



**FIELD SAFETY NOTICE**  
**VOLUNTARY PRODUCT RECALL**

July 31, 2014

Dear Chief of Surgery, Risk Manager, Materials Management Personnel and Chief Executive Officer (CEO),

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY  
WHO USE ETHICON Morcellation Devices**

This is to inform you of a voluntary product recall involving:

**ETHICON Morcellation Devices including Generators and Disposables**  
**Product Codes MX0100, MX0200, MX0100R, MX0200R, DV0015, DV0025, MD0100,**  
**MD0200, MD0140, MD0120**

At Ethicon, Inc. (ETHICON) our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products.

As an expansion of our April 2014 global commercial suspension, Ethicon is initiating a worldwide voluntary product recall of all Ethicon Morcellation Devices that currently remain in the market.

On July 10-11, 2014, the U.S. Food and Drug Administration's (FDA) Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee met to evaluate the risks and benefits of the use of laparoscopic power morcellators during minimally invasive hysterectomy for symptomatic uterine fibroids and myomectomy. The discussion at this meeting demonstrated the complexity of this issue, particularly with respect to:

- The difficulty for medical professionals to preoperatively diagnose some malignancies, such as leiomyosarcoma
- The risk of disseminating unsuspected malignant tissue while using power morcellation devices
- Methods to mitigate this risk.

We believe Ethicon Morcellation Devices perform as intended and there are patients who can benefit from procedures using laparoscopic power morcellators, but the risk-benefit assessment associated with the use of these devices in hysterectomy and myomectomy procedures for removing fibroids remains uncertain. Because of this uncertainty, Ethicon believes that a product recall of Ethicon Morcellation Devices is the appropriate course of action at this time until further medical guidelines are established and/or new technologies are developed to mitigate the risk. The FDA and EU National Competent Authorities have been notified of this letter.



**Actions requested on your part:**

1. Immediately review inventory to determine if you have any Ethicon Morcellation Devices which are the subject of this product recall.
2. If you have provided Ethicon Morcellation Devices to any hospital within your system, you are responsible for notifying the appropriate parties immediately.
3. Complete the Business Reply Form (BRF) Attachment A and provide a copy to [Local Affiliate or Sales Representatives Email Address, Fax number] within 3 business days of receipt **even if you do not have product to return**. If you have product to be returned, keep a copy of this form for your records.
4. If you do not have Ethicon Morcellation Devices (generators and devices) in your inventory, you should still complete and return the Business Reply Form, indicating you have no affected product.
5. Please share this information with all of the appropriate staff at your facility.

**Prorated credit will be issued for purchased generators returned by December 30, 2014. Full credit will be issued for unopened, unexpired disposables.** Any product returned after December 30, 2014 will not be eligible for credit. To return affected product, photocopy your completed Business Reply Form, place it in the box with your product, and return the product to your Sales Representative.

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

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

Thank you for your attention and cooperation.

Sincerely,

Ethicon, Inc.

**ATTACHMENT A:** Business Reply Form (BRF)