Urgent: Field Safety Notice

ConMed Corporation VCARE® Vaginal-Cervical Ahluwalia's Retractor-Elevator

February 15, 2011

Dear Customer:

ConMed Corporation is sending this communication to provide you with important information concerning the Instructions for Use (IFU) for the VCARE® Vaginal-Cervical Ahluwalia's Retractor-Elevator uterine manipulators. This communication does not apply to ConMed's VCareDX device.

Please review your inventory of **VCARE®** devices for any of the following catalog numbers:

- **60-6085-100**
- **60-6085-101**
- **60-6085-102**

Please place a copy of the enclosed Instructions for Use, Part No. 14071 (Rev. A), with any inventory in your possession with an expiration date **prior to** August 2011 (2011-08). Please dispose of any other Instructions for Use in your possession. A copy of the enclosed Instructions for Use is already packaged with all devices bearing later expiration dates. Any inventory in your possession with an expiration date prior to January 2011 (2011-01) is expired and should not be used.

If you have provided these devices to other facilities or distributors, or you are a distributor, please forward this information as appropriate. It is imperative that all end users of these devices receive this notice.

The IFU changes are as follows:

1. A new warning statement # 6 asks the user to verify the presence of all the components of the device upon removal of the VCARE® device from the patient. This statement replaced an earlier, briefer statement.

   "6. Upon removing VCARE, the surgeon should visually inspect the VCARE device, and the patient, to make sure that the entire VCARE device was properly removed and that no components or fragments of these components were retained in the patient. There are 5 parts/components to the VCARE Cervical Elevator Retractor. These are: 1) the balloon; 2) the forward "cervical" cup; 3) the back or vaginal cup; 4) the locking assembly with thumb screw; 5) the metal shaft and handle with balloon inflation valve. "

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2. A new warning statement # 10 addresses removal of the uterus through the vaginal canal. It draws the user's attention to the inherent risk of removing a large uterus and suggests using alternative methods for those deemed large by the physician.

   "10. Removal of a large uterus through the vaginal canal poses certain inherent risk to the patient. If using VCARE to remove the uterus, as with any device, care should be taken and surgeon judgment used to determine if the uterus is of a size that can be delivered through the vaginal canal without injury to the patient. Morcellation or other methods should be used to reduce the size of a uterus deemed too large before attempting to remove through the vaginal canal."

3. A new warning statement # 11 addresses precautions to take when performing a laparoscopic supra-cervical (sub-total) hysterectomy using VCARE®. While excising the uterus at the cervical stroma, the shaft of the device is in the plane of excision. Care is required to avoid damage to the VCARE® device.

   "11. If using a VCARE device during a laparoscopic supra-cervical hysterectomy the user should be aware of the position of the VCARE device during excision of the uterus. While during this process the shaft of the device provides an excellent indication of location and orientation of the cervical canal, the potential for damage to the device, particularly to the balloon, potentially exists. This potential is heightened if the device is not fully inserted into the fundus of the uterus or if the uterus is unusually small. Care should be taken to avoid contact with the VCARE device with the device being used to excise the uterus during this part of the procedure."

If you have questions or need additional information please contact ConMed Regulatory Affairs at +1-315-624-3237 or by email at vcare@conmed.com

You may also contact our Authorized Representative MDSS GmbH situated in Germany via email at info@mdss.com or via phone at +49 511 6262 8630.

We apologize for any inconvenience this will cause you or your staff.

The US Food and Drug Administration have been notified of this action. In addition, the appropriate foreign competent authorities have also been notified.

Sincerely,

[redacted]