HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Lone Star® Single-Use Elastic Stays and CPO-6 Colpo-Pneumo Occluder

Priority 2 – Warning

HPRA Safety Notice: SN2019(23) **Issue Date: 26th June 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
CooperSurgical Inc.	V37298

ISSUE

CooperSurgical has recalled 11 lots of its SINGLE-USE ELASTIC STAYS due to the possibility that the seal of the sterile pouch may be compromised, thereby increasing the risk of infection.

In addition, CooperSurgical has recalled 26 specific lots of its CPO 6 OCCLUDERS, however they have indicated that none of the affected lots have been supplied to the Irish market.

HPRA is advising users however to maintain awareness of this issue when using any of the devices, irrespective of lot number, by performing a visual inspection of the device prior to use to ensure that the seal integrity is intact.

Please see the accompanying field safety notices (FSNs) for further information.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying FSNs and follow the recommendations provided.
2. Acknowledge receipt of the FSN to the supplier.
3. Ensure that affected product is quarantined and returned to the manufacturer.

4. Forward a copy of this Safety Notice and the FSN, to all relevant personnel within your organisation, or to any organisation/persons to which/whom these devices have been transferred.
5. **Please maintain awareness of this issue when using any of these devices. For lots not listed on the FSN, please perform a visual inspection of the device packaging prior to use, to ensure that the seal integrity is intact. If the seal does not appear to be intact or in any way compromised, do not use the device and report this issue, including the lot number, to the manufacturer and the HPRA.**

TARGET GROUPS

General Surgeons Colorectal Surgeons Gynaecologists Neurosurgeons Head and Neck Surgeons All surgical wards and theatres Theatre Staff Directors of nursing	Hospital Managers / CEOs Risk Managers Supplies managers Purchasing Managers

BACKGROUND

CooperSurgical conducted a lot specific recall for 11 lots of its SINGLE-USE ELASTIC STAYS [CooperSurgical part numbers 3314-1G; 3316-1G; 3550-1G] and 26 lots of its SINGLE-USE COLPO-PNEUMO OCCLUDER™ [CooperSurgical part number CPO-6].

The Elastic Stays are a sterile single-use medical device providing retraction to achieve and maintain optimal visualization throughout a variety of procedures.

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 recalled the affected lots of these products due to the possibility that the seal of the sterile pouch may be compromised, thereby increasing the risk of infection.

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. Please see the accompanying FSNs for pictures which represent examples of acceptable / not acceptable conditions.

MANUFACTURER / AUTHORISED REPRESENTATIVE CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

CooperSurgical Inc.
75 Corporate Drive, Trumbull, CT, USA, 06611

Telephone:
203-601.5200 Ext. 3100
E-mail:
ProductSurveillance@CooperSurgical.com

Enquiries to the **authorised representative** should be addressed to:

Emergo Europe
Prinsessegracht 20, The Hague, NL, 2514 AP

Telephone: 31 70 345 8570
E-mail: EmergoVigilance@ul.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie