MED CERT®

Certification. Medical Only.

EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Bentley InnoMed GmbH
Lotzenäcker 25
72379 Hechingen
Germany

With its facility as per attachment 1

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

- **Coronary stent graft systems**
- **Peripheral vascular stent systems**
- **Peripheral vascular stent graft systems**
- **Aortic stent graft systems**

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II excluding section 4

The license of certification is subject to surveillance by MEDCERT.

For the for the placing on the market of Class III devices covered by this certificate, an additional EC design-examination certificate according to Council Directive 93/42/EEC Annex II (4) is required.

This certificate is valid from 17 December until 18 April 2023

Report No.: 7490IA01F
Process No.: QS - 7490
Certificate No.: 7490GB410181217

Hamburg, 17 December 2018

MEDCERT Identification No.: 0482

MEDCERT Certification Body
(Dr. Andreas Schich)

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Digitally signed by Grabazei Alexandru
Date: 2022.10.08 21:07:04 EEST
Reason: MoldSign Signature
Location: Moldova

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Attachment 1
EC-Certificate of Conformity
QS – 7490

This attachment is valid only in connection with certificate No: 7490GB410181217

Facility

Bentley InnoMed GmbH
Lotzenäcker 3
72379 Hechingen
Germany

Hamburg, 17 December 2018

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Bentley

BeGraft

peripheral

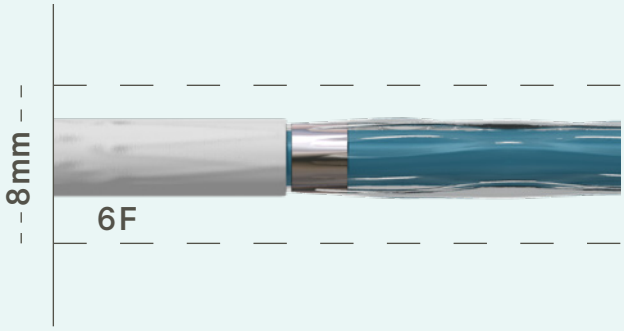
ENGINEERED & MANUFACTURED IN GERMANY
ENDOVASCULAR INNOVATIONS

BeGraft
peripheral

This peripheral stent graft system excels with a high radial force whilst maintaining extraordinary flexibility and low profile. The cobalt-chrome stent platform is covered with a micro-porous ePTFE membrane.

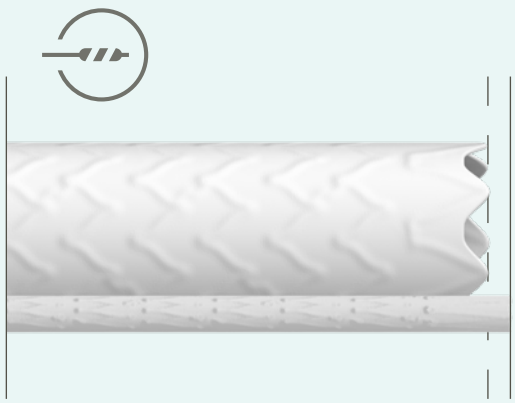
Less trauma, faster procedures

through low profile
(6F compatibility up to 8mm)



Outstanding lesion access

through exceptional flexibilty



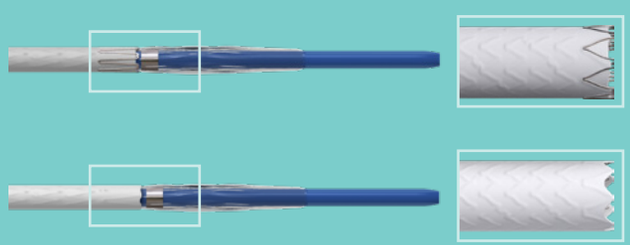
Predictable stent behaviour

through low foreshortening
& high radial force

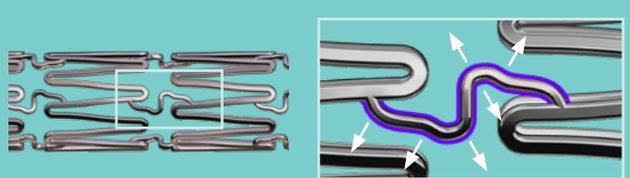
Bentley

A second generation, including the following design modifications, has been launched in October 2015

1. The ePTFE covering is now fixed from the inside at both stent ends to eliminate the risk of detachment of the graft material (e.g. when using a too small introducer sheath).



2. The connector width has been increased by approx. 20% to improve the longitudinal stiffness of the stent.



3. The thickness of the ePTFE cover has been increased by a factor of 2 to improve the mechanical stability.

Initial Thickness (100 µm) Modified Thickness (200 µm)

These design modifications do not negatively affect the valued advantages in regards to profile (6F up to 8mm), flexibility, trackability and foreshortening nor compromise the safety and efficacy of the design for its intended use (indications).

Your specification

Graft Material	Micro-porous ePTFE tubing (203 ± 25µm)
Stent Material (Composition)	CoCr (L605)
Stent Graft Design	Single Stent
Strut Dimensions (Width x Thickness)	0.135 x 0.145 mm (SV) 0.145 x 0.145 mm (MV) 0.165 x 0.145 mm (LV)
Delivery System	OTW
Introducer Sheath Compatibility	6F up to Ø 8 x 57 mm 7F
Guide Wire	0.035”
Shaft Size	5F
Balloon Marker Material	Platinum / Iridium
Nominal Pressure	9 bar Ø 5.0 - 7.0 mm 8 bar Ø 8.0 - 10.0 mm
Rated Burst Pressure	13 bar Ø 5.0 - 7.0 mm 12 bar Ø 8.0 - 10.0 mm
Catheter Shaft Length	75 cm and 120 cm
Expanded Stent Graft Diameter	5.0, 6.0 mm (SV) 7.0, 8.0 mm (MV) 9.0, 10.0 mm (LV)
Nominal Stent Graft Length	18, 22, 28, 38, 58 mm (SV) 18, 23, 27, 37, 57 mm (MV) 27, 37, 57 mm (LV)
Shelf Life	up to 3 years

ENGINEERED & MANUFACTURED IN GERMANY
ENDOVASCULAR INNOVATIONS

Indications

The BeGraft Peripheral Stent System is indicated for intraluminal chronic placement in iliac and renal arteries for:

- Restoring and improving the patency
- Treating aneurysms, acute perforations, acute ruptures and fistulas

Ordering information

Expanded Stent Graft Diameter	Nominal Stent Graft Length	Introducer Sheath Size	Catalogue Number for Catheter Length	
			75 cm	120 cm
5 mm	18 mm	6 F	BGP1805_1	BGP1805_2
	22 mm		BGP2205_1	BGP2205_2
	28 mm		BGP2805_1	BGP2805_2
	38 mm		BGP3805_1	BGP3805_2
	58 mm		BGP5805_1	BGP5805_2
6 mm	18 mm	6 F	BGP1806_1	BGP1806_2
	22 mm		BGP2206_1	BGP2206_2
	28 mm		BGP2806_1	BGP2806_2
	38 mm		BGP3806_1	BGP3806_2
	58 mm		BGP5806_1	BGP5806_2
7 mm	18 mm	6 F	BGP1807_1	BGP1807_2
	23 mm		BGP2307_1	BGP2307_2
	27 mm		BGP2707_1	BGP2707_2
	37 mm		BGP3707_1	BGP3707_2
	57 mm		BGP5707_1	BGP5707_2
8 mm	27 mm	6 F	BGP2708_1	BGP2708_2
	37 mm		BGP3708_1	BGP3708_2
	57 mm		BGP5708_1	BGP5708_2
9 mm	27 mm	7 F	BGP2709_1	BGP2709_2
	37 mm		BGP3709_1	BGP3709_2
	57 mm		BGP5709_1	BGP5709_2
10 mm	27 mm	7 F	BGP2710_1	BGP2710_2
	37 mm		BGP3710_1	BGP3710_2
	57 mm		BGP5710_1	BGP5710_2

Be innovative

We focus on the development of unique products and strive to find creative answers to questions posed by the healthcare industry

Be dedicated

A marked customer focus and compliance to international standards help us to uphold unsurpassed quality in products and services

Be responsible

We care for better health, our region and the environment. Every member of our team is motivated to make a vital contribution to the quality of life

Be effective

We strive for time- and cost efficient solutions to satisfy the versatile interests of our customers and patients worldwide

www.bentley.global

Bentley

Bentley InnoMed GmbH
Lotzenäcker 3, 72379 Hechingen, Germany
tel + 49 7471 984 995 10
mail info@bentley.global

Bentley

MANUFACTURER'S DECLARATION OF CONFORMITY

According to the EC – Medical Devices Directive 93/42/EEC, as last amended by Directive 2007/47/EC

FULL QUALITY ASSURANCE PROCEDURE

DECLARATION DE CONFORMITÉ DU FABRICANT
selon la Directive CE 93/42/CEE relative aux dispositifs médicaux modifiée par la directive 2007/47/CE
SYSTÈME COMPLET D'ASSURANCE QUALITÉ

Reference: *Référence:*		**DoC**	**18-018**	
Manufacturer's Name & Business Address : *Nom du fabricant et adresse postale:*		**Bentley InnoMed GmbH** **Lotzenäcker 25, 72379 Hechingen, Germany**		
Manufacturing Location: *Adresse de la production:*		**Lotzenäcker 3, 72379 Hechingen, Germany**		
Medical Device Trade Name: *Denomination commercial du dispositif médical:*		**BeGraft Peripheral Stent Graft System**		
Medical Device Generic Name: *Denomination générique du dispositif médical:*		**Peripheral Stent Graft System** ***Système d'endoprothèse périphérique couverte***		
Classification: *Classification:*	Class: *Classe:*	**IIb**	acc. Annex IX MDD 93/42/EEC, rule: *selon annexe IX DDM 93/42/CEE, règle :*	***8***
GMDN Code : *Code GMDN:*	***47932***	Term: *Terme:*	***Multiple Peripheral Arteries Stent***	
UMDNS Code: *Code UMDNS:*	***17-461***	Term: *Terme:*	***Stent, Vascular***	

This declaration is applicable to below listed models/variants (REFs):
La présente déclaration s'applique à tous les lots de références mentionnées ci-dessous :

UL [cm]	Stent length / Longueur stent [mm]	Stent diameter / *Diamètre stent* [mm]					
		5	6	7	8	9	10
75	18	BGP1805_1	BGP1806_1	BGP1807_1	BGP1808_1	BGP1809_1	BGP1810_1
	22/23	BGP2205_1	BGP2206_1	BGP2307_1	n.a.	n.a.	n.a.
	27/28	BGP2805_1	BGP2806_1	BGP2707_1	BGP2708_1	BGP2709_1	BGP2710_1
	37/38	BGP3805_1	BGP3806_1	BGP3707_1	BGP3708_1	BGP3709_1	BGP3710_1
	57/58	BGP5805_1	BGP5806_1	BGP5707_1	BGP5708_1	BGP5709_1	BGP5710_1
120	18	BGP1805_2	BGP1806_2	BGP1807_2	BGP1808_2	BGP1809_2	BGP1810_2
	22/23	BGP2205_2	BGP2206_2	BGP2307_2	n.a.	n.a.	n.a.
	27/28	BGP2805_2	BGP2806_2	BGP2707_2	BGP2708_2	BGP2709_2	BGP2710_2
	37/38	BGP3805_2	BGP3806_2	BGP3707_2	BGP3708_2	BGP3709_2	BGP3710_2
	57/58	BGP5805_2	BGP5806_2	BGP5707_2	BGP5708_2	BGP5709_2	BGP5710_2

Herewith we declare, under our sole responsibility, that each lot of above mentioned medical device, to which the Full Quality Assurance Procedures have been applied, complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Bentley

Nous déclarons sous notre entière responsabilité que chaque lot des dispositifs médicaux mentionnes ci-dessus, auxquels le système complet d'assurance qualité a été appliqué, correspond aux exigences essentielles, aux règles de classification, applicables a toutes les phases, depuis la conception du dispositif jusqu'à 'a son contrôle final avant livraison.

Conformity Assessment Body (acc. MDD 93/42/EEC, Annex XI) *Organisme notifié (selon annexe XI DDM 93/42/CEE)*	Notified Body Number *No de l'Organisme notifié*	Address *Adresse*
MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH	*0482*	*Pilatuspool 2, 20355 Hamburg, Germany*

Certificate Type *Type de certificat*	Certificate Number *No certificat*	Assessment route acc. MDD 93/42/EEC *Procédures d'évaluation de conformité, selon DDM 93/42/CEE*
Full Quality Management System (class I(s), I(m), IIa, IIb, III) *Certificat du Système complet d'assurance qualité (classe I(s), I(m), IIa, IIb, III)*	*7490GB410181217*	*Annex II, excluding section 4* *Annexe II, à l'exclusion de section 4*
Design Examination Certificate (class III devices only) *Certificat d'examen CE de la conception (que pour dispositifs de classe III)*	*Not applicable*	*Annex II, section 4* *Annexe II, section 4*

This Declaration is valid until:
La présente déclaration est valable jusqu'au : *April 18th, 2023*

Authorized Signatory:
Signataires autorisés:

Christian Bader — *December 18th, 2018*
Manager Quality Assurance — Date

Judith Müller — *December 18th, 2018*
Manager Regulatory Affairs (CE) — Date