

Rev 1: September 2018

FSN Ref: PMS 2021 14 FSN

FSCA Ref:

PMS 2021 14 FSCA

Date: 14-12-2021

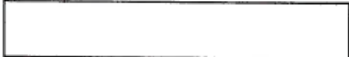
**Urgent Field Safety Notice**  
**Push Brace for High/low:X**

For Attention of\*:National Distributor


Contact details of local representative (name, e-mail, telephone, address etc.)\*

Etac R82 B.V.  
Tinweg 8  
NL-8445 PD Heerenveen

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**Urgent Field Safety Notice (FSN)**  
**Device Commercial Name**  
**Risk addressed by FSN**

1. Information on Affected Devices*	
1	1. Device Type(s)*   Push Brace for assistive frame for disabled persons.
1	2. Commercial name(s) Push Brace
1	3. Unique Device Identifier(s) (UDI-DI) N/A
1	4. Primary clinical purpose of device(s)* The push brace transfers force from caregiver to the product to provide movement/mobility
1	5. Device Model/Catalogue/part number(s)* 8910545
1	6. Software version N/A
1	7. Affected serial or lot number range Production date from 09-08-2021 to 03-10-2021
1	8. Associated devices N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem* Production problem with the chrome surface in the period mentioned above. The problem results in the chrome surface peeling off and in some cases creating a sharp edge.
2	2. Hazard giving rise to the FSCA* The sharp edge may involve a risk for the caregiver to cut his/her hand.
2	3. Probability of problem arising The potentially sharp edge can occur on the push brace where the caregiver is likely to place the hands, so the risk for a cut is high.
2	4. Predicted risk to patient/users The severity is set to medium and the occurrence is high that gives an unacceptable risk. We have had one reported incident of a caregiver who sustained a cut in the hand.
2	5. Further information to help characterise the problem Field Safety Notice (FSN) is to alert the caregiver about the chrome that might crack during use. We want the caregiver to inspect the push brace before every use until the push brace has been replaced.

2	<b>6. Background on Issue</b>
	Feedback from market
2	<b>7. Other information relevant to FSCA</b>
	The production problem with the chrome surface resulted in the potentially of a sharp edges on the push brace where the caregiver is likely to place the hands. The safety of the caregiver is of utmost importance to us and R82 has decided to make a FSN on replacing the push brace with the weak chrome surface.

<b>3. Type of Action to mitigate the risk*</b>	
<b>3.</b>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input type="checkbox"/> Identify Device                    <input type="checkbox"/> Quarantine Device                    <input type="checkbox"/> Return Device                    <input checked="" type="checkbox"/> Destroy Device             </p> <p> <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other                      <input type="checkbox"/> None             </p> <p>                 This Field Safety Notice is to inform about and replace the push brace.                  The push brace can be used if it is visually inspected before every use until it has been replaced.                  It is not necessary to return devices.                  In case of questions the user can contact the national distributor.                  The replacement push brace will be provided by the national distributor.             </p>
<b>3.</b>	<p><b>2. By when should the action be completed?</b></p> <p style="text-align: right;">Specify where critical to patient/end user safety</p>
<b>3.</b>	<p><b>3. Particular considerations for:</b>                      N/A</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p> <p>Replacement push braces, mounting instructions and an explanatory letter will be sent out by R82 by Etac to national dealer as specified at the front page of this FSN page.</p>
<b>3.</b>	<p><b>4. Is customer Reply Required? *</b>                      No (If yes, form attached specifying deadline for return)</p>
<b>3.</b>	<p><b>5. Action Being Taken by the Manufacturer</b></p> <p> <input type="checkbox"/> Product Removal                      <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Software upgrade                      <input type="checkbox"/> IFU or labelling change  <input checked="" type="checkbox"/> Other    <input type="checkbox"/> None             </p> <p>One to one replacement with new push brace.</p>
<b>3</b>	<p><b>6. By when should the action be completed?</b></p> <p style="text-align: right;">Specify where critical to patient/end user safety</p>

3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Yes	Appended to this FSN

<b>4. General Information*</b>	
4.	1. FSN Type* <span style="float: right;">New</span>
4.	2. For updated FSN, reference number and date of previous FSN <span style="float: right;">N/A</span>
4.	3. For Updated FSN, key new information as follows: N/A
4.	4. Further advice or information already expected in follow-up FSN? * <span style="float: right;">No</span>
4	5. If follow-up FSN expected, what is the further advice expected to relate to: Eg patient management, device modifications etc
4	6. Anticipated timescale for follow-up FSN <span style="float: right;">N/A</span>
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name <span style="float: right;">R82 A/S</span>
	b. Address <span style="float: right;">Parallelvej 3, 8751 Gedved</span>
	c. Website address <span style="float: right;">www.etac.com</span>
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	9. List of attachments/appendices: <span style="float: right;">N/A</span>
4.	10. Name/Signature

<b>Transmission of this Field Safety Notice</b>	
	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.