HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Coloplast Testicular Implant and Vaginal Stent

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2015(26) **Issue Date: 19 October 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Coloplast A/S	V25772 MS20954

ISSUE
Coloplast Testicular Implant and Vaginal Stent are manufactured by Silimed Industria de Implantes Ltda and CE-marked under Coloplast A/S name, following an Own Brand Label procedure. The German notified body, recently carried out an inspection of the Silimed manufacturing plant in Brazil. This established, following preliminary testing, the presence of particles on the surface of some of the devices. As a result, the CE certificate is temporarily suspended for the marketing and distribution of all medical devices manufactured by Silimed Industria de Implantes Ltda. As the Coloplast Testicular Implants and Vaginal Stents are manufactured by Silimed they are to be quarantined until further notice. Affected Batches: Testicular Implant: REF. PR3001, PR3002, PR3003, PR3004, PR3005 Vaginal Stent – Inflatable: REF. VS3020, VS3022, VS3024, VS3026 The manufacturer has issued a field safety notice (FSN) for this issue.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Do not implant / use affected devices.
2. Quarantine all remaining stock by serial/batch number and label "Do Not Use."
3. Please pass this notice on to all those who need to be aware within your organisation or to any organisation / persons where the potentially affected devices have been transferred.
4. Please notify the HPRA of any complaints or adverse incidents.
5. Await further information from the manufacturer / distributor or the HPRA.

TARGET GROUPS

Medical directors	Private cosmetic clinics
General practitioners	Public and private hospitals
General surgeons	Paediatric surgeons
Gynaecologists and gynaecology departments	Plastic surgeons
Obstetricians and obstetrics departments	Theatres, theatre managers, theatre nurses
Practice managers	Urology surgeons and urology departments
Practice nurses	Risk managers
	Supplies / procurement managers

BACKGROUND

The HPRA published Safety Notice SN2015(25) on 30/09/2015 in relation to the Silimed CE mark suspension.

The HPRA is investigating the background to this suspension in collaboration with other European regulators.

To date, there has been no indication that the issue under investigation poses a risk to the health of anyone who has received these implants. The measures being introduced at this time are precautionary but any person concerned should contact their implanting surgeon or clinic.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

Coloplast A/S
Holtedam1,
3050,
Humlebaek,
Denmark

Telephone: +45 4911 3339
E-mail: vigilance@coloplast.com
Website: www.coloplast.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
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie