

URGENT FIELD SAFETY NOTICE

SAM Junctional Tourniquet (SJT) Auxiliary (Accessory) Strap

2014/11/06

Device Modification/Exchange/Destruction

Dear SAM Medical Customer/Distributor,

The purpose of this letter is to advise you that SAM Medical, based on customer feedback and subsequent internal testing, is initiating a Field Safety Corrective Action (FSCA) for the SAM Junctional Tourniquet (SJT) Auxiliary (Accessory) Strap, which is intended for use in the control of difficult bleeds in the axilla area. **ONLY THE AUXILIARY STRAP IS AFFECTED.** The remaining components of the SJT are not impacted by this FSCA and function as intended. This FSCA includes the following SAM Medical part numbers:

<u>Part#</u>	<u>Description</u>
SJT 102	SAM Junctional Tourniquet, 2 Target Compression Devices (1 with Extender), Hand Pump, Auxiliary Strap
SJT 112	Target Compression Device with Extender, Hand Pump, Auxiliary Strap

Note: No serious injuries and/or deaths have occurred. 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 FSCA

It was determined through customer feedback and subsequent internal testing that the rear retaining clip (shown below in Figure 1 and Figure 2) failed in a very small number of devices during training demonstrations. No reports of patient injuries have been received by SAM Medical nor has the device been reported to fail during actual patient use. SAM Medical is taking a proactive approach by offering a replacement strap for all SJT units shipped to our customers.

Note: It is important to note that this FSCA is specific to the auxiliary accessory strap. The primary SJT device is NOT subject to recall and remains fully functional for the SJT-specific intended uses (to control difficult bleeds in the inguinal area and to immobilize a pelvic fracture).

- **Frequency of failures and complaints**

To date SAM Medical is aware of only two product failures (out of 3633 units in distribution)

- **Potential magnitude of a failure**

Although the chances are remote, there is the possibility of serious injury or death occurring in the advent of a failure, due to the loss of pressure being applied while the auxiliary strap is actively being used on a patient in the axilla region.

- **Adverse events**

No reports of adverse events have been received by SAM Medical to date.

Figure 1 – Current Auxiliary Strap Clip Close Up

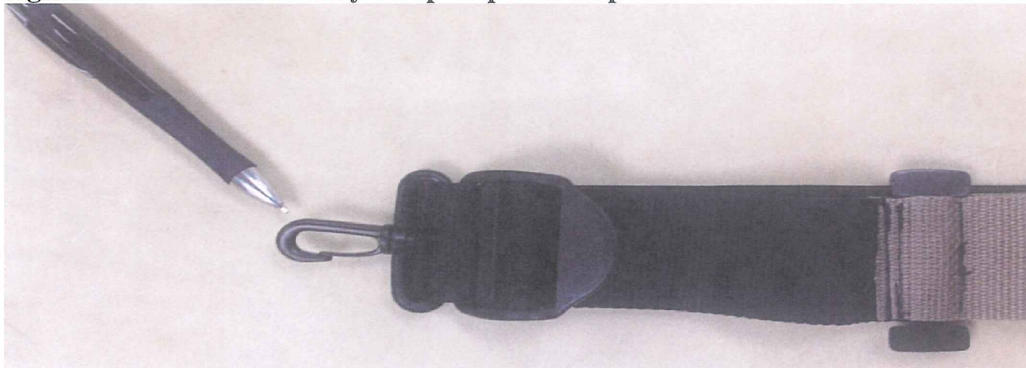
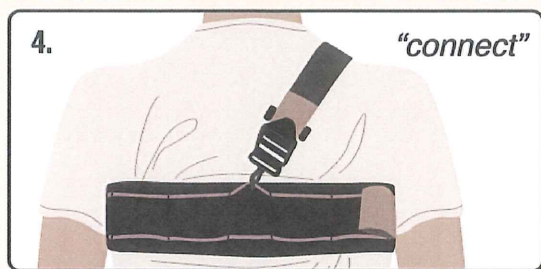


Figure 2 – Auxiliary Strap Application



Connect the auxiliary strap to the cord on the back of the SJT using the small clip, as close as possible to the patient's mid-line.

Risk to Health

As mentioned above, the primary SJT device remains fully functional and only the axilla indication would be affected by the potential failure of the Auxiliary Accessory Strap. The primary risk is that the failure could possibly occur after the Auxiliary Accessory Strap has been attached to the SJT and pressure has been applied to the Axilla area. Should the failure occur while medical personnel are attending to other patients, the bleeding could continue unabated until it was observed by medical personnel, the patient, or other attending personnel.

The device failure itself will be readily recognized because the failure of the clasp will either prevent initial tightening of the strap or will cause the strap to detach from the SJT, resulting in an immediate loss of pressure to the axilla area.

Replacement of Auxiliary (Accessory) Strap

Customers will receive one complete Auxiliary Accessory Strap at no charge with a reinforced metal clip as a replacement. Once received, the existing strap should be removed from the SJT and replaced with the new strap. SAM Medical is making best efforts to quickly produce replacement straps for all affected units and to get them to all affected customers.

Corporate Offices
PO Box 3270
Tualatin, OR 97062

sammedical.com
toll: 800.818.4726
fax: 503.639.5425

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 SJT device:

1. Should a failure occur in the field, discontinue use of the Auxiliary Strap and apply direct pressure by hand to the Axilla area, as needed.
2. **SAM Medical** will contact each Distributor to determine best location and timing of shipment of replacement straps.
3. **SAM Medical** will ship to distributors (based on sales records) the total number of straps as units received since product release.
4. **SAM Medical** will forward a FAX Back document to each distributor for the purpose of acknowledging initial receipt of the letter and confirmation of actions taken.
5. SAM Medical **Distributors** will in turn notify their customers via this letter and the included FAX Back document of the actions being taken as well as ship the replacement straps to individual customers.
6. **Customers/End Users** will remove the original Auxiliary Strap from each SJT in their possession and replace with the new strap.
7. **Customers/End Users** will destroy each removed, original strap and will inform the distributor of the number of straps that were replaced and the number of original straps that were destroyed.
8. **Customers/End Users** will complete and return the FAX Back document to the distributor from whom the FAX Back was sent.
9. SAM Medical **Distributors** will document and report to SAM Medical that all customers have been notified and replacement straps delivered to these customers. They (Distributors) will notify SAM Medical that the replaced straps have been destroyed. This information will be documented on the included FAX Back document and then returned to SAM Medical (via FAX, e-mail, or mail, per instructions on the FAX Back document).

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

Product and Distribution Information Table			
Part Number	Product Names/Description	Lot Number	Qty
SJT 102	SAM Junctional Tourniquet, 2 Target Compression Devices (1 with Extender), Hand Pump, Auxiliary Strap	See Attached	3632
SJT 112	Target Compression Device with Extender, Hand Pump, Auxiliary Strap	6/5/14	1

Type of Action by the Company:

SAM Medical is actively working to upgrade the clasp in question in order to ensure full functionality and structural integrity going forward. All replacement straps will be of the same upgraded construction.

Failure Investigation findings: Investigation into the two reported product failures revealed that the failure was due to a flaw in manufacturing process for the clasp (plastic construction).

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PO Box 3270
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fax: 503.639.5425

Contact Information:

SAM Medical Customer Service at –

- email customerservice@sammedical.com
- phone (503) 639-5474, Monday through Friday, 7:30 – 4:30, Pacific Time
- toll free 1-800-818-4726
- Website www.sammedical.com

Authorized by:

Name (Print): Will Fox

Signature: 

Title: Director, Operations, Product Development and Business Partnerships

- email will.fox@sammedical.com
- phone (503) 783-6924, Monday through Friday, 8:00 – 5:00, Pacific Time
- toll free 1-800-818-4726, ext. 207

SAM Junctional Tourniquet (SJT) Auxiliary Strap Field Safety Corrective Action

Each of the SJT 102 product lot numbers listed below are subject to the SJT recall described in the attached letter and/or FAX Back response form.

SJT 102 Product lot numbers (represented as date codes)

3/29/13	2/25/14	4/22/14
5/15/13	3/4/14	4/28/14
6/11/13	3/5/14	4/29/14
7/16/13	3/19/14	5/5/14
7/16/13	3/21/14	6/12/14
8/27/13	3/24/14	7/1/2014
9/3/13	3/31/14	7/2/2014
9/10/13	4/1/14	8/4/2014
11/4/13	4/2/14	8/7/2014
12/9/13	4/4/14	8/7/2014
12/11/13	4/7/14	8/7/2014
1/10/14	4/9/14	8/11/2014
1/30/14	4/11/14	

URGENT: Field Safety Corrective Action (FSCA)

FAX BACK

MEDICAL DEVICE RECALL RESPONSE FORM

Response is Required

SAM Junctional Tourniquet (SJT) Auxiliary (Accessory) Strap

Affected Lot numbers: See attached

I have read and understand the recall instructions provided in the November 6, 2014 letter. Yes No

Any adverse events associated with the FSCA related product? Yes No

If yes, please explain:

Affected Product Information: Please provide information that is applicable for affected product.

Affected Product Information Table					
Product Name/Description	Part Number	Lot Number(s) received	Quantity in inventory	Quantity replaced	Quantity destroyed/ returned
SAM Junctional Tourniquet, 2 Target Compression Devices (1 with Extender), Hand Pump, Auxiliary Strap	SJT 102				
Target Compression Device with Extender, Hand Pump, Auxiliary Strap	SJT 112				

Distributors: check all that apply

- I have checked my stock and have quarantined inventory consisting of _____ (units, cases, etc.).
- I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification** _____)
- I have attached a list of customers who received/may have received this product. Please notify my customers (**Customer contact information must be provided**).

Questions: (when applicable)

- Please have Customer Service contact me.

Authorized Signature and Date _____

Name/Title	
Telephone	
Email address	

PLEASE FAX OR E-MAIL A PDF OF THE COMPLETED RESPONSE FORM TO:

Fax. #: 503-639-5425

E-mail: customerservice@sammedical.com

Please complete and return this form within 10 business days of receipt.