



URGENT FIELD SAFETY NOTICE

Combat Application Tourniquet (C-A-T)

Device Exchange

FSCA 21382/20

Manufacturer:

C-A-T Resources, LLC
483 Lakeshore Pkwy
Rock Hill, SC, USA 29730
+1 803.325.9300
info@catresources.com

January 21, 2021

To whom it may concern,

C-A-T Resources, LLC, is writing this field safety notice to notify customers and end users of a low risk defect that has been identified in a limited number of lots. This defect includes sporadic delamination of the time strap from the nylon latch ears. This potential defect is low risk, as delamination of the time strap does not affect the tourniquet's main function to occlude blood flow. Although this defect is low risk, it is a defect that may cause potential confusion and inconvenience during emergency medical situations. For this reason, we are issuing this field safety notice.

Our records indicate that your facility has received one or more shipments of the potentially affected product.

We are asking that you take the following actions:

- 1) See the table below of potentially affected lots and identify which of these lots you have in stock. Please note that if you identify a lot and the instruction for use (IFU) is marked with a green dot, the product has been quality certified and does not fall under this notice. The green dot can be found to the right side of the distributor's logo on the IFU, as seen below. This view of the IFU is visible as the tourniquet is packaged and does not require opening the shrink wrap.



- 2) Notify end users of whom any of the affected lots may have been distributed to.
- 3) Return any defective product to our facility. We will replace all returned tourniquets, at no cost. As always, please report any customer feedback to us as well. Customers should contact the manufacturer at info@catresources.com or by phone at +1 803-325-9300 to facilitate these replacements.



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A Composite Resources Company
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- 4) Distributors to send completed notification acknowledgement form back to the manufacturer.

Manufactured Lots

C-A-T Tactical Black Tourniquet Lot #s

200F680, 210F680, 200G780, 200G790, 200H840, 210H810, 220H850, 200I990, 210I950, 210I960, 210I970, 220I910, 220I920, 220I930, 220I940, 220I950, 220I980, 220I990, 230I900, 201J010, 201J050, 201J060, 201J070, 211J020, 211J030, 221J010, 221J020, 221J060, 201K190, 211K110, 211K120, 211K160, 211K170, 221K130, 221K140, 201L210, 201L220, 201L230

C-A-T Trainer Blue Tourniquet Lot #s

210H810, 210I950, 201K190, 211K120, 211K170, 221K140

These devices were manufactured from June 8th, 2020 to Dec 3rd, 2020.

Quantity on the Market: EU – 266,232

Distribution: EU – Estonia, Italy, Poland, Finland, Sweden, Switzerland, Netherlands, Denmark, Turkey, France, Germany, Czech Republic

Field Safety notices are planned to be sent to distributors by Feb 4, 2021. Products are planned to be replaced by March 4, 2021. These are planned dates and that deviations may occur depending on the response rates of customers and end users.

Please share this notification with others in your organization as appropriate or to any organization where the potentially affected product may have been transferred, and maintain awareness of this issue throughout the rest of the year. Also, please give any details of any affected devices that may have been transferred to other organizations, to the manufacturer. The competent authority of your country has been notified of this advisory notice.

Please feel free to contact us at info@catresources.com or by phone at +1 803-325-9300 with any questions or comments.

We appreciate your cooperation and apologize for the inconvenience this may cause you.

Sincerely,

[Redacted Signature]



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Customer Reply Form

1. Field Safety Notice (FSN) information		
FSN Reference number*		
FSN Date*		
Product/ Device name*		

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation												
<input type="checkbox"/>	<ul style="list-style-type: none"> I confirm receipt of the Field Safety Notice and that I read and understood its content. 											
<input type="checkbox"/>	<ul style="list-style-type: none"> I performed all actions requested by the FSN. I did not perform all or some actions requested by the FSN No action is applicable to me 											
<input type="checkbox"/>	<ul style="list-style-type: none"> The information and required actions have been brought to the attention of all relevant users and executed. The information and required actions have NOT been brought to the attention of all relevant users and NOT executed. No action is applicable to me 											
<input type="checkbox"/>	I have identified the following lots for device exchange	<table border="1"> <thead> <tr> <th>Quantity</th> <th>Lot/Batch Number</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td>N/A</td> <td>Comment:</td> </tr> </tbody> </table>	Quantity	Lot/Batch Number							N/A	Comment:
Quantity	Lot/Batch Number											
N/A	Comment:											
<input type="checkbox"/>	Other Action (Define):											

FSCA Ref: 21382/20

3. Customer action undertaken on behalf of Healthcare Organisation		
<input type="checkbox"/>	I do not have any affected devices.	
<input type="checkbox"/>	I have a query please contact me	
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	info@catresources.com
Customer Helpline	+1 803-325-9300
Postal Address	483 Lakeshore Pkwy Rock Hill, SC, USA 29730
Web Portal	http://www.combattourniquet.com/
Fax	+1 803-325-9331
Deadline for returning the customer reply form*	01 MAR 2020

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.