UITM

United Italian Trading (M) Sdn Bhd
(Company No: 50802-P)
L16-03 & L16-03A, PJX-HM Shah Tower, No. 16A, Persiaran Barat,
Seksyen 52, 46050 Petaling Jaya, Selangor, Malaysia
Tel : 603-7965 3000 Fax : 603-7965 3001

URGENT: MEDICAL DEVICE RECALL

Name: _____

Address: _____
_____
_____
_____

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that LaproSurge Ltd is voluntarily recalling its Thoracic Trocars due to Breakage of cannula tip occurred when there is an extreme angulation of the inserted device (usually the endoscope).

This recall applies from LaproSurge through to the end-user level for Thoracic Trocars:

LaproSurge THORACIC TROCAR Subject to This Voluntary Recall		
Thoracic Trocars	**LaproSurge Product Code Number**	**Lot Number**
6mm Thoracic Cannula and Blunt Trocar 70mm	TC6S	8631707239
	TC6S	8632010204
	TC6S	8632011079
11mm Thoracic Cannula and Blunt Trocar 70mm	TC11S	8631707240
	TC11S	8632006213
	TC11S	8632101044
	TC11S	8632103269
	TC11S	8632104162
13mm Thoracic Cannula and Blunt Trocar 70mm	TC13S	8631707241
	TC13S	8632010205
	TC13S	8632011080
15mm Thoracic Cannula and Blunt Trocar 70mm	TC15S	8631707242
	TC15S	9921110201
	TC15S	9982202042

Reason for the voluntary recall:
LaproSurge Ltd is recalling Thoracic Trocar because of a product problem where breakage of cannula tip occurred when there is an extreme angulation of the inserted device (usually the endoscope).

The Thoracic Trocar is used during thoracic surgery to create a port entry for the instruments and endoscope. LaproSurge Ltd has, through the product complaints system, become aware of situations where the tip of the trocar cannula breaks. According to the investigation, it seems that the device functions well under normal manipulation, but breakage could occur when there is an extreme angulation of the inserted device (usually the endoscope) or where there is more than one device inserted inside the cannula at the same time. MIR was issued for the incident ref LAP03-2022, in the

meantime additional cases occurred. Due to the increase in the numbers of these events, it is decided to proceed with a precautionary Field Safety Corrective Action. As our investigation continues, we may provide follow up direction and advice.

LaproSurge Ltd has discontinued manufacture of the affected Thoracic Trocar and has initiated a ship-hold and new orders-hold for these products.

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 Thoracic Trocar 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 Thoracic Trocar and that 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 LaproSurge Sales (if you receive product directly from LaproSurge facility) or, if you receive product from an authorized LaproSurge product distribution organization, contact that organization and follow their directions to initiate an RMA (Returned Material Authorization_ for return of the Thoracic Trocar.

Availability of alternative products.
Your LaproSurge sales representative or your authorized distributor of LaproSurge products will be in contact with you regarding the availability of Thoracic Trocar that are counterparts to the Thoracic Trocar where applicable

Product Identification Information:
All lots of the following products are included in this recall notification.

TABLE 1

LaproSurge THORACIC TROCAR Subject to This Voluntary Recall		
Thoracic Trocars	**Product Code Number**	**Lot Number**
6mm Thoracic Cannula and Blunt Trocar 70mm	TC6S	8631707239
11mm Thoracic Cannula and Blunt Trocar 70mm	TC11S	8631707240
13mm Thoracic Cannula and Blunt Trocar 70mm	TC13S	8631707241

Contact Us:
For more information, please email to janice.lim@uitm.net

We are actively investigation 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.
This recall is being made with the knowledge of all applicable EU National Competent Authorities and MDA Malaysia.

Yours sincerely,

(Liew Ooi Lee)
General Manager

MEDICAL DEVICE RECALL RETURN RESPONSE

Acknowledgement and Receipt Form

Response is Required

Customer or Distributor Information:

Name: _____

Address: _____
_____
_____
_____

LaproSurge Thoracic Trocar

Please distribute this information to the appropriate personnel at your facility including surgeons who may have received the product which is the subject of this recall notice.

According to our records you have received Lot number below:

No.	Name of Product	Product Identifier	Lot Number
1.	6mm Thoracic Cannula and Blunt Trocar 70mm	TC6S	8631707239
2.	11mm Thoracic Cannula and Blunt Trocar 70mm	TC11S	8631707240
3.	13mm Thoracic Cannula and Blunt Trocar 70mm	TC13S	8631707241

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 UITM and have been given a Sales Return/Consignment Return to return all product relevant to the Recall Notification Letter.
Yes _ No_

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

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 - FSN-*UITM-01-2022 – Thoracic Trocar*

LaproSurge Product Code Number	Lot Number	Inventory Quantity of **Individual Thoracic Trocar **(new unopened product)**	Quality of **Used** **Individual Thoracic Trocar Removed from Service	Total Quantity Returned per Product Code Number

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

Return Response Box:

Please provide any additional information, if applicable.

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
PLEASE RETURN COMPLETED RESPONSE FORM TO:

Fax. # <03-79653001 >, ATTN: <Janice Lim > or email to: janice.lim@uitm.net