

December 27, 2010

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

URGENT VOLUNTARY PRODUCT RECALL
ETHILON™ Suture,
ETHIBOND™ and MERSILENE™ Polyester Fiber SUTURES and MERSILK™ SUTURES,
MULTIPLE LOTS

Dear Sirs:

This letter is to inform you that ETHICON is voluntarily recalling multiple lots (see attachment 1) of **ETHILON™ (black, blue), ETHIBOND™, MERSILENE™ and MERSILK™ SUTURES.**

Summary

This action is being taken as a result of a potential defect in the packaging of select lots of these products produced during the September 2010 to December 2010 timeframe. This packaging defect could compromise the integrity of the primary seal on product packaging for the identified product codes/lots and we therefore cannot assure sterility of these products.

Actions

We have identified 3 affected lots imported into Malaysia as below (Total of 27 boxes). We will immediately quarantine any of the recalled products listed from our inventory

Item	Lot
W4843	CK2GCSS0
W748	CK2GMWS0
W4843	CK2BLKS0

NOTE: THIS RECALL ONLY IMPACTS THE Ethilon™ (black, blue), Ethibond™, Mersilene™ and Mersilk™ SUTURE CODES AND LOT NUMBERS IDENTIFIED IN ATTACHMENT 1 totaling one hundred and four (104) lots. OTHER 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 suture product codes and lot numbers are printed on container boxes.

ETHICON also confirms that this notice has been notified to the appropriate European Regulatory Agency.

Kind Regards



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

Attachment 1: List of recalled products

Sales code	Lot #	Sales code	Lot #	Sales code	Lot #
18533G	CK2DDWN0	F2416	CL2CGTR0	W319	CL2DHHQ0
18537G	CM2CBGN0	F2417	CK2BMJR0	W320	CK2BMBQ0
611H	CM2BLHR0	F2417	CL2CKXR0	W320	CK2CTDQ0
623H	CK2GKJN0	F2417	CM2CCLR0	W320	CK2CZCQ0
624H	CM2CGZN0	F2418	CL2BRQR0	W320	CK2DDQQ0
6522H	CL2DKHN0	F2419	CK2DXPR0	W320	CL2BXGQ0
660H	CK2BTWR0	F2419	CK2GCDR0	W4843	CK2BLKS0
663H	CL2BKHR0	F2420	CK2DSMR0	W4843	CK2CJQS0
663H	CL2BKJR0	F2420	CL2DPDR0	W4843	CK2CLSS0
663H	CL2GCBR0	F2435	CK2BXXR0	W4843	CK2GCSS0
664H	CK2BMGR0	F2435	CL2BWCR0	W526	CK2CTGQ0
669H	CL2BWLR0	F2445	CK2BDQS0	W568	CM2BSGR0
869G	CL2DKBN0	F2521	CL2CMWH0	W6761	CK2CBLN0
B976H	CL2CMZN0	F2526	CL2BHJH0	W6767	CL2BHXN0
EH7012H	CK2CHJQ0	F2541	CK2CJZH0	W6977	CK2DPKN0
EH7113H	CK2DDBQ0	F2541	CK2CRZH0	W6977	CL2BTBN0
EH7143H	CK2CZHQ0	F3216	CM2BRWQ0	W737	CK2BMLR0
EH7143H	CK2DXJQ0	F3221	CK2GJDQ0	W737	CL2CXJR0
EH7271H	CK2DSQQ0	F3222	CL2CWTQ0	W745	CM2BCLR0
EH7506H	CL2CXDR0	F3227	CK2GHZQ0	W748	CK2GMWS0
EH7724H	CK2DJMN0	MIC253H	CL2CJBN0	W749	CM2BQLS0
EH7792H	CL2DHKQ0	P662H	CL2BPBR0	W768	CL2DHTS0
EH7794H	CK2DDCQ0	P662H	CL2DHLR0	W776	CK2CDKQ0
EH7794H	CK2GRJQ0	P680H	CK2CHPR0	W786	CK2DLHQ0
EH7795H	CK2CHRQ0	W1616T	CK2CZDQ0	W786	CL2CPPQ0
EH7795H	CK2CLBQ0	W1616T	CL2CKZQ0	W795	CL2CGKS9
EH7795H	CL2BRRQ0	W1620T	CK2GBWQ0	W798	CL2DWSS9
EH7796H	CM2BZLQ0	W1621T	CK2DLQ0	X31034	CK2DPGN0
EH7798H	CK2CHLQ0	W1621T	CK2GRBQ0	X32071	CL2DGBN0
EH7825H	CK2BTKQ0	W1621T	CK2GRCQ0	X32081	CM2BCPS0
EH7825H	CL2CKPQ0	W1625T	CK2DSLQ0	EPK4802	CM8DWHZ0
EW319	CK2DCWQ0	W1625T	CK2GMDQ0	EPK275	CL8LCLZ0
EW661	CK2DDGQ0	W1626T	CL2BMZQ0	EPK4268	CM8JGZZ0
EW776	CL2BRWQ0	W1632T	CM2CZGQ0		
EW788	CK2DLMQ0	W1675	CK2CCXQ0		
F2413	CK2BZHR0	W1685T	CK2DXKQ0		
F2415	CL2BXLR0	W1851T	CK2CLHR0		