Unimax Medical Systems Inc.
8F-2, No. 127, Lane 235, Pao Chiao Road, Xindian Dist,
New Taipei City 231, Taiwan
Tel: +886-2-8919-1698
www.unimaxmeds.com

Rev 2: February 2020
FSN Ref: FSN-EP24002 FSCA Ref: FCA-EP24002

Date: 2024.02.05

Field Safety Notice
Detachable Endo Retrieval Pouch

For Attention of*:Theatre Manager

Contact details of local representative (name, e-mail, telephone, address etc.)*
Mölnlycke Health Care AG Contact's Name: Natalia Kasperowicz Email: info.ch@molnlycke.com Phone: +41 (0) 44 744 54 00 Country: Switzerland Address: Brandstrasse 24, 8952 Schlieren – Switzerland Post Code: 8952

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Field Safety Notice (FSN)
Detachable Endo Retrieval Pouch

1. Information on Affected Devices*

1. 1. Device Type(s)*

Detachable Endo Retrieval Pouch
Small (250-300ml) / 10mm introducer diameter
Medium /Large (500-700ml)/ 10mm introducer diameter
Extra Large (1150-1500ml)/12mm and 15 mm introducer diameter

1. 2. Commercial name(s)*

Detachable Endo Retrieval Pouch

1. 3. Unique Device Identifier(s) (UDI-DI)

07323190272792 (model 899102)
07323190272808 (model 899103)
07323190272815 (model 899104)
07323190272907 (model 899112)

1. 4. Primary clinical purpose of device(s)*

The detachable endo pocket is a device that is used to collect and extract specimens during laparoscopic surgery.

1. 5. Device Model/Catalogue/part number(s)*

899102; 899103; 899104; 899112

1. 6. Affected serial or lot number range

Model no# 899102					
6252207126	6252208039	6252208096	6252208124	6252209038	6252209071
6252209263	6252207098	6252210099	6252212169		
Model no# 899103					
6252207125	6252208121	6252208125	6252209039	6252209072	6252209264
6252211001	6252211014	6252212024	6252212170	6252301132	
Model no# 899104					
6252209041					
Model no# 899105					
6252207131	6252208101	6252208132	6252209053	6252209080	6252211005
6252212026	6252212178				

2. Reason for Field Safety Corrective Action (FSCA)*

2. 1. Description of the product problem*

The mechanism of the listed article number operates in a way that the tube within detaches during the removal process. If the tube is not precisely fixed, part of the tube may stretch out from the opening after detachment and fall into the abdomen of the patient.

2. 2. Hazard giving rise to the FSCA*

The reported incidence is potentially serious to patients as the extending part may fall into the cavity

2. 3. Probability of problem arising

Overall occurrence rate: within 0.0001

2. 4. Predicted risk to patient/users

Prolonged surgery or surgical intervention

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2.	5. Background on Issue
	The device is used to contain and remove specimen removed during laparoscopic surgery. The mechanism of the listed article number operates in a way that the tube within detaches during the removal process. If the tube is not precisely fixed, part of the tube may stretch out from the opening after detachment and fall into the abdomen of the patient. It was thus decided to proceed with a field safety corrective action to replace the current version with an improved design variant thus reducing the potential for the tube stretching out / falling into the patients abdomen.

3. Type of Action to mitigate the risk*			
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☐ None		
3.	2. By when should the action be completed?	Estimated within 6 months	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)		Yes
3.	**4. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ Software upgrade ☐ Other ☐ On-site device modification/inspection ☐ IFU or labelling change ☐ None		
3.	5. By when should the action be completed?	- Distribution of the FSN scheduled for 1-3 weeks. - Expected return of customer reply form in 1-2 months - Replacement of affected devices scheduled for 3-6 months depends on the quantity.	
3.	6. Is the FSN required to be communicated to the patient /lay user?		No

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4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Unimax Medical Systems Inc.
	b. Address	8F-2, No. 127, Lane 235, Pao Chiao Road, Xindian Dist., New Taipei City, Taiwan
	c. Website address	http://www.unimaxmeds.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes.	
4.	5. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	6. Name/Signature	Magellan C.L. Yu / Regulatory Affairs Specialist
		[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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Rev 1: July 2018

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-EP24002
FSN Date*	2024.02.05
Product/ Device name*	Detachable Endo Retrieval Pouch
Product Code(s)	1. 899102 2. 899103 3. 899104 4. 899112
Batch/Serial Number (s)	1. 899102: 6252207126/6252208039/6252208096/6252208124/ 6252209038/6252209071/6252209263/6252207098/ 6252210099/6252212169. 2. 899103: 6252207125/6252208121/6252208125/6252209039/ 6252209072/6252209264/6252211001/6252211014/ 6252212024/6252212170/6252301132 3. 899104: 6252209041 4. 899114: 6252207131/6252208101/6252208132/6252209053/ 6252209080/6252211005/6252212026/6252212178

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):

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☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
☐	Other Action (Define):			
☐	I do not have any affected devices.	Customer to complete or enter N/A		
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query		
Print Name*		Customer print name here		
Signature*		Customer sign here		
Date*				

4. Return acknowledgement to sender	
Email	ra@unimaxmeds.com
Customer Helpline	+886-2-8919-1698
Postal Address	Unimax Medical Systems Inc. 8F-2, No. 127, Lane 235, Pao Chiao Rd., Xindian District, New Taipei City, Taiwan
Web Portal	http://www.unimaxmeds.com/
Fax	+886-2-8919-1528
Deadline for returning the customer reply form*	Within 1-2 months

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.