Date: 2022-02-16
Ref: ISS-900
Doc ID: QR-RA-AN-ID-1

For the attention of:

Urgent Field Safety Notice (FSN)
OpClear Disposable Procedure Kit
Issue: risk of foreign body reaction

Dear Customer,

Cipher Surgical has determined that some batches of OpClear Disposable Procedure Kit have a manufacturing defect that could in rare 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 with a single lot number for each. The products affected are:

Product Code	Lot Number	UDI	Expiry Date
CS-SZ10-00	A25/2/0041/21Z	(01)50603468006840(17)240630(10)A25/2/0041/21Z	2024-06-30
CS-SZ10-30	A26/2/0041/21Y	(01)50603468006918(17)240630(10)A26/2/0041/21Y	2024-06-30
CS-SR10-00	A28/2/0041/21W	(01)50603468007076(17)240731(10)A28/2/0041/21W	2024-07-31
CS-SR10-30	A27/2/0041/21X	(01)50603468007144(17)240731(10)A27/2/0041/21X	2024-07-31

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 small (circa 0.5mm) sterile plastic fragments of the device were present on some devices due to a manufacturing defect. Not all devices in the batch are affected.

There is a small possibility that these fragments could enter the patient abdominal cavity during product use. The probability of harm occurring is assessed to be very low based on the likelihood of the fragment entering the patient and then there being an adverse foreign body reaction. 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 28th February 2022.

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 28th February 2022.

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,

Justin Buch

Chief Operations Officer

Field Safety Notice Response Form

Reference: OpClear FSN ISS-900 dated 2022-02-15

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

Product Code	**Lot Number**	**Quantity Destroyed**
CS-SZ10-00	A25/2/0041/21Z	
CS-SZ10-30	A26/2/0041/21Y	
CS-SR10-00	A28/2/0041/21W	
CS-SR10-30	A27/2/0041/21X	

☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.
☐	I performed all actions requested by the FSN.
☐	I have identified customers affected by this FSN and communicated the FSN to them on _____ [date of communication] (if applicable)
☐	I have received confirmation of reply from all identified customers (if applicable)
Select one of the following:	
☐	All affected devices in my inventory (and at customers, where applicable) have been destroyed
☐	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 **28 February 2022.**

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.

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