Contract Medical International GmbH
Lauensteiner Strasse 37
01277 Dresden, Germany

URGENT: MEDICAL DEVICE RECALL

blueflow Venous Stent

Corrected version on August 20, 2025: Manufacturing Dates and Expiration Dates updated in the "Product and Distribution Information Table". Correct information highlighted in yellow.

August 14, 2025

Regulatory Affairs Department
Contract Medical International GmbH (dba Heraeus Medevio)
Lauensteiner Strasse 37
01277 Dresden, Germany

Dear Device Customer/Distributor,

The purpose of this letter is to inform you that Contract Medical International GmbH is voluntarily recalling **blueflow Venous Stent** delivery system**.**

The blueflow Venous Stent device consists of a 10 Fr delivery system preloaded with a self-expanding stent made of woven Nitinol (nickel titanium alloy) wires in a closed loop design. The blueflow Venous Stent is intended to treat Symptomatic, dilatable obstructions, such as those caused by May-Thurner-Syndrome (MTS) and other clinical conditions, Deep Venous Thrombosis (DVT), Prevent Post Thrombotic Syndrome (PTS), and in certain markets, other forms of iliac vein compression (tumor, radiation) in the common iliac, external iliac or femoral veins.

Reason for the Voluntary Recall:

This recall has been initiated due to evidence of the pebax layer delaminating, and in some instances, pebax material detachment from the outer surface of the stent pusher. Use of this product has the potential to embolize and in the most severe cases, it could cause cardiac and cardiovascular dysfunction (cardiac arrest), cerebrovascular dysfunction (stroke, TIA) especially in patients with PFO (Patent Foramen Ovale) or ASD (Atrial Septal Defect), or pulmonary embolism when introduced into a patient's circulatory system. To date, there have been zero complaints related to this potential product failure. **Note: There have been ZERO reports of serious injuries or deaths.**

Risks to Health:

Use of the affected devices could lead to a mechanical device malfunction resulting in a nonfunctional product, failure during stent deployment, incomplete stent expansion, damage to the stent or vessel wall. In addition, if particulates are released from the device and into the

patient's circulatory system, cardiac and cardiovascular dysfunction (cardiac arrest), cerebrovascular dysfunction (stroke, TIA) especially in patients with PFO (Patent Foramen Ovale) or ASD (Atrial Septal Defect), pulmonary embolism, local vascular injury and bleeding, or thrombosis (venothromboembolic events) could occur. There is no method to recognize if an unused device will fail before use.

Actions to be taken by the Customer/User:

Contract Medical International GmbH requests that you immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter. This recall should be carried out to the consumer / end user level.

Please complete the form attached to this medical device recall and email scanned copy to medevioregulatoryaffairs@heraeus.com and quality@plusmedica.org.

Or by mail to:

Attn: Regulatory Affairs Department
Contract Medical International GmbH (dba Heraeus Medevio)
Lauensteiner Strasse 37
01277 Dresden, Germany

Product and Distribution Information:

We began shipping this product on February 22, 2024, and our records indicate the affected product was shipped to you.

The following table provides the product information for lots impacted by this recall.

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Contract Medical International GmbH
Lauensteiner Strasse 37
01277 Dresden, Germany

Product and Distribution Information Table

Primary Unique Device Identifier (UDI)	Manufacturer's Product Number / Catalog Number (REF)	Lot Number	Manufacturing Date (YYYY/MM/DD)	Expiration Date (YYYY/MM/DD)	Quantity
04251244500351	FG-02234-004A / VS14150	900203	~~2024-01-18~~ 2025-05-27	~~2026-01-18~~ 2027-06-23	36
04251244500405	FG-02234-009A / VS12100	900183	~~2024-01-18~~ 2025-03-04	~~2026-01-18~~ 2027-03-21	26
04251244500405	FG-02234-009A / VS12100	900193	~~2024-01-18~~ 2025-03-21	~~2026-01-18~~ 2027-04-28	25
04251244500368	FG-02234-005A / VS14100	900204	~~2024-01-18~~ 2025-05-27	~~2026-01-18~~ 2027-06-23	39
04251244500412	FG-02234-010A / VS12060	900209	~~2024-01-18~~ 2025-06-23	~~2026-01-18~~ 2027-06-23	15
04251244500337	FG-02234-002A / VS16100	900201	~~2024-01-18~~ 2025-05-27	~~2026-01-18~~ 2027-06-23	20
04251244500351	FG-02234-004A / VS14150	900178	~~2024-01-18~~ 2025-03-04	~~2026-01-18~~ 2027-21-03	28
04251244500368	FG-02234-005A / VS14100	900179	~~2024-01-18~~ 2025-04-03	~~2026-01-18~~ 2027-03-21	20
04251244500368	FG-02234-005A / VS14100	900190	~~2024-01-18~~ 2025-03-21	~~2026-01-18~~ 2027-04-28	21
04251244500405	FG-02234-009A / VS12100	900208	~~2024-04-04~~ 2025-06-23	~~2026-04-04~~ 2027-06-23	25
04251244500382	FG-02234-007A / VS18100	900206	~~2024-04-04~~ 2025-06-23	~~2026-04-04~~ 2027-06-23	10
04251244500351	FG-02234-004A / VS14150	900189	~~2024-04-04~~ 2025-03-21	~~2026-04-04~~ 2027-04-28	20
04251244500320	FG-02234-001A / VS16150	900200	~~2024-04-04~~ 2025-05-27	~~2026-04-04~~ 2027-06-23	15
04251244500344	FG-02234-003A / VS16060	900202	~~2024-04-04~~ 2025-05-27	~~2026-04-04~~ 2027-06-23	10
04251244500344	FG-02234-003A / VS16060	900177	~~2024-04-04~~ 2025-03-04	~~2026-04-04~~ 2027-03-21	10
04251244500344	FG-02234-003A / VS16060	900188	~~2024-04-04~~ 2025-03-21	~~2026-04-04~~ 2027-04-28	5
04251244500375	FG-02234-006A / VS14060	900205	~~2024-04-04~~ 2025-05-27	~~2026-04-04~~ 2027-06-23	21
04251244500399	FG-02234-008A / VS18060	900207	~~2024-04-04~~ 2025-06-23	~~2026-04-04~~ 2027-06-23	10
04251244500399	FG-02234-008A / VS18060	900182	~~2024-04-04~~ 2025-03-04	~~2026-04-04~~ 2027-03-21	5
04251244500399	FG-02234-008A / VS18060	900192	~~2024-07-19~~ 2025-03-21	~~2026-07-19~~ 2027-04-28	5
04251244500412	FG-02234-010A / VS12060	900194	~~2024-07-19~~ 2025-03-21	~~2026-07-19~~ 2027-04-28	5
04251244500337	FG-02234-002A / VS16100	900187	~~2024-07-19~~ 2025-03-19	~~2026-07-19~~ 2027-04-28	10
04251244500337	FG-02234-002A / VS16100	900176	~~2024-07-19~~	~~2026-07-19~~	5

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Primary Unique Device Identifier (UDI)	Manufacturer's Product Number / Catalog Number (REF)	Lot Number	Manufacturing Date (YYYY/MM/DD)	Expiration Date (YYYY/MM/DD)	Quantity
			2025-03-04	2027-03-21	
04251244500320	FG-02234-001A / VS16150	900186	~~2024-07-19~~ 2025-03-19	~~2026-07-19~~ 2027-04-28	10
04251244500382	FG-02234-007A / VS18100	900191	~~2024-07-19~~ 2025-03-21	~~2026-07-19~~ 2027-04-28	5
04251244500412	FG-02234-010A / VS12060	900184	~~2024-07-19~~ 2025-03-04	~~2026-07-19~~ 2027-03-21	11
04251244500320	FG-02234-001A / VS16150	900175	~~2024-07-19~~ 2025-03-04	~~2026-07-19~~ 2027-03-21	10
04251244500382	FG-02234-007A / VS18100	900181	~~2024-07-19~~ 2025-03-04	~~2026-07-19~~ 2027-03-21	5
04251244500375	FG-02234-006A / VS14060	900180	~~2025-02-20~~ 2025-03-04	~~2027-02-20~~ 2027-03-21	5
04251244500368	FG-02234-005A / VS14100	900033	~~2025-02-20~~ 2023-12-04	~~2027-02-20~~ 2026-01-18	40
04251244500351	FG-02234-004A / VS14150	900034	~~2025-02-20~~ 2023-12-04	~~2027-02-20~~ 2026-01-18	29
04251244500344	FG-02234-003A / VS16060	900035	~~2025-02-20~~ 2023-12-04	~~2027-02-20~~ 2026-01-18	25
04251244500337	FG-02234-002A / VS16100	900036	~~2025-02-20~~ 2023-12-04	~~2027-02-20~~ 2026-01-18	35
04251244500320	FG-02234-001A / VS16150	900037	~~2025-02-20~~ 2023-12-04	~~2027-02-20~~ 2026-01-18	20
04251244500412	FG-02234-010A / VS12060	900031	~~2025-02-20~~ 2023-12-04	~~2027-02-20~~ 2026-01-18	5
04251244500375	FG-02234-006A / VS14060	900040	~~2025-02-20~~ 2024-01-22	~~2027-02-20~~ 2026-01-18	25
04251244500399	FG-02234-008A / VS18060	900038	~~2025-02-20~~ 2023-12-04	~~2027-02-20~~ 2026-01-18	10
04251244500382	FG-02234-007A / VS18100	900039	~~2025-02-20~~ 2023-12-04	~~2027-02-20~~ 2026-01-18	10
04251244500412	FG-02234-010A / VS12060	900072	~~2025-06-23~~ 2024-03-19	~~2027-06-23~~ 2026-04-04	39
04251244500405	FG-02234-009A / VS12100	900071	~~2025-03-21~~ 2024-03-07	~~2027-03-21~~ 2026-04-04	32
04251244500375	FG-02234-006A / VS14060	900068	~~2025-04-28~~ 2024-03-07	~~2027-04-28~~ 2026-04-04	22
04251244500368	FG-02234-005A / VS14100	900067	~~2025-06-23~~ 2024-03-07	~~2027-06-23~~ 2026-04-04	31
04251244500351	FG-02234-004A / VS14150	900066	~~2025-06-23~~ 2024-03-07	~~2027-06-23~~ 2026-04-04	17
04251244500344	FG-02234-003A / VS16060	900065	~~2025-06-23~~ 2024-03-07	~~2027-06-23~~ 2026-04-04	6
04251244500337	FG-02234-002A / VS16100	900064	~~2025-03-21~~ 2024-03-07	~~2027-03-21~~ 2026-04-04	19
04251244500320	FG-02234-001A / VS16150	900063	~~2025-03-21~~ 2024-03-07	~~2027-03-21~~ 2026-04-04	10

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04251244500399	FG-02234-008A / VS18060	900070	~~2025-04-28~~ 2024-03-07	~~2027-04-28~~ 2026-04-04	20
04251244500382	FG-02234-007A / VS18100	900069	~~2025-06-23~~ 2024-03-07	~~2027-06-23~~ 2026-04-04	18
04251244500412	FG-02234-010A / VS12060	900093	~~2025-06-23~~ 2024-06-10	~~2027-06-23~~ 2026-07-19	16
04251244500405	FG-02234-009A / VS12100	900092	~~2025-04-28~~ 2024-06-10	~~2027-04-28~~ 2026-07-19	35
04251244500375	FG-02234-006A / VS14060	900089	~~2025-06-23~~ 2024-06-04	~~2027-06-23~~ 2026-07-19	20
04251244500368	FG-02234-005A / VS14100	900088	~~2025-06-23~~ 2024-06-10	~~2027-06-23~~ 2026-07-19	36
04251244500351	FG-02234-004A / VS14150	900087	~~2025-03-21~~ 2024-06-10	~~2027-03-21~~ 2026-07-19	39
04251244500337	FG-02234-002A / VS16100	900086	~~2025-04-28~~ 2024-06-10	~~2027-04-28~~ 2026-07-19	14
04251244500320	FG-02234-001A / VS16150	900085	~~2025-06-23~~ 2024-06-10	~~2027-06-23~~ 2026-07-19	10
04251244500399	FG-02234-008A / VS18060	900091	~~2025-06-23~~ 2024-06-10	~~2027-06-23~~ 2026-07-19	5
04251244500382	FG-02234-007A / VS18100	900090	~~2025-03-21~~ 2024-06-10	~~2027-03-21~~ 2026-07-19	10
04251244500412	FG-02234-010A / VS12060	900173	~~2025-04-28~~ 2025-01-14	~~2027-04-28~~ 2027-02-20	3
04251244500405	FG-02234-009A / VS12100	900172	~~2025-04-28~~ 2025-01-14	~~2027-04-28~~ 2027-01-14	14
04251244500375	FG-02234-006A / VS14060	900169	~~2025-04-28~~ 2025-02-20	~~2027-04-28~~ 2027-02-20	21
04251244500368	FG-02234-005A / VS14100	900168	~~2025-03-21~~ 2025-02-20	~~2027-03-21~~ 2027-02-20	33
04251244500351	FG-02234-004A / VS14150	900167	~~2025-04-28~~ 2025-02-20	~~2027-04-28~~ 2027-02-20	32
04251244500344	FG-02234-003A / VS16060	900166	~~2025-04-28~~ 2025-02-20	~~2027-04-28~~ 2027-02-20	10
04251244500337	FG-02234-002A / VS16100	900165	~~2025-03-21~~ 2025-02-20	~~2027-03-21~~ 2027-02-20	35
04251244500320	FG-02234-001A / VS16150	900164	~~2025-03-21~~ 2025-02-20	~~2027-03-21~~ 2027-02-20	28
04251244500399	FG-02234-008A / VS18060	900171	~~2025-03-21~~ 2025-02-20	~~2027-03-21~~ 2027-02-20	15
04251244500382	FG-02234-007A / VS18100	900170	~~2025-03-21~~ 2025-02-20	~~2027-03-21~~ 2027-02-20	16

Contract Medical International GmbH
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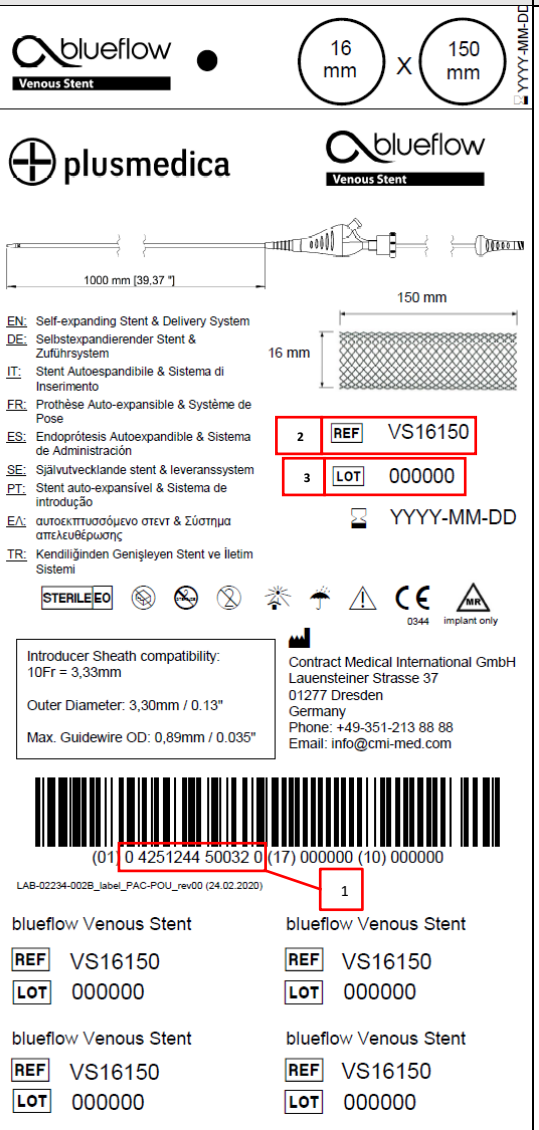
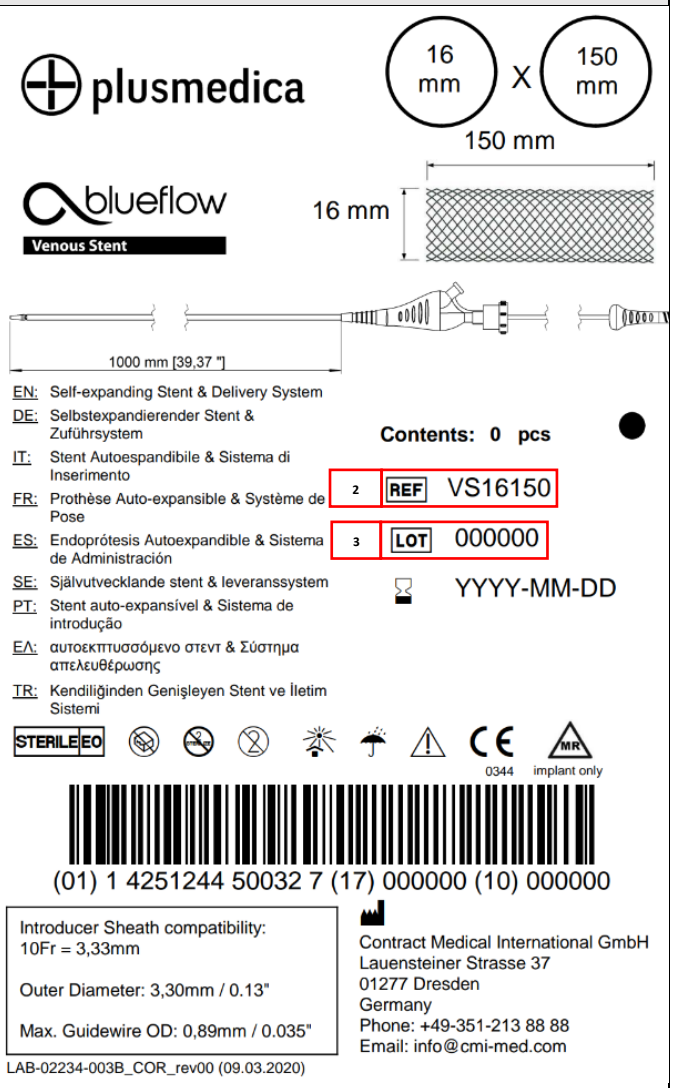
Please see the following examples of product labeling for examples of how to locate the product specific information.

Pouch Label	Carton Label
	

1. Primary UDI	2. Catalog Number (REF)	3. Lot Number

Actions taken by the Company:

Contract Medical International GmbH has voluntarily initiated this recall with the intent to remove the affected lots from commercial distribution and your assistance is appreciated and necessary to prevent potential patient harm.

Contract Medical International GmbH
Lauensteiner Strasse 37
01277 Dresden, Germany

Upon receiving the completed *Attachment I Consumer Recall Response Form* from distributers, healthcare facilities and users, Contract Medical International GmbH will contact you and provide further details on the return shipment of the affected product back to our facility.

Please complete and return the enclosed response form as soon as possible. This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of this action.

If you have any questions, call Christelle Elson at +49-351-213-8873 or medevioregulatoryaffairs@heraeus.com.

This recall is being made with the knowledge of the Competent Authority BfArM.

Authorized by:

Name: Christelle Elson

Title: Regulatory Affairs Manager

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Contract Medical International GmbH
Lauensteiner Strasse 37
01277 Dresden, Germany

Attachment I - Consumer Recall Response Form

blueflow Venous Stent

Please read the URGENT: MEDICAL DEVICE RECALL letter before answering.
Please read each question and indicate an answer.

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions provided in the August 14th, 2025 letter.

☐ I have checked my stock and have quarantined inventory consisting of _____ units from lot number(s):
_____.

☐ Indicate disposition of recalled product:

Number of devices already used:_____
Please list each used device including the device catalog number, the device lot number, the date when the device was used:

_____

Number of devices held for return:____
Please specify device catalog number, lot number, quantity, date and method of return:

_____

Number of already returned devices:_____
Please specify device catalog number, lot number, quantity, date and method of return:

_____

☐ I have identified and notified my customers that were shipped or may have been shipped this product by (please specify date and method of notification):

_____

_____

Any adverse events associated with recalled product? ☐ Yes ☐ No

If yes, please explain: _____

Contract Medical International GmbH
Lauensteiner Strasse 37
01277 Dresden, Germany

Name/Title: _____

Tel. number: _____

email: _____

Company name: _____

Address: _____

City/State/Country: _____

Please Email Completed Response Form To: medevioregulatoryaffairs@heraeus.com and quality@plusmedica.org.

Or Mail To:
Attn: Regulatory Affairs Department
Contract Medical International GmbH (dba Heraeus Medevio)
Lauensteiner Strasse 37
01277 Dresden, Germany

USt-IdNr.: DE 213 207 464
Registergericht: Amtsgericht Dresden HRB 19782 · Sitz der Gesellschaft: Dresden
Geschäftsführer: Dr. Frank A. U. Thiel