Rev 2: Maart 2023 FSN Ref: 01.481.655.1 **FSCA Ref:** 01.481.655

Date: 30-3-2023

Urgent Field Safety Notice

For Attention or: Dealers/verkopers en eigenaren van Raam KIVO tandem

Contact details of local representative (name. e-mail, teleohone, address etc.)*
Van Raam Reha Bikes B.V; afdeling Aftersales; +31 315 257373; aftersales@vanraam.com

Urgent Field Safety Notice (FSN)
Van Raam Kivo Tandem
Afbreken bracket voorvork

1. Information on Affected Devices*	
1	1. Device Type(s)*
	Kivo tandem (2W + 3W)
1	2. Commercial name(s)
	Kivo
1	3. Uniaue Device Identifier(s) (UDI-DI)
	(01)08719327508701 /(01)08719327508725
1	4. Primarv clinical purpose of device(s)*
	Theraov Tandem / Theraov Tricycle
1	5. Device Model/Catalogue/part number(s)*
	376-xxxx / 377-xxxx
1	6. Software version
	N.v.t.
1	7. Affected serial or lot number ranqe
	Bouwjaar 2016-2022
1	8. Associated devices
	N.v.t.

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
	De gelaste bracket aan de voorvork kan afbreken.
2	2. Hazard oivinq rise to the FSCA*
	Als de bracket aan de voorvork afbreekt wordt de fiets onbestuurbaar.
2	3. Probability of problem arising
	Bij intensief gebruik kan de bracket afbreken, maar de kans hieroo is erq klein.
2	4. Predicted risk to patient/users
	Het afbreken van de bracket kan leiden tot een onbestuurbare fiets, wat kan leiden tot verwondinqen.
2	5. Further information to help characterise the problem
	Na een eerste analyse zijn er een aantal gebroken brackets gevonden.
2	6. Background on Issue
	Er zijn 2 qevallen vanuit de markt qemeld met dit probleem.
2	7. Other information relevant to FSCA
	N.v.t.

3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

1 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)

181 Other ☐ None

De fiets door de dealer laten inspecteren en indien nodig voorvork laten vervangen.

3.	2. By when should the action be completed?	31-12-2023

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 reauired

3. 4. Is customer Reply Required? * Yes
(If ves, form attached soecifvina deadline for return)

3. 5. Action Being Taken by the Manufacturer

☐ Product Removal 181 On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

De Kivo tandems worden door de dealer geïnspecteerd en indien nodig wordt de voorvork vervangen.

3	6. By when should the action be completed?	31-12-2023

3. 7. Is the FSN required to be communicated to the patient /lay user? No

3 8. If yes, has manufacturer provided additional information suitable tor the patienUlay user in a patienUlay or non-professional user information letter/sheet?

No Not aooended to this FSN

	4. General Information*	
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	Previous FSN: 01.481.655 dated 1-3-2023
4.	**3.** For Updated FSN, kev new information as fellows:	
	Proces van inspectie en vervangen voorvorken loopt.	
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:	
4	6. Anticipated timescale for follow-up FSN	N.v.t.
4.	7. Manufacturer information <For contact details of local representative refer to page 1 of this FSN)	
	a. Comoanv Name	**Van Raam Reha Bikes B.V.**
	b. Address	**Guldenwea 23 7051HT Varsseveld**
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers: IT 2076456	
4.	9. List of attachments/aooendices:	**Zie dealer brief.**
4.	10. Name/Signature	

	Transmission of this Field Safet 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 Com etent Authori if a ro riate, as this rovides im ortant feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.