FDA Public Health Notification[1]: Counterfeit Polypropylene Mesh

Updated: May 7, 2004

Original Date: December 19, 2003

This is to alert you to our findings concerning a counterfeit mesh product labeled as PROLENE* polypropylene mesh.

Ethicon's Alert

PROLENE's* manufacturer, ETHICON, INC., issued an alert to healthcare professionals on the counterfeit polypropylene mesh on October 28, 2003. The counterfeit product is labeled with lot numbers RBE609 (expiration date JAN07) and RJJ130 (expiration date JUL07). This notification does not involve ETHICON's PROLENE* suture products.

FDA's Testing of the Counterfeit Product

FDA's testing of the counterfeit polypropylene mesh indicates that some samples are not sterile. At this time, we have not seen any elevation in the number of cases of infection related to the counterfeit mesh. We will continue to monitor our database for increased risk of infection associated with the counterfeit mesh.

Although FDA testing indicates that the counterfeit device has chemical and mechanical properties similar to other polypropylene mesh products currently on the market, the counterfeit products were manufactured in facilities that were not inspected by FDA. Therefore there is no assurance that these products were designed and manufactured according to FDA requirements.

Recommendations

If you suspect that counterfeit product was implanted in patients, we recommend that you continue to monitor them as you would any patient with a polypropylene mesh implant. Although we have not had reports of excess infections with the counterfeit product, we continue to be concerned about sterility issues.

We are continuing to investigate whether the counterfeit product is still being marketed. In the meantime, we recommend that physicians, nurses and other healthcare professionals carefully examine all polypropylene mesh products and not use any suspected of being counterfeit. If you think you have counterfeit product in your inventory, contact your distributor or local FDA office.

Identifying Counterfeit Product

PROLENE* mesh is a nonabsorbable polypropylene mesh (3" x 6") used in the repair of hernias and other fascial deficiencies. The company noted several characteristics of the counterfeit product that may help to distinguish it from genuine PROLENE*:

- A packaging seal that does not tear open smoothly,
- An additional small seal on top corner edges of the package,
- A fabric end that is jagged or not cleanly cut on the 3" side, and
- An ETHICON logo in a thicker than usual typeface.

For more information on identifying the counterfeit product, see http://www.ethicon.com/html/ethicon/notice.jsp?

Reporting Adverse Events to FDA

The FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices to the device manufacturer and/or the FDA. If you suspect that a reportable adverse event was related to the use of the counterfeit mesh, we request that you follow the procedures established by your facility for such mandatory reporting. Since this is a counterfeit product, there is no manufacturer. You will need to submit all of your reports directly to the FDA.

We also encourage you to report adverse events related to the counterfeit mesh that do not meet the requirements for mandatory reporting. You can report these directly to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch one of four ways: online at http://www.fda.gov/medwatch/report.htm by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787.

Getting More Information

Should you have questions regarding this notification, please contact Nancy Pressly, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. You may subscribe at http://list.nih.gov/archives/dev-alert.html.

Sincerely yours,

Daniel G. Schultz, MD
Acting Director
Center for Devices and Radiological Health
Food and Drug Administration

[1] CDRH Web Notifications are intended to augment the existing Safety Notification program by providing a mechanism to quickly disseminate device–related safety information that may be beneficial to healthcare providers. Unlike other forms of Notifications, such as Safety Alerts or Public Health Advisories, Web Notifications usually do not make specific recommendations and are typically used in situations where the available information and our understanding of an issue are still evolving.