FSN Ref. / FSCA Ref.: CAPA 26-046

Urgent Field Safety Notice

Voluntary Field Safety Corrective Action
- Product Recall -

"BeFlow Iliac Covered Stent System"

[redacted]

[redacted]

Contact person of sender:
Complaint Department
e-mail: complaint@bentley.global

For Attention of: **- Distributor**
- Hospital

1 Information on Affected Devices:

1.1 Device Type

BeFlow Iliac Covered Stent System

The BeFlow Iliac Covered Stent System is a sterilely supplied covered stent system that is intended for the treatment of stenotic lesions in iliac arteries. The device is used in a hospital or clinic by healthcare professionals under hygienic conditions in an aseptic environment under continuous fluoroscopic control.

The following products are affected by this voluntary recall:

UDI-DI	Product description	REF-Numbers (catalogue numbers)	Lot Numbers
04260279095442	BeFlow Iliac Covered Stent System	BFI0737_1	251401, 252601

2 Reason for Field Safety Corrective Action

2.1 Description of the product problem

During internal review Bentley became aware that two lots of the BeFlow Iliac Covered Stent System were manufactured with a different crimping program than intended by the manufacturing work instruction. The affected devices were therefore manufactured outside of the parameter range covered by the associated process validation. The usage of a lower crimping force might lead to an increased stent profile and a reduced stent retention force. As a result, the covered stent might dislodge from the balloon during the advancement to the target lesion.

2.2 Hazard giving rise to the FSCA

Based on the underlying risk analysis a stent dislodgement can lead to a delay in the procedure since the covered stent system needs to be replaced. If in such cases the device is removed against the description provided within the Instructions for Use, said removal can result in ischemia in case the stent is shoved from the balloon into the bloodstream.

As of today, Bentley InnoMed GmbH has not received any complaints or serious incidents regarding the affected lots.

3 Type of Action to mitigate the risk

3.1 Action to be Taken by the User

- Please identify if any of the affected products are inside your storage facility.
- Please no longer use the affected products and quarantine them immediately.
- If you have any products affected by this recall in your stock, please return those to Bentley InnoMed GmbH.
- Please complete the attached Reply Form completely and send it to us as soon as possible and no later than 01-Dec-2026.

3.2 Actions to be taken by the Distributor

- Please identify if any of the affected products are inside your storage facility.
- Please stop the distribution of the products affected by this FSCA and quarantine them immediately.
- Identify the customers affected by this FSCA and inform them immediately. Forward this Field Safety Notice as well as the Customer Reply Form to the affected customers.
- Please check your stock and return the products affected by this FSCA to Bentley InnoMed GmbH.
- Please complete the attached Reply Form and send it to us as soon as possible and no later than 01-Dec-2026.

3.3 Is the FSN required to be communicated to the patient?

No, a communication to the patient is not required, since the detected problem solely affects the implantation procedure of the device. If an affected device was successfully implanted, there is no increased risk to the patient.

4 General Information

4.1 FSN Type

New

4.2 Further advice or information already expected in follow-up FSN?

Not yet known.

4.3 The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Transmission of this Field Safety Notice

Please ensure within your organization that all users of the above-mentioned products and other persons to be informed are made aware of this safety information. If you have delivered the products to third parties, please forward a copy of this information or inform the contact persons listed below.

The Federal Institute for Drugs and Medical Devices (BfArM, German Competent Authority) and all other relevant Competent Authorities worldwide as well as our Notified Body received a copy of this voluntary safety information.

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

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Contact persons:

Quality Affairs Department
e-mail: complaint@bentley.global
tel: +49 7471 9999 0
Lotzenäcker 3
72379 Hechingen

Bentley

FSN Date: 16-Nov-2026

Customer Reply Form
FSN Ref.: CAPA 26-046

Urgent Field Safety Notice

Action Being Taken by the Manufacturer: Product Removal

„BeFlow Iliac Covered Stent System“

1. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Department / Unit:	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email address	
Area Sales Manager:	

2. Return acknowledgement to Sender	
Email	complaint@bentley.global
Fax:	+49 7471 984 995 9
Postal Address	Bentley InnoMed GmbH Attn.: FSN Ref.: CAPA 26-046 Lotzenäcker 3 72379 Hechingen Germany
Deadline for returning the reply form	01-Dec-2026

3. Distributors/Importers (Tick all that apply)

Bentley

Customer Reply Form

FSN Ref.: CAPA 26-046

FSN Date: 16-Nov-2026

☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.
☐	We performed a thorough search for concerned products. There are no more concerned products in our inventory or in the stock of the users supplied by us (s. completely filled table below). **No products will be returned.**
☐	Concerned products were found (s. completely filled table below). These will be returned, stating the following reference number. **Reference-Number: CAPA 26-046**

REF (Catalogue number)	Batch (Lot) number	Number of shipped products	To be completed by the returning party:	
			Number of already implanted products	Number of returned products
BFI0737_1	251401			
BFI0737_1	252601			

Please sign the form and send it back to Bentley by fax or e-mail.
If affected items are in stock, please contact Bentley InnoMed GmbH (complaint@bentley.global) for further details regarding the return and enclose a copy of the form with the return shipment.

Print Name	
Date	
Signature	