

April 26, 2010

Encik Zamanee Bin Abdul Rahman
Medical Device Bureau
Ministry of Health Malaysia
Level 5, no 26 Boulevard Plot 3C4
Persiaran Perdana, Precint 3
62675 Putrajaya, Malaysia

RE: Expansion of 2008 Voluntary Recall

VICRYL RAPIDE* (polyglactin 910) Suture

Dear Sir,

This letter is to inform you that ETHICON has expanded the 2008 voluntary product recall of VICRYL RAPIDE* Suture to include six (6) additional lots of product as listed in Attachment 1.

Summary

The 2008 recall was initiated because ETHICON discovered a defect in the packaging of select suture lots produced during the May to June 2007 timeframe. This packaging defect could compromise the integrity of the primary seal which could lead to premature suture degradation and/or impair the sterile barrier of the product. As a result of a complaint report, ETHICON is expanding the recall to include all other lots of VICRYL RAPIDE* suture produced during the May to July 2007 timeframe.

Actions

We will notify all customers who has received the affected product to the use of any product with affected lot numbers immediately. The product code and the affected lot number identified listed on Attachment 1 will be removed from all inventories and returned to our distributor for destruction. VICRYL RAPIDE* suture product codes and lot numbers are printed on container boxes.

THIS RECALL EXPANSION ONLY IMPACTS THE VICRYL RAPIDE* SUTURE CODES AND LOT NUMBERS IDENTIFIED ON ATTACHMENT 1. VICRYL* and VICRYL* PLUS PRODUCT CODES ARE NOT INCLUDED IN THIS RECALL.

Communication of this Field Action

All our customers will be notified to return all recalled product to our distributor. Replacement product will be provided for all returned materials.

The Food and Drug Administration has been notified of this action.

Sincerely,



Ong Yean Ting
Johnson & Johnson Sdn Bhd, Medical Division
Regulatory Affairs Manager

Attachment 1

List of Recalled Product

Product Code	Lot #
XNV2920H	ZE8CZGR0
XNV4930H	ZE8GGMQ0
XNV4420H	ZE8HBPR0
XNV4420H	ZG8CJBR0
XNV4420H	ZG8DTHR0
XNV2920H	ZE8CZGR0

How to Identify Recalled Product



Product Code

Lot Number