Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/012 Issued: 28 February 2019 at 11:00

Potentially breached sterile packaging of: rectal tubes, Unoversal drainage systems, SimpaVac, sterile suction connecting tubes, sterile connecting pieces, suction handles/sets (FilterFlow™/Deltaflo), oxygen catheters, sterile nasal oxygen cannulas, sterile oxygen connecting tubes, and sterile forceps

Summary

Manufactured by ConvaTec Limited - use of affected devices may increase risk of patients acquiring infections – extension to MDA/2018/034 as additional devices are affected

Action

- Identify if you have any affected devices - check the manufacturer's Field Safety Notice (FSN) dated 04 Jan 2019 for a list of affected product codes and lots.
- Stop using and quarantine affected devices as instructed in the manufacturer's FSN.
- Complete the 'Recall Response Form for END USERS' in the FSN, even if you don't have affected devices left in stock, and return it to convatecproductrecall@stericycle.com to arrange return of affected devices.
- Report any incidents or complaints involving this product to unomedical-uk.customerservice@convatec.com and through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.
- Note that this is an extension to MDA/2018/034 as more affected products have been identified. None of the products listed in the latest FSN were listed in the previous version of the FSN.

Action by
All healthcare professionals who are responsible for or who use these devices

Deadlines for actions
Actions underway: 21 March 2019
Actions complete: 29 April 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.

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

The breach in the packaging is not visible so affected devices can only be identified by comparing product code/REF and LOT/Batch Number stated on the packaging to the product list in attachment 1 of the manufacturer's FSN.

Manufacturer contacts

ConvaTec Limited
Tel: 01244 832206
Email: convatecproductrecall@stericycle.com
unomedical-uk.customerservice@convatec.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:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Clinical perfusionists
- Colposcopy departments
- Community children's nurses
- Community defibrillation officers
- Community dental practices
- Community hospitals
- Community midwives
- Community nurses

- Coronary care departments
- Coronary care nurses
- Day surgery units
- Dental departments
- District nurses
- ENT departments
- ENT medical staff
- ENT services, directors of
- Equipment libraries and stores
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Health visitors
- Hospital at home units
- Infection control nurses
- Infection prevention and control directors
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical libraries
- Midwifery departments
- Midwifery staff
- MRI units, directors of
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Operating department practitioners
- Oral surgeons
- Orthopaedic surgeons
- Outpatient clinics

- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Purchasing managers
- Renal medicine departments
- Renal medicine, directors of
- Resuscitation officers and trainers
- Risk managers
- School nurses
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments
- Walk-in centres

NHS England area teams

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

- General dental practitioners
- General practitioners (for information only)
- Nutritional nurse specialists
- General practice managers
- General practice nurses

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.

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
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Equipment supplies managers

- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers

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)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED
- Children's services
- Educational establishments with beds for children
- Residential special schools

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/2019/012** or **2018/007/009/291/014.**

Technical aspects

Emma Rooke and Eliz Mustafa, 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).