Safety Notice

Medical Devices

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

S-Shaped Urethral (F8-F24) Dilators & Urethral Dilators (F6-F16)

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2018(13) **Issue Date: 03 May 2018**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Manufacturer: Zhejiang Chuangxiang Medical Technology Co. Limited, China *Distributor:* MED Surgical (Sisk Healthcare), Dublin	V35739 / MS35639

ISSUE

The HPRA is aware that non-CE marked S-shaped urethral dilators (F8-F24) and urethral dilators (F6-F16) have been placed on the Irish market by Zhejiang Chuangxiang Medical Technology Co. Limited.

This safety notice is to alert healthcare professionals to examine their stock and quarantine any affected medical devices identified.

ACTION OR RECOMMENDATIONS

The HPRA advises that healthcare professionals:

1. Examine your stock to determine if you have the affected devices.

2. Stop using the device immediately and quarantine the affected units. Contact the Irish distributor to arrange return of the affected units.

3. Forward a copy of this safety notice to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.

4. Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs Risk Managers	Purchasing Managers Stores / Supplies Managers

BACKGROUND

The HPRA is aware that non-CE marked S-shaped urethral dilators (F8-F24) and urethral dilators (F6-F16) have been placed on the Irish market.

This safety notice is to alert health care professionals to examine their stock and quarantine any affected medical devices identified. All S-shaped urethral dilators (F8-F24) and urethral dilators (F6-F16) placed on the Irish market by Zhejiang Chuangxiang Medical Technology Co. Limited are affected by this action.

The safety and quality of these medical devices cannot be guaranteed as they may not be manufactured to the required standards or conform to the requirements of the medical devices legislation.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Zhejiang Chuangxiang Medical
Technology Co. Limited
301B, No. 22 Xin Yan Road
Yuhang Economic Development Zone
31100 Hangzhou
Zhejiang
China

Telephone: +86-0571-89167088
E-mail: dora.zhang@med-nova.com

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

MED Surgical (Sisk Healthcare)
Howth Junction Business Centre
Dublin 5

Telephone: +353-1-6754835
E-mail: vicki.oreilly@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