Rev 1: 2021 April 20th.
FSN Ref: 2021001 FSCA Ref: 2021001

Date: 20/04/2021

Urgent Field Safety Notice: 2021001
Device Commercial Name:
RaceRunner/Frame runner:
Petra/Cross Runner/X STRONG Size 4 & 5

For Attention of*: Dealers and Authorities

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

United Kingdom	QUEST	....	.....	+44 1952 468558	Aston Street, SHIFNAL, Shropshire TF11 8DW UK
Netherlands	Rollick	.....	.....	+31 636 599 832	Henry Dunantlaan 45 7548 AB Enschede holland
Sweden	Fysioad	....	k.....	+46 70 740 83 74	Östanbrotorpet 725 98 VÄSTERÅS
Norway	Hjelpemiddel-eksperten As	....	.....	+47 913 47 440	Vassbygdvegen 104 7512 Stjørdal
Lithuania	Vildoma UAB	....	.....	+370 5 2 36 36 56	Granito str. 3, LT-02241 Vilnius, Lithuania
France	Colibrius	....	.....	+33 6 26 85 26 86	Pépinières Entreprises Atelier "K" 75 rue Oehmichen BP 21100 - 25461 Etupes Cedex
Switzer-land	RaceRunning Switzerland GmbH	....	.....	+41 79 722 41 74	Bundesstrasse 12 | 6003 Luzern | Switzerland
Austria	Rudolf Jordan, Clever Cycling	....	.....	+43 664-819 3548	Grillparzerstraße 23 4800 Attnang Puchheim Austria
Faroe Islands	Almannaverkið Hjálpartól og Endurvenjing	....	.....	+298 358 302	Smyrilsvegur 14 FO-110 Torshavn Færøerne
Iceland	Ozon ehf		.....	+354 89 890 97	Sulunes 20 210 Gardaabaer ICELAND

BYCONNIEHANSEN

Rev 1: 2021 April 20th.
FSN Ref: 2021001 FSCA Ref: 2021001

Urgent Field Safety Notice (FSN): 2021001
Device Commercial Name: Petra/Cross Runner Size 4 & 5
Risk addressed by FSN: Risk of Frame Crack of Droplink

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	3-wheeled walk-running frame – not delivered sterile
1.	2. Commercial name(s)
	Petra Size 4 & 5, Cross Runner Size 4 & 5, and X STRONG 4 & 5
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Not specified for clinical purpose. For everyday sports and recreational use
1.	5. Device Model/Catalogue/part number(s)*
	Catalogue numbers: 15013-4, 15013-5, 10008-4, 10008-5, 10016-4 and 10016-5
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	Where relevant. If not known, use manufacturing/distribution/expiration date as appropriate. Add as Appendix if necessary or provide web-based look-up tool.
1.	8. Associated devices
	Within context of the FSCA eg for IVD reagents and platforms.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	We have been notified by dealer that three frames have cracked. Linkhead/main tube welding seems in some cases insufficient, which results in a risk of the frame cracking.
2.	2. Hazard giving rise to the FSCA*
	If the frame cracks, there is a risk of the user falling off.
2.	3. Probability of problem arising
	1 - 5 %
2.	4. Predicted risk to patient/users
	They may hurt themselves falling off
2.	5. Further information to help characterise the problem
	Risk off weak melting TIG assembling
2.	6. Background on Issue
	Information on reclamation from dealer and inspection of products
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

	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 Taken in for reinforcement	
3.	2. By when should the action be completed	May 10th.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
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 Informed our dealers: Products need to be returned for a full welding. Our stock is repaired and future design corrected for full welding.	
3	6. By when should the action be completed?	June 20th.
3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes, included or as a Layman letter
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	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
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	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**By Conniehansen 2015 aps**
	b. Address	**Byåsen 18, Ganløse 3660 stenløse**
	c. Website address	**www.by-conniehansen.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**List of dealers and Layman letter**
4.	10. Name/Signature	**.....** 

	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.