UPDATED URGENT FIELD SAFETY NOTICE

Commercial name of the affected product:	Blueflow Venous Stent
Date of related Field Safety Corrective Action (FSCA) report:	Health Hazard Evaluation HHE 0007-2024
Type of action:	**UPDATE:** The Blueflow Venous Stent missing the stent was identified. The recommendation given can be disregarded. *(A Blueflow Venous Stent device can potentially not have a stent loaded in its packaging. For this reason, it is recommended to have a second device available during the procedure.)*

Date: 12. August 2024
Attention: Distributors and End Users in the hospital

Dear Sir or Madam,

In the interest of patient safety, we Heraeus Medevio, Contract Medical International GmbH, Lauensteiner Straße 37, 01277 Dresden, Germany, must inform you about the following measures for the Blueflow Venous Stent devices.

Details on affected device:

Product Name	Blueflow Venous Stent		
Model Number	VS14150 (FG-02234-004A)	Lot Number	900066

Description of problem:
LOT 900066, which has been released to the distributor and end users, contains two devices that do not have a stent loaded in them. One of the devices containing no stent has already been identified.
UPDATE: The second device containing no stent was identified. No device missing a stent remains on the market.

Advise on action to be taken by the user:
UPDATE: It is not any longer recommended to have a second device for use available when using a device from lot number 900066 for the procedure.

This notice needs to be passed on to all those within your organization who work with the potentially affected devices and to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organizations that are impacted by this action.

Please maintain awareness of this notice and the resulting action for an appropriate period of time in order to ensure effectiveness of the corrective action.

Contact reference person:

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