Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/002 Issued: 16 January 2020 at 12:00 Valid until January 2021

Convex two-piece skin barriers (Natura /Surfit /Combihesive Wafers) for use with ostomy bags – recall due to risk of stoma injury, bleeding and leakage under the skin barrier

Summary

Manufactured by ConvaTec – specific batches of convex two-piece skin barriers have been incorrectly manufactured with off-centre starter/stoma hole.

Action

- Identify if you have any devices from the affected lots listed in the manufacturer's FSN.
- Contact ConvaTec to arrange return of affected devices and replacements, free of charge.
- Share this information with all those who may also have affected product, including patients.
- Complete the 'End User Response Form' in the FSN even if you don't have affected devices left in stock, and return it to tracey.fairclough@amcaregroup.co.uk
- Report suspected or actual 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
Healthcare professionals and users of the device.

Deadlines for actions
Actions underway: 30 January 2020
Actions complete: 13 February 2020

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.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

SurFit™/ Combihesive™ Wafers, manufactured from February 2017 to September 2018:

- System 92 Secure Moldable Convex Durahesive™ Wafer
- System 92 Secure Durahesive Wafer with Convex

Problem / background

A number of these devices have been produced with an off-centre starter hole as shown in Figure 1 below.

Off Center Starter Hole (Stoma Hole)
This product may be out of specification

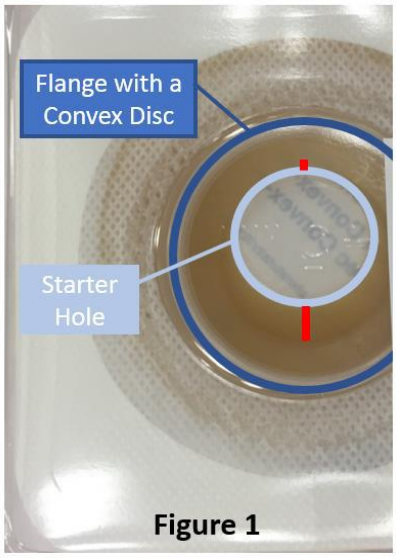

Figure 1

The starter hole should be "centered" in relation to the flange.

The red lines in the photo on the left should be more equal.

The green lines in the photo on the right are more equal.

Centered Starter Hole (Stoma Hole)
This product should be within specification

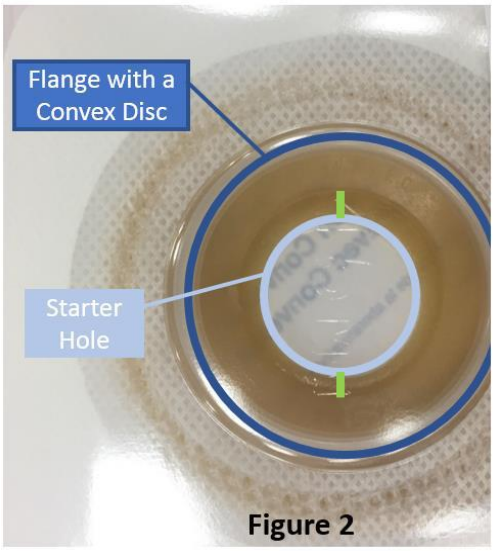

Figure 2

Manufacturer contacts

The manufacturer of the device is Convatec.

Distributors, retailers and wholesalers should contact:
Stericycle
Phone: 0800 069 8202
Email: Convatec2p@stericycle.com

Patients should contact:
Tracey Fairclough
Phone: 07442 188 256
Email: tracey.fairclough@amcaregroup.co.uk

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:

- Adult intensive care units
- Community children's nurses
- Community hospitals
- Community nurses
- District nurses
- Equipment stores
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- General surgery
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Oncology nurse specialists
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Palliative care teams
- Pharmacists
- Purchasing managers
- Renal medicine departments
- Renal medicine, directors of
- Urological surgeons
- Urological surgery, directors of
- Urology departments

GP Practices registered with CAS

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

NHS England area teams

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

- Community pharmacists
- GP practices not yet registered with CAS (for information only)

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Equipment stores
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes

Independent distribution

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

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

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/2020/002** or **2019/008/028/701/002**.

Technical aspects

Eliz Mustafa or Emma Rooke, 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 (Northern Ireland)
Tel: 028 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 255278 or 03000 255510
Email: Haz-Aic@gov.wales

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).