Class 2 Device Recall CQUR Edge Mesh

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See Related Information[22]

Date Posted	August 09, 2013
Recall Status1	Open
Recall Number	Z-1937-2013
Recall Event ID	65698[23]
Premarket Notification 510(K) Number	K050311[24]
Product Classification	Mesh, Surgical, Polymeric[25] - **Product Code** FTL[26]
Product	C-QUR Edge Mesh (All sizes and shapes). Intended for use in soft tissue deficiencies.
Code Information	Product lines with lot number 10405513 and higher
Recalling Firm/ Manufacturer	Atrium Medical Corporation 5 Wentworth Dr Hudson, New Hampshire 03051-4929
For Additional Information Contact	same 603-880-1433
Manufacturer Reason	Additional Instructions for Use and Storage Conditions as Coated mesh can adhere to

for Recall	the inner packaging liner due to exposure to high humidity conditions
Action	Atrium Medical issued Recall Letter via UPS and e-mail on 7/19/13 to the accounts and field representatives. The notification identifies the problem, product, and risk factors. If the Product is exposed to excessive humidity for an extended period of time, then the increased humidity occurring inside the pouch can potentially cause the coating on the mesh to strongly adhere to the inner handling sleeve. A reply for is requested to be completed to acknowledge receipt to the notification. Additional language to the instructions for use (IFU) to include: Prolonged exposure to high humidity may result in increased rate of adherence of the C-QUR mesh to its handling sleeve. Store in a Controlled Room Temperature (25 C / 77 F) or less. Brief exposure to up to 40 C (104 F) is acceptable. Questions please contact Atrium Medical Customer Service at 1- 800-528-7486 Monday through Friday 9:00 am to 5:00 pm EDT.
Quantity in Commerce	1501 units
Distribution	USA (nationwide) including Puerto Rico and the countries of Australia Austria Bahrain Brazil Canada Chile Colombia Dominican Republic Ecuador El Salvador France Germany Great Britain Greece Honduras Hong Kong India Ireland Israel Italy Japan Jordan Korea Malaysia Mexico Netherlands New Zealand Nicaragua Norway Panama Peru Portugal Romania Saudi Arabia Singapore South Africa Spain Sri Lanka Switzerland Taiwan Thailand Turkey and Venezuela.
Total Product Life Cycle	TPLC Device Report[27]

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]

510(K) Database

510(K)s with Product Code = FTL and Original Applicant = ATRIUM MEDICAL CORP.[29]

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U.S. Food and Drug Administration
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