# Urgent – Medical Device Recall

## Lumenis VersaCut+ Tissue Morcellator *(GA-4769200 and GA-4768700)*

## Stop Use Immediately

07 August 2015

To our Valued Customer,

Lumenis is initiating a global voluntary recall of **All** hand pieces for the Lumenis VersaCut+ Tissue Morcellator (GA-0007600) because there is a probability the hand piece may operate inconsistently and unpredictably during the morcellation procedure resulting in damage to non-target tissue.

Lumenis is aware of five (5) patient adverse event reports (three (3) in Australia, one (1) in France and one (1) in the US) stating surgeons experienced difficulty during the morcellation procedure. The five event reports described extension of surgical procedures beyond the physicians' reasonable expectations and in four (4) of the cases reported handpiece devices cycling on and off leading to damage to non-target tissue. At this stage, Lumenis cannot rule out the possibility that the hand piece contributed to the reported adverse events. **Therefore, as a cautionary measure, Lumenis highly recommends you immediately stop using the product and destroy the existing Operator Manual while Lumenis investigates the root cause of reported adverse events**.

You are receiving this letter because you are identified as a customer who has purchased a VersaCut+ Tissue Morcellator from Lumenis or one of our distributors.

> ***Note:*** *The Lumenis VersaCut Tissue Morcellator (Model: 0637-245-01 (starter kit) and 0636-470-01 (Control Box)) IS NOT affected by this recall. Only the hand pieces of the VersaCut+ Tissue Morcellator (GA-4769200 and GA-4768700) are affected.*

The U.S. Food and Drug Administration and international Competent Authorities have been advised of this recall.

**Reason for Recall**

Lumenis was made aware that in five (5) instances during the use of the VersaCut+ Tissue Morcellator surgeons reported difficulty engaging tissue in the morcellator blades and cycling on and off leading to extension of the procedure beyond their reasonable expectations. The hand piece operation during the procedure was reported to be inconsistent resulting in four (4) adverse event reports of damage to non-target tissue.

Lumenis Ltd.
Yokneam Industrial Park
P.O.B. #240
Yokneam 20692, Israel
Tel. +1-801-656-2663
Fax. +1-801-656-2415
www.lumenis.com
versacutmorcellator@lumenis.com

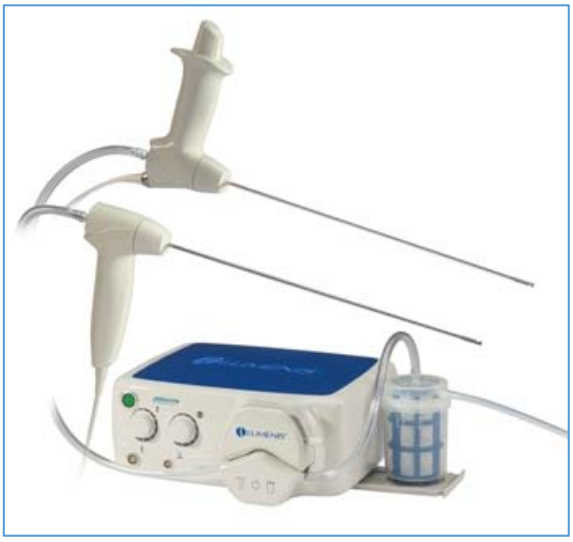


Lumenis®
Energy to Healthcare

# Urgent – Medical Device Recall

## Lumenis VersaCut+ Tissue Morcellator *(GA-4769200 and GA-4768700)*

**Product Description & Intended Use**



**Intended Use:** The Lumenis VersaCut + Tissue Morcellator system is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, endoscopic, laparoscopic, percutaneous and open surgical procedures whenever access to the surgical site is limited.

**510(k):** K133272

**The affected Lumenis model numbers are:** GA-0007500 (VersaCut + System with Inverted H/P) and GA-0007600 (VersaCut + System with Regular H/P). Only the hand pieces for the system (**SA4769200** inverted HP, **SA4768700** regular HP) are affected by this recall.

**Affected Serial Numbers:** All VersaCut+ Tissue Morcellator hand pieces.

**Steps of this Recall**

1. **Lumenis recommends that you immediately stop use of the VersaCut+ Tissue Morcellator while Lumenis completes an investigation of the root cause of the reported problem. Additionally, you should destroy the Operator Manual in your possession.**
2. Lumenis will determine the root cause of the reported problem and will make corrections as necessary to assure the hand piece meets all specifications and quality standards.
3. A Lumenis Representative will be contacting you directly, within 45-days of this notice, to issue an RMA number for the return of the effected VersaCut+ Morcellator hand piece. Alternatively you may contact the Recall Coordinator, Brett Godfrey, to arrange to return the hand piece to Lumenis immediately.
4. Upon your receipt of the replacement hand piece and operator manual, unpack the new hand piece and destroy the old operator manual if you haven't done so already.
5. You can begin using the new replacement hand piece according to indications and instructions in the IFU that will be provided with the new hand piece.
6. Complete the Recall Verification form provided with the new replacement hand piece and operator manual.
7. Pack the affected hand piece in the packaging or similar packaging if the original packaging is unavailable within 30-days of receipt of the new replacement hand piece and operator manual.
8. Return the affected hand piece unit(s) and Recall Verification form to Lumenis using the UPS prepaid shipping information provided with the new replacement hand piece.

Lumenis Ltd.
Yokneam Industrial Park
P.O.B. #240
Yokneam 20692, Israel
Tel. +1-801-656-2663
Fax. +1-801-656-2415
www.lumenis.com
versacutmorcellator@lumenis.com



Lumenis® Energy to Healthcare

# Urgent – Medical Device Recall

## Lumenis VersaCut+ Tissue Morcellator *(GA-4769200 and GA-4768700)*

**Recalling Firm**

Lumenis Ltd.
Yokneam Industrial Park
P.O.B. # 240
Yokneam 20692, Israel
+972-(4)-9099492

**Recall Activities Firm**

Lumenis Inc.
1870 Milestone Drive
Salt Lake City
Utah, 84104, USA
Tel. +1-801-656-2663
Fax. +1-801-656-2415
VersaCutMorcellator@lumenis.com

**Public Contact**

If you have questions about this recall, you can email versacutmorcellator@lumenis.com or contact Lumenis' Lumenis VersaCut + Tissue Morcellator Recall Coordinator, Brett Godfrey, at 801-656-2663.

**This notification includes the following**

1. A Customer Response Card to be returned with the recalled VersaCut+ Tissue Morcellator hand piece. Please complete the card and return it to Lumenis after you receive the new replacement hand piece and operator manual.

If you are not the right individual to receive this notification, please forward it to the appropriate party. If you are no longer the owner of a VersaCut+ Tissue Morcellator device(s) or you have a VersaCut Morcellator device(s) that are no longer in use, please indicate this on the response card shipped with this Notification and provide the contact information for the new owner of the device, if possible.

If you have distributed this product, please identify your customers and promptly notify them of this field notification regarding VersaCut+ Tissue Morcellator devices, including the recommendation to stop use immediately. Your notification to customers may be supported by including a copy of this letter and the Return Confirmation Card.

We thank you for your prompt attention and cooperation in this matter. If you have any questions, please contact our VersaCut+ Tissue Morcellator field correction administrator:

Brett Godfrey
Manager, Global Post Market Surveillance, Regulatory Affairs
VersaCut Morcellator Field Administrator E-mail:
VersaCutMorcellator@lumenis.com

Sincerely,

Brett Godfrey
Manager, Global Post Market Surveillance, Regulatory Affairs
Lumenis, Inc.

**European Union Authorized Representative:**

**Lumenis (Germany) GmbH**
Heinrich-Hertz-Str. 3
D-63303 Dreieich-Dreieichenhain
Germany
Tel: +49 (0)6103-8335-0
Fax: +49 (0)6103-8335-300

# Urgent – Medical Device Recall

## Lumenis VersaCut+ Tissue Morcellator *(GA-4769200 and GA-4768700)*

### RETURN CONFIRMATION CARD

**Please complete this form and return it to Lumenis with your recalled VersaCut+ hand piece.**

**NOTE: You will be contacted by a Lumenis authorized representative directly, within 45 days of this notice, who will coordinate replacement of your existing hand piece and return of this form.**

**Your signature confirms that you understand the requirements of this recall.**

**We have completed the following steps of this recall (please check all that apply):**

- ☐ We have removed the existing hand piece from service.
- ☐ We have removed and destroyed the existing operator manual.
- ☐ We have received and placed the new hand piece into service.
- ☐ We have received and replaced the new operator manual.
- ☐ We no longer have any VersaCut+ devices.
- ☐ We have notified everyone to whom we have distributed the product of this field action

VersaCut+ Hand Piece Serial No. _____

Facility Name _____

Contact Name _____

Address _____

City, ST, ZIP, Country _____

Phone _____

Signature _____Date_____

**Once you have completed the form, please return it with the recalled VersaCut+ Tissue Morcellator hand piece using the packaging from the new replacement hand piece and operator manual**

**Lumenis will provide a United Parcel Service (UPS) pre-paid shipping return label with the new replacement hand piece. If you no longer possess a Lumenis VersaCut+ Tissue Morcellator fax this form to +1 801-656-2415. Thank you.**

Lumenis Ltd.
Yokneam Industrial Park
P.O.B. #240
Yokneam 20692, Israel
Tel. +1-801-656-2663
Fax. +1-801-656-2415
www.lumenis.com
versacutmorcellator@lumenis.com



Lumenis®
Energy to Healthcare