MICROLINE™
SURGICAL

800 Cummings Center, Suite 166T
800 Cummings Center, Suite 157X
Beverly, MA 01915, USA
Tel: 978.922.9810
Fax: 978.922.9209
www.microlinesurgical.com

# FIELD SAFETY CORRECTIVE ACTION

## URGENT ReNew Long Fenestrated Grasper URGENT

*Date:*

*Company Name:*
*Contact Person:*
*Address:*
*Country*

*Dear,*

This is to inform you of a FIELD SAFETY CORRECTIVE ACTION involving:

**ReNew Long Fenestrated Grasper, Single Patient Use,**
**Product Number 3262, Lot Number 00105332**

The reason for this FSCA is: the product inside the sterile barrier which was labeled as a Long Fenestrated Grasper, Product Number 3262, instead contains a Super-Atrau Grasper, Product Number 3642.

Use of this product may result in user confusion due to expectation of one type of grasper but receiving another. There should be no risk to the patient as they are both atraumatic graspers, and the surgeon will instantly know the difference between the two product numbers. The devices are both single use.

See enclosed label for ease in identifying product.

X boxes of the above product were shipped on July XX, 2011.

Immediately examine your inventory and quarantine product subject to this recall. In addition, if you may have further distributed this product, please identify your customers and notify them immediately of this FSCA. Your notification to your customers may be enhanced by including a copy of this FSCA letter.

Please contact Microline BV's Customer Service Department for a Return Authorization Number to return the product.

This FSCA should be carried out to the hospital level. Your assistance is appreciated and necessary to prevent the User from utilizing the incorrect grasper.

Please complete and return the enclosed FSCA Return Response Form as soon as possible. If you have any questions please call Bill McCallum, Regulatory Affairs Manager at 978-867-1726.

The relevant National Competent Authorities have been advised of the FSCA.

Best Regards,

William S. McCallum
Regulatory Affairs Manager


# Sterile Barrier Label

# Box Containing 10 Units Label

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# FSCA RETURN RESPONSE FORM

**ReNew Long Fenestrated Grasper, Single Patient Use,**
**Product Number 3262, Lot Number 00105332**

**Please check ALL appropriate boxes.**

☐ I have read and understand the recall instructions provided in the July 18, 2011 letter.
☐ I have checked my stock and have quarantined inventory consisting of _____ boxes of 10 each.
☐ Returned (**specify quantity, date and method**)/held for return
Qty_____Date_____Method_____
☐ I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**);
Qty_____Date_____Method_____
Attached is a list of customers who received/may have received this product. Please notify my customers.

_____
☐ (**specify quantity**) have been used in surgery and are not available to return. Qty_____

_____
Any adverse events associated with recalled product? ☐ Yes ☐No
If yes, please explain: _____

Please check the appropriate box(es) to describe your business
☐ Wholesaler/Distributor
☐ Hospital
☐ Sales Personnel

Name: _____
Title: _____
Tel. Number: (  ) _____

Firm Name: _____
Address: _____
City/State: _____

PLEASE FAX COMPLETED RESPONSE FORM TO Tel. # **978-867-1782**
OR MAIL TO:
**Microline Surgical**
**Attn: Bill McCallum**
**800 Cummings Center Suite 166T**
**800 Cummings Center Suite 157X**
**Beverly, Massachusetts 01915**
**USA**