Date: 2022-10-06

Field Safety Notice
aerstent® TBJ

For Attention of:Customer of Art. 533-18-040 of LOT 210061

GRIBI AG BELP
Hühnerhubelstrasse 59
CH-3123 Belp

Field Safety Notice (FSN)
aerstent® TBJ
Mix up with aerstent® TBS

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	J Carina Stent, OTW 24 F, completely silicone covered 40 mm length, 18 mm diameter
1.	2. Commercial name(s)*
	aerstent® TBJ
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The stent is intended to maintain or enable the patency of natural and artificial lumen in the body and/or to cover pathological changes.
1.	5. Device Model/Catalogue/part number(s)*
	533-18-040
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	LOT 210061
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	There is a chance that the product labeled aerstent® TBJ Art. 533-18-040 of LOT 210061 contains aerstent® TBS Art.503-20-060.
2.	2. Hazard giving rise to the FSCA*
	The TBS Art.503-20-060 is different in shape and size to TBJ Art. 533-18-040. The Therapeutic effect will be different from the planning of the implantation.
2.	3. Probability of problem arising
	According internal investigations one TBS Art.503-20-060 is missing and the LOT 210061 is most probable for the mix up.
2.	4. Predicted risk to patient/users
	The Therapeutic effect will be different from the planning of the implantation.
2.	5. Further information to help characterise the problem
	The difference between TBJ Art. 533-18-040 and TBS Art.503-20-060 is easy to recognize when the stent is expanded. Only an insider can tell the different, when the stent is loaded in the delivery system.
2.	6. Background on Issue
	The mix up was due to an human error during the assembly. Internal prevented actions are started.
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	
3.	2. By when should the action be completed?	As soon as possible
3.	3. Particular considerations for: Implanted device Is follow-up of patients or review of patients' previous results recommended? Monitoring of the patient and/or replace implant.	
3.	4. Is customer Reply Required? *	Yes
3.	**5. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Internal prevented action for assembly.	
3.	6. Is the FSN required to be communicated to the patient /lay user?	Yes
3.	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No	

4. General Information*		
4.	1. FSN Type*	New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	bess pro
	b. Address	Gustav-Krone Str. 7, D 14167 Berlin
	c. Website address	www.bess.de
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	5. Name	Marcus A. Eisenhut

	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.