to compare the healing and tissue attachment characteristics of Atrium C-QUR™ Coated Mesh to uncoated polypropylene mesh and Gore DualMesh® material. A full thickness abdominal wall defect was made by removing approximately 2cm x 3cm of muscle and fascia. The mesh samples were then implanted to repair the defect by suturing them over the defect site using 4-0 Prolene sutures. An overlap of mesh was placed over the defect to ensure proper repair, with the mesh samples being 2.5cm x 3.5cm in size. Suture knots were made on the abdominal wall side of the implant rather than the visceral side so as to not interfere with tissue attachment. The mesh was explanted at approximately 30 days. Five samples of each type were evaluated.

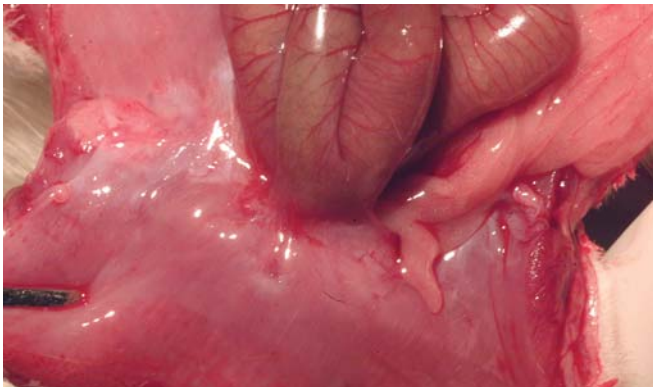
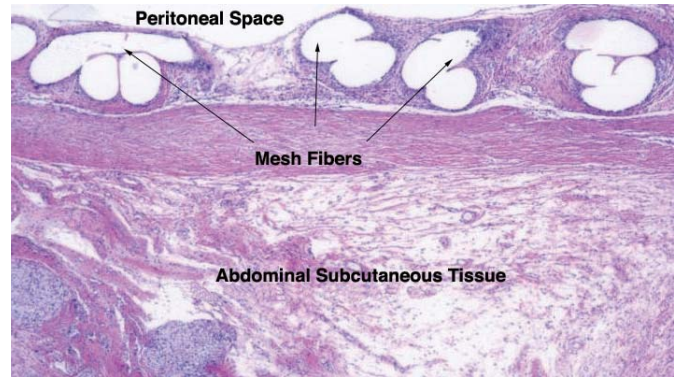
At gross explant, each mesh sample was graded for amount, type, and tenacity of tissue attachment, as well as for signs of infec-



C-QUR Coated Mesh



Uncoated Polypropylene Mesh



Gore DualMesh®

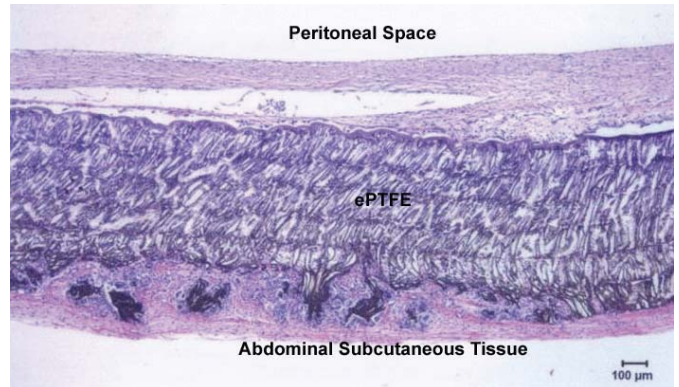


Figure 1

tion and other complications. Tissue samples were then placed in fixative, and slides were prepared for histology. See Figure 1.

Histological evaluation including inflammatory cell reaction and foreign body response was

performed in a blinded manner.

Upon gross examination, Atrium C-QUR™ Coated Mesh demonstrated similar or less tissue attachment with lower tenacity than the uncoated polypropylene mesh or Gore

DualMesh® controls on the side of the mesh exposed to the viscera. There was no evidence of infection or other complications seen with the test or control materials. Histological evaluation results indicated that C-QUR™ Coated Mesh had a lower inflammatory and foreign body response compared to either the uncoated polypropylene mesh or Gore DualMesh® materials, as also shown in Figure 2.

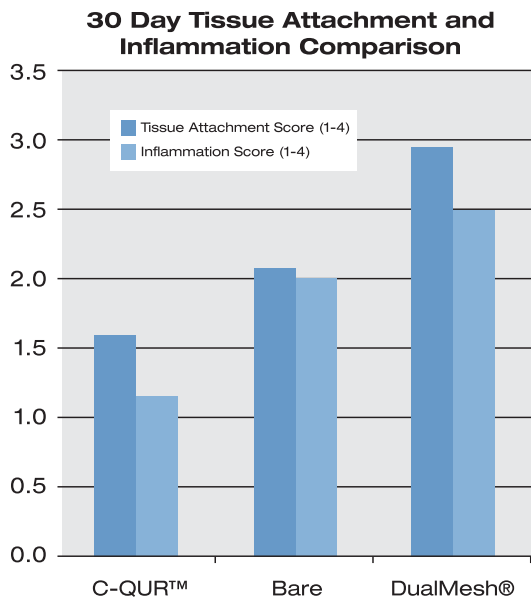


Figure 2

Small Animal Study #2

A second evaluation was conducted using a similar rat, full abdominal defect model, evaluating healing response and tissue attachment between Atrium C-QUR™ Coated Mesh and Atrium ProLite Ultra™ polypropylene mesh. Materials were explanted at 4, 7, 14, 21, and 28 days and evaluated for healing characteristics and tissue attachment. See Figure 3.

Histological assessment showed that by 28 days stable connective tissue had formed on the abdominal wall surface of both the uncoated control and the coated samples,

with a similar wound healing response at the various timepoints.

Gross assessment on the visceral surface at the various timepoints shows lower tissue attachment and tenacity at all timepoints with the Atrium C-QUR™ Coated Mesh samples as compared to the bare polypropylene mesh samples. This is illustrated in Figure 4.

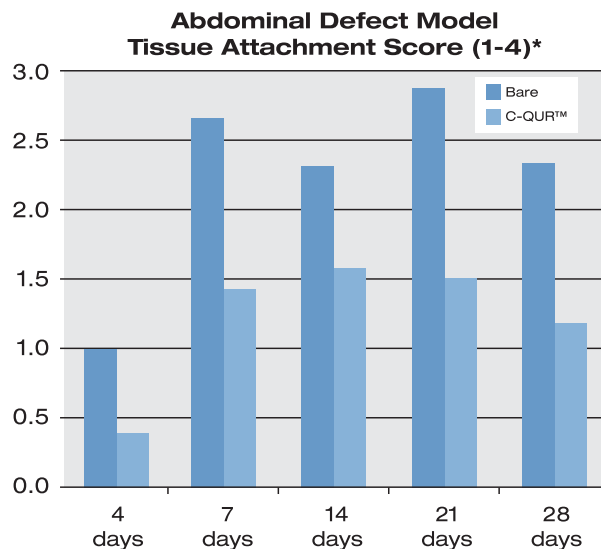
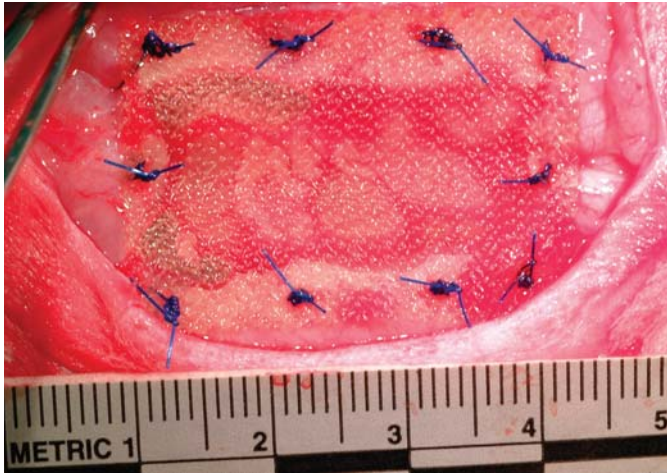


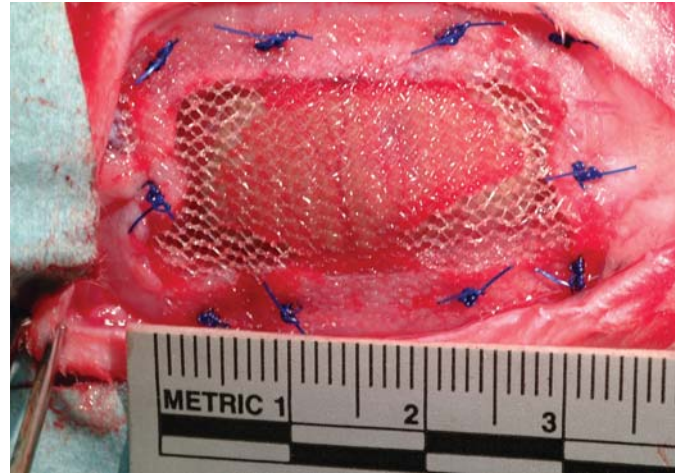
Figure 4

Rabbit Study

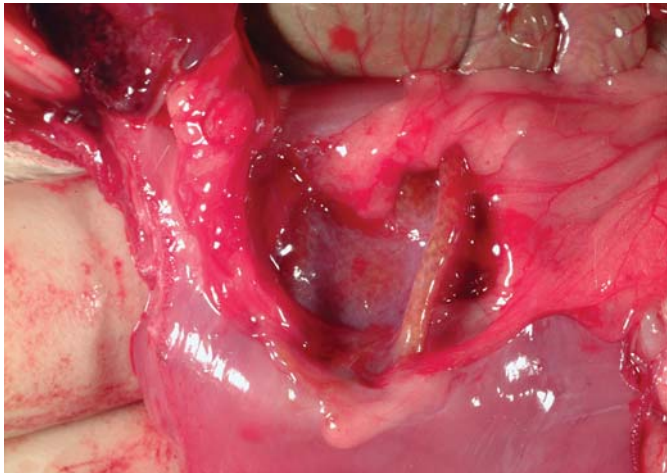
A third preclinical study conducted used a rabbit intact peritoneum model, simulating laparoscopic placement of the mesh. Atrium C-QUR™ Coated Mesh was compared to bare polypropylene mesh and several commercially available products commonly used for intraperitoneal hernia repair. The mesh products were implanted for 120 days, and upon explant were evaluated for extent of visceral tissue attachment, propensity of abdominal wall ingrowth, inflammatory response to the material, re-mesothelialization and formation of neoperitoneum, and degree of contraction. All mesh samples were implanted through a midline laparotomy with two pieces of 3cm x 3cm mesh being implanted per animal in a



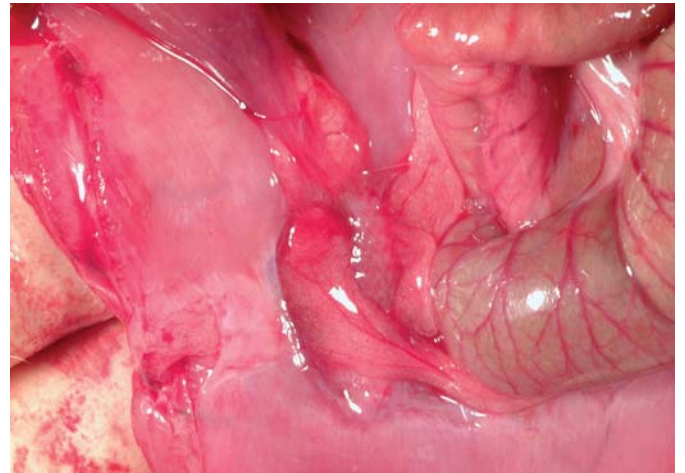
At Implant - C-QUR™



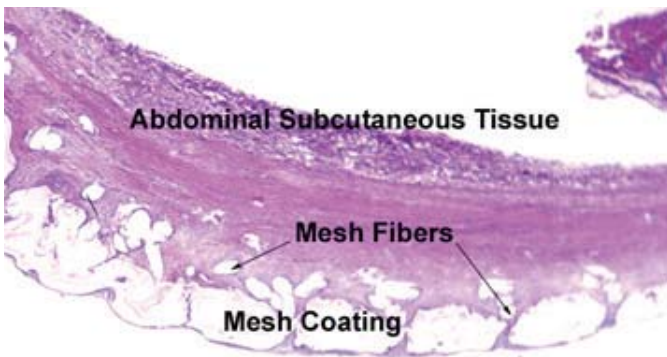
At Implant - Uncoated



28 Day - C-QUR™

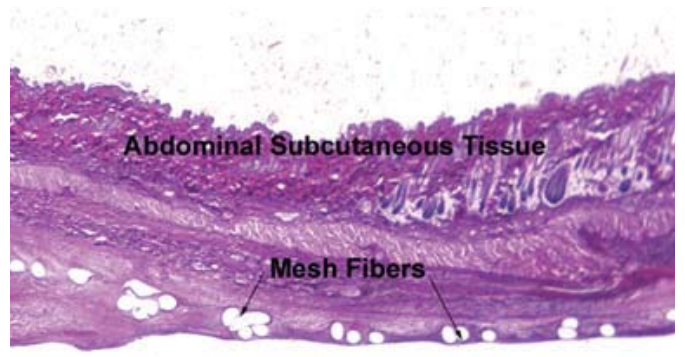


28 Day - Uncoated



Peritoneal Cavity

28 Day - C-QUR™



Peritoneal Cavity

28 Day - Uncoated

Figure 3

	Tissue Attachment Amount (%) 120 Days	Tissue Attachment Tenacity (1-4) 120 Days	Mesh Contraction (%) 120 Days
Atrium C-QUR™	3.0 ± 7.3	1.2 ± 0.4	3.3 ± 2.1
ProLite Ultra™	10.7 ± 19.8	1.7 ± 1.1	9.1 ± 8.3
Composix®	24.8 ± 37.0	1.9 ± 1.2	7.2 ± 7.1
DualMesh®	1.4 ± 4.4	1.3 ± 0.9	39.0 ± 6.0
Parietex®	0.8 ± 2.0	1.2 ± 0.4	14.7 ± 5.0
Proceed®	28.8 ± 16.1	2.8 ± 1.0	29.7 ± 12.5
Sepramesh®	0.0 ± 0.0	1.0 ± 0.0	6.4 ± 8.4

Table 1
Explant Tissue Attachment Scores*

Tenacity Scale (adapted from Garrard et al. (1999) Surgical Endoscopy 13: 10-13):

1- No tissue attachment; 2- Filmy tissue attachment, easily broken manually; 3- Dense tissue attachment requiring blunt dissection to separate viscera from mesh; 4- Very dense tissue attachment, viscera matted to mesh surface, requiring sharp dissection to separate viscera from mesh.

random fashion. Each mesh sample was secured using eight interrupted polypropylene sutures. At the time of explant, visceral attachment scores were assigned to each sample, graded by the amount of adhesion coverage (%) and tenacity of tissue attachment on a 1-4 grading scale. Mesh size was also recorded to determine degree of contraction from the original implant size. Table 1 shows the mean values for all mesh types studied and evaluated.

Histology was also evaluated for each mesh sample. Abdominal wall tissue incorporation, inflammatory response, mesothelialization, capsule formation, vascularization, and necrosis were evaluated and compared. All samples showed similar scores in all histological traits at 120 days, although C-QUR™ Coated Mesh trended lower in inflammatory response.

According to the study Principal Investigator,

“Given its comparable histologic characteristics, lack of intra-abdominal tissue attachment and propensity to retain its original implantation size, C-QUR™ Coated Mesh represents a viable alternative to numerous other meshes currently on the market for use in laparoscopic ventral hernia repair.”

Based on these preclinical models as well as extensive bench testing and various handling tests, Atrium's Omega 3 coated mesh performed as well as or better than currently marketed products for intraperitoneal hernia repair.

*Data on file at Atrium Medical Corporation.

TECHNICAL DATA REPORT No. 11



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