Life-Assist
Helping Heroes Save Lives

URGENT MEDICAL DEVICE RECALL

Thursday, May 3, 2018

Dear Valued Life-Assist Customer,

According to our records you may have purchased a product that has been recalled by the manufacturer. Please examine your inventory to determine if you have the following product, with an affected lot number in your possession.

SAM® Extremity Tourniquet, Hi-Viz Orange

Life-Assist, Inc. Product Code	Manufacturer Product Code	Lot #s
TQ999XTC	SAM XT-C	X1711 thru XT1811

Reason for Recall:

Sam Medical has initiated this voluntary recall after internal testing 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.

Please read the enclosed press release from the manufacturer for more information.

Action Required:

1. Immediately forward this notification to any pertinent personnel, department, and/or location within your organization.
2. Use the methods of identification from the enclosed manufacturer press release to inspect your inventory and quarantine any affected product. If the affected stock has been depleted, you may disregard this notification.
3. Contact Life-Assist Customer Service at 800-824-6016 or salesservice@life-assist.com to obtain a Return Authorization.

We apologize for any inconvenience.

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customerservice@life-assist.com
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FOR IMMEDIATE RELEASE

URGENT MEDICAL DEVICE RECALL: SAM XT EXTREMITY TOURNIQUET

WILSONVILLE, OR, May 1, 2018 -- SAM Medical today announced it is conducting a voluntary international recall of all unused SAM XT Extremity Tourniquets (SAM XT). The company initiated the recall after internal testing 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. To date, there have been no reports of adverse health consequences received. This recall is being made with the knowledge of the Food and Drug Administration and other relevant Competent Authorities.

Product Identification

The recall involves all unused SAM XTs manufactured with the multi-pass straight lockstitch (Fig A.2), distributed from March 2017 through April 2018, with the following lot numbers. The lot number is located on the face of the buckle.

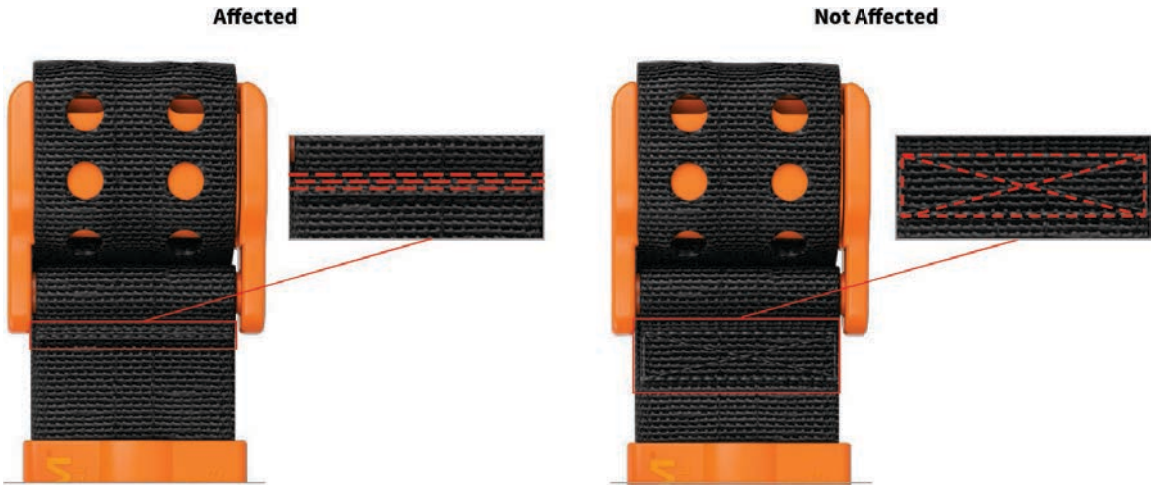
PART NUMBER	MODEL	LOT NUMBERS w/ multi-pass straight lockstitch **(see Fig A.2)**
SAM XT-M	Tactical Black or Military	XT1711 thru XT1811
SAM XT-C	Hi-Viz Orange or Civilian	XT1711 thru XT1811
SAM XT-B	Hi-Viz Blue	XT1808 thru XT1811

To help identify whether you have a tourniquet that is subject to the recall, in addition to the lot numbers in the prior table, please read Figures A.1 and Figure A.2 below.

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.

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).



Remedy

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 consistently reliable. Production and replacement of all recalled SAM XTs with the improved stitching is currently underway.

Notifications Made

Concurrent with this press release, SAM Medical is notifying all SAM XT distributors and direct sales customers by email and signature-required postage. Each customer will receive instructions on how to arrange for a return of all recalled product. Customers and distributors must return all unused affected product through their distribution channel.

If you purchased product directly from SAM Medical:

1. Immediately examine your inventory and quarantine product subject to recall pursuant to the identification instructions above.
2. Immediately discontinue use and/or distribution of any affected products.
3. If you received a recall information packet from SAM Medical, follow the instructions in that packet for return of the recalled product.
4. If you have not received an information packet from SAM Medical by May 16, 2018, please contact the company at xtrecall@sammedical.com.

If you purchased product from a party other than SAM Medical:

1. Immediately examine your inventory and quarantine product subject to recall pursuant to the identification instructions above.
2. Immediately discontinue use and/or distribution of any affected products.
3. Contact the seller of the product and ask for instructions for return of all unused SAM Medical XTs through that distributor.
4. If you do not have information on where you purchased the SAM XT, please contact the company at xtrecall@sammedical.com

Customers with questions may contact the company at **+1 800-580-3519** between the hours of **8:00 a.m. and 5:00 p.m. PT.** Customers may also contact the company by email at xtrecall@sammedical.com or through the website at www.sammedical.com/xtrecall.

About SAM Medical
For over 30 years, SAM Medical has developed and manufactured innovative medical products used for military, law enforcement, emergency, wilderness and sports medicine, and pre-hospital care around the world. A resounding favorite of medical professionals, SAM Medical's lineup of products is engineered to preserve life. Innovations include SAM XT Extremity Tourniquet, SAM Splint, SAM Chest Seal, SAM Junctional Tourniquet, SAM Pelvic Sling, ChitoSAM, and SAM Soft Shell Splint. For more information, visit sammedical.com.

Contact:
Customer Service
+1 800-580-3519
xtrecall@sammedical.com

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.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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