

## **Urgent Field Safety Notice**

**FSN Ref:** FSN\_PR20210830-01\_EN\_CH

**FSCA Ref:** FSCA\_PR20210830-01

### **Risk of unstable fixation of accessories**

**For the attention of:** **Healthcare professional and system distributor**

**Contact details of local representative:**

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#### **Information on Affected Devices**

<b>Device type</b>	
<p>Affected devices are:</p> <p>This FSN concerns the standard accessory Footrest and optional accessory Shoulder Support, designed for use with Celex and Intelli-C diagnostic medical X-ray systems.</p>	
<b>Commercial name(s)</b>	
<p><b>Name</b></p> <p>Celex, Right</p> <p>Celex, Left</p> <p>Intelli-C EU, Right</p> <p>Intelli-C EU, Left</p>	<p><b>REF</b></p> <p>03200000</p> <p>03200010</p> <p>03500000</p> <p>03500010</p>
<b>Involved accessories:</b>	
<p><b>Name</b></p> <p>Footrest</p> <p>Shoulder Support</p>	<p><b>REF</b></p> <p>03282000 (delivered as standard with all devices)</p> <p>03283000 (optional accessory)</p>
<b>Primary clinical purpose of device(s)</b>	
<p>Accessories designed for use with diagnostic medical X-ray system, Celex and Intelli-C</p>	
<b>Reason for Field Safety Corrective Action (FSCA)</b>	
<b>Description of the product problem</b>	
<p>This FSN is distributed to inform users about a risk that a friction rubber block, used in the clamping mechanism of the mentioned accessories, may become loose from the clamping profile.</p>	
<b>Hazard giving rise to the FSCA</b>	

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<p>If the friction rubber become loose, the accessory may not sufficiently grab on to the patient tabletop, resulting in an unsecure fixation.</p>
<p><b>Probability of problem arising</b></p>
<p>The probability of the problem arising again (recurrence) is low if the instructions in the Operators Manual are followed.</p>
<p><b>Background on Issue</b></p>
<p>The described scenario has been reported to us on one occasion from a customer using the Footrest.</p>
<p><b>Other information relevant to FSCA</b></p>
<p>The condition of the friction rubber (one on each side of the accessory) may be easily checked by the user (see appendix B), and if they are found to be loose, the accessory should not be used.</p>
<p><b>Type of Action to mitigate the risk</b></p>
<p><b>Action To Be Taken by the User</b></p>
<p style="text-align: center;"><input checked="" type="checkbox"/> <b>Identify Device</b>    <input checked="" type="checkbox"/> <b>On-site device inspection</b></p> <p>Please inspect your Footrest and optional Shoulder Support as specified in appendix B. If you find that the friction rubber is loose or damaged, arrange with your local dealer to have the affected accessories repaired.</p>
<p><b>By when should the action be completed?</b></p>
<p>As soon as possible.</p>
<p><b>Is customer Reply Required?</b></p>
<p>Yes, please fill in the Customer Reply Form on the last page.</p>
<p><b>Action Being Taken by the Manufacturer</b></p>
<p>A new clamping profile with a bolted-on friction rubber is being designed and NRT will arrange for replacement of the old clamping profiles, starting April 2022.</p>
<p><b>By when should the action be completed?</b></p>
<p>We plan for completion of all actions by end of 2022.</p>
<p><b>General Information</b></p>
<p><b>FSN Type</b></p>
<p>New</p>
<p><b>Manufacturer information</b> (For contact details of local representative refer to page 1 of this FSN)</p>

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Company Name Address Website address	NRT X-Ray A/S Birkegaardsvej 16, Hasselager, Denmark <a href="http://www.nrtxray.com">www.nrtxray.com</a>
<b>List of attachments/appendices</b>	
Appendix A: List of affected devices Appendix B: Friction rubber inspection instructions	
<b>Name/Signature</b>	
  Jan Malling Quality Manager	
<b>Transmission of this Field Safety Notice</b>	
<p style="color: red;">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)</p> <p style="color: red;">Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p style="color: red;">Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p style="color: red;">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.</p>	

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<b>Customer Reply Form</b>	
<b>Please fill in the below section</b>	
<input type="checkbox"/>	The undersigned hereby confirm to have read and understood the information in this FSN
<input type="checkbox"/>	We confirm that we intend to perform the required actions, as specified
<b>Date</b>	
<b>Site name and address</b>	
<b>Name (type)</b>	
<b>Signature</b>	

**Important!**

Please return the signed Customer Reply Form as soon as possible, either scanned via e-mail or take a photo with your smartphone and e-mail – to [support@nrtxray.com](mailto:support@nrtxray.com)

## Appendix B

### Friction rubber inspection instructions

#### Scope of document

As referenced in the FSN, this document gives instructions on how to inspect the condition of the friction rubber, used in the clamping mechanism of the Celex and Intelli-C accessories, Footrest and Shoulder Support (optional).

With the rubber in place there is no risk of the accessory sliding or falling to the floor once the clamping mechanism has been engaged in accordance with the instructions in the Operators Manual.

The probability of the problem arising again (recurrence) is low if the instructions in the Operators Manual are followed.

#### Identification

First make sure that you have identified the affected accessories as described in the FSN.



03282000 - Footrest clamped to the patient tabletop



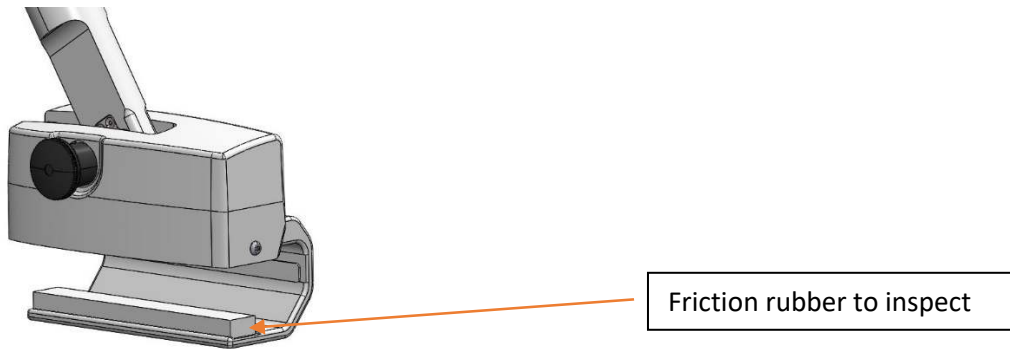
03283000 – Shoulder Support clamped to the patient tabletop

#### Inspection

The Footrest and Shoulder Support use the same clamping mechanism and should be inspected in the same way.

The clamping mechanism consists of two clamping profiles, one for each side of the tabletop. Both sides should be inspected.

The friction rubber that must be inspected is placed inside the clamping profile, see illustration below. It is the thick rubber seen in the illustration, which must be firmly in place. The rubber is glued on the profile, and you should look for the overall adhesion. If slightly pressed from each side and end, the rubber should not show signs of detachment from the profile.



If the rubber is firmly in place, you may continue using the equipment.

If the rubber is detaching along either side or end, do not use the accessory until the repair has been made.

**End of inspection instructions.**

## Customer Response Card

The undersigned hereby declare that the required inspection of affected accessories has been carried out as specified, with the results listed below:

Inspection result	Footrest	Shoulder Support
	(Indicate with check mark below, as applicable)	(Indicate with check mark below, as applicable)
<b>Accessory Serial Number</b> (From label on the accessory)		
<b>PASS</b> (Inspection showed no signs of friction rubber being loose or damaged)		
<b>FAIL</b> (Inspection showed that one or both friction rubber blocks have become loose)		

System Serial Number	Location (Full address)

Printed name	Signature	Date

Return the completed response card to:

[support@nrtxray.com](mailto:support@nrtxray.com)

(Either scan the document or take a photo with your phone and send by e-mail)