Class 2 Device Recall CQUR TacShield Mesh

See Related Information 22

Date Initiated by Firm	July 19, 2013
Date Posting Updated	August 09, 2013
Recall Status[1]	Terminated [3] on March 18, 2016
Recall Number	Z-1939-2013
Recall Event ID	65698[23]
510(K)Number	K100076[24]
Product Classification	Mesh, surgical, polymeric[25] - **Product Code** FTL[26]
Product	C-QUR TacShield 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 NH 03051-4929
For Additional Information Contact	same 603-880-1433
Manufacturer Reason for Recall	Additional Instructions for Use and Storage Conditions as Coated mesh can adhere to the inner packaging liner due to exposure to high humidity conditions
FDA Determined Cause [2]	Package design/selection
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	15,630 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] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29].

510(K) Database 510(K)s with Product Code = FTL and Original Applicant = ATRIUM MEDICAL CORP.[30]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=65698
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K100076
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=FTL
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=FTL

27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=FTL
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
30. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=FTL&knumber=&applicant=ATRIUM%20MEDICAL%20CORP%2E

Page Last Updated: 02/21/2017

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA