04 August 2026

| Urgent Field Safety Notice – CARDIOROOT Woven grafts | |
|---|---|
| **Manufacturer SRN:** | FR-MF-000002878 |
| **Manufacturer's Reference Number:** | RC045 – 1574541 |
| **Notification Type:** | New |

| Product or Trade Name | Reference or Model Number (s) | UDI-DI | Model Name | Serial/Lot Numbers |
|---|---|---|---|---|
| CARDIOROOT Woven | HEWROOT0024 | 00384401013884 | CARDIOROOT Woven | List of affected products can be found in Annex I. |
| | HEWROOT0026 | 00384401013891 | | |
| | HEWROOT0028 | 00384401013907 | | |
| | HEWROOT0030 | 00384401013914 | | |
| | HEWROOT0032 | 00384401013921 | | |
| | HEWROOT0034 | 00384401013938 | | |
| **Manufacturing Dates:** | All CARDIOROOT Woven products within labeled shelf life. | | | |

Dear Customer/Hospital contact,

The purpose of this letter is to advise you that Intervascular SAS, a subsidiary of Getinge, is voluntarily recalling **CARDIOROOT Woven grafts** because internal testing conducted on samples from the affected product failed to meet the specified acceptance criteria for Integral Water Permeability (IWP).

CARDIOROOT Woven is a collagen-coated vascular graft within the INTERGARD Woven product range. INTERGARD woven vascular grafts are intended for surgical repair, bypass, or replacement of the thoracic and abdominal aorta, and proximal peripheral arteries, when open surgical operation is required.
CARDIOROOT grafts are specifically designed for use on the thoracic aorta, as they feature a bulged section intended to mimic the anatomy and blood flow dynamics of the natural sinuses of Valsalva.

## Issue Description

The IWP test is a release test used to verify that the vascular grafts meet the specified water permeability requirements. Internal testing of samples from CARDIOROOT vascular grafts produced IWP results outside the limit specified in the product Instructions for Use (IFU) (ie. <5 ml/cm²/min). Given that the affected products did not meet the specified acceptance criteria for water permeability, they are out of specification, and may pose risks to health described in the section below.

## Risks to Health/Potential Hazards

Based on the observed IWP results, **there is a potential for additional perioperative bleeding through the affected graft wall during implantation.** During its investigation, Intervascular SAS determined that such perioperative bleeding may result in:

- Hemorrhage;
- Minor or major hematoma requiring additional intervention, and/or leading to life-threatening impairment, permanent impairment, or death.

Depending on the clinical situation, additional haemostatic measures may also be required.

A review of post-market surveillance data identified five (5) complaints between January 2021 and May 2026 (i.e., approximately 0.028% of all sold devices during this period), reporting intraoperative bleeding and/or difficult hemostasis during CARDIOROOT implantation procedures, including one (1) reported death and four (4) reported serious or temporary injuries. Investigations of these complaints did not identify any manufacturing defect or product nonconformance, and no causal relationship with the Integral Water Permeability (IWP) issue described in this notice was established.

## Actions To Be Taken by User

| | | | |
|---|---|---|---|
| ☒ **Identify Device** | ☒ **Quarantine Device** | ☒ **Return Device** | ☐ Destroy Device |
| ☐ On-site Modification/inspection | ☐ Take note of amendment/reinforcement of instructions for use | ☐ Patient follow-up | ☐ Review of patients' previous results |

## Actions To Be Taken by Manufacturer

| | | |
|---|---|---|
| ☒ **Product Removal** | ☐ On-site modification/ inspection | ☐ Software Upgrade |
| ☐ IFU or Labeling Change | ☒ **Other:** Upon return of the affected products, provide the customer with credit. | ☐ Customer Information Only |

## Recommended Mitigations/Patient Management Recommendations

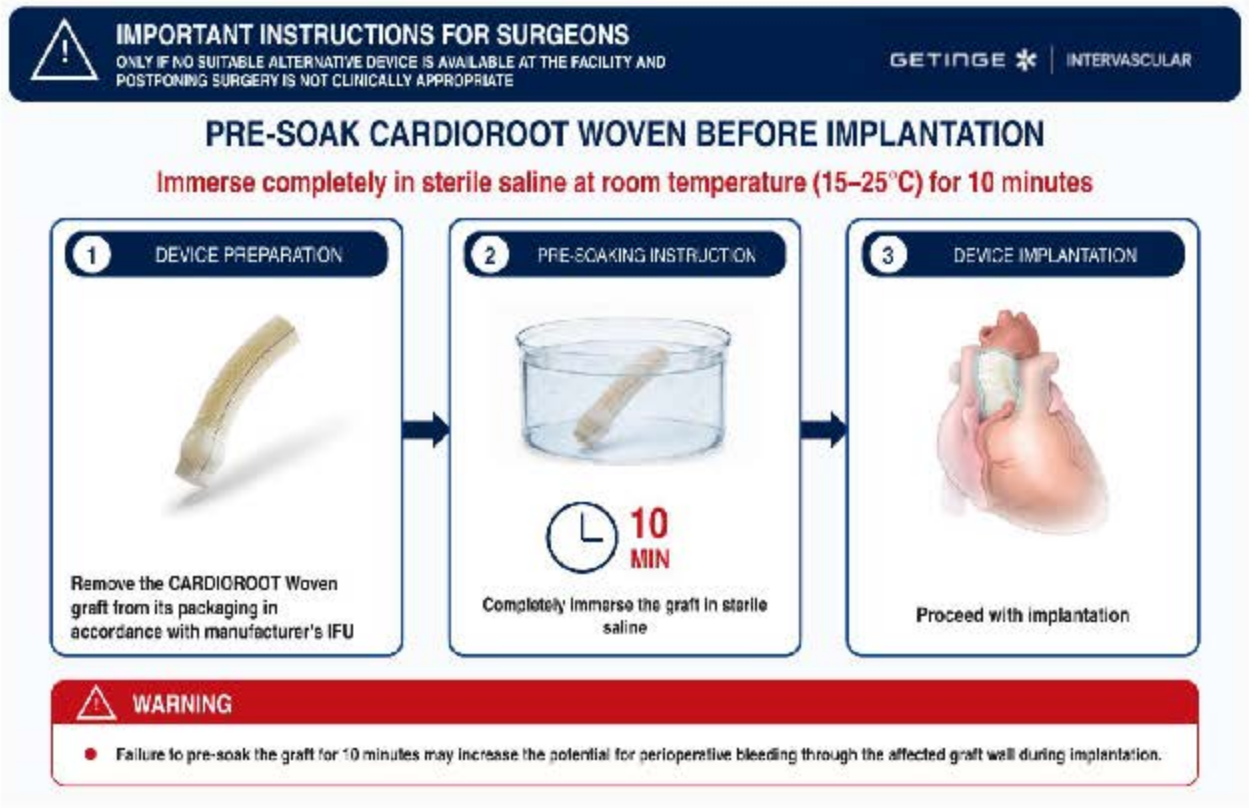
As a precaution, all affected **CARDIOROOT vascular grafts** should be **removed from inventory and quarantined immediately for return to the manufacturer**. Product distribution remains on hold until compliant products become available.

Please ensure that all relevant surgical and purchasing personnel are informed of this Field Safety Notice.

Please note that the implementation of this Field Safety Corrective Action may lead to temporary supply constraints. As compliant devices are not expected to be available in the short term, healthcare facilities should be informed of this delay to support forward planning and, where appropriate, the evaluation of alternative solutions.

**Exception:** Internal testing demonstrated that conducting a 10-minute saline pre-soak restored the IWP value to within the specified acceptance criteria in all tested CARDIOROOT Woven samples. Given this fact, if no suitable alternative device is available at the facility, and postponing surgery is not clinically appropriate, the operating physician must follow the following instructions:

- **Pre-soaking instruction:** After removing the graft from its packaging, the CARDIOROOT Woven graft shall be immersed in sterile saline solution at room temperature (15-25°C) for **10 minutes** before implantation. The prosthesis should not be allowed to dry out prior to implantation.
  Once implanted, confirm hemostasis of the CARDIOROOT device.




**No additional patient follow-up is recommended for patients who have already received an affected graft**, as the identified issue would be detected and managed during the implant procedure.

Customers should complete and return the acknowledgement/response form according to instructions and timelines provided with this notice. Additional information will be communicated if further actions become necessary based on the ongoing investigation. Alternative compliant products should be used whenever available.

## Customer Actions

Our records indicate that you have received one or more of the serial numbers that are affected by this recall. As a result, Getinge requests that you take the following actions:

1. Ensure all affected product in your inventory has been properly **quarantined**.
2. Please ensure this message is forwarded to all individuals that need notification within your organization or any organization where the affected devices have been transferred, including any third party organizations that should be ware of this information.
3. Contact local Customer Service via email at **<insert address of SSU Customer Service>** or <insert phone number> to **return your unused affected product(s)**. Credit will be issued for returned product.
4. Always report any adverse events potentially related to the affected products to your Getinge representative.
5. Complete and return the enclosed Letter of Acknowledgement and return it to your local Getinge representative as soon as possible, latest by <*2027-01-30*>. Include Ref – RC045 as reference in the subject line of your mail.
6. Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

## Contact Details of Local Representative

<insert local SSU or distributor contact details – include name/address/phone/email>

We regret any inconvenience this may cause and remain committed to patient safety. Getinge is communicating this information to regulatory authorities as required. We appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative.

Sincerely,

Electronically signed by: Clémence Vaneenoge
Reason: I approve this document.
Date: Aug 4, 2026 14:56:17 GMT+2

**Clémence Vaneenoge**
**P/O Laure Fraysse**
Director Quality Regulatory Compliance
Cardiovascular Surgery - Acute Care Therapies
Intervascular SAS

## Enclosed documents:

- **Appendix 1 – List of products**
- Customer Response Form

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# Appendix 1

Our records indicate that one or more CARDIOROOT 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 REF. | SERIAL NO. | LOT NO. | LOCATED AT YOUR FACILITY? (Yes / No) | PRODUCT IMPLANTED? (Yes / No) |
|---|---|---|---|---|
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➔ **Complete the last columns of above table as appropriate to precise if the affected device is currently located at your facility**

<DD:MMM:YYYY>

# *Customer Response Form*

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

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

By signing below, the Facility Representative confirms that this Field Safety Notice has been read and understood and that all users of the affected CARDIOROOT Woven grafts at this facility have been informed of the required actions.

Please check the appropriate boxe(s) below:

☐ We have reviewed and understood the information provided in this Field Safety Notice, acknowledge the required actions, and confirm that all unused affected products will be returned. Note: If any products were implanted prior to the release of this letter, please indicate as such in the corresponding column of the table in Appendix 1.

**If checked : please confirm facility information where the affected devices are physically located and/or were implanted.**

| | | | |
|---|---|---|---|
| **Current Facility Name** | | | |
| **Contact Name / Title** | | | |
| **Address (no PO boxes, please)** | | | |
| **City, State, Zip** | | | |
| **Phone Number** | | **Fax:** | |
| **E-Mail Address:** | | | |

☐ We have sold/moved the device to another facility.

**If checked : please provide new facility information below.**

| | | | |
|---|---|---|---|
| **New Facility Name** | | | |
| **Contact Name / Title** | | | |
| **Address*** | | | |
| **City, State, Zip** | | | |
| **Phone Number** | | **Fax:** | |
| **E-Mail Address:** | | | |