URGENT FIELD SAFETY NOTICE

SAM XT Extremity Tourniquet
SAM FSCA 2018-01
Type of action - Return of Medical Device

Company / Customer:
Address:
Address:

Date: 2018-05-03

Attention: Distributors and Direct Customers

Details on affected devices:
SAM XT Extremity Tourniquet Tactical Black (PN SAM XT-M)
SAM XT Extremity Tourniquet Hi-Viz Orange (PN SAM XT-C)
SAM XT Extremity Tourniquet Hi-Viz Blue (PN SAM XT-B)

The lots affected by this recall were manufactured from March 2017 to April 2018 are listed in the table below:

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

For additional information in identifying affected product please go to the SAM Medical website:
www.sammedical.com/xtrecall

Description of the problem:

The purpose of this notification is to inform you of a Field Safety Corrective Action (FSCA) for the SAM XT Extremity Tourniquet product family. The SAM XT Extremity Tourniquet (SAM XT) with the identified lot numbers could contain a manufacturing error that was not caught by inspection. The manufacturing error is caused by manual sewing operations that could cause the seam retaining the buckle to the belt to fail. The probability of a failure in a clinical situation was estimated to be 1 in 524,800 uses when the windlass is rotated at least 3 times. If the failure occurs in a clinical situation, it could lead to a delay in treatment by a first responder who may have to apply a second tourniquet, use manual pressure or use an alternate technique to control arterial bleeding.

Advise on action to be taken by the Distributor:

As part of this FSCA we need you to:

- Conduct a thorough inventory of SAM XT Extremity Tourniquets at your facility to identify and quarantine affected unused devices.

- Cease further distribution of the affected devices.
- Contact any sub-distributors and/or customers that you have shipped product to providing them with a copy of this FSCA/Response Form and advise them to quarantine their affected devices.
- Sub-distributors and customers should return the SAM XT Extremity Tourniquet to the Distributor from whom the device(s) were purchased.
- Return the completed Recall Response Form to the Distributor.
- As the In-Country Representative for your market, you will need to contact the Competent Authority regarding this recall. Please contact Jeff Lipps if additional documentation is needed.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Return of Affected Product

Contact the distributor from whom you purchased the device to arrange for a return authorization and shipping information. Shipping will be provided free of charge.

Once the unused devices have been returned, an equal number of replacement devices will be provided. Your replacement may consist of a device that includes one of the lots identified above but can be differentiated from affected devices by the placement of a "Box X Stitch" icon on the IFU and the presence of a "Box X" stitch on the nylon belt adjacent to the attachment site of the buckle.

Contact reference person:

Jeff Lipps, Director of RA/QA
SAM Medical Products
xtrecall@sammedical.com

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

NOTE: The appropriate Competent Authorities have been notified of this FSCA.

Kindest regards,

Jeff Lipps