Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

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.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

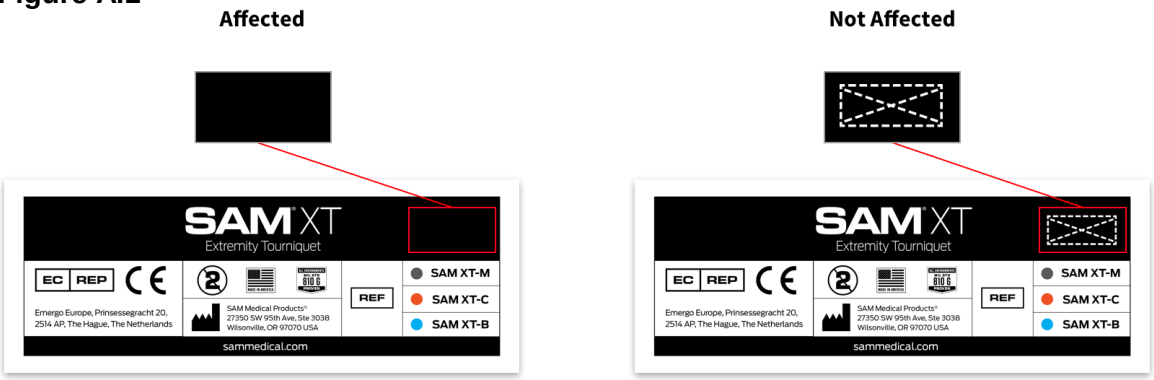
Device details

The 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.

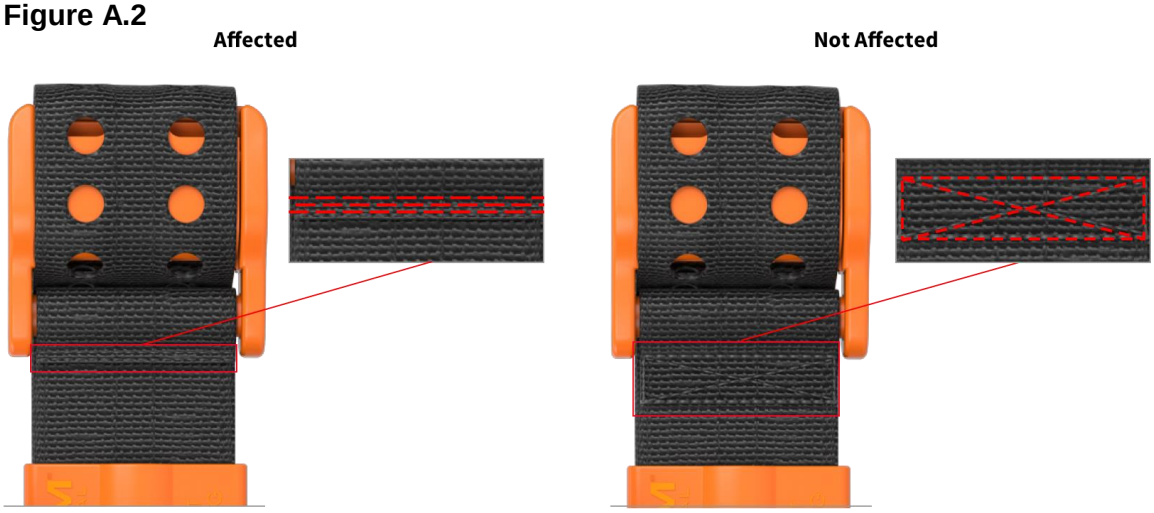
An affected tourniquet will **NOT** have the box-stitch icon on the device or on the upper right of the Instructions For Use (IFU) insert.

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 95th Ave
Suite 3038
Wilsonville
OR
97070
US
Tel: 001-503-783-6915
Email: 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

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 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 or sara.vincent@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: 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
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.iric@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

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).