ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT : MEDICAL DEVICE MARKET WITHDRAWAL

July 30, 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 market withdrawal 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 market withdrawal 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 market withdrawal 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 has 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 market withdrawal.

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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 fax or email it to Stericycle at **1-855-695-8527 or Ethicon6331@stericycle.com within 3 business days, even if you do not have product to return.** Please reference **Event 6331**. If you have product to be returned, keep a copy of this form for your records. A unique JJHCS number has been pre-populated on the BRF.

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 affix the pre-printed UPS shipping label to return to Stericycle.

As with any medical device, adverse reactions or quality issues experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: Use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm
- Mail to: MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787; or Fax to: 1-800-FDA-0178

If you have any questions related to this notice, please contact our Customer Support Center, 1-877-ETHICON (877-384-4266). If you need an additional communications letter, contact the Stericycle support center at 1-855-827-6584 and reference **Event 6331**.

Thank you for your attention and cooperation.

Sincerely,

Ethicon, Inc.

ATTACHMENT A: Business Reply Form (BRF)