Rev 1: Dec 4, 2020

FSCA Ref: MM-FSA-01

Date: 2020-12-04

Urgent Field Safety Notice
Tourni-Cot Universal – “Uni-Cot”

For Attention of*:

Contact details of local representative (name, e-mail, telephone, address etc.)*
Van Straten Medical Niels van Straten, M.B.A., nielsvanstraten@vanstratenmedical.com, 31 30 602 38 30, Edisonbaan 20 | P.O. Box 440 | 3430 AK Nieuwegein | The Netherlands

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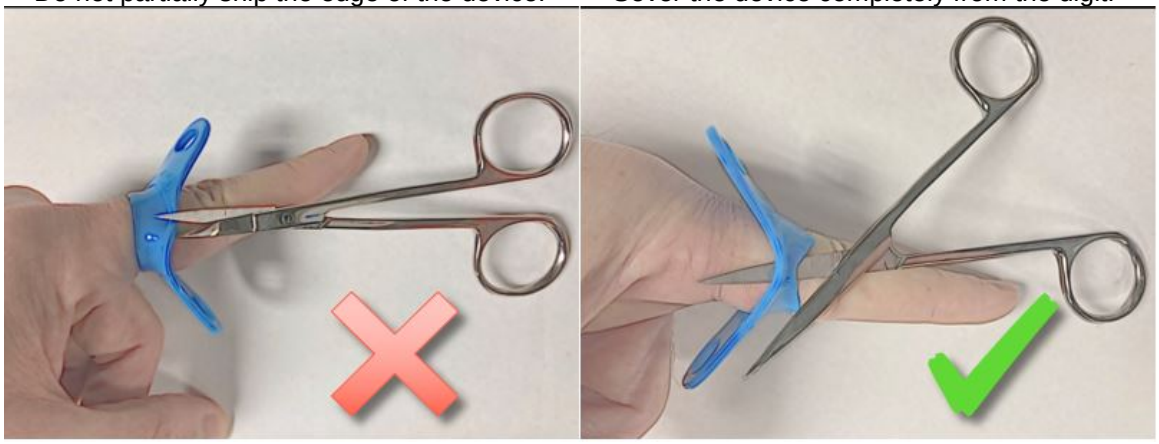
Urgent Field Safety Notice (FSN)
Tourni-Cot Universal – "Uni-Cot"

1. Information on Affected Devices*	
1.	1. Device Type(s)
	Tourni-Cot - Universal: This is an exsanguinating digit tourniquet. It is the universal size of the Tourni-Cot family of products. It is supplied sterile.  
1.	2. Commercial name(s)
	Uni-Cot, TCU
1.	3. Unique Device Identifier(s) (UDI-DI)
	00855364004085
1.	4. Primary clinical purpose of device(s)*
	Digital tourniquet used to exsanguinate when applied and occlude blood flow.
1.	5. Device Model/Catalogue/part number(s)*
	TCU-6001
1.	6. Affected serial or lot number range
	All units
1.	7. Associated devices
	None

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	In rare instances, the device may split into two pieces during removal leaving a portion of the device on the patient's digit. If a portion of the device is in place, it will continue to constrict blood flow to the digit resulting in ischemia. This split can occur when removal is attempted by making a partial snip at the edge of the device and then pulling the device from the affected digit, leaving a constricting band on the patient. Removal of a portion of the device may give user the false impression that the entire device was removed if not observed with care.
2.	2. Hazard giving rise to the FSCA*
	Incomplete removal resulting from a partial cut and pull of the device may ultimately result in ischaemia causing permanent damage and/or amputation of the patient's digit. Following the guidance in this FSN and clearer instructions in the future should reduce the chance of failure to zero. Further device design changes will also reduce likelihood of this occurring.
2.	3. Probability of problem arising
	This failure is extremely rare, with a known failure rate of less than .01%. We are aware of two instances of this type of failure (both reported to Mar-Med in the same complaint) out of a total of approximately 52,000 units in distribution since its introduction in 2015. Of

	those two instances, only one resulted in an adverse impact to the patient. The other was identified by the user.
2.	4. Predicted risk to patient/users
	This problem has a very rare likelihood of occurring, but a severe outcome to the patient if the problem occurs (ischaemia to the affected digit).
2.	5. Further information to help characterise the problem
	Failure of proper removal is a recognized risk factor for all tourniquet devices and the user should have procedures in place to reduce this general risk. The issue associated with this FSCA requires a failure during removal and failure to notice that the removal was incomplete.
2.	6. Background on Issue
	A user facility formally reported an incident with the device to the manufacturer. The user facility reported that one of their clinicians applied the device to a patient and then attempted removal by partially snipping the edge of the device and pulling the device off the affected digit. The pulling caused the device to split into two pieces. Most of the device was removed but a small band of the device was left remaining on the digit. This band was not noticed by the clinicians and the patient was bandaged and discharged. The patient reported continued pain and a follow up visit required amputation because of ischaemia to the digit. The user facility identified two root causes in the report: (1) failure of the tourniquet to split fully as intended by the manufacturer when cut from the patient's finger, and 2) human error resulting in failure to recognize the tourniquet was incomplete on removal and a piece had been left in-situ. The manufacturer accepts both findings. This potential problem, while very unlikely, may impact all units of the device and is not restricted to one lot number or batch. Manufacturer will address this problem through a combination of (1) notice to user facilities of the potential issue, (2) updates to the device Information for Use, and (3) design changes to the device, including adding a warning tag that will not release from the digit unless the device is completely removed.
2.	7. Other information relevant to FSCA
	The manufacturer believes that this failure can be largely mitigated by following standard best practices for the use of tourniquets, specifically by reviewing the affected digit for complete removal of device prior to completion of the procedure. See images below for guidance: Do not partially snip the edge of the device. Sever the device completely from the digit. 

	3. **Type of Action to mitigate the risk***	
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	Prior to use of device.
3.	3. Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? *	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☒ Other ☐ None Mar-Med will take the following actions to address this risk: **Phase 1**: Include a notice in each newly sold box of the current device that identifies the risk of this type of failure and provides guidance on how to avoid it. **Phase 2**: Update to an interim design of the device that includes a warning tag on the current device design. The warning tag eliminates the possibility of this type of failure by remaining in place if the tourniquet is not fully removed. **Phase 3**: Update the design of the device to better address usability and removal, maintaining the inclusion of the warning tag. An updated IFU will also be designed to provide clearer instructions and warnings.	
3	6. By when should the action be completed?	Phase 1: To be completed by December 4, 2020. Phase 2: To be completed by January 1, 2021. Phase 3: To be completed by March 1, 2021.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

	4. **General Information***	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Mar-Med**
	b. Address	**333 Fuller Ave NE, Grand Rapids, MI 49503, USA**
	c. Website address	**info@marmed.com, www.marmed.com**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	5. List of attachments/appendices:	**None**
4.	6. Name/Signature	**xxx**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Template for a Field Safety Notice Distributor/Importer Reply Form
Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	MM-FSA-01
FSN Date*	December 4, 2020
Product/ Device name*	TCU-6001
Product Code(s)	1 2 3
Batch/Serial Number (s)	1 2 3

2. Distributor/Importer Details	
Company Name*	Van Straten Medical
Account Number	
Address*	Edisonbaan 20 | P.O. Box 440 | 3430 AK Nieuwegein | The Netherlands
Shipping address if different to above	
Contact Name*	Niels van Straten, M.B.A.
Title or Function	
Telephone number*	31 30 602 38 30
Email*	nielsvanstraten@vanstratenmedical.com

3. Return acknowledgement to Sender	
Email	info@marmed.com
Distributor/Importer Helpline	
Postal Address	
Web Portal	
Deadline for returning the Distributor/Importer reply form*	December 20, 2020

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form

☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.