HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

ACTIV.A.C.™ Therapy Units

Priority 2 – Warning

HPRA Safety Notice: SN2020(07) **Issue Date: 17 June 2020**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
KCI USA Inc.	V43852

ISSUE
KCI, now part of 3M, has become aware that ACTIV.A.C™ Therapy Units may power off without notification to the user (i.e., no alarm or warning) resulting in a stoppage of negative pressure wound therapy. KCI is performing a software change for all models of this device whereby the ACTIV.A.C.™ Therapy Unit software will provide a screen notification requiring acknowledgement by the user before the unit shuts down. The manufacturer has issued a Field Safety Notice (FSN) for both customers and distributors of this device in order to inform all users of this issue and subsequent software change. The manufacturer has advised that it is not necessary to discontinue therapy on patients using the ACTIV.A.C.™ Therapy Units. As per the Instructions for Use, users are advised to replace V.A.C.® dressing with alternate dressing if therapy is interrupted or if the unit is powered off for more than two hours. Please see the accompanying FSNs for further details.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Read the accompanying FSNs carefully. The manufacturer has issued two FSNs – a customer letter and a distributor letter.

2. Follow the instructions in the relevant FSN to identify whether you have affected devices in use at your facility or in the home / community setting.

3. Acknowledge receipt of the FSN if you have not already done so.

4. Forward a copy of this Safety Notice and the FSNs to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.

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

TARGET GROUPS

All Wards Caregivers Clinical Directors Clinical Engineers Community Care Managers Community Nurses General Practitioners Hospices Hospitals	Hospital Managers / CEOs Nursing Homes Nursing Managers Nursing Staff Palliative Care Staff Purchasing Managers Risk Managers Supplies Managers

BACKGROUND

KCI has become aware that ACTIV.A.C™ Therapy Units may power off without notification to the user (i.e., no alarm or warning) resulting in a stoppage of negative pressure wound therapy.

Since April 2017, KCI has received seven reports of injuries associated with this issue globally, including reversible maceration, localized infection or wound deterioration. The HPRA has not received any reports of this issue occurring in Ireland.

The ACTIV.A.C.™ Therapy Unit is indicated for patients with wounds being treated in the acute, post-acute and home care settings under the supervision of a clinician. As a result of this issue, patients in extended and home care settings may not be monitored continuously and may not be aware that the device has shut down, which could result in a longer period with inactive therapy that may lead to injury.

KCI is performing a software change for all models of this device whereby the ACTIV.A.C.™ Therapy Unit software will provide a visual and audio notification with Confirmation Screen prior to device shutting off, requiring acknowledgement by the user before the unit shuts down. If Confirmation Screen for power off is not acknowledged, therapy will continue. Repair procedures have been updated to include specific instructions for proper handling of the power switch component during storage and installation onto the ACTIV.A.C.™ unit.

The HPRA is issuing this Safety Notice to raise awareness of this issue. Please see the accompanying manufacturer's FSNs for further information.

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

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

KCI USA Inc.
12930,
Interstate I-10 West,
San Antonio,
TX 78249,
USA

Telephone: +1 (210) 374 3188

E-mail: kci3mfieldactionresponse@mmm.com

Website: https://www.3m.com/

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

KCI Manufacturing
IDA Business & Technology Park,
Dublin Road,
Athlone,
N37,
Ireland

Telephone: +353 87 703 9195

E-mail: EMEARegulatory@Acelity.com

Website: https://www.3m.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

E-mail: devicesafety@hpra.ie

Website: www.hpra.ie