Date: 21.05.2026

Urgent Field Safety Notice: Recall
BSS Deltamedica

For Attention of: All customers (pharmacy personnel, healthcare institution personnel, responsible person for recalls at distributors), who received BSS DELTAMEDICA batches no. 25011546 (500mL bottle) and no. 25013938 (250mL bottle)

Contact details of local representative (name, e-mail, telephone, address etc.)*
Deltamedica GmbH, Ernst-Wagner-Weg 1-5, 72766 Reutlingen, Germany, Phone: +49 (0)7121-9921-15

Please forward to the person responsible for medical device safety!

Dear Sir or Madam,

With this information letter, we would like to inform you of a voluntary batch recall by DELTAMEDICA GmbH for the product:

BSS DELTAMEDICA
10 x 250 ml Plastic bottle, PZN 09155632, Batch: 25013938, Expiry: 05/2027
20 x 500 ml Plastic bottle, PZN 19336777, Batch: 25011546, Expiry: 04/2027

Reason:

Due to a notification from a hospital, we became aware that fragments of the rubber stopper may enter the bottle or the irrigation system during use. Although no such case has been reported to us, DELTAMEDICA GmbH currently cannot exclude with certainty that these fragments could also enter a patient's eye.

We ask you to take the following measures:

Our records show that your facility has received the affected product/batch combination. We kindly ask you to initiate the following actions immediately and as a priority:

- **Identify the affected products and ensure they cannot be used.**
  Do not use the affected products any longer.

- Read this safety notice and ensure that all users of the above-mentioned products in your organization are informed about this safety notice.

- We kindly ask you to **confirm** receipt of this urgent safety information **in writing**. For this purpose, please find the corresponding reply form attached. Please return it to DELTAMEDICA GmbH using the contact details provided below no later than 26 May 2026.

- Destroy the products on stock, if possible. Please document the destruction in the attached destruction record. You will, of course, receive a credit for the destroyed goods.
- If you would like the goods to be collected, please also indicate this on the reply form. We will then arrange the collection after consultation with you.

Unfortunately, we cannot provide you with an alternative/ replacement product!

This urgent safety information has been reported to the competent national authority.

We apologize for any inconvenience caused and remain at your disposal should you have any questions regarding the process:

Confidential business information

We kindly ask for your understanding and thank you for your cooperation.

Rev 1: September 2018
FSN Ref: BSS -FSN-English-2026-05-21 FSCA Ref: BSS-FSCA-English-2026-0-21

Urgent Field Safety Notice (FSN)
BSS Deltamedica
Recall

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	BSS DELTAMEDICA 250 ml / BSS DELTAMEDICA 500 ml  
1.	2. Commercial name(s)
	BSS DELTAMEDICA 250 ml / BSS DELTAMEDICA 500 ml
1.	3. Unique Device Identifier(s) (UDI-DI)
	4260081270020(20 x 500mL), 4260081270655 (10 x 250mL) (UDI-DI not printed on the label yet)
1.	4. Primary clinical purpose of device(s)*
	Sterile eye irrigation solution (Balanced Salt Solution)
1.	5. Device Model/Catalogue/part number(s)*
	Article Numbers 9155632-D (250mL) and 19336777 (500mL)
1.	6. Software version
	Device has no software.
1.	7. Affected serial or lot number range
	Recall for the following batches: Batch 25013938 (250mL bottle), Batch 25011546 (500mL bottle)
1.	8. Associated devices
	not applicable

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Deltamedica GmbH received a report from a hospital that rubber fragments originating from the Septum of the BSS Bottle closure were generated after inserting the application/transfer set.
	2. Hazard giving rise to the FSCA*

2.	As reported by our customer, there was one case where the rubber particle was detected in the transparent bottle before use. In another case, the fragment was transferred to the irrigation system, but detected in time and did not harm the patient. Mild to severe injury to the patient's eye cannot be excluded in case a rubber particle is generated and if the user does not detect the rubber particle before application of the product.
2.	3. Probability of problem arising
	In total, 17600 bottles were sold worldwide since January 2026 (combined number for 250mL and 500mL bottles). One customer of 47 customers reported rubber fragments in two cases for the 250mL bottle and difficulties with piercing the 250mL and 500mL bottles with the application/transfer set. At this time of the ongoing investigation, DELTAMEDICA GmbH cannot exclude that a container closure fragment might get into the eye of the patient.
2.	4. Predicted risk to patient/users
	If a bottle closure fragment is transferred into the eye of a patient, it could cause mild to severe injury to the eye.
2.	5. Further information to help characterise the problem
	This incident will be investigated, but as a voluntary precautionary measure in order to prevent any patient harm DO NOT USE the product and please follow the recall instructions.
2.	6. Background on Issue
	The most probable cause is an incompatibility between the BSS Deltamedica bottles and the used transfer set. Therefore, DELTAMEDICA cannot offer any alternative product of the balanced salt solution for irrigation of the eye to customers.
2.	7. Other information relevant to FSCA
	DELTAMEDICA has stopped to place further bottles of BSS Deltamedica on the market and will not do so until the investigations on the root cause are completed. Therefore, DELTAMEDICA cannot offer any alternative products to the customer.

	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 *In case return of the products is preferred by the customer, please inform Deltamedica GmbH beforehand (please see attached recall form)	
3.	2. By when should the action be completed?	Time critical. The customer is asked to confirm receipt of this message as soon as possible, but latest until Tuesday, 26-May-2026 and fill the attached form as soon as possible.

3.	3. Particular considerations for: not applicable 4. Is follow-up of patients or review of patients' previous results recommended? No No patient harm occurred in the reported incident.	
3.	5. Is customer Reply Required? *	Yes, reply needed as soon as possible but latest until 26-May-2026
3.	**6. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Stop of placement on the market for BSS Deltamedica and recall of aforementioned batches.	
3	7. By when should the action be completed?	See above, recall procedure started. Confirmation of receipt of recall letter.
3.	8. Is the FSN required to be communicated to the patient /lay user?	No
3	9. 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 Not appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	**3.** For Updated FSN, key new information as follows:	
	Not applicable	
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:	
	Not applicable	
4	6. Anticipated timescale for follow-up FSN	Not yet known
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Confidential business data
	b. Address	
	c. Website address	
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *EU Authorities will be informed today (21-May-2026).	
4.	9. List of attachments/appendices:	**Product Recall Form to be filled by the customer**
4.	10. Name/Signature	Personal information
		Personal information

	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..*

BATCH RECALL

RESPONSE FORM

DELTAMEDICA GmbH

21 May 2026

Confidential business data

Batch recall:

BSS DELTAMEDICA 20x500ml plastic PZN: 19336777

BSS DELTAMEDICA 10x250ml plastic PZN: 09155632

Dear Sir or Madam,

I hereby confirm receipt of the information regarding the batch recall

A check of our stock has yielded the following result:

The following goods are still in on stock:

Product	Batch	Quantity
19336777	25011546	
09155632	25013938	

☐ **No stock available**

☐ **Stock is being destroyed (see customer destruction protocol)**

☐ **Collection by Deltamedica GmbH requested:**

- **Contact person's name:**
- **Telephone number: / or your email address:**

PLEASE NOTE: **Collection only after consultation with Deltamedica GmbH**

Goods should not be returned without prior consultation with Deltamedica GmbH!

Signature

Position/Stamp

Customer Destruction Log

Delivery note no.	
Invoice No.	
Customer No.	
Customer name	
Street/House number	
Postcode/Town	
DISPOSED OF GOODS	
PZN / Item No.	
Product name	
Batch No.	
Serial number(s) Use an additional sheet if necessary	
Quantity	
Reason for destruction	Recall
Date of destruction	

We hereby confirm that we have duly destroyed the goods listed above, which were delivered in a damaged condition. We also confirm that, in the case of serialised goods, we did not write them off for issue prior to destruction.

Name	Stamp
Date/Signature	

DELTAMEDICA INTERNAL

SERIALISED GOODS? ☐ Yes, please forward to QM ☐ No	Has the SN Outgoing form been completed? ☐ Yes ☐ No	Date / Signature (QM/RA)