HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

RENASYS™ ® range of Negative Pressure Wound Therapy (NPWT) devices

Priority 2 – Warning

HPRA Safety Notice: SN2014(44) **Issue Date: 26th November 2014**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Smith & Nephew	V22296

ISSUE

On 01 October 2014, Smith & Nephew issued a field safety notice (FSN) to:

- inform users of changes that have been implemented on RENASYS™ devices and to instruct users to discard certain RENASYS™ consumables and
- to highlight to users of the amended Instructions For Use ('IFU') for RENASYS™ devices and to remind customers of the importance of patient monitoring requirements during negative pressure wound therapy.

On the 07 October 2014 a second FSN was issued follow further investigation by Smith & Nephew that identified that two additional RENASYS™ product codes were affected by the corrections identified in the FSN of 01 October 2014.

Full listings of affected product codes are in the attached FSN 07 October 2014.

The Health Products Regulatory Authority (HPRA) is circulating this Safety Notice to ensure that all users RENASYS™ range of Negate Pressure Wound Therapy ("NPWT") devices are aware of the changes made to the original and subsequent FSN and to highlight the actions to be undertaken as part of this field safety corrective action (FSCA).

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Follow the actions outlined by Smith & Nephew in the attached FSN.
2. Identify all lots and products affected by the attached FSN.
3. In the event that you still have any RENASYS™ Canister Kits and Soft Ports Kits with lot numbers within the scope of this FSCA, discard any inventory in line with the FSN.
4. Follow the guidelines proposed in the amended IFU (see FSN).
5. Complete and return the attached Acknowledgement and Receipt Form to Smith & Nephew, even if you do not have any product in your inventory.
6. Forward this Safety Notice to all those that need to be aware within your organisation or to any organisation / person where these devices have been transferred. Please also maintain an awareness of this notice for an appropriate time period.
7. In case of any further questions in relation to this FSN including product replacements, contact Smith & Nephew via email Advice.Healthcare@smith-nephew.com or telephone (IRE) 1800 30 36 22.

TARGET GROUPS

HSE Hospital Staff	Supplies Managers
Private Hospital Staff	Risk Managers
Nursing Home Staff	Clinical Engineers / Biomedical Engineer
Purchasing Managers	

BACKGROUND

As a part of the continuous process improvement, Smith & Nephew has completed the following product changes:

- Bacterial Overflow Guard material change (RENASYS™ EZ / EZ Plus System)
- Soft Port Aperture change (all RENASYS™ Systems)
- Soft Port backing paper slit addition (all RENASYS™ Systems)
- PVC tubing material change on the 800ml canisters (RENASYS™ EZ / EZ Plus System).

Moreover, Smith & Nephew has become aware of cases where a blockage can occur beneath the RENASYS™ devices film dressing, reducing fluid removal from the dressing through the port and into the canister. If a blockage occurs in this way, the exudate may accumulate or "pool" beneath the film dressing, which creates a potential risk of maceration to surrounding tissue and can eventually cause the dressing to lift and allow exudate to leak from the wound. Smith & Nephew determined that RENASYS™ devices may not be able to detect such blockages if the vacuum between the pump and the dressing is still present. In these circumstances, RENASYS™ devices may not alarm to alert the user to the presence of the blockage.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Smith & Nephew Healthcare Limited
David Wright
Healthcare House
101 Hessle Road
Hull HU3 2BN
United Kingdom

Telephone: (IRE) 1800 30 36 22
(UK) +44 1482 222200

E-mail: Advice.Healthcare@smith-nephew.com
Website: www.smith-nephew.com

Enquiries to the **distributor** should be addressed to:
N/A

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