Order for Planning Support / Order Patient-individual Medical Device

PETER BREHM
Die Präzision in Titan
für den Menschen

Dear Customer,

PETER BREHM GmbH is pleased to support you with preoperative planning for our standard implant systems as well as with the development and provision of patient-individual medical devices.

To enable the planning and manufacturing of a patient-individual medical device in accordance with EU-MDR 2017/745 and the German Medical Devices Implementation Act (MPDG), we kindly ask you to fill in this form diligently and complete.

Attending Physician:

Name and function:	
Hospital or Clinic:	
Department:	
ZIP code, city and country:	
Phone:	
E-Mail:	

Patient data: (The following information is mandatory!)

First and last name or ID:			
Sex:	☐ M	☐ F	☐ D
Date of birth:			
Height [cm]:			
Weight [kg]:			

Diagnosis and Case specification:

Diagnosis:		
Description of function(s) to be provided, and if necessary specific design characteristics:		
Anatomical position:	☐ left	☐ right

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Specification of the patient-individual Medical Device:

Note: By filling in the following points, you confirm that the corresponding patient's care could not be provided satisfactorily during preoperative planning / intraoperative reduction with standard products already available on the market.

Specific needs for the design can be given in the following comments:

☐ **Partial Pelvic Replacement / Individual Cup[1] with trabecular structure** Note: Separate consultation is necessary if you wish for no trabecular structure.		
Needed design characteristics / Anchoring choices	☐ Iliac Peg ☐ Pole Screws ☐ Cranial Flange ☐ Caudal hook(s) / contact surfaces	

☐ **KAM Monoblock[2]**			
Component:	☐ Femur	☐ Tibia	
Curvature:	☐ yes	☐ no	
Locking:	☐ yes	☐ no	
Cementation:	☐ yes[3]	☐ no	

☐ **Other / specific requirements:**
Detailed description:

The described products can only be offered in sterile condition.

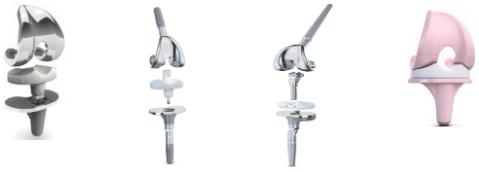
[1] Note: This medical device is defined as a custom-made device. As such, according to EU-MDR 2017/745, the final implant design is the responsibility of the physician.
[2] Note: This medical device can be offered as a patient-matched device within a predefined design scope. As such, according to EU-MDR 2017/745, the final implant design is the responsibility of the manufacturer. Outside of the specifications of the design scope, a custom-made solution can be offered as long as the anatomical characteristics of the patient justify the need. For a custom-made solution, Note 1 applies, see above.
[3] Note: A cemented version is not covered by the predefined design scope of a patient-matched device, making this solution a custom-made device. As such, Note 1 applies, see above.

Planning support standard products:

Note: The created planning does not replace the product-specific Instructions for Use to be observed for the corresponding implant system.

MRS-TITAN Modular Revision Cup	
☐ MRS-TITAN Comfort	
☐ MRS-TITAN Standard ☐ MRS-TITAN Maximum	

MRP-TITAN Modular Revision Stem	
☐ MRP-TITAN	

BPK-S Integration Brehm Precision Knee system	
☐ BPK-S Integration	

KAM-TITAN Knee Arthrodesis Modular system	
☐ KAM-TITAN	

Comments regarding the Planning Support:

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Management board:
Oliver Brehm, Martin Brehm
Chairman of the supervisory board: Peter Brehm
Legal residence: Weisendorf, Germany
Commercial register: Fürth Abt. B 3261

Az.Nr.: REC-0000000000
Version: 1

Bank details:
HypoVereinsbank BIC: HYVEDEMM417
IBAN: DE21 7632 0072 0006 3187 11

VR-Bank BIC: GENODEF1NEA
IBAN: DE74 7606 9559 0001 5380 63

CT-Scan Specification:

The provided CT scan data have to represent the patient's current anatomical and osseous status at the time of submission.

Reconstruction	CT scan Specification
Acetabulum	- 1 mm slice thickness - whole pelvis (cranial: pelvic crest / caudal: ischial tuberosity)
Femur / Tibia	- 2-3 mm slice thickness - defect area + 10 cm (both sides)

Further process:

Please send the completed form including the CT scan to:

PETER BREHM GmbH, Sonderanfertigung, Am Mühlberg 30, 91085 Weisendorf GERMANY.

Alternatively, you may provide the data via online transfer. In this case, please send the completed form to: sonderanfertigung@peter-brehm.de. You will then receive a personalized access to a secured cloud platform for the upload of up to 10 GB of CT scan data.

If the data are available on other platforms (e.g., hospital systems or patient portals), you are welcome to provide the access credentials so that we can securely download the data ourselves.

As soon as we received all necessary data, we will send you a planning proposal. After you return your final written approval of the proposed design, we will be pleased to prepare a corresponding offer.

Formal Requirements:

By submitting of this order, the attending physician, or the submitting person on behalf of the attending physician, requests planning services from PETER BREHM GmbH and confirms that the named patient expressly consents to the disclosure of their data.

All information for the user regarding the specific handling and implantation of the patient-individual device will be provided in English only.

For the conception, a flat fee of 399,- € plus VAT will be charged.

This flat fee will not be charged if the offer for a patient-individual medical device ("Custom-made construction") is accepted.

By submitting this order form, you confirm the acknowledgement of the aforementioned requirements.

PETER BREHM GmbH: Date of receipt and processing number:
