URGENT: MEDICAL DEVICE RECALL

Voluntary Recall of SAM XT Extremity Tourniquet

2018-05-03

Dear SAM Medical Customer/Distributor,

The purpose of this letter is to advise you that SAM Medical is voluntarily recalling all unused SAM XT Extremity Tourniquets (SAM XT). Based on internal testing, results indicated a possible failure of the stitches securing the buckle to the nylon belt could occur, posing a potential risk when used on a human patient to stop arterial blood flow. This voluntary recall involves all unused SAM XTs manufactured with the multi-pass straight lockstitch, distributed from March 2017 through April 2018. This recall is being carried out to the end-user level.

Note: To date, no reports of adverse health consequences have been received. There is a remote chance that a serious injury and/or death could occur as a result of the failure of the device.

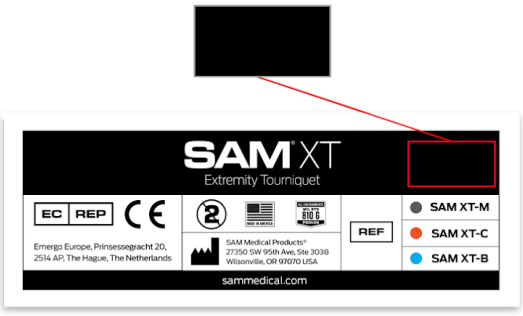
Reason for the Voluntary Recall

It was determined through customer feedback and subsequent internal testing that the stitched seam securing the Buckle Assembly to the Belt (shown below in Figure A.2), failed in a very small number of devices when rotational forces from the Windlass were applied during use on the HapMed training manikin.

Figure A.1

An affected tourniquet will not have the “Box X Stitch” icon on the upper right of the folded Instructions For Use (IFU) insert. Tourniquets not affected will display the “Box X Stitch” icon on the upper right of the folded IFU.

Affected



Not Affected

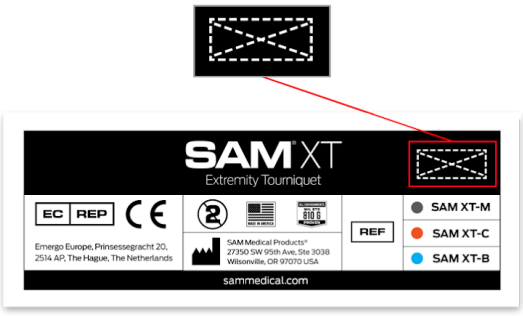
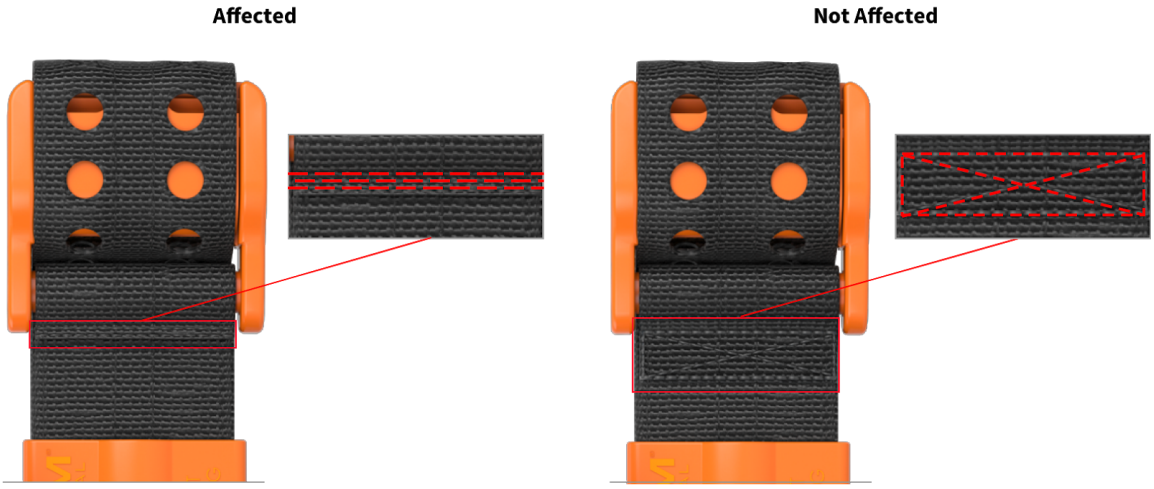


Figure A.2
An affected tourniquet will have a multi-pass straight lockstitch. Tourniquets not affected will have a “Box X” stitch (stitching is highlighted in red for display purposes only).



Risk to Health

The primary risk is that failure of the SAM XT could possibly occur while being applied on a patient’s injured limb or extremity area and would not be effective in stopping arterial bleeding. Should a failure occur in the field, apply another tourniquet or apply direct pressure by hand to the extremity area, as needed.

- **Frequency of failures and complaints**
  To date, there have been no reports of adverse health consequences received.
- **Potential magnitude of a failure**
  Although the chances are remote, there is the possibility of serious health consequences occurring in the event of a failure, due to loss of sufficient circumferential pressure necessary to stop arterial bleeding on the limb of a patient.
- **Adverse events**
  No reports of adverse events have been received by SAM Medical to date.

Actions to be taken by Distributor/Customer/End User

The following actions will be taken by SAM Medical, SAM Medical Distributors, and customers/end users of the SAM XT device:

- SAM Medical Distributors should first discontinue shipments of affected SAM XTs.
- SAM Medical Distributors should inventory and quarantine their stock of affected SAM XTs.
- SAM Medical will contact each SAM Medical Distributor and direct customer to determine best location and timing of shipment of replacement tourniquets.
- SAM Medical will ship replacement SAM XTs to SAM Medical Distributors and direct customers for the total number units returned to SAM Medical since the initiation of the recall.

- SAM Medical will provide a Recall Response document to each SAM Medical Distributor and direct customer for the purpose of acknowledging initial receipt of the letter and confirmation of actions taken.
- SAM Medical Distributors and direct customers will in turn notify their sub-distributors or end users by sending a copy of the included Recall Response document of the actions being taken as well as ship the replacement SAM XTs to sub-distributors and end user customers. The Recall Response document should be returned by the sub-distributors and end users through their distribution channel back to SAM Medical.
- SAM Medical Distributors and direct customers who have resold the SAM XT to sub-distributors and end users will document and report to SAM Medical that all customers have been notified. This information will be documented in the included Recall Response document and then returned to SAM Medical (via FAX, e-mail, or mail, per instructions on the email Back document).
- If any adverse event or complaint is received please document it on the Recall Response form.

Product and Distribution Information: The table below contains information on all of the product that is subject to this recall.

PART NUMBER	**MODEL**	**LOT NUMBERS** w/ multi-pass straight lockstitch **(see Fig A.2)**
SAM XT-M	Tactical Black or Military	XT1711 thru XT1811
SAM XT-C	Hi-Viz Orange or Civilian	XT1711 thru XT1811
SAM XT-B	Hi-Viz Blue	XT1808 thru XT1811

Type of Action by the Company

All SAM XTs are now being manufactured with a “Box X” stitch which produces an inherently stronger stitch pattern. In addition, the company initiated more extensive simulated-use testing to ensure the revised stitching process is more consistently reliable. Production and replacement of all recalled SAM XTs with the improved stitching is currently underway.

Failure Investigation Findings: Investigation into the product failures revealed during internal testing were due to inconsistencies in the stitching process.

Contact Information

SAM Medical Customer Service at:

- **Email:** xtrecall@sammedical.com
- **Phone:** +1 800 580-3519, Monday through Friday, 8:00 a.m. – 5:00 p.m., Pacific Time
- **Website:** www.sammedical.com
- **SAM XT Updates:** www.sammedical.com/xtrecall

Authorized by

Signature: 

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Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA'S MedWatch Adverse Event Reporting program either online, by regular mail or by fax.