Rev 2: February 2020
FSN Ref: CC-23-006 FSCA Ref: CC-23-006

Date: 2023:08:11

Field Safety Notice
Anasthesia Frame Carbon Fibre

For Attention of*:**OZG AG, Mülibodenstrasse 3, 8172 Niederglatt, Switzerland**

Contact details of local representative (name, e-mail, telephone, address etc.)*
OZG AG, Mülibodenstrasse 3, 8172 Niederglatt, Switzerland

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Field Safety Notice (FSN)
Anasthesia Frame Carbon Fibre
Insufficient delivery of gas or liquids during surgery or examination.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Anasthesia Frame
1.	2. Commercial name(s)*
	Anasthesia Frame Carbon
1.	3. Unique Device Identifier(s) (UDI-DI)
	07350111830953
1.	4. Primary clinical purpose of device(s)*
	Device Anesthesia frame for draping e.g. sterile cloth to create a sterile barrier during surgery. The product is to be used by medical professionals within a medical facility.
1.	5. Device Model/Catalogue/part number(s)*
	10-313, 10-313-UK, 10-313-US, 10-313-BER
1.	6. Software version
	N/A
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*
	The product has been broken in the edge of the post.
2.	2. Hazard giving rise to the FSCA*
	A customer has registered this issue.
2.	3. Probability of problem arising
	This can only happen if someone force the post with side power. It is not how it is intended to be used and it is not designed for that kind of handling. The SWL is only in total 4 kgs from upwards and down. It is not built for being pushed/pulled from the side.
2.	4. Predicted risk to patient/users
	If you use it as it is intended to be there is no risks.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	We received a customer complaint from the Distributor of the same problem and gave the Distributor instructions on how this can have happened. The Distributor has forwarded this information to the end user. We have seen when we have investigated this, that this product will brake if someone try to use it as a transport handle or if they drop the product on the floor.
2.	7. Other information relevant to FSCA
	N/A

	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 Please send the devices back to: Reison Medical AB, Eriksbergsvägen 32, SE-734 92 Hallstahammar, Sweden. Alternatively, to receive repair kits, contact: Reison Medical AB, info@reison.se,	
3.	2. By when should the action be completed?	Latest 2023-11-30
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. 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 We can help the custome to repair the post.	
3.	6. By when should the action be completed?	Latest 2023-12-31
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 for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	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	Reison Medical AB
	b. Address	Eriksbergsvägen 32, SE-734 92 Hallstahammar, Sweden
	c. Website address	www.reison.se
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Lena Q Olsson, Quality Assurance Manager 

	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.