Bentley

Safety Information

Voluntary Device Recall regarding 6 batches of the „BeGraft Peripheral Stent Graft System“, size 9x57mm

Hechingen, March 19th 2018

Sender:
Bentley InnoMed GmbH
Lotzenäcker 25
72379 Hechingen
Germany

Addressees: Distributors and users of the affected batches of the product "BeGraft Peripheral Stent Graft System" (BGP) of Bentley InnoMed GmbH

Identification of the concerned medical devices:

„BeGraft Peripheral Stent Graft System“
This voluntary recall only applies to the batches listed below (91 pieces).

REF-Numbers (catalogue numbers)	Batch-Numbers (Lot)
BGP5709_1	200675 200713
BGP5709_2	200546 200635 200676 200753

Description of the problem including the identified cause (s):

Description of the problem:
This safety information only concerns the above-mentioned batches and size (Lot and REF-Numbers) of the "BeGraft Peripheral Stent Graft System".

During the last internal quality control (final release test) of three products of one batch (according to the sampling plan), it was found that the stent protective cover (protector), which is pushed over the crimped stent graft during packaging, could no longer be removed from the stent graft system of one product. As a result, all other products of this batch were tested. In one additional product, the stent protective cover (protector) could not be removed either. Thus, a total of 2 out of 31 products presented this problem. The protectors of the other 29 products could be removed, but the forces to remove them were higher than usual. So far, no previous release test showed this increased pull-off force. This indicates that previous batches of this protector size are unaffected. In addition, there was no customer complaint about a similar problem.

If the protector cannot be removed at all from the stent graft system during the preparation of the procedure, the product cannot be used.
If it is difficult to remove the protector, the higher pull-off forces may cause the stent graft to loosen or shift on the balloon. If this is not noticed by the user as part of the inspection prior to use (see user information below), it may in the worst case lead to the loss of the stent graft.

These situations could lead to delays and/or complications during the placement of the stent graft, resulting in serious patient health problems (e.g. prolonged bleeding time, stent embolism).

User information according to the currently valid instructions for use of the "BeGraft Peripheral Stent Graft System" (Chapter 7.1 Inspection Procedure Prior To Use):
„Prior to using the BeGraft Peripheral Stent Graft System, carefully remove the system from the package and inspect the catheter for bends, kinks and other damage. Verify that the BeGraft Stent Graft is located between the radiopaque balloon markers. Do not use the system if any defects are noted."

Already implanted products are not concerned by this safety information!

Identified Cause(s):
It was confirmed that the protector-batch, used for the packaging of the above mentioned products, shows an inner diameter which is too small.

What actions have to be taken by the addressees?

1. Please no longer use the products that are still in stock and return them to Bentley InnoMed GmbH by March 29th 2018 at the latest.
2. Also please acknowledge the receipt of this "Safety Information" in writing (see the Safety Information Receipt Form at the end of this letter) and complete the information requested therein.

Distribution of the information provided here (distributors / customer clinics):
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. Please keep this information at least until the measures have been completed. The Federal Institute for Drugs and Medical Devices (German Competent Authority) and all other relevant EU Competent Authorities as well as our Notified Body received a copy of this voluntary safety information.

Contact persons:

Signature

Frank Schulte-Hunsbeck
QA/RA Manager
Lotzenäcker 25
72379 Hechingen

Tel: +49 (0)7471 984 995 20
Mob: +49 (0)171 456 2988
Fax: +49 (0)7471 984 995 9
Email: f.schulte-hunsbeck@bentley.global

Signature

Christian Bader
Product Manager
Lotzenäcker 25
72379 Hechingen

Tel: +49 (0)7471 984 995 32
Mob: +49 (0)151 1415 5262
Fax: +49 (0)7471 984 995 9
Email: c.bader@bentley.global

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Acknowledgement of receipt of the "safety information" / "Voluntary Device Recall" of March 19th 2018

Please complete the following form after thoroughly reviewing your inventory. If affected items are in stock, please contact Bentley InnoMed GmbH (complaint@bentley.global) for further details regarding the return.

Product: BeGraft Peripheral Stent Graft System	
Organization (Returning party):	
Name, First name:	
Title / Function:	
Phone number:	
E-mail address:	
Address:	**Street:**
	Zip code / Postal code:
	City:
	Country:
Area Sales Manager:	

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
BGP5709_1	**XXXXXX**	X		
BGP5709_2	**XXXXXX**	X		

☐ 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.

No products will be returned.

☐ Concerned products were found. These will be returned, stating the following reference number.

Reference-Number: CAPA 18-004

Please sign the form and send it back to us by fax or e-mail. Please enclose a copy of the form with the return shipment. The return of the form and, if applicable, the products should be made by March 29th 2018 to the following address.

Bentley InnoMed GmbH
Ref.-No.: **CAPA 18-004**
Lotzenäcker 25
72379 Hechingen
E-mail: complaint@bentley.global
Fax: +49-7471-984-995-9

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Date / Name / Signature