



Llywodraeth Cymru  
Welsh Government

# Medical Device Alert

**10<sup>th</sup> July 2018**

Parc Cathays  
Caerdydd CF10 3NQ

Cathays Park  
Cardiff CF10 3NQ

## SAM XT Extremity Tourniquet - Recall due to the risk of tourniquet failing in use

- Refer to Device Details below for identification of affected devices
- Refer to the manufacturer's [FSN](#) for a list of affected lot numbers
- Identify and quarantine affected devices
- Return any affected devices and the completed recall response form to the distributor

### Sent to:

NHS Wales Shared Services Partnership  
Directors of Public Health,  
Chief Executives, NHS Trusts  
Chief Executives, LHBS  
Medical Directors, NHS Trusts  
Nurse Directors, LHBS  
Executive Nurses, NHS Trusts  
NHS Direct  
CSSIW  
Social Services  
HIW

A list of people who need to have early sight of this information is given in the Notice.  
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

### Points of particular importance in Wales:

**Healthcare Quality Division  
Welsh Government  
Cathays Park  
Cardiff CF10 3NQ**



# Medical Device Alert

MDA/2018/022R

Issued: 06 July 2018 at 13:00

Valid until: July 2019

## SAM XT Extremity Tourniquet - Recall due to the risk of tourniquet failing in use

### Summary

Manufactured by SAM Medical Products - An error in the manual sewing operations of devices manufactured from March 2017 to April 2018 may cause the seam holding the buckle to the belt to fail.

### Action

- Refer to Device Details below for identification of affected devices
- Refer to the manufacturer's [FSN](#) for a list of affected lot numbers
- Identify and quarantine affected devices
- Return any affected devices and the completed recall response form to the distributor

#### Action by

Healthcare Professionals

#### Deadlines for actions

Actions underway: 20 July 2018

Actions complete: 03 August 2018

**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.

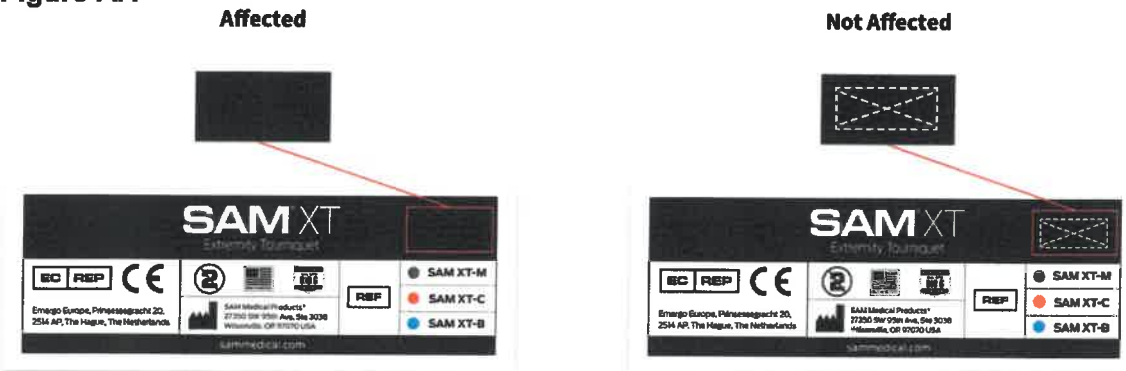
## Device details

The SAM XT devices affected by the recall can be distinguished from non-affected devices by 3 methods.

1. The absence of a Box X stitch on the IFU, see Figure A.1
2. The absence of a Box X stitch on the device, see Figure A.2
3. Any Lot Number from XT1711 to XT1811, see Figure A.3.

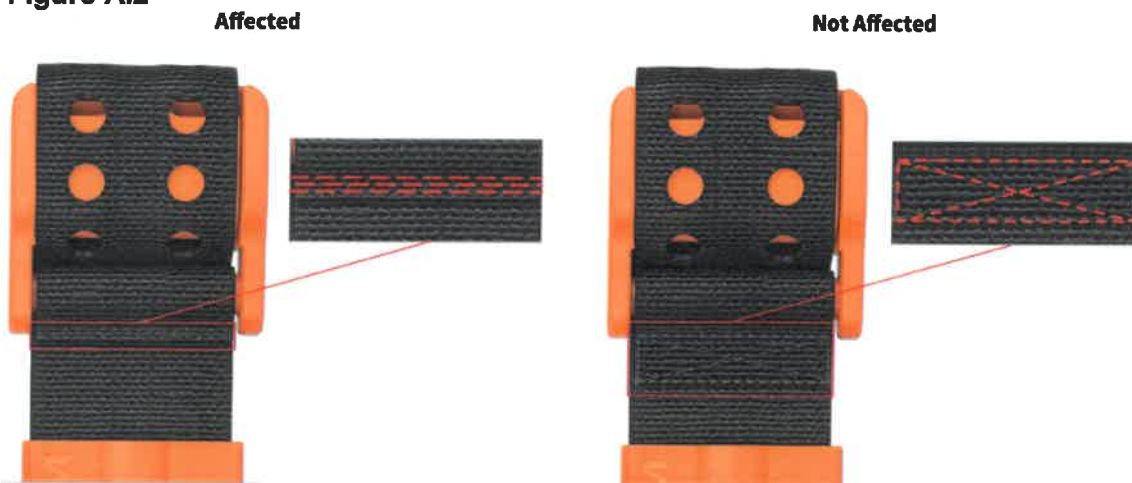
An affected tourniquet will **NOT** have the box-stitch icon on the device or on the upper right of the Instructions For Use (IFU) insert.

**Figure A.1**



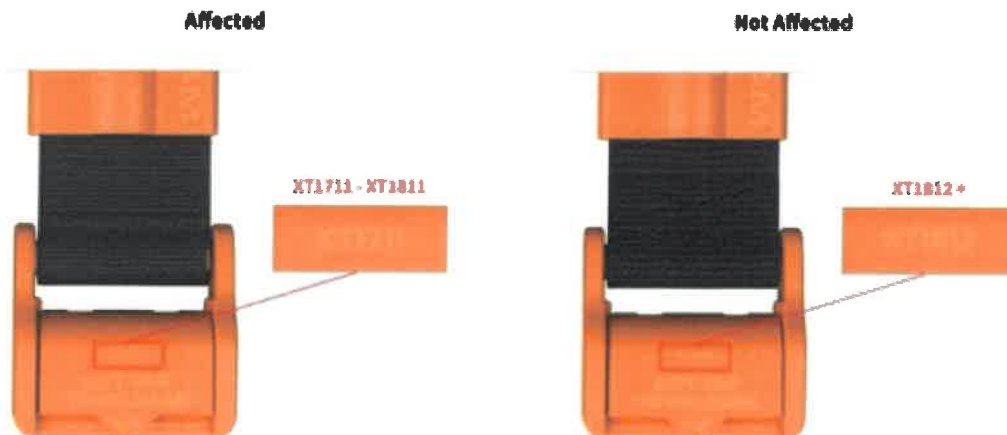
An affected tourniquet will have a multi-pass straight lockstitch seam as shown on the left of Figure A.2.

**Figure A.2**



An affected tourniquet will have a Lot Number between XT1711 and XT1811 as shown in Figure A.3.

**Figure A.3**



## Manufacturer contacts

SAM Medical Products  
27350 SW 95<sup>th</sup> Ave  
Suite 3038  
Wilsonville  
OR  
97070  
US  
Tel: 001-503-783-6915  
Email: [jeff.lipps@sammedical.com](mailto:jeff.lipps@sammedical.com)

Water-Jel Europe LLP  
3&4 The Mead Business Centre  
Mead Lane,  
Hertford  
SG13 7BJ  
Tel: +44 1992 583222  
Email: [terry.obrien@waterjel.net](mailto:terry.obrien@waterjel.net)

## 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
- Ambulance services directors
- Ambulance staff
- Paramedics
- Paramedic staff

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/2018/022** or **2018/005/003/601/011**.

### Technical aspects

Sophie Clewlow or Sara Vincent, MHRA

Tel: 020 3080 6871 or 020 3080 7169

Email: [sophie.clewlow@mhra.gov.uk](mailto:sophie.clewlow@mhra.gov.uk) or [sara.vincent@mhra.gov.uk](mailto:sara.vincent@mhra.gov.uk)

### Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto:dct@mhra.gov.uk)

### Reporting adverse incidents in England

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

### Northern Ireland

Alerts in Northern Ireland are distributed via the [NICAS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, 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)

<https://www.health-ni.gov.uk/niaic>

### Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the [forms on our website](#).

### Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

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

Tel: 0131 275 7575

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

### Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to [Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to [Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

**Wales**

Enquiries in Wales should be addressed to:  
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

**Reporting adverse incidents in Wales**

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> 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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