IDS Medical Systems (Singapore) Pte. Ltd.
20 Science Park Road, Teletech Park
#01-23/25, Singapore 117674
T : +65 6690 7330
F : +65 6690 7380
E : sgpidsmedicalsystems@idsmed.com
www.idsMED.com

FIELD SAFETY NOTICE

19 September 2018

<Customer Name>
<Customer Address Line 1>
<Customer Address Line 2>

IDS REFERENCE:	**FSCA-2018-017**
MANUFACTURER REFERENCE:	**N/A**
SUBJECT: Cooper Surgical SINGLE-USE CPO-6 COLPO-PNEUMO OCCLUDER Product Recall	
FOR THE ATTENTION OF: Chairman Medical Board (CMB), BME, Nursing and Medical staff using these devices in the various departments and the relevant Head of Departments.	
DEVICE:	SINGLE-USE CPO-6 COLPO-PNEUMO OCCLUDER
PRODUCT CODE:	CPO-6
BATCH / SERIAL NO:	244131, 244132, 244670,244671, 244887, 244888, 244889, 244890, 245228, 245325,245326,245327, 245613, 245614, 245615, 245976, 245977, 245978, 245979, 246810, 246811,247262, 247608, 247609, 247610 , 248112
PROBLEM:	CooperSurgical is recalling this product due to the possibility that the seal of the sterile pouch may be compromised, thereby increasing the risk of infection. This condition was detected during a complaint investigation unrelated to the packaging seal. There have not been any adverse events reported to CooperSurgical due to this potential issue.
ACTION TO BE TAKEN:	Please be advised that CooperSurgical has initiated a corrective action to inspect finished goods in inventory for potential unsealed pouches. If any product from the 26 lots is in your possession and has a green label affixed to the outer display box as displayed below, it is not affected by this recall action.  Please discontinue use of the product with any packaging irregularities, quarantine the product, and to arrange for credit to your account.

We apologize for any inconvenience caused due to this notice. Meanwhile, should you require further clarification, please do not hesitate to contact Sharon Yeo [redacted]

Thank you.

IDS Medical Systems (Singapore) Pte. Ltd.
20 Science Park Road, Teletech Park
#01-23/25, Singapore 117674
T : +65 6690 7330
F : +65 6690 7380
E : sgpidsmedicalsystems@idsmed.com
www.idsMED.com

With regards,
Tan Qi Lun
Regulatory
IDS Medical Systems (Singapore) Pte Ltd
Email: [redacted]

IDS Medical Systems (Singapore) Pte. Ltd.
20 Science Park Road, Teletech Park
#01-23/25, Singapore 117674
T : +65 6690 7330
F : +65 6690 7380
E : sgpidsmedicalsystems@idsmed.com
www.idsMED.com

IDS Reference:	FSCA-2018-017
Manufacturer Reference:	N/A
Subject:	CooperSurgical SINGLE-USE CPO-6 COLPO-PNEUMO OCCLUDER Product Recall

---

I acknowledge receipt of this letter dated 19 September 2018.

If you have any questions, please contact Sharon Yeo [redacted]

Customer Name:	<Customer Name>		
Department:	<Dept>		
Address:	<Customer Address Line>		
Name:		Tel:	
Designation:			
Signature:		Company Stamp:	

Check the applicable boxes below:	
	I **DO NOT** have affected medical devices remaining. All have been used or discarded.
	I **DO** have unused inventory of affected medical devices, which I will return for *credit / exchange.

Please refer to the supply records as attached.

**** Please delete accordingly.***
**** Please fax this acknowledgement to IDS Medical Systems at 66907380 or email to*** [redacted]

Thank you.

75 Corporate Drive
Trumbull, CT 06611
(203) 601-5200
FAX (203) 601-9870
Regulatory Affairs & Quality Assurance

September 4, 2018

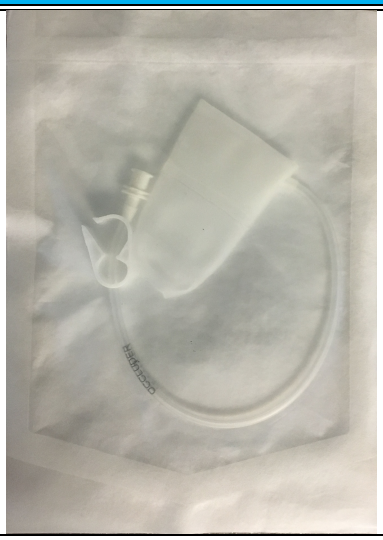
URGENT MEDICAL DEVICE RECALL NOTIFICATION

COOPERSURGICAL SINGLE-USE CPO-6 COLPO-PNEUMO OCCLUDER™

Dear Valued CooperSurgical Customer,

CooperSurgical has issued a voluntary recall for 26 lots in the enclosed list on page 3 of its SINGLE-USE COLPO-PNEUMO OCCLUDER™ [CooperSurgical part number **CPO-6**]. The Colpo-Pneumo Occluder™ is a sterile single-use medical grade silicone device designed for use with CooperSurgical's RUMI® System and the Koh Cup Vaginal Fornices Delineator in laparoscopic procedures where it is desirable to minimize the loss of pneumoperitoneum after a colpotomy incision has been made.

CooperSurgical is recalling this product due to the possibility that the seal of the sterile pouch may be compromised, thereby increasing the risk of infection. This condition was detected during a complaint investigation unrelated to the packaging seal. There have not been any adverse events reported to CooperSurgical due to this potential issue.

ACCEPTABLE **(packaging seal with uniform 1/8" seal)**	**NOT ACCEPTABLE** **(packaging with void in seal)**
	

Our records indicate you have purchased the affected product from CooperSurgical. This recall only affects 26 lot numbers manufactured between February 2018 and July 2018. Please be advised that CooperSurgical has initiated a corrective action to inspect finished goods in inventory for potential unsealed pouches. If any product

75 Corporate Drive
Trumbull, CT 06611
(203) 601-5200
FAX (203) 601-9870
Regulatory Affairs & Quality Assurance

from the 26 lots is in your possession and has a green label affixed to the outer display box as displayed below, it **is not affected** by this recall action.

A product is acceptable for use if it is visually confirmed that the pouch's seal is intact. As indicated in the Directions for Use (DFU), each package should be handled with care and inspected for damage, including the seal area before use. Inspect the package contents and the sterile seal along the entire periphery of the package. Refer to the table below for examples of acceptable / not acceptable conditions.

Please discontinue use of the product with any packaging irregularities, quarantine the product, and complete the attached **Acknowledgement and Receipt Form** to arrange for either a product replacement or credit to your account through CooperSurgical. Once the form is completed and returned to CooperSurgical, a Customer Service Representative will contact you with a Return Merchandise Authorization (RMA) number and provide instructions for the return of product to CooperSurgical. If replacements are requested, a replacement order will be placed immediately. If you do not have affected stock, please complete and return the enclosed **Acknowledgement and Receipt Form**, in order for us to document receipt of this letter.

The U.S. Food and Drug Administration has been notified of this action. CooperSurgical is committed to high quality, safe and effective products. We apologize for any inconvenience caused by this action and feel free to reach us at 203-601-5200 ext. 3300.

Sincerely,

[redacted]

Peter Niziolek
Product Surveillance Manager

75 Corporate Drive
Trumbull, CT 06611
(203) 601-5200
FAX (203) 601-9870
Regulatory Affairs & Quality Assurance

COOPERSURGICAL® SINGLE-USE CPO-6 COLPO-PNEUMO OCCLUDERS

Affected Lots

Lot
244131
244132
244670
244671
244887
244888
244889
244890
245228
245325
245326
245327
245613
245614
245615
245976
245977
245978
245979
246810
246811
247262
247608
247609
247610
248112

CooperSurgical

75 Corporate Drive
Trumbull, CT 06611
(203) 601-5200
FAX (203) 601-9870
Regulatory Affairs & Quality Assurance

Acknowledgement and Receipt Form: Response is required

Please complete this form and return in the attached prepaid envelope or fax to **203.601.9870 ATTN: Product Surveillance.** CooperSurgical will arrange for a product replacement or credit after this form has been received.

Customer Account #: _____ Account Name: _____

Street Address: _____ Town, State, Zip Code:_____

Contact Name: _____ Phone Number: _____

Email address: _____

I have read and understand the recall instructions provided in the August 1, 2018 letter. Yes ____ No___

Any adverse events associated with recalled product? Yes _____ No____

If yes, please explain: _____

Affected Product Information: Please check the appropriate boxes below and complete the table if applicable.

☐ We have no inventory within the scope of this recall.

☐ We have the following affected product at our facility and have discontinued use and distribution. We have quarantined the affected product and will return the following quantities.

Lot Number	Quantity to be Returned

Please select one of the following;

☐ Send replacements

☐ Credit our account

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at **203.601.5200** Ext. **3300** or email us at **recall@coopersurgical.com**. 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.

75 Corporate Drive
Trumbull, CT 06611
(203) 601-5200
FAX (203) 601-9870
Regulatory Affairs & Quality Assurance

Acknowledgement and Receipt Form: Response is required

Please complete this form and return in the attached prepaid envelope or fax to **203.601.9870 ATTN: Product Surveillance.** CooperSurgical will arrange for a product replacement or credit after this form has been received.

FOR DISTRIBUTORS ONLY:

Customer Account #: _____ Account Name: _____

Contact Name/Title: _____ Phone Number: _____

Email address: _____

Affected Product Information: Include information that is applicable for affected product.

I have read and understand the recall instructions provided in the August 1, 2018 letter. Yes __ No__

I have checked my stock and have quarantined inventory consisting of _____units_____boxes

Lot/Serial Number shipped to Customer : _____ Quantity Shipped:_____

I have identified and notified my customers that were shipped or may have been shipped this product by _____
_____(Specify date and method of notification)

or

Please notify the attached is a list of customers who received/may have received this product.

Signature of Receipt: _____

PLEASE FAX COMPLETED RESPONSE FORM TO: **203.601.9870** ATTN: **Product Surveillance**