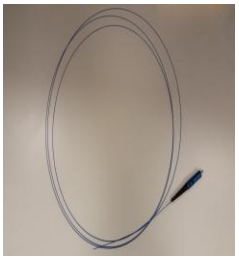
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

SureFlex™ Reusable Fibers and Reusable Stripper and Cleaver Accessories



Priority 1 – For Immediate Action

HPRA Safety Notice: SN2015(19) **Issue Date: 17th July 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
American Medical Systems Inc.	V24638

ISSUE
American Medical Systems Inc. (AMS) has determined that validation data relating to cleaning instructions and sterilisation methods, and the methods defined in instructions for use (IFU), for the Sureflex™ Reusable Fibers and the Reusable Stripper and Cleaver Accessories are insufficient.

AMS has concluded that improper cleaning and sterilisation of the product could result in potential for cross contamination and potentially lead to exposure to micro-organisms that could lead to an infection.

ACTION OR RECOMMENDATIONS

The HPRA advise that users:

1 Check your inventory to determine if you have the affected products.

2 Remove the affected products from use and quarantine.

3 Follow the instructions outlined in the attached Field Safety Notice (FSN) and complete the customer reply form provided by AMS.

4 Forward a copy of this HPRA Safety Notice to all those who need to be aware of this issue within your organisation and to any organisation / person to whom these devices have been transferred.

TARGET GROUPS

Accident & Emergency Staff	Medical Physicists
Biomedical / Clinical Engineers	Nursing Staff
Clinical Directors	Purchasing / Procurement Managers
Central Sterile Supply Department (CSSD) Staff	Risk Managers
Hospital CEOs	Supplies Staff
Infection Control Staff	Theatre Staff
Intensive Care Staff	

BACKGROUND

AMS has issued a FSN recalling all affected devices from the market. **All model numbers** for the SureFlex Reusable Fibers and **all model numbers** for the Reusable Stripper and Cleaver Accessories are affected by this issue.

AMS has developed a replacement Sureflex™ Single Use Fiber but does not currently intend to develop alternative stripper and cleaver accessories.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **European Authorised Representative** should be addressed to:

American Medical Systems Europe B.V.
Haarlerberg
Amsterdam
1101CH
Netherlands

Telephone: +31 20 5938800
Fax: N/A
E-mail: regulatoryaffairsEU@ammd.com
Website:
www.americanmedicalsystems.com

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

Sisk Healthcare Ltd.
Wilton Works
Naas Rd.,
Clondalkin
Dublin 22

Telephone: +353 1 675 4835
Fax: N/A
E-mail: vicki.oreilly@siskhealthcare.ie
Website: www.siskhealthcare.ie

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
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie