FSN Ref: U473
FSCA Ref: 36063/23
Datum: 30.11.2023

VOSTRA GmbH
Im Süsterfeld 3
D-52072 Aachen
SRN: DE-MF-000005277

Tel. +49 241 96850-0
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Field Safety Notice
(Sicherheitsanweisung im Feld)

Here: Updating the instructions for use (IFU)
Hier: Aktualisierung der Gebrauchsanweisung (IFU)

Device Commercial Name **Rhinotamp®**
Rhinotamp® latexfrei

For Attention of: **Authorised representative for medical device safety, OP Management**

Contact details of local representative
For further information or assistance regarding the information contained in this FSN, please contact your regional sales representative or the manufacturer: VOSTRA GmbH, Im Süsterfeld 3, D-52072 Aachen, Germany, www.vostra.de, eMail: QM@vostra.de

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. Please transfer this notice to other organisations on which this action has an impact. 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.*

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Device Commercial Name **Rhinotamp®**
Rhinotamp® latexfrei

	1. Information on Affected Devices*
1.	**1. Device Type(s)***
	Rhinotamp® is a prefabricated tamponade for the nose consisting of a thermostable foam with a rubber coating, the reinforcement threads of which run through both the foam and the rubber coating. They develop their effect through compression.
1.	**2. Commercial name(s)**
	Rhinotamp® Rhinotamp® latexfrei
1.	**3. Unique Device Identifier(s) (UDI-DI)**
	42504352xxxxxxxxxxxxxxPP
1.	**4. Primary clinical purpose of device(s)***
	Haemostasis and stabilisation after operations in the area of the nasal and paranasal sinuses for the following indications: Conchotomy, maxillary sinus / ethmoid operations, nosebleeds, rhinoplasty
1.	**5. Device Model/Catalogue/part number(s)***
	1237xxxx 1238xxxx 1248xxxx 1249xxxx
1.	6. Software version
	The product does not contain any software
1.	7. Affected serial or lot number range
	LOT in the range from LOT 743384 to LOT 772283
1.	8. Associated devices
	N/A

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2. Reason for Field Safety Corrective Action (FSCA)*	
2.	**1. Description of the product problem***
	As part of the PMS activities, VOSTRA has become aware of a case of use with the product RHINOTAMP in which a user pulled on the reinforcing threads with his hands, contrary to the instructions in the instructions for use. In this case, a tamponade / tamponade component remained in situ after detamponation. The complaint is due to two application errors/errors in use, as the user acted contrary to the warnings in the instructions for use and did not take into account the state of the art and good clinical practice. During detamponation, the reinforcement threads were pulled, which can lead to disintegration of components of the tamponade, so that component parts can enter the site in an uncontrolled manner. Correct consideration of the state of the art and Good Clinical Practice would have been sufficient even if the instructions for use - "Do not pull out Rhinotamp by the reinforcement threads! Removal after application with forceps or similar instruments. instruments." - would have completely prevented the event in question. This is achieved by appropriate follow-up checks of the site and completeness checks of all tamponade components after detamponation has been completed. The FMECA considers the error and application case. However, this takes into account the state of the art and the GCP. The FSCA is intended to provide the user with revised instructions for use that now explicitly provide implicit information from the state of the art and the GCP. According to MDCG 2023-3, the present event is not to be classified as an incident.
2.	**2. Hazard giving rise to the FSCA***
	Parts of the component get out of control in situ
2.	**3. Probability of problem arising**
	impropable
2.	**4. Predicted risk to patient/users**
	4 = Risk mitigation measure
2.	**5. Further information to help characterise the problem**
	There were no incidents or serious incidents as defined by the MDR.
2.	**6. Background on Issue**
	See Point 2.1
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
	☒	Take note of amendment/reinforcement of Instructions For Use (IFU)		

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	☒	Other / Miscellaneous **You do not need to return a product. The product conforms to specifications and can still be used!** Please check your stock immediately and isolate the above-mentioned products without delay. Please also inform your users! Remove the existing instructions for use and replace them with FB_4.2.3.2_IFU-RT_Rev5, revision 5 of 10.11.2023 Then destroy the removed instructions for use. After replacing the instructions for use the product can be released. Change in IFU: Addition of the warning: After removing the tamponades, check that all tamponades or tamponade components have been completely removed). If you have redistributed the product that is the subject of this Field Safety Notice (FSN), please identify your other customers and inform the customer(s) concerned of this FSN immediately. We would ask you to monitor and follow up the measures taken by your customers! fill out the enclosed response form completely and send it to our address by post, e-mail or fax by 15 December 2023 at the latest. Please return the completed reply form even if you no longer have any remaining stock of the product in question. Due to legal requirements, we must ensure and document that you have received this FSN, and your reply serves as proof of this. **Please pass this FSN on to the relevant departments in your organisation!** Please ensure that all persons in your organisation who use or apply the product concerned are aware of this FSN. We confirm that the competent supervisory authority has been informed of this measure. We apologise for any inconvenience caused to you in connection with this FSN and thank you in advance for your support in enabling us to implement this measure quickly and effectively.
3.	2. By when should the action be completed?	Immediately, by 15th December 2023 at the latest
3.	3. Particular considerations for N/A Is follow-up of patients or review of patients' previous results recommended?	☐ *yes* ☒ *no*
3.	4. Is customer Reply Required?* (If yes, form attached specifying deadline for return)	☒ *yes* ☐ *no*

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3.	5. Action Being Taken by the Manufacturer ☐ Removal of the product ☒ IFU or labelling change ☐ Other	
3	6. By when should the action be completed?	Immediately
3.	7. Is the FSN required to be communicated to the patient /lay user?	☐ *yes* ☒ *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?	☐ *yes* ☐ *no*
	4. General Information*	
4.	1. FSN-Typ*	☒ New ☐ Update
4.	2. For updated FSN, reference number and date of previous FSN	☐ yes ☒ no
4.	3. For Updated FSN, key new information as follows:	
4.	4. Further advice or information already expected in follow-up FSN? *	☐ yes ☒ no ☐ not yet planned
4	5. If follow-up FSN expected, what is the further advice expected to relate to: N/A	
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	VOSTRA GmbH
	b. Address	Im Süsterfeld 3 D-52072 Aachen (Germany)
	c. Website address	www.vostra.de
	d. SRN	DE-MF-000005277
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.*	
4.	9. List of attachments/appendices:	FB_4.2.3.2_IFU-RT_Rev5 Revision 5 of 10.11.2023
4.	Name PRRC Signature PRRC	Sebastian Harren

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Reply form / *Antwort-Formular*

Customer-No. ***Kunden-Nummer***	
Name of the organisation ***Name der Einrichtung***	
Street ***Straße***	
PLZ/ Stadt ***Postcode / City***	
Email	

Action taken by the client on behalf of the healthcare facility
Im Auftrag der Gesundheitseinrichtung durchgeführte Maßnahme des Kunden

Please tick the boxes below to indicate which measures have been completed. If a measure does not apply, please enter N/A in the right-hand column.
Bitte in den nachfolgenden Kästchen ankreuzen, welche Maßnahmen abgeschlossen wurden. Wenn eine Maßnahme nicht zutrifft, bitte N/A in der rechten Spalte eintragen.

☐	I confirm that I have received the Field Safety Notice and that I have read and understood its contents. *Ich bestätige den Erhalt der Field Safety Notice (Sicherheitsanweisung im Feld) und dass ich deren Inhalt gelesen und verstanden habe.*	
☐	The information and the necessary measures have been brought to the attention of all affected users and implemented. *Die Information und die erforderlichen Maßnahmen sind allen betroffenen Anwendern zur Kenntnis gebracht und durchgeführt worden.*	
☐	There are no affected products remaining in stock at our facility. *Es sind keine betroffenen Produkte im Vorrat unserer Einrichtung verblieben.*	

Name in block capitals Name in Druckbuchstaben	
Date Datum	
Signature Unterschrift	