HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Various Endotherapy products

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2021(01) **Issue Date: 27th Jan 2021**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Olympus Medical Systems Corporation	V45568

ISSUE
The Health Products Regulatory Authority (HPRA) is issuing this Safety Notice to highlight the recall of certain Endotherapy products being undertaken by Olympus Medical Systems Corporation. Olympus Medical Systems Corporation has identified that the sterility of the devices and associated lot numbers listed in the accompanying field safety notice (FSN) may have been compromised due to a defective seal, which may allow a breach of the package's sterile barrier. The manufacturer has indicated that the breach may be difficult to detect with the naked eye. Olympus Medical Systems Corporation has not received any complaints of injury associated with defective packaging seals, however, the use of non-sterile products may introduce microbes and potentially increase the risk of post-operative infection.

ACTION OR RECOMMENDATIONS
The HPRA advises that users:

1. Check your inventory to see if you have received any of the devices (model numbers and lot numbers) listed on the FSN. The lot number can be found on the sterile pack as shown in the FSN Attachments.
2. Immediately cease further use of the devices within the scope of this action
3. Quarantine the devices and contact your Olympus customer service representative
4. Complete the questionnaire provided by the manufacturer and return it to the manufacturer in the manner specified in the FSN.
5. Forward a copy of this Safety Notice and the accompanying FSN to all relevant personnel within your organization and to any other organizations/ persons to which/ whom these devices have been transferred to.
6. Report any adverse events/ incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS	
Clinical Engineers Emergency Department Consultants General Surgeons Vascular Surgeons Hepatobiliary Surgeons Urologists Orthopaedic Surgeons	Procurement/ Purchasing Staff Risk Managers Supplies Managers Theatre Managers/ Staff Hospital Managers/ CEOs ICU Staff

BACKGROUND

Olympus Medical Systems Corporation has noticed an anomaly in the packaging process of certain devices. The anomaly may cause the sterility of the devices to be compromised. A potential breach to the sterile barrier may be difficult to detect with the naked eye and may result in a non-sterile product being used.

The manufacturer has confirmed that the recall is limited to certain lots of the affected devices as detailed in the attachments accompanying the FSN. However, as the affected devices span a number of applications and might be used across multiple faculties within a given healthcare facility, the HPRA is issuing this Safety Notice to raise awareness of the issue and to request users to complete the action being recommended by the manufacturer.

MANUFACTURER / AUTHORISED REPRESENTATIVE / DISTRIBUTOR CONTACT INFORMATION (amend as required)

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

Olympus Medical Systems Corporation, 2951 Ishikawa-cho, Hachioji-shi, Tokyo - 192-8507, Japan

Telephone: N/A
E-mail: fsca@olympus-europa.com

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

Olympus Europa SE & Co. KG, Wendenstrasse 14-18, Hamburg - 20097, Germany	Telephone: E-mail:	N/A fsca@olympus-europa.com

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

SISK Healthcare (UK) Limited trading as Cardiac Services, 6 Wildflower Way, Boucher Road, Belfast - BT12 6TA	Telephone: E-mail: Website:	 +44(0)2890669000 https://www.cardiac-services.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: E-mail: Website:	+353-1-6764971 devicesafety@hpra.ie www.hpra.ie