

URGENT: FIELD SAFETY NOTICE
ETHICON Temporary Cardiac Pacing Wire Product Codes
TPW10 and TPW30

September 3, 2015

Dear Operating Room Supervisors, Materials Management Personnel and Chief of Surgery:

ETHICON has initiated a voluntary recall for **select lots** of **ETHICON Temporary Cardiac Pacing Wire** (Product Codes TPW10 and TPW30)(the Temporary Cardiac Pacing Wires). The Temporary Cardiac Pacing Wires provided in these product codes do not reflect the product labeling requirements under Medical Device Directive for CE Marked Product. This voluntary product recall (removal) is being executed because the content of the labeling and associated Instructions For Use for these lots of affected product are not in accordance with the approved documentation, do not contain a CE mark and do not contain the applicable translations. The lack of this information does not present a clinical risk.

EFFECTIVE IMMEDIATELY – DO NOT USE PRODUCT CODE TPW10 or TPW30 WITH PRODUCT LOTS NOTED BELOW:

Device Name	Product Code	Product Lot	Date of Manufacture	Affected Expiry Date
ETHICON Temporary Cardiac Pacing Wire	TPW10	HGE933	16-Jun-14	31-Jan-19
		HGP061	17-Jun-14	31-Jan-19
		HJP291	18-Aug-14	31-Jul-19
		HKH299	27-Sep-14	31-Jul-19
	TPW30	HCP809	22-Mar-14	31-Jan-19
		GJR342	28-Aug-13	31-Jul-18

Please see **Attachment A** for a Product Identification Tool to assist in identifying the impacted lots of product using package labels.

PLEASE NOTE: This recall involves only the specified lots listed above of ETHICON Temporary Cardiac Pacing Wire Product Code TPW10 and TPW30. No other product lots are affected. This recall is only in effect for EU countries who require the CE Marked version of this product.

The voluntary recall has been communicated to the European Competent Authorities in the countries affected by this product recall.

ETHICON has received no reports of adverse events associated with the affected product.

Voluntary Recall of ETHICON Temporary Pacing Wire Product Code TPW10

URGENT FIELD SAFETY NOTICE

ETHICON Temporary Pacing Wire

Product Code TPW10 and TPW30

Action Needed:

1. Examine your inventory immediately to determine if you have recalled product on hand. **Remove and quarantine** the recalled product and communicate the issue to relevant operating room or materials management personnel or anyone else in your facility who needs to be informed.
2. If any product included in this recall has been forwarded to another facility, contact that facility to arrange return.
3. Complete the Business Reply Form (BRF) (**Attachment B**) confirming receipt of this notice within three (3) business days. The BRF may be sent to [enter local Affiliate or Sales Representatives Email Address, Fax number]. Please return the BRF **even if you do not have affected product**.
4. Keep this notice visibly posted for awareness with or near all product listed above until all such product has been returned to ETHICON. While processing your returns, please maintain a copy of this notice with the affected product and keep a copy for your records
5. Credit is available for customers who return affected product.
 - All affected product must be returned immediately. Any product returned after February 28, 2016 will not be eligible for credit.
 - To return affected product, photocopy the completed BRF, place it in the box with the product, and return the product to your Sales Representative.
6. For help to identify an alternative product code, please speak directly with your Sales Representative.

If you need clinical or product support, please contact your local Sales Representative or ETHICON.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported your Sales Representative, directly to ETHICON, or your National Health Authority.

If you have any further question related to this notice or if you need an additional communications letter, please contact your Sales Representative.

Attachments:

Attachment A: Product Identification Tool

Attachment B: Business Reply Form

URGENT FIELD SAFETY NOTICE ETHICON Temporary Pacing Wire Product Code TPW10 and TPW30

ATTACHMENT A: Product Identification Tool

ETHICON Temporary Cardiac Pacing Wire Product Code TPW10 and TPW30

This tool will help customers identify the impacted lots of product using package labels. This document applies to the box labels and packaging for product code TPW10 and TPW30.

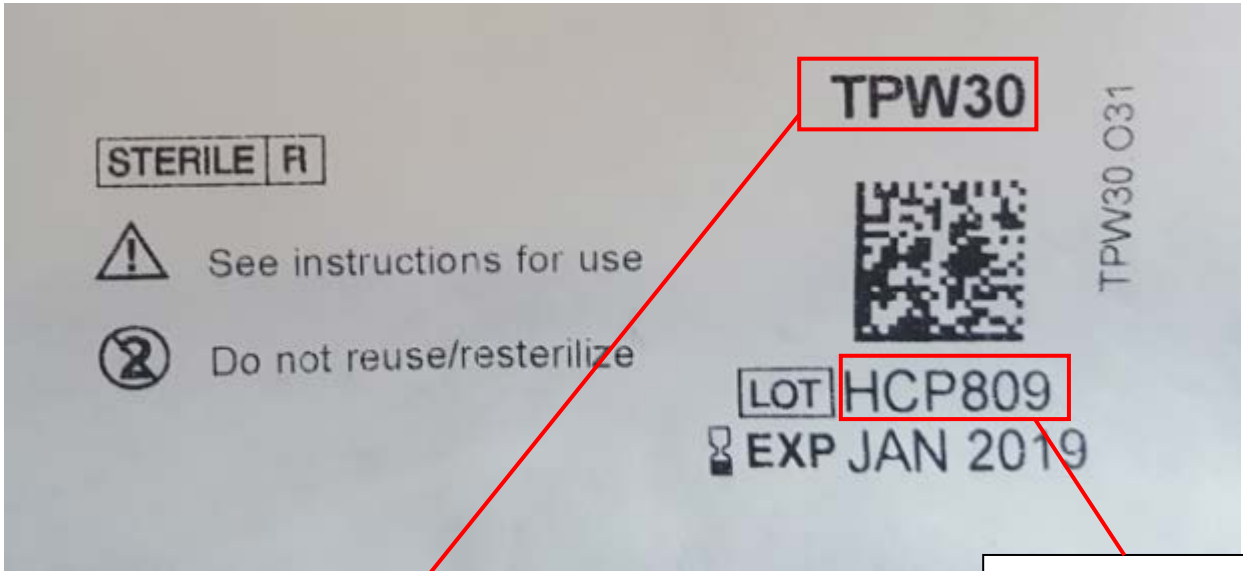
Product Code TPW30 is used as the example.

Example of Graphics on Box



URGENT FIELD SAFETY NOTICE
ETHICON Temporary Pacing Wire
Product Code TPW10 and TPW30

Example of Graphics on Package



Product Code

Lot Number



URGENT FIELD SAFETY NOTICE
ETHICON Temporary Pacing Wire
Product Code TPW10 and TPW30

ATTACHMENT B: Business Reply Form

Please confirm that you have received the FIELD SAFETY NOTICE regarding the product recall of **ETHICON Temporary Cardiac Pacing Wire Product Code TPW10 or TPW30**. Your timely response to this notification is requested. Please complete and fax/e-mail this form to [Local Affiliate, Email Address, Fax number] within 3 business days, even if you do not have product to return.

If you have **ETHICON Temporary Cardiac Pacing Wire** devices to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

Product Inventory – please check one

- We have no affected ETHICON Temporary Cardiac Pacing Wire devices for return.
- We have affected ETHICON Temporary Cardiac Pacing Wire devices and are returning the following devices:

Device Name	Product Code	Product Lot	Date of Manufacture	Affected Expiry Date	Quantity Returning
ETHICON Temporary Cardiac Pacing Wire	TPW10	HGE933	16-Jun-14	31-Jan-19	
		HGP061	17-Jun-14	31-Jan-19	
		HJP291	18-Aug-14	31-Jul-19	
		HKH299	27-Sep-14	31-Jul-19	
	TPW30	HCP809	22-Mar-14	31-Jan-19	
		GJR342	28-Aug-13	31-Jul-18	

Facility Name:	Street Address:	City, Country, Postal Code:

Print Name of Person Completing Business Reply Form:	Telephone Number:
Customer Number if Applicable:	Date:
Signed*:	
<small>*Your signature provides confirmation that you have received and understood this notification</small>	
Your comments are welcome.	