50 Dunham Road, Suite 1500
Beverly, MA 01915, USA
Tel: 978-922-9810
Fax: 978-922-9209
www.microlinesurgical.com

July 13, 2017

URGENT: MEDICAL DEVICE RECALL

PRODUCT: **ReNew™ Reusable Tips (Scissors, Graspers and Dissectors)**

Attention:

Customer Name
Device Name
Street Address
City, State, Zip Code

Dear Device Customer/Distributor:

The purpose of this letter is to advise you that Microline Surgical, Inc. ("Microline") is voluntarily recalling its ReNew Reusable Scissor, Grasper and Dissector Tips due to a malfunction related to the heat-shrink insulation tube that is located immediately proximal to the metal tip.

This recall applies from Microline through to the end-user level for all product codes of the ReNew Reusable Tips.

This recall does not involve ReNew Disposable Tips.
This recall does not involve the ReNew Reusable Universal Handpieces.
This recall does not involve the ReNew Electrocautery Probes.

ReNew Reusable Tips are intended for cutting, grasping, dissecting and coagulation of tissue in endoscopic and laparoscopic surgical procedures where instruments are introduced into the body through a cannula.

Microline Surgical, Inc. is recalling all ReNew Reusable Scissor, Grasper and Dissector Tips because it has received customer reports that the heat-shrink insulation tube may split during autoclave sterilization/re-sterilization. If a split occurs, the heat-shrink could fall off during a surgical procedure and if cautery is needed, there is a potential for burn due to insulation failure.

Microline has discontinued manufacture of the affected ReNew Reusable Tips and has initiated a ship-hold and new orders-hold for these products.

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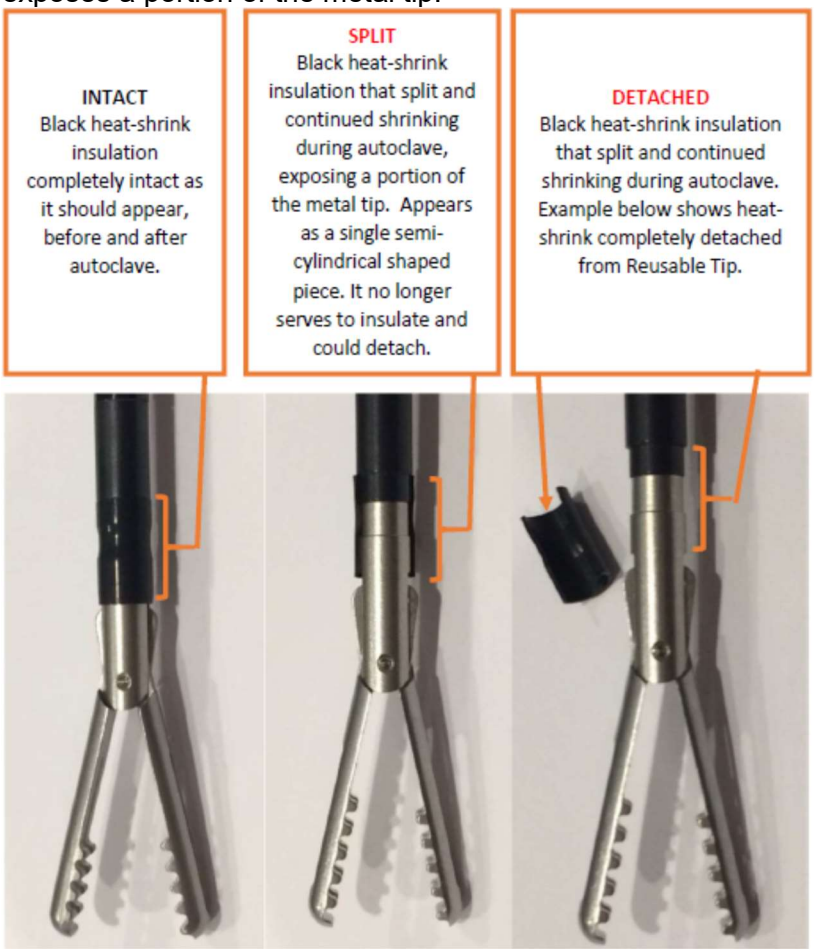
Reason for the Voluntary Recall:

It has come to Microline's attention that the electrical insulation tube component of the ReNew Reusable Tips (scissors, graspers and dissectors), which is made of black heat-shrink, may split during autoclave sterilization/re-sterilization. The heat-shrink tubing is located immediately proximal to the metal tip (picture below). If a split occurs, the appearance of the failure is consistent and visible to the naked eye. The heat-shrink insulation splits longitudinally and exposes a portion of the metal tip.



The heat-shrink tube remains in one piece but gives the appearance that a longitudinal portion is missing. This is because after splitting it shrinks in size to expose a portion of the metal tip (see picture below). If a split occurs, the heat-shrink could detach from the device before or during surgery and, if cautery is needed, there is the potential for burn due to insulation failure.

If the heat-shrink tubing splits but is not noticed, there is risk of injury from two hazards;

1) If used for electro-cautery, the insulation failure could cause electric shock or burn.
2) The insulation heat-shrink-tube could fall into the surgical field.

To date, Microline has not received complaints of patient injury. However, because surgical procedures may be delayed or prolonged if a physician believes the heat-shrink may have fallen into the patient, and there is a risk that the heat-shrink could fall into the patient and/or burn may occur if the cauterizing function is used, Microline is recalling all ReNew Reusable Tips and asks that you immediately remove these products from use.

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Actions to be taken by the Customer/ User:

1. Immediately determine if you are in possession of the products subject to recall.
2. Immediately stop use and quarantine all Microline Renew Reusable Tips subject to this recall, regardless of whether you have observed the malfunction described above.
3. All affected products should be quarantined- both new un-opened Reusable Tips AND Reusable Tips that have been used or are in current use.
4. Utilize Table 1 found in the Product Identification Information section to complete the form entitled, **MEDICAL DEVICE RECALL RETURN RESPONSE Acknowledgement and Receipt Form.** This form and Table 1 are both included at the end of this letter.
5. We ask that you complete and return the **Acknowledgment and Receipt Form** even if you never received any of these products or have none in stock since we must document that information in our records.
6. Follow the directions on the bottom of the last page of the **Acknowledgment and Receipt Form** to Contact Microline Customer Service (if you receive product directly from a Microline facility) or, if you receive product from an authorized Microline product distribution organization, contact that organization and follow their directions to initiate an RMA (Returned Material Authorization) for return of the ReNew Reusable Tips. All product returns will be credited to your customer account.

Actions to be taken by the Distributor:

1. Immediately determine if you are in possession of the products subject to recall.
2. If you are a distributor or further distributed this product, we require that you immediately remove affected products from inventory and stop sales and shipping. Please identify customers immediately and notify them of this product recall using this Recall Notification Letter. We request that you direct your customers to return affected products (both new un-opened Reusable Tips AND Reusable Tips that have been used or are in current use) to your facility for subsequent return to Microline. The FDA will be monitoring the recall so your efforts should be carefully documented.
3. Utilize Table 1 found in the Product Identification Information section to complete the form entitled, **MEDICAL DEVICE RECALL RETURN RESPONSE Acknowledgement and Receipt Form.** This form and Table 1 are both included at the end of this letter.
4. We ask that you complete and return the **Acknowledgment and Receipt Form** even if you never received any of these products or have none in stock since we must document that information in our records.
5. Follow the directions on the bottom of the last page of the **Acknowledgment and Receipt Form** to Contact your Microline Customer Service office and initiate an RMA (Returned Material Authorization) for return of the ReNew Reusable Tips. All product returns will be credited to your customer account.

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Availability of alternative products.

Your Microline sales representative or your authorized distributor of Microline products will be in contact with you regarding the availability of ReNew Disposable Tips that are counterparts to the reusable version (where applicable).

Product Identification Information:

All lots of the following products are included in this recall notification.

TABLE 1

Microline ReNew Reusable Tips Subject to This Voluntary Recall		
Product Names	**Microline Product Code Number**	**Lot Number**
ReNew Metzenbaum Scissor Tip, Reusable	3111	All
ReNew Micro Scissor Tip, Reusable	3121	All
ReNew EndoCut Scissor Tip, Reusable	3141	All
ReNew Mini EndoCut Scissor Tip, Reusable	3151	All
ReNew Delicate Metzenbaum Scissor Tip, Reusable	3161	All
ReNew Traditional Grasper Tip, Reusable	3201	All
ReNew Fenestrated Grasper Tip, Reusable	3221	All
ReNew Modified Traditional Grasper Tip, Reusable	3231	All
ReNew Grabber Grasper Tip, Reusable	3241	All
ReNew Lapclinch Grasper Tip, Reusable	3251	All
ReNew Long Fenestrated Grasper Tip, Reusable	3261	All
ReNew Modified Babcock Grasper Tip, Reusable	3271	All
ReNew Birkett Grasper Dissector Tip, Reusable	3281	All
ReNew Modified Raptor Grasper Tip, Reusable	3291	All
ReNew Babcock Dissector Tip, 5mm, Reusable	3301	All
ReNew Dolphin Nose Dissector Tip, Reusable	3311	All
ReNew Modified Maryland Dissector Tip, Reusable	3321	All
ReNew Right Angle Dissector Tip, 5mm, Reusable	3331	All
ReNew Right Angle Dissector Tip, 10mm, Reusable	3341	All
ReNew Traditional Maryland Dissector Tip, Reusable	3351	All
ReNew Hunter Grasper Tip, Reusable	3361	All
ReNew Allis Grasper Dissector Tip, Reusable	3371	All
ReNew Babcock Dissector Tip, 10mm, Reusable	3381	All
ReNew Micro Fenestrated Grasper Tip, Reusable	3401	All
ReNew Cobra Tooth Grasper Tip, Reusable	3411	All
ReNew Cup Tooth Grasper Tip, Reusable	3421	All
ReNew Biopsy Punch Grasper Tip, Reusable	3431	All

Contact Us:

For more information, please email ReusableTipRecall@microlinesurgical.com. We are actively investigating this matter and seeking a long-term solution. In the meantime, we appreciate your assistance and sincerely apologize for any inconvenience this may have caused you.

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This recall is being made with the knowledge of the Food and Drug Administration.

Recall Authorized by Martin J. Leighton

Signature:  Date: July 13, 2017

Title: Director of Regulatory Affairs and Quality

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Customer or Distributor Information:
Customer Name
Street Address
Town, State, Zip Code

ReNew Reusable Tips (Scissors, Graspers and Dissectors)

Affected Lot numbers: All (no specific date range)

I have affected product.
Yes_ No_

If no, please sign last page and return to noted address. **Response is required even if you have no affected product.**

If yes, I have completed the **Affected Product Information Table (Table 2)**, and have contacted Microline or the authorized distributor and have been given an RMA# to return all product relevant to the Recall Notification Letter. Yes _ No_

Any adverse events associated with recalled product? Yes _ No _

If yes, please explain:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

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Affected Product Information: Include information that is applicable for affected product. Note: One lot number per line. Copy and use multiple pages if needed.

Table 2

Affected Product Information Table

Microline Product Code Number	Lot Number (if known)	Inventory Quantity of **Individual** ReNew Reusable Tips (**new unopened product**)	Quantity of **Used** **Individual ReNew Reusable Tips Removed from Service	Total Quantity Returned per Product Code Number

**Please provide the number of individual Tips being returned, not the number of multi-unit boxes.

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Distributors:

I have identified and notified of the recall those customers that were shipped or may have been shipped one or more affected products by (**specify date and method of notification below):**

List Method of Notification and Date

_____
_____
_____

I have requested all customers affected by the recall to return affected products to our facility and am returning all products received to Microline.

_____
_____

ALL CUSTOMERS, USERS, AND DISTRIBUTORS ARE TO REVIEW AND SIGN BELOW

I certify that I have read and understand the instructions provided herein and that the information contained in the **Acknowledgement and Receipt Form** is accurate and complete.

Signature _____ Date: _____

Name/Title	
Telephone	
Email address	

RESPONSE FORM RETURN INSTRUCTIONS

MICROLINE DIRECT CUSTOMERS AND DISTRIBUTORS
PLEASE RETURN COMPLETED RESPONSE FORM BY ONE OF THE FOLLOWING METHODS:

- E-MAIL A SCANNED COPY TO: ReusableTipRecall@microlinesurgical.com
- Fax: 978-522-8490, ATTN: Reusable Tip Recall,
- MAIL TO: Microline Surgical, Inc, 50 Dunham Road, Suite 1500, Beverly, MA 01915, ATTN: Recall Department

Request RMA numbers via the FAX or EMAIL instruction above.

CUSTOMERS OF DISTRIBUTORS
PLEASE CONTACT YOUR AUTHORIZED DISTRIBUTOR TO OBTAIN INSTRUCTIONS FOR RETURN OF THE PRODUCT AND COMPLETED RESPONSE FORM.