



# Medical Device Alert

MDA/2019/029

Issued: 12 September 2019 at 14:00

Valid until September 2020

## Deltec Gripper non-coring needles and PORT-A-CATH trays containing Gripper needles – recall due to risk of needle occlusion

### Summary

Manufactured by Smiths Medical: due to a manufacturing process failure, needles may be occluded, potentially causing a delay to treatment.

### Action

- Identify and quarantine affected devices, which were manufactured from 11 June 2018 to 21 February 2019 inclusive, as listed in attachment 2 of the manufacturer's [Field Safety Notice \(FSN\)](#) dated July 2019.
- Return affected devices by following the instructions in the manufacturer's FSN.
- 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 the manufacturer if your local or national systems do not.

#### Action by

All healthcare professionals who are responsible for, or who use these devices.

#### Deadlines for actions

Actions underway: 03 October 2019

Actions complete: 05 December 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.

## Device details

The GRIPPER non-coring safety needle is indicated for the administration or withdrawal of fluids from implanted ports.

The PORT-A-CATH system is indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.

The date of manufacture is on the packaging.

## Problem / background

If a GRIPPER needle is occluded, it will need to be replaced, which will delay the start of therapy.

MHRA is publishing this alert to ensure that all hospitals are aware of the issue and that adequate action is taken to mitigate risks to patients.

## Manufacturer contacts

Smith's Medical

Tel: 0845 850 0445

Email: [GRIPPERocclusion2019@smiths-medical.com](mailto:GRIPPERocclusion2019@smiths-medical.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
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Clinical perfusionists

- Community children's nurses
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- District nurses
- Endocrinology units
- Endocrinology, directors of
- ENT departments
- ENT medical staff
- ENT services, directors of
- Equipment stores
- Equipment libraries and stores
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- General surgical units, directors of
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Minor injury units
- Maternity units
- Medical directors
- Medical oncologists
- Medical oncology, directors of
- Medical physics departments
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- 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 oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Peritoneal dialysis units
- Phlebotomists
- Purchasing managers
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Radiologists
- Radiology departments
- Radiology directors
- Renal medicine departments
- Renal medicine, directors of
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments
- Walk-in centres

### ***Independent distribution***

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

- Adult placement
- Care homes providing nursing care (adults)
- Clinics
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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](mailto:safetyalerts@mhra.gov.uk) and requesting this facility.

## Enquiries

### England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/029** or **2019/007/010/228/011**.

#### Technical aspects

Eliz Mustafa or Roopa Prabhakar, MHRA

Tel: 020 3080 6000

Email: [DSS-TM@mhra.gov.uk](mailto:DSS-TM@mhra.gov.uk)

#### Clinical aspects

##### Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto: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: 028 9052 3868

Email: [niaic@health-ni.gov.uk](mailto: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.irc@nhs.net](mailto:nss.irc@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](mailto: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 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.

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