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 GmbH Industriestrasse 13 D-45699 Herten E-mail: Benjamon.Koelsch@etac.com Phone: + 49 2366 50060

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.	6. Background on Issue
	Feedback from market
2.	7. Other information relevant to FSCA
	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.

	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 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 distributer.	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No 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.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None One to one replacement with new push brace.	
3	6. By when should the action be completed?	Specify where critical to patient/end user safety

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	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
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	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	R82 A/S
	b. Address	Parallelvej 3, 8751 Gedved
	c. Website address	www.etac.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	[redacted]

	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.

Explanatory letter regarding our Field Safety Notice concerning push brace 8910545

R82 A/S has received feedback from the market that the chrome surface on our push brace (8910545) can crack during use. As the cracked chrome can form a sharp edge it can potentially pose a risk of cutting the person touching the push brace. On this background we have decided to issue a Field Safety Notice.

The affected items are those manufactured in the period 9th August 2021 to 3rd October 2021.

Push brace item number 8910545

The safety of the caregiver is of utmost importance to us, and we have decided to make a Field Safety Notice to ensure removal of the affected push braces with the potentially defective chrome surface from the market.

Until the push braces have been replaced, they must be inspected visually for cracks prior to every use and be disposed of should any cracks be detected.

Mounting instruction (9996097703) is provided along with the replacement push brace to facilitate local replacement of the push brace.

This explanatory letter is for informational purposes only. Replacement push brace will be provided with reference to this Field Safety Notice.

It is not necessary to return the push braces, but they must be taken out of use and disposed of properly.

R82 A/S has notified your national regulatory authorities about this matter.

If you are not the end-user of the affected product, please ensure that this letter is distributed to the final end-user.

We sincerely regret any difficulties this may cause you. R82 A/S remains dedicated to patient and caregiver safety and will continue to monitor device performance to ensure the product integrity and usage.

R82 A/S

[redacted]