Bentley

FSN Ref. / FSCA Ref.: CAPA 20-003

Urgent Field Safety Notice

Voluntary Field Safety Corrective Action
- Product Recall -

„BeGraft Coronary Stent Graft System“
Diameter 3 mm, Length 18 - 24 mm

Hechingen, 22 of April 2020

Address of sender:
Bentley InnoMed GmbH
[redacted]

Contact person of sender:
Uta Fischinger
complaint@bentley.global

For Attention of: Distributors and users of the affected batches of the product "BeGraft Coronary Stent Graft System" of Bentley InnoMed GmbH

Identification of the affected devices:
"BeGraft Coronary Stent Graft System"
This voluntary recall only applies to the batches listed below.

REF-Numbers (catalogue numbers)	Lot Numbers
BG18300 Length: 18mm / Diameter: 3mm	208374 208523 209016 209377 209490 209824
BG21300 Length: 21mm / Diameter: 3mm	209176 209901
BG24300 Length: 24 mm / Diameter: 3mm	208275 208972 209387 209900

1 Reason for Field Safety Corrective Action (FSCA)

1.1 Description of the product problem

During the last internal quality control (destructive testing during final release test), it was found that there is a potential for the occurrence of a pinhole during the inflation of the balloon; thus, the complete expansion of the stent graft to the labelled nominal diameter cannot be guaranteed in the concerned products.

Immediate investigations showed that the above-mentioned batches and sizes (REF- and Lot numbers) of the BeGraft Coronary Stent Graft System might be affected.

However, no complaints, patient injuries or deaths have been reported with regard to the described failure mode at this time.

Already implanted products are not concerned by this safety information!

1.2 Hazard giving rise to the FSCA

If the stent graft cannot be completely expanded to the labelled nominal diameter due to the described failure mode, the stent graft may have limited or no performance function in the emergency situations the product is indicated for. In addition, the incompletely expanded stent graft may continue to migrate in the coronary system due to limited wall contact, and downstream tissue sections may be displaced, or if post-dilatation using another balloon catheter is not possible, open heart surgery may be required as the acute coronary artery perforation, acute coronary artery rupture, coronary artery aneurysm and coronary bypass-vein graft aneurysm cannot be sufficiently sealed.

2 Actions to be taken by the user

- Please no longer use the products concerned by this FSCA and quarantine them immediately.
- Please check your stock with regard to the products covered by this FSCA.
- If there are products affected by the recall to be returned to Bentley, we will provide you with a return number and furthermore, with a credit note or exchange products (Ø3.5mm) upon receipt of the affected products.
- Please complete the attached Reply Form completely and send it as soon as possible and no later than the 1st of May 2020 to the address given.

3 Actions to be taken by the distributor

- Please stop the distribution of products concerned by this FSCA and quarantine them immediately.
- Please identify the customers affected by this FSCA immediately.
- Please forward this Field Safety Notice as well as the attached Customer Reply Form to the customers that have received products concerned by this FSCA.
- Please check your stock with regard to the products covered by this FSCA.
- If there are products affected by the recall to be returned to Bentley, we will provide you with a return number and furthermore, with a credit note or exchange products (Ø3.5mm) upon receipt of the affected products.
- Please complete the attached Reply Form completely and send it as soon as possible and no later than the 1st of May 2020 to the address given.

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.