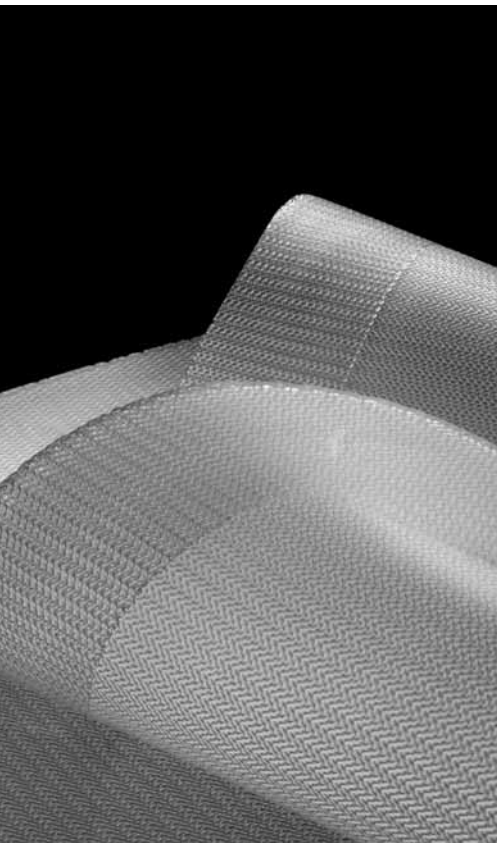




**C·QUR™**  
MESH

**PRODUCTS**



Instructions for Use

**GB Instructions For Use**

**Device Tracking Labels**

The enclosed Device Tracking Labels should be attached to the patient/hospital records.

**Description**

Atrium C-QUR™ Mesh products are sterile, knitted polypropylene monofilament mesh material for tissue reinforcement with a coating derived from a biological oil composed of fatty acids, lipids and glycerides (BAO - Bioabsorbable Oil Coating).

**Indications for Use**

Atrium C-QUR Mesh products are 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.

**Contraindications**

Atrium C-QUR Mesh products are contraindicated for use in infected wounds and in infants, children or pregnancy where future growth may be compromised by its use.

**Warnings**

1. Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.
2. Single Use - Do not sterilize.
3. Adequate mesh fixation is required to minimize post operative complications and recurrence. The fixation technique, method, and products used (including sutures, tacks, staples or other means) is left to the discretion of the surgeon to optimize clinical outcomes.
4. This device is supplied sterile. Please inspect packaging to ensure it is intact and not damaged prior to use.

**Precautions**

1. Please read all instructions prior to use.
2. Handling of mesh should be with clean sterile gloves and/or instruments.
3. Careful attention to surgical mesh handling, suture, staple, or tacker fixation is required in the presence of nerves and vessels in the surgical field.

**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.

**Preclinical Studies**

Pre-clinical in-vivo small animal studies were conducted to assess the rate of healing in tissue with sterilized 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.

**Handling & Operative Techniques**

The Atrium C-QUR Mesh must be removed from the handling sleeve using sterile technique prior to use.

Atrium C-QUR Mesh products should be shaped, sized and anchored taking into consideration the patient's posture, weight and anatomical location. In order to minimize anchor means disruption, the C-QUR Mesh should be sized and positioned so that it extends adequately beyond the margins of the defect.

Careful attention to suture/staple/tacker placement and spacing will help prevent excessive tension or disruption of the mesh material and/or underlying tissue. It is recommended that suture/staples/tackers be placed a minimum of 5 mm from the edge of the mesh for best results.

**Sterilization & Storage**

Atrium C-QUR Mesh is an ETO sterilized single use device; must not be re-sterilized. Store at 25°C (77°F) or less. Brief exposure up to 40°C (104°F) is acceptable.

**SYMBOLS USED ON PRODUCT LABELS**

**REF** CODE NUMBER **LOT** LOT NUMBER

**STERILE** **EO** STERILE. STERILIZED BY ETHYLENE OXIDE.

**!** SEE PACKAGE INSERT **⊗** SINGLE USE ONLY **⌚** EXPIRATION DATE

**Rx Only** PRESCRIPTION ONLY **DIM** DIMENSIONS

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- USA** BAO Coated Polypropylene Mesh
- GB** Treillis en polypropylène enduit d'huile bioabsorbable
- F** BAO-beschichtetes Polypropylen-Netz
- D** Malla de polipropileno revestida con aceite bioabsorbible
- E** Maglia in propilene rivestita di BAO
- I** Malha de rede de polipropileno revestida com óleo bioabsorvível
- P** Polypropyleen mesh met BAO-laag
- NL** BAO-belagt polypropylen net
- DK** BAO-belagt polypropylenät
- S** BAO-päälysteinen polypropyleeniverkko
- FIN** BAO-belagt polypropylenett
- N** Επικαλυμμένο πλέγμα πολυπροπυλενίου BAO
- GR** Polipropylenowa siatka powleczona olejem biochłanianym (BAO)
- PL** BAO コーティング済みポリプロピレンメッシュ
- J** BAO 涂层聚丙烯修补网
- CN**

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