Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/028 Issued: 27 August 2019 at 14:00 Valid until August 2020

Microneedling pens: Dermapen 3 and Dermapen Cryo
Sterile single use needle cartridge tips for: Dermapen 3 – risk of injury or infection

Summary

Manufactured by Equipmed and other trading names (listed in the 'Manufacturer contacts' section), distributed in the UK by Naturastudios – do not use affected devices as they have been manufactured to unknown standards and their safety cannot be verified.

Action

- Identify and do not use any affected devices in your possession.
- Circulate this medical device alert within your organisation and ensure all device users are aware they should stop using these devices.
- Contact manufacturer / distributor for further advice.
- Report suspected or adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
Users of the device

Deadlines for actions
Actions underway: 03 September 2019
Actions complete: 24 September 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Dermapen 3 devices are intended to stimulate the skin for natural collagen induction. Affected devices were manufactured after 30 May 2017.

Dermapen Cryo devices are intended to treat skin tags, lesions, warts and benign moles.

Affected serial and batch numbers are listed below:

Device model name	Device details
Dermapen (3) device	Serial numbers: 3MD1605456 to 3MD1702134 inclusive
Dermapen (3) needle tips	Batch numbers: DP164278, DP180226 and DP180109
Dermapen Cryo	All

Problem / background

The devices' packaging have a CE mark but this has not been obtained through appropriate regulatory oversight.

Manufacturer contacts

Stene Marshall
Equipmed
(t/a DermapenWorld Pty Ltd, Equipmed USA, Equipmed Europe Limited or Equipmed International Pty)
Tel: +61 (0) 29889 3636 (Australia)
Email: info@dermapenworld.com and info@equipmed.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Dentists
- Dermatologists
- Health and safety managers

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Optometrists

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Hospitals in the independent sector
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/028** or **2019/002/027/451/001**.

Technical aspects

Feza Haque, MHRA
Tel: 020 3080 6000
Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health, Social Services and Public Safety
Tel: 0208 9052 3868
Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government
Tel: 03000 250986 / 03000 255510
Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).