

**Urgent Field Safety Notice and Voluntary Product Recall of Versator® Handpiece
(VR-0030)**

Date: 19-08-2016
Reference No.: VMT-RA-01
(Rev-B)

TO WHOMSOEVER IT MAY CONCERN,

Kind Attention: _____
(Name of the Distributor)

**Sub: Notice regarding voluntary recall and FSCA for VERSATOR® Handpieces
(VR-0030).**

This is to inform you of a medical device voluntary product recall and field safety correction involving VERSATOR® Handpieces. You may have received one or more **Versator® Handpieces** individually or as a kit (Product code- VR-0030).

Veol Medical Technologies Pvt. Ltd wants to ensure that our products continue to remain safe and effective.

VERSATOR® Handpieces :

The VERSATOR® Handpiece is part of VERSATOR® Tissue Morcellation System and is intended for gynecologic and general surgical endoscopic use by individual surgeons who have been professionally trained for the use of similar devices. The device can be used for the extraction of tissues during laparoscopic gynecological or general surgery.

VERSATOR® Handpieces contains a stationary plastic inner tube in it. The function of the stationary inner tube is to work as a barrier between the rotating cutter tube and the morcellated tissue so as to avoid twisting of the tissue due to contact with the rotating cutter tube during the extraction process.

It has come to our attention that some of the VERSATOR® Handpieces bear an inner tube of low strength.

Due to this, if forceps or grasper (that is used to pull out the tissue) is not sufficiently closed during the surgical procedure, then there is a possibility that the open ends of the grasper (not fully closed) may make contact with the plastic inner tube. Due to low strength of the plastic inner tubes (in the identified batches), the inner tube may get twisted, resulting in stoppage of the surgery.

Veol Medical Technologies P. Ltd.

A-747, Near Pavan Bus Stop, MIDC - Pawane, TTC Industrial Area, Koparkhairane,
Navi Mumbai - 400 705. Maharashtra, India Phone: +91-22-27634771
CIN : U73100MH2008PTC187836

Please note:

This has not caused any patient safety issue. This letter is intended only for customers who may use VERSATOR® Handpiece from below mentioned batch numbers.

Details of Affected VERSATOR® Handpiece Batches:

NAME OF THE PRODUCT	BATCH NUMBER
VERSATOR® Handpiece	VR-HL-201502002
	VR-HL-201502003
	VR-HL-201507004
	VR-HL-201507005
	VR-HL-201509006
	VR-HL-201510008
	VR-HL-201510010
	VR-HL-201512013
	VR-HL-162201

Use of these VERSATOR® Handpiece batches may delay the surgery as the VERSATOR® Handpiece might stop functioning.

European Representative of Veol Medical Technologies Pvt. Ltd:

Dr. Rajiv Varma

10 Spingate, Hillwood Grove, Shenfield, CM13 2PD, UK.

Phone: +44 1277514206 / +44 7879817335. Email: vvarma99@aol.com

Action to be taken by the user:

Please take the following steps to ensure the voluntary recalled products is handled appropriately:

1. Quarantine the products:

According to our records, your facility may have a supply of VERSATOR® Handpieces. Please quarantine any unused boxes (Full or partial) of the above mentioned batch products that you have in your facility and contact to Veol Medical Technologies Pvt Ltd. at hp@veollabs.com for further information.

2. To obtain replacement products:

To obtain replacement product free of charge please acknowledge receipt of this notification by completing and returning the attached Voluntary Recall and Field Correction Acknowledgement form , with the date of letters receipt noted.

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When completing this form be certain to:

- Count the number of product packages in quarantine and detail this on this form
- Indicate your choice for receiving replacement products
- Email the form to hp@veollabs.com

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (If appropriate).

Please transfer this notice to other organizations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for appropriate period to ensure effectiveness of the corrective action. (If appropriate)

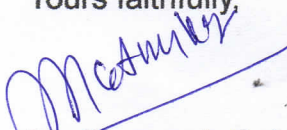
Contact reference person:

If you have any additional questions or concerns, please feel free to contact us on hp@veollabs.com.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

We sincerely apologies for any inconvenience and assure you that we are working diligently to resolve this issue in a timely manner.

Yours faithfully,



Mr. Mangesh Patankar
Managing Director
Veol Medical Technologies Pvt. Ltd.



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VOLUNTARY RECALL AND FIELD CORRECTION ACKNOWLEDGEMENT FORM

Product details: VERSATOR[®] Handpiece (Part of VERSATOR[®] Tissue Morcellation System) Product Code: VR-0030

This is to acknowledge receipt of the above referenced voluntary recall and field safety correction notification dated 19-08-2016.

Please confirm inventory levels of the affected batches with below details at your facility:

1	2	3	4	5	6*
Product	Batch no.	Quantity received	Quantity used	Quantity in inventory	Responsible persons Initials
Versator [®] Handpiece					

(If you have inventory of affected batches at your facility and would like to receive replacement products, please check the box below:)

I hereby certify that I have returned the existing inventory of Versator[®] Handpieces of above Batches (* as per the column 6 above) in our facility and ask that replacement product equal to the amount of quarantined product shown above.

Date _____ **Name** _____
Facility Name _____ **Signature** _____
Address _____ **Telephone No.** _____

Please complete, sign and return this form to:
hp@veollabs.com

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