URGENT: MEDICAL DEVICE CORRECTION (Notification)
ETHICON MERSILENE™ TAPE
(Twelve (12) Product Codes, All Unexpired Lots)

04th Aug 2016

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

At Ethicon, Inc. ("Ethicon"), our first priority is to our customers and their patients, and that includes the safe and effective use of our products.

We have initiated a worldwide medical device correction (notification) for unexpired lots of select ETHICON MERSILENE™ Tape (also referred to as MERSILENE™ Polyester Fiber Strip or MERSILENE™ Fiber Ligature) products as we discovered that a group of MERSILENE™ Tape product codes are being supplied with an incorrect Instructions for Use (IFU) insert. The product codes subject to this correction are being supplied with a MERSILENE™ Suture IFU. The indications for MERSILENE™ Suture are different from the indications for MERSILENE™ Tape.

This medical device correction letter is to notify you of the correct IFU belonging to the MERSILENE™ Tape device. Please refer to **Attachment 1** for the correct MERSILENE™ Tape IFU.

Corrective actions are currently being implemented to include the correct MERSILENE™ Tape IFU with future shipments of MERSILENE™ Tape products. There is no anticipated supply disruption for this product. This letter serves as an immediate correction to provide you with the correct MERSILENE™ Tape IFU.

Ethicon has not received any complaints or reports of Adverse Events related to this correction.

The scope of this correction includes the product codes of ETHICON MERSILENE™ Tape listed below in Table A.

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE ANY OF THE FOLLOWING PRODUCT CODES prior to thoroughly reading and adhering to the actions required below. The products subject to this correction can be used in accordance with the correct IFU included within this letter (Attachment 1):

Table A – Product Subject to this Correction

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT
MERSILENE™	RS20	All Unexpired Lots
MERSILENE™	RS21	All Unexpired Lots
MERSILENE™	RS22	All Unexpired Lots

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MERSILENE™	RS23	All Unexpired Lots
MERSILENE™	D10076	All Unexpired Lots
PRODUCT NAME	**PRODUCT CODE**	**PRODUCT LOT**
MERSILENE™	D10117	All Unexpired Lots
MERSILENE™	D5789	All Unexpired Lots
MERSILENE™	D7164	All Unexpired Lots
MERSILENE™	D8014	All Unexpired Lots
MERSILENE™	D8062	All Unexpired Lots
MERSILENE™	D8113	All Unexpired Lots
MERSILENE™	D9212	All Unexpired Lots

IDENTIFICATION OF PRODUCT SUBJECT TO THIS CORRECTION:

Product subject to this correction in your inventory can be identified by product code (see product code listing above in Table A). All unused (unexpired) ETHICON MERSILENE™ Tape products, listed in Table A, are subject to this correction and are required to be accompanied with the correct IFU included within this correction letter (Attachment 1).

The product codes can be determined by using the Product Identification Tool found in Attachment 2.

ACTIONS REQUIRED FROM YOU

1. Examine your inventory immediately to determine if you have product subject to this correction on hand and locate such product(s). Refer to **Attachment 2** for the Product Identification Tool to identify the products that are subject to this correction by using package labels.

2. Please read **Attachment 1** included within this letter thoroughly - “MERSILENE™ Tape Instructions for Use (IFU)”.

3. Ensure all users are aware of the issue by distributing this notice to all users of the Ethicon MERSILENE™ Tape devices in your facility.

4. Replace the existing incorrect MERSILENE™ Suture Instructions for Use (IFU) with the MERSILENE™Tape Instructions for Use (IFU) provided in Attachment 1 and dispose of the incorrect MERSILENE™ Suture Instructions for Use (IFU) per your internal procedures.

5. Complete the Customer Acknowledgement Form confirming receipt of this notice within two (2) business days and return the Customer Acknowledgement Form to your Ethicon sales representative or fax it to 67200750. Please return the Customer Acknowledgement Form **even if you do not have product subject to this correction.**

6. Keep this notice visibly posted with product subject to this correction in your facility for awareness.

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Health care practitioners that have treated patients using ETHICON MERSILENE™ Tape should continue to follow those patients in the usual manner.

This worldwide medical device correction (notification) has been communicated to the U.S. Food and Drug Administration (FDA).

We recognize that this correction for the ETHICON MERSILENE™ Tape may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this correction or to report any customer complaints, please contact your Ethicon Sales Representative.

Thank you for your attention and cooperation.

Yours sincerely,

Lee Ching Hwee

Associate Manager Regulatory Affairs

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ATTACHMENT 1: MERSILENE™ Tape Instructions for Use (IFU)

DESCRIPTION
MERSILENE™ Tapes are white (undyed) flat woven polyester tapes (polyethylene terephthalate) with the formula $(C_{10}H_8O_4)_n$. MERSILENE™ Tapes are available in various widths and lengths, non-needled or attached to stainless steel needles.

INDICATIONS
MERSILENE™ Tape is indicated for circular suture of the cervix. Non-needled tapes are used as retraction and/or fixing tape during surgery.

APPLICATION
After incision of the anterior and posterior cervical mucosa, the MERSILENE™ Tape is passed from the left and right underneath the mucosa by means of both blunt point needles so that the ligature encircles the entire cervix.
The MERSILENE™ Tape is tied into a knot and pulled tight in order to close the incompetent cervix. If necessary, the ligature can be sutured to the cervix. Non-needled MERSILENE™ Tapes are used for temporary retraction and/or fixing of organs or parts of organs (e.g., intestine) during an operation. After completion of the operation, the tapes are removed and disposed.

PERFORMANCE
Cervical cerclage during the second trimester of pregnancy can be achieved by a ligature for the remaining period of pregnancy. At term, the tape can be cut, thereby removing the ligature. Because of its flat woven structure, MERSILENE™ Tape is appropriate for retraction of organs and parts of organs without injuring the tissue involved.

CONTRAINDICATIONS
None known.

WARNINGS/PRECAUTIONS/INTERACTIONS
Although MERSILENE™ Tapes are well-tolerated by the body, the tape should be removed after Caesarean section to avoid erosion of neighboring tissues and organs (e.g., bladder). Acceptable surgical practice should be followed for the management of infected/contaminated wounds.

Care should be taken to avoid damage when handling surgical needles of armed MERSILENE™ Tape. Grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in “Sharps” containers. Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.

ADVERSE REACTIONS
Like all foreign bodies, MERSILENE™ Tape may potentiate an existing infection. Potential adverse reactions are those typically associated with surgically implantable materials, which include chronic inflammatory foreign body reaction, seroma formation, infection potentiation, adhesion and/or fistula formation and extrusion.

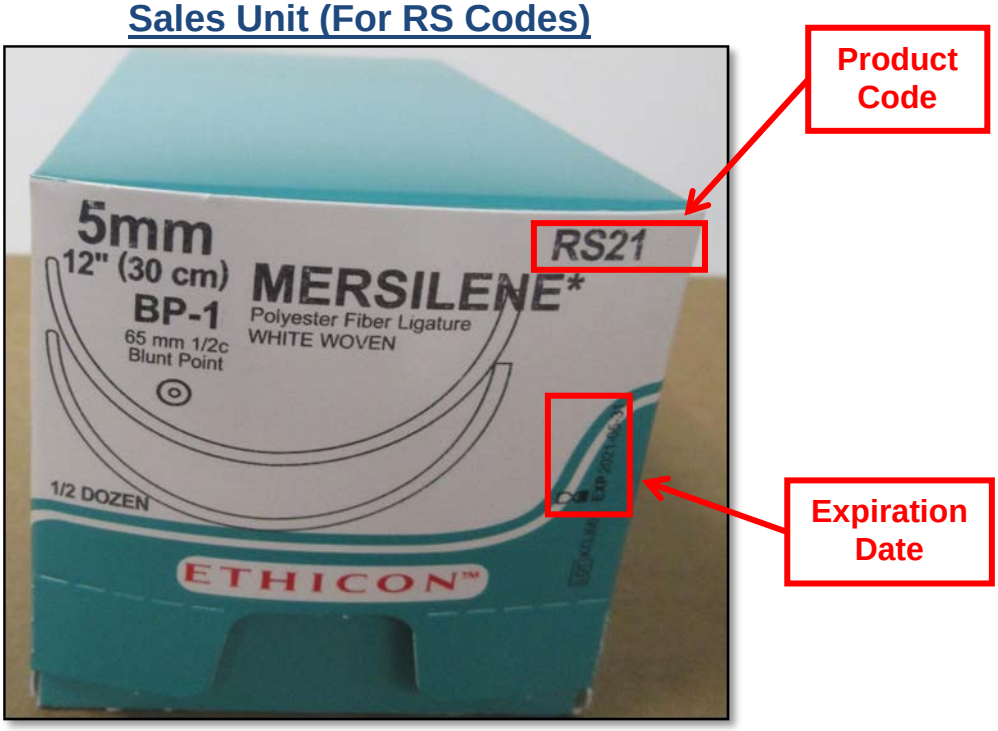
STERILITY
MERSILENE™ Tapes are sterilized by irradiation. Do not resterilize. Do not use if package is opened or damaged. Discard open, unused product.

STORAGE
No special storage conditions required. Do not use after expiry date.

ATTACHMENT 2: Product Identification Tool for ETHICON MERSILENE™ Tape (Twelve (12) Product Codes, All Unexpired Lots)

This tool will help customers identify the products subject to this correction by using the packaging labels. This document applies to the Foil Pouch/Tyvek and Sales Unit Graphics for the product codes identified in **Table A** of this correction letter.

Sales Unit (For RS Codes)



Foil Pouch/Tyvek (For RS Codes)

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Sales Unit (For D Special Codes)

Foil Pouch/Tyvek (For D Special Codes)

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