Ref: FSN-HEM/PAN-21-001-V0

Urgent Field Safety Notice (FSN)

HEMOTESE® Haemostatic Compress

Date: 22/04/2021

To the attention of all distributors and end-users,

SYMATESE wants to inform its customers of the implementation 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.

We kindly ask you to consult this Field Safety Notice which lists all the references and batches of products concerned.

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** in order to ensure the effectiveness of this corrective action.

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**

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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)
HEM25X35	Parallelepiped	2,5	3,5	0,6
HEM7X5	Parallelepiped	7	5	0,6
HEM10X7	Parallelepiped	10	7	0,4
HEM127X9	Parallelepiped	12,7	9	0,6

6. Software version

Not applicable.

7. Serial or batch number range

HEMOTESE® References	Batch numbers
HEM25x35	19HEM040 - 19HEM070
HEM7X5	18HEM060 - 19HEM020 - 19HEM030
HEM10X7	18HEM040 - 19HEM080 - 20HEM040
HEM127X9	18HEM050 - 19HEM050 - 19HEM060 - 19HEM100 - 20HEM020

8. Associated devices

Not applicable.

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)

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

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 and the follow-up of the defect trend analysis, SYMATESE has decided to implement 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/user

☐ 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

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		We kindly ask you to: **For Distributors** - Read carefully the Field Safety Notice, - Make an inventory of the batches of products that you have in stock and communicate the information of these stocks in the acknowledgement of receipt (Appendix 2) to be returned to us **within 3 working days**, - Upon receipt of this Field Safety Notice and no later than **5 working days after receipt**: Forward this Field Safety Notice with the additional HEMOTESE® instruction for opening outer pouch (Appendix 3) **to all your customers** who have already received at least one batch of product concerned by the defect, - Stop the distribution of the products batches upon receipt of this Field Safety Notice in order to implement the following corrective action at the latest after **10 working days:** Corrective Action: Include the additional HEMOTESE® instruction for opening the outer pouch (Appendix 3) in all your shipping boxes, for the batches of products affected by the defect and as indicated below. ➔ 1 additional opening instruction per product delivered. **For End Users** - Read carefully the Field Safety Notice, - Make an inventory of the batches of products that you have in stock and communicate us the information on these stocks in the acknowledgement of receipt (Appendix 2) to be returned **within 3 working days**, - Communicate in your internal organization the additional HEMOTESE® instruction for opening the outer pouch (Appendix 3),
	2. When the action should be done?	- Acknowledgement of receipt with inventory status: **3 working days** upon receipt of the FSN. - Transmission to all customers of this Field Safety Notice with the additional HEMOTESE® instruction for opening the outer pouch (Appendix 3): **5 working days** upon receipt of this FSN. - Include the additional HEMOTESE® instruction for opening the outer pouch (Appendix 3) in all concerned shipping cartons: **10 working days** after receipt of this FSN.

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	3. Special considerations for implantable devices Is there any specific follow-up of the patient or the patient's previous results recommended?	No.
	4. Is an acknowledgement of receipt from the customer/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 /patienst?	No.
	6. If yes, has manufacturer provided a suitable information/letter to the lay users / patients?	Not applicable.

4. General Information		
	1. FSN Type	Initial
	2. For updated FSN, the identification number and date of the previous FSN	Not applicable.
	3. Has the Competent Authority of your country been informed about this FSN?	Yes.
	4. List of appendices	
	Manufacturer Contact for this FSN **.....** Materiovigilance correspondent vigilance@symatese.com	

Transmission of this Field Safety Notice

This notice shall be forwarded to all those who need to be notified within your organisation or to any organisation to which the device batches concerned have been transferred.
Please apply and maintain this FSN and its resulting actions for all device batches concerned.
In order to ensure the effectiveness of the corrective action, please apply the necessary number of reminders to ensure that end-users have received the information.

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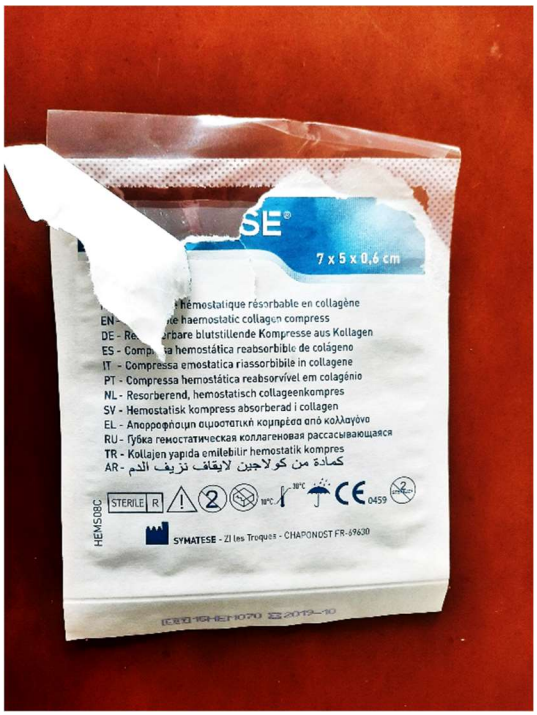
APPENDIX 1 Product picture – visualization of the defect

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-V0
FSN Date	xx/04/2021
Product/ Device name	HEMOTESE® Haemostatic Compress
Product References/ Batch numbers	

HEMOTESE®	References	Batch numbers
	HEM25x35	19HEM040 - 19HEM070
	HEM7X5	18HEM060 - 19HEM020 - 19HEM030
	HEM10X7	18HEM040 - 19HEM080 - 20HEM040
	HEM127X9	18HEM050 - 19HEM050 - 19HEM060 - 19HEM100 - 20HEM020

2. Distributor Information	
Company Name	XXXXXXXX
Address	XXXXXXXX
Shipping address if different to above	XXXXXXXX
Contact Name	XXXXXXXX
Title or Function	XXXXXXXX
Telephone number	XXXXXXXX
Email	XXXXXXXX

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☐ I am a distributor

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

☐ I confirm that I have stopped the distribution of the batches of products concerned by this Field Safety Notice until the implementation of the additional instruction (Appendix 3) in the next deliveries of the batches concerned.

☐ I confirm I have identified (or I am in the process of identifying) the customers/organisations that have received or may have received the batches of concerned products.

☐ I undertake to communicate this Field Safety Notice and the additional HEMOTESE® instruction for opening outer pouches (Appendix 3) to all the customers concerned.

☐ I undertake to attach the additional HEMOTESE® instruction for opening pouches to any new delivery of the batches concerned to all my customers, to trace this communication and to inform SYMATESE as soon as the action is completed.

☐ I have checked the status of my stocks for the concerned batches and the data collected are reported in the table below.

☐ I am an end user

☐ I certify that I have received, read and understood this Warning Note and acknowledge receipt.

☐ I confirm that I have communicated the additional instruction for opening the pouches to anyone who may be concerned within my organization.

☐ I have checked the status of my stocks for the concerned batches and the data collected are reported in the table below.

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Device	Reference	Batch	Country of distribution	Quantity received	Quantity in stock

Attach a separate file with this form by transferring the columns from the above table.

Name: Date:

Function:

Signature:

Email: Company Stamp:

Client code:

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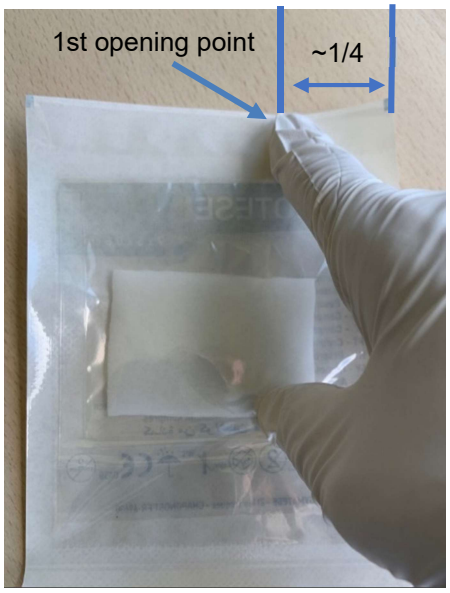
ANNEXE 3 - ADDITIONAL HEMOTESE® INSTRUCTION FOR OPENING THE OUTER POUCH

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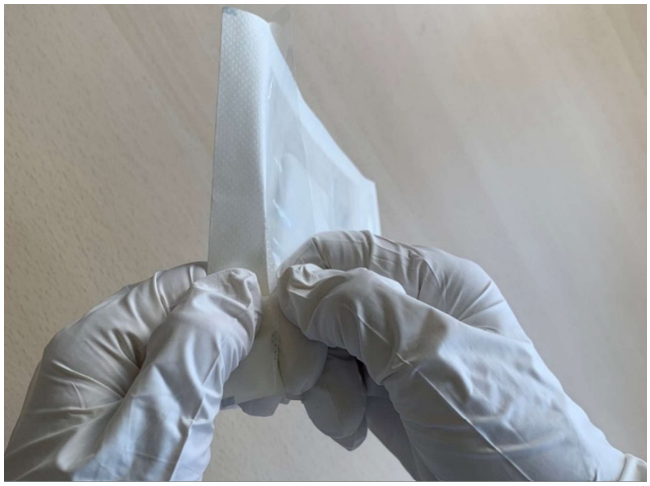
4. Repeat this operation on the other side of the seal on the left (always on the opposite side to the one with the batch number of the pouch).



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.