

For the attention of:

Urgent Field Safety Notice (FSN)
OpClear Disposable Procedure Kit
Issue: Risk of sheath cracking

Dear Customer,

Cipher Surgical has determined that some batches of OpClear Disposable Procedure Kit have a manufacturing defect that could in some circumstances pose a risk for patients. As a precaution, Cipher is releasing this field action to inform affected customers and describe the actions to be taken by the customer to reduce any potential risk.

1. Information on Affected Devices

The affected devices are the OpClear Disposable Procedure Kits that are supplied for use with OpClear and are intended to remove visual obstructions such as condensation, blood, and other tissue particulates from the distal lens of a laparoscope during surgery and therefore maintaining a clear image of the surgical site.

There are four product variants affected by this notice:

Product Code	Lot Number	UDI	Expiry Date
CS-10-00-315	A48/3/0041/22E	(01)50603468008516(17)250806 (10)A48/3/0041/22E	06-Aug-2025
	A02/4/0041/23E	(01)50603468008516(17)250806(10)A02/4/0041/23E	06-Aug-2025
	A18/6/0041/23E	(01)50603468008516(17)260531(10)A18/6/0041/23E	31-May-2026
CS-10-30-315	A11/6/0041/23F	(01)50603468008684(17)260331(10)A11/6/0041/23F	31-Mar-2026
	A38/4/0041/22F	(01)50603468008684(17)250930 (10)A38/4/0041/22F	30-Sep-2025
	A05/5/0041/23F	(01)50603468008684(17)260228(10)A05/5/0041/23F	28-Feb-2026
CS-10-00-330	A15/3/0041/23G	(01)50603468008752(17)260430(10)A15/3/0041/23G	30-Apr-2026
CS-10-30-330	A09/3/0041/23H	(01)50603468008820(17)260228(10)A09/3/0041/23H	28-Feb-2026
	A50/6/0041/22H	(01)50603468008820(17)250806(10)A50/6/0041/22H	06-Aug-2025

The product code and lot number are printed on the label on the device box and on individual device pouches.

2. Reason for the Field Safety Action

During internal testing by Cipher, it was found that upon application, the disposable sheaths were cracking and causing shattering in some cases due to a manufacturing defect. Not all devices in these batches are affected.

There is a possibility that the fragments could enter the patient abdominal cavity during product use. There are currently no reports of adverse incidents from this defect in any market that the product is available.

3. Actions Required and Timelines

a. Local Distributors/Representatives

Identify customers who have received any affected items and share the content of this FSN. Request customers to stop using the affected products and destroy them. Collate the responses from customers of product destruction and return the information to Cipher Surgical. Please confirm the completion of the actions taken by 29th March 2024.

b. Healthcare Professionals

End users are requested to NOT use any of the affected products. All devices within inventory should be identified and destroyed. Confirm quantity destroyed back to Cipher Surgical or local representative. Please confirm the completion of the actions taken by 29th March 2024.

4. 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. The information in this FSN is NOT required to be communicated to patients.

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.

5. Contact Information

If you have any questions or concerns regarding this notification, please contact Cipher Surgical at customerservice@ciphersurgical.com or your local representative.

This notice has been reported to the appropriate Regulatory Authorities.

We apologise for any inconvenience this may cause and hope for your understanding and support.

Sincerely,



Andrew Newell

Managing Director

Field Safety Notice Response Form

Reference: OpClear FSN ISS-1117 dated 8th March 2024

Details	
Organisation Name	
Organisation Address	
Department/Unit	
Contact Name	
Telephone number	
Email	

Product Code	Lot Number	Quantity Destroyed
CS-10-00-315	A48/3/0041/22E	
	A02/4/0041/23E	
	A18/6/0041/23E	
CS-10-30-315	A11/6/0041/23F	
	A38/4/0041/22F	
	A05/5/0041/23F	
CS-10-00-330	A15/3/0041/23G	
CS-10-30-330	A09/3/0041/23H	
	A50/6/0041/22H	

<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.
<input type="checkbox"/>	I performed all actions requested by the FSN.
<input type="checkbox"/>	I have identified customers affected by this FSN and communicated the FSN to them on _____ [date of communication] (if applicable)
<input type="checkbox"/>	I have received confirmation of reply from all identified customers (if applicable)
Select one of the following:	
<input type="checkbox"/>	All affected devices in my inventory (and at customers, where applicable) have been destroyed
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory

Name:

Position:

Date:

Please return this form to your local representative or to customerservice@ciphersurgical.com

by **29 March 2024.**

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.