Ref : FSN-HEM/PAN-21-001-V2

Urgent Field Safety Notice (FSN)

HEMOTESE® Haemostatic Compress

Date : xx/xx/2023

To the attention of all distributors,

SYMATESE wants to inform its customers of the **maintenance of a Voluntary Field Safety Notice** concerning HEMOTESE® products, haemostatic compresses, due to a possible risk of tearing of the outer pouch during its opening, which may make it difficult to grip the inner pouch, as corrective actions identified in the initial FSCA submitted to the Health Authorities did not fully reach its objective.

We kindly ask you to consult this Field Safety Notice. No HEMOTESE® products has been yet manufactured using outer pouches with readjusted sealing parameters (corrective action n°2).

SYMATESE informs you that this Field Safety Notice has been communicated to the relevant Health Authorities including ANSM (French Authority).

Upon receipt, we kindly ask you to take note of this Warning Note and to acknowledge receipt of it by returning to us **Appendix 2 completed and signed within 3 working days of receipt**.

SYMATESE would like to assure you that we take the quality of our products very seriously and that all necessary corrective measures will be taken to prevent this problem from recurring.

We apologize for the inconvenience and are available to answer any questions you may have on this matter at the following address: vigilance@symatese.com.

Please accept, dear Madam, Sir, our respectful greetings.

…
Materiovigilance correspondent
SYMATESE

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HEMOTESE® Haemostatic Compress

Manufacturer Details	Distributor Details
SYMATESE ZI les Troques 69630 Chaponost – France	**XXXXXXXX**
Manufacturer SRN number	
FR-MF-000003718	

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Product failure
- Opening the outer pouch

Associated risks of
- Tear of outer pouch when opening,
- Lack of opening of the outer pouch which may make it difficult the access to the inner pouch containing the haemostatic compress.

1. **Information of the Device concerned**	
	1. Device Type
	Haemostatic compress: Type I native collagen compress (bovine origin), resorbable, freeze-dried. The compress is supplied sterile (sterilization method: β-irradiation). The double pouch consisting of an inner pouch directly in contact with the compress and an outer pouch enveloping the inner pouch, constitutes the sterile barrier.
	2. Commercial name
	HEMOTESE®, collagen resorbable haemostatic compress.
	3. Unique Device Identifier (UDI-DI)
	Not applicable.
	4. Primary clinical purpose of device
	HEMOTESE® compresses are indicated as local haemostatic agents during surgical procedures when bleeding control is ineffective and impracticable by ligature or other conventional means. They can be used to stop capillary, venous, or arterial haemorrhage.

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5. Commercial references

HEMOTESE References	Shape	Width (cm)	Length (cm)	Thickness (cm)	GTIN
HEM25X35	Parallelepiped	2,5	3,5	0,6	03760172160052
HEM7X5	Parallelepiped	7	5	0,6	03760172160069
HEM10X7	Parallelepiped	10	7	0,4	03760172160038
HEM127X9	Parallelepiped	12,7	9	0,6	03760172160045

6. Software version

Not applicable.

7. Serial or batch number range

All batches are concerned.

8. Associated devices

Not applicable.

9. Types of end recipients in the distribution chain known to the manufacturer

Pharmacy of internal use (hospitals, clinics)

2. Reason for Field Safety Corrective Action (FSCA)

1. Description of the product problem

Several complaints have been registered by SYMATESE following a difficulty encountered when opening the external pouch of haemostatic compresses similar to HEMOTESE®, with the same packaging as the HEMOTESE® product (See Appendix 1 – presentation of the defect).
The defect concerns the outer pouch, which may tear at the opening. This defect may induce difficulty in extracting the inner pouch containing the haemostatic compress.
It is also possible that the opening of the outer pouch may not be possible when the strip delaminates, which may require the user to open another compress.
It is important to note that no complaints were received for HEMOTESE® product but only on a similar product.
To our knowledge, none of the returns on the similar product have generated any damage or deterioration in the health condition of the patient or the user of the product.
Neither the safety nor the performance of HEMOTESE® haemostatic compresses were questioned during this investigation.

2. Risks associated to the Field Safety Corrective Action (FSCA)

The tear of the outer pouch mainly causes an inconvenience for the end user to extract the inner pouch containing the haemostatic compress.

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	After reviewing the risk analysis of the product, the failure to open the pouch did not identify any direct damage to the health of the patient or the user. However, the defect could lead to indirect damage such as a delay in the medical procedure due to the inconvenience caused to extract the compress. A residual risk of contamination of the product during the handling cannot be excluded if the user forces on the outer pouch during opening. It could occur if the user tries to open the pouch without complying with the recommendations of aseptic handling of the product, which would not correspond to a "normal use" of the device.
	3. Probability of occurrence of the defect
	To date, the frequency of the defect remains below the defect tolerance threshold (0.1%) of our risk analysis. However, as part of its investigations, the follow-up of the defect trend analysis and despite the implementation of the corrective actions approved in the initial FSCA, SYMATESE has decided to maintain an additional instruction for opening the HEMOTESE® outer pouch (Appendix 3) which allows the defect to be corrected significantly and the haemostatic compress to be accessed without difficulty.

3. Type of Action to reduce the risk		
	1. Action to be taken by the distributor ☐ Device identification ☐ Device quarantine ☐ Device return ☐ Device destruction ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other (see below) ☒ None	
	2. When the action should be done?	Not applicable.
	3. Special considerations for implantable devices Is there any specific follow-up of the patient or the patient's previous results recommended?	No.

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	4. Is an acknowledgement of receipt from the distributor required? * (If yes, indicate the time frame for returning the completed acknowledgement)	Yes See Appendix 2 of this FSN To be returned within **3 working days** after receipt.
	5. Is the FSN required to be communicated to lay users /patients?	No.
	6. If yes, has manufacturer provided a suitable information/letter to the lay users / patients?	Not applicable.

4. General Information		
	1. FSN Type	Update
	2. For updated FSN, the identification number and date of the previous FSN	FSN-HEM/PAN-21-001 V0 (22/04/2021)
	3. Has the Competent Authority of your country been informed about this FSN?	Yes.
	4. List of appendices	
	Manufacturer Contact for this FSN **Mélodie VUARCHEY** Materiovigilance correspondent vigilance@symatese.com	

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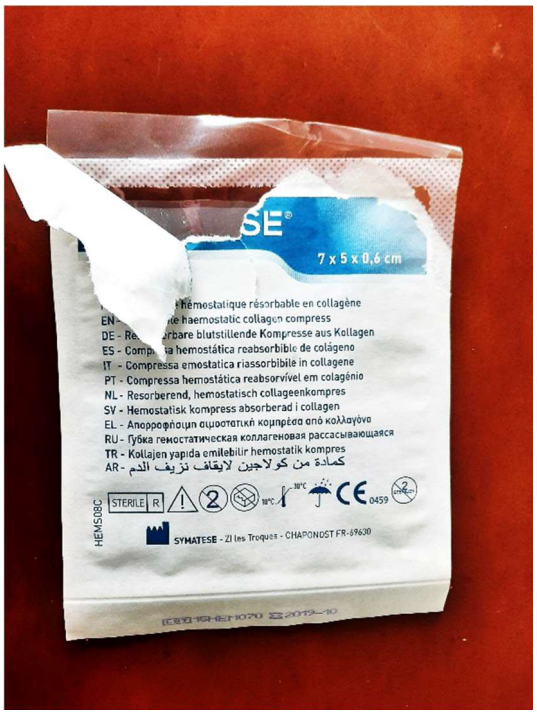
APPENDIX 1 Product picture – visualization of the defect

Pictures to illustrate the defect – tear in the outer pouch at opening



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APPENDIX 2 - ACKNOWLEDGEMENT OF RECEIPT

PLEASE RETURN A COMPLETED AND SIGNED COPY NO LATER THAN 3 WORKING DAYS AFTER RECEIPT :
By email vigilance@symatese.com By Fax +33 (0) 4 78 56 00 48

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN-HEM/PAN-21-001-V2
FSN Date	xx/xx/2023
Product/ Device name	HEMOTESE® Haemostatic Compress
Product References/ Batch numbers: All commercial references and batches concerned	

2. Distributor Information	
Company Name	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

☐ **I am a distributor**

☐ I confirm the receipt, the reading and understanding of this Field Safety Notice.

Name: Function: Signature:	Date:
Email:	Company Stamp:

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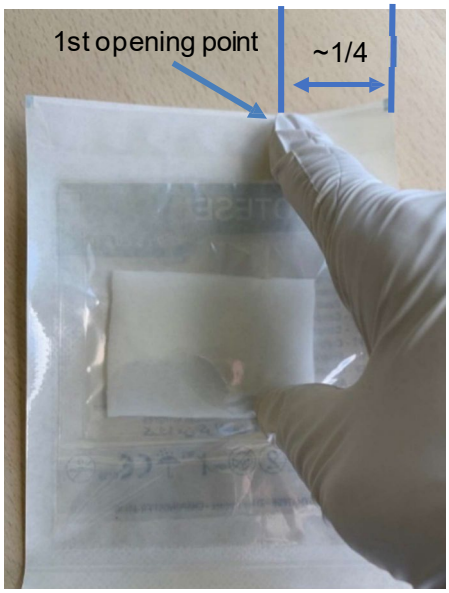
ANNEXE 3 - ADDITIONAL HEMOTESE® INSTRUCTION FOR OPENING THE OUTER POUCH

1. Identify the side to open on the pouch. It has one side on which is written the batch number and the expiration date; and another side without any inscription. It is on this side without inscription that the opening must be practiced.

2. Identify the area approximately one quarter of the width of the pouch and on the opposite side of the batch number inscription.



3. Start the opening from this point, without trying to open the pouch entirely.

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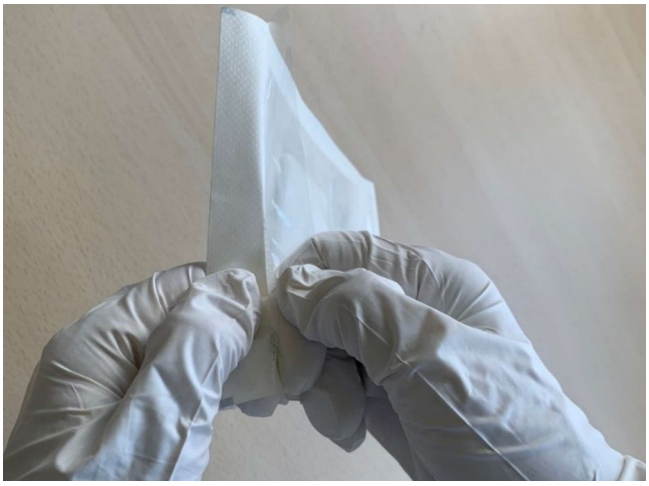
4. Repeat this operation on the other side of the seal on the left (always on the opposite side to the one with the batch number of the pouch).



5. Once the opening is started on both sides, accompany the opening gently and smoothly for optimal access to the compress.

Note

If one of the edges starts to tear, go to the other side accompanying smoothly the opening.
If despite this the opening is not sufficient, or if a tear hinders the recovery of the inner pouch, do not insist and take another compress.