[April DD, 2025]

FIELD SAFETY NOTICE
HEMAPATCH WOVEN

Affected Product(s):	HEMAPATCH Woven
Affected Product References:	HEW100/100P (1), HEW25/100P (1), HEW25/50P (1), HEW50/50P (1), HEW75/75P (1)
Affected Lot No(s).:	All lots starting from Lot 21A07 - Please see complete list in Appendix 1.

Dear Customer/Hospital contact,

Intervascular/Getinge is providing this letter to inform you of a non-compliance in the Directions For Use (DFU), point (e) of HEMAPATCH/HEMAGARD PATCH Instructions For Use (IFU). This Medical Device Safety Notice only concerns HEMAPATCH Woven products:

Products covered by HEMAPATCH/HEMAGARD PATCH IFUs	Affected products by the Field Safety Notice
HEMAPATCH Woven	**Yes**
HEMAPATCH Knitted	No
HEMAGARD PATCH Knitted	No

- Specifically, in the DFU section, the point (e) of HEMAPATCH/HEMAGARD PATCH IFU states:

> e. The external velour surface, which has a darker yellow tint, should face outward, away from the blood flow. The paler yellow inner non-velour surface should face inward, in contact with the blood flow.

Figure 1: HEMAPATCH/HEMAGARD PATCH (IFU) extract – Directions For Use section

- The DFU above is specific to HEMAPATCH/HEMAGARD PATCH **Knitted** and **is not applicable for HEMAPATCH Woven.**
- The DFU for HEMAPATCH Woven is provided in the section related to the action taken by Intervascular/Getinge (page 4).

Risk to Health:

- The **most likely harm** of a HEMAPATCH Woven implanted with the external velour side (paler yellow tint) facing inward, in contact with the blood flow, is **none or would be insignificant**.

- **Harms that could potentially occur are a short delay** if the surgeon were to voice concern with the placement/orientation, remove the patch, and implant the patch or a replacement patch a second time.

- The placement of HEMAPATCH Woven with the external velour side (paler yellow tint) facing inward, in contact with the blood flow, is **likely to go unnoticed and be uneventful clinically**.

- The placement of HEMAPATCH Woven with the external velour side (paler yellow tint) facing inward, in contact with the blood flow could be associated with a slight increase in the risk for thrombosis and thromboembolism as compared to the opposite surface. Elderly patients with atherosclerosis and or coagulation disorders would be at a slightly higher risk to present with thrombosis or thromboembolism.

- No complaint related to this non-conformance in DFU, point (e), has been reported following the introduction of the error in HEMAPATCH/HEMAGARD PATCH IFU (since December 07, 2020).

Actions to be taken by Customer:

Our records indicate that you have received one or more **HEMAPATCH Woven product(s)** (please refer to **Appendix 1** in page 5 of this document). Please follow the steps below:

1. **No devices need to be returned as part of this Field Safety Notice.**

2. Please forward this information to all current and potential **HEMAPATCH Woven** users within your hospital / facility to **ensure users are aware of the non-conformance in HEMAPATCH/HEMAGARD PATCH IFU(s).**

    - For HEMAPATCH/HEMAGARD PATCH **Knitted, the instructions provided in the current IFU/DFU are accurate**. Please do not change your way of implanting these patches.

- For **HEMAPATCH Woven**, the direction for use below should be followed:

"The **external velour surface**, which has a **paler yellow tint**, should face outward, away from the blood flow. The **darker yellow inner non-velour surface** should face inward, in contact with the blood flow."

See below for an image, displaying the two surfaces:

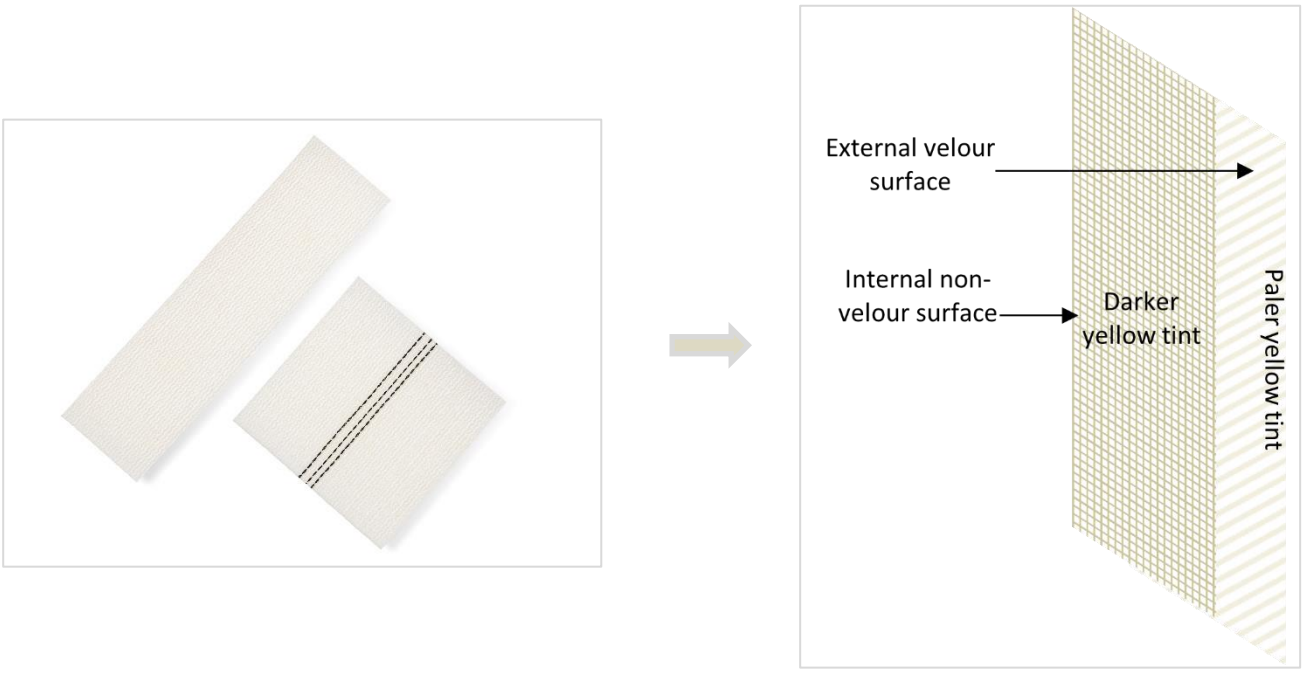

Figure 2: HEMAPATCH Woven surfaces

3. If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

4. Please complete and sign the attached MEDICAL DEVICE - FIELD SAFETY NOTICE-RESPONSE FORM (on page 7 of this document) to acknowledge that you have received this notification.

PLEASE RETURN YOUR COMPLETED FORM BY EMAIL TO [INSERT SSU CONTACT]:

XXX XXX

xxxxxxx@getinge.com

Tel: +xxxxxx

Adverse events or quality problems experienced with the use of any of the products identified in **Appendix 1** of this document may be reported to local Competent Authorities. Please follow the current regulations on adverse event reporting in your country.

Type of action by Intervascular/Getinge:

- Corrections in HEMAPATCH/HEMAGARD PATCH IFU are currently undertaken by Intervascular/Getinge:

    1. To clarify that the point (e) in DFU Section **is specific to** HEMAPATCH/HEMAGARD PATCH **Knitted:**

e. **For HEMAPATCH/HEMAGARD PATCH Knitted**, the external velour surface, which has a darker yellow tint, should face outward, away from the blood flow. The paler yellow inner non-velour surface should face inward, in contact with the blood flow.

    2. For the placement of HEMAPATCH Woven, the following direction (f) will be added:

f. **For HEMAPATCH Woven**, the external velour surface, which has a paler yellow tint, should face outward, away from the blood flow. The darker yellow inner non-velour surface should face inward, in contact with the blood flow.

If you have any questions, please contact your Getinge representative.

Sincerely,

Laure FRAYSSE
Director Quality Regulatory Compliance – Vascular Systems – La Ciotat
Acute Care Therapies

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Intervascular SAS
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ZI Athélia 1
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Appendix 1

Our records indicate that one or more HEMAPATCH Woven product(s) was delivered to your location. Please verify if you have the listed device that is affected by this Field Safety Notice:

Product References	Lot Numbers
HEW100/100P (1)	21A07 – 21A14 – 21B18 – 21C11 – 21C25 – 21F17 – 21G08 – 21H19 – 21J02 – 21J16 – 21K21 – 21M23 – 22A06 – 22B03 – 22B10 – 22B24 – 22C31 – 22D07 – 22D14 – 22D28 – 22E05 – 22E12 – 22G28 – 22H04 22H18 – 22H25 – 22J08 – 22J15 – 22J29 – 23B03 – 23B23 – 23C09 – 23C16 – 23D23 – 23D20 – 23D27 – 23E04 – 23E11 – 23E18 – 23F01 – 23G06 – 23G20 – 23H31 – 23J07 – 23L02 – 23L09 – 23L30 – 23M07 – 24A04 – 24A11 – 24A25 – 24B22 – 24B29 – 24C21 – 24C28 – 24D18 – 24D25 – 24E30 – 24F06 – 24F20 – 24G04 – 24G11 – 24H01 – 24H29 – 24J19 – 24J26 – 24K03 – 24K24 – 24L21 – 25B13
HEW25/100P (1)	21A07 – 21A14 – 21B11 – 21C11 – 22D07 – 22D14 – 22D28 – 22E12 – 24A25
HEW25/50P (1)	21A07 – 21A14 – 21B18 - 21C25 – 21F17 – 21G08 - 21J02 – 21J23 – 22B03 – 22B10 - 22E12 – 22G28 – 22H04 - 22H18 – 22H25 – 22J08 – 22J15 – 23B03 - 23C16 - 23D20 - 23E11 – 23G13 – 23G20 – 23H31 – 23J07 – 23L30 – 23M07 – 24A25 – 24B22 – 24D18 – 24D25 – 24E30 – 24H01 –24H29 – 24J19 – 24J26 - 24K03 – 24K24 – 24M05 - 25A09 – 25B27
HEW50/50P (1)	21A07 – 21A14 - 21F17 - 21G08 - 21J02 – 21J16 – 21J23 – 21M23 – 22B03 – 22B10 – 22B24 – 22C31 – 22D14 – 22E05 – 22E12 – 22H25 – 22J08 – 22J15 – 23G20 – 23H31 – 23J07 – 23L09 – 24A25 – 24D18 – 24E30 - 24F06 – 24F20 – 24H29 – 24J19 – 24J26 – 24K03 – 24K24 – 24K31 – 24L21 – 25A09

Product References	Lot Numbers
HEW75/75P (1)	21A07 – 21A14 - 21B11 – 21C11 – 21C25 – 21G08 – 21H19 – 21J16 – 23B23 – 23C09 – 23C16 – 23D20 – 23D27 – 23E04 – 23E18 – 23G06 – 23J07 – 23L09 – 23L30 – 23M07 – 24A04 – 24A11 – 24A25 – 24C21 – 24D18 – 24E30 – 24H01 – 24J19 – 24K24 – 24L21 – 24M05 – 25A09 - 25B13

[April DD, 2025]

MEDICAL DEVICE – FIELD SAFETY NOTICE RESPONSE FORM
HEMAPATCH Woven
Return the completed form by EMAIL to [INSERT SSU CONTACT]

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

Please acknowledge that you have read and understand this Medical Device Field Safety Notice for the HEMAPATCH Woven. Please ensure that all users of the HEMAPATCH Woven at this facility are aware of this notice and **that all users of the HEMAPATCH Woven have been informed to the above non-compliance in Directions For Use (DFU), point (e) of HEMAPATCH/HEMAGARD PATCH IFU.** Signature of the Facility Representative below represents confirmation of the non-compliance awareness for all **HEMAPATCH Woven** users.

No product is required to be returned as a result of this Field Notification.

Facility Representative Information

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and State:_____

Return the completed form by EMAIL to [INSERT SSU CONTACT]

XXX XXX

xxxxxxx@getinge.com

Tel: +xxxxxx