Biomet Orthopedics
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Signature Personalized Patient Care System:
Acetabular Guide System

ATTENTION OPERATING SURGEON

DESCRIPTION
The **Signature Personalized Patient Care System – Acetabular Guide System** (guides are considered custom-made per EU definition) which are patient-specific instruments used to assist with acetabular cup positioning during hip replacement surgery. This **Acetabular Guide System** is developed using the software (Signature Planner) of the **Signature Personalized Patient Care System.** The **Acetabular Guide System** is based on patient-specific anatomic landmarks necessary for alignment and positioning of the implant identified on preoperative patient imaging scans.

MATERIALS
Polyamide

INDICATIONS FOR USE
The **Signature Personalized Patient Care System – Acetabular Guide System** is intended to be used as a surgical instrument to assist in the positioning of acetabular cup components intra-operatively using anatomical landmarks of the pelvis that are clearly identifiable on preoperative MRI imaging scans.

The **Signature Personalized Patient Care System – Acetabular Guide System** can be used with all Biomet 510(k) cleared, legally marketed, primary acetabular systems and their respective components.

The **Signature guides** are intended for single use only.

CONTRAINDICATIONS
The Signature Guides are contraindicated for patients with significant anatomical disruption or distortion of the pelvis. This may include patients with pelvic and/or acetabular fractures and/or dislocations, metabolic bone diseases (such as Paget's Disease), pelvic instability, heterotopic ossifications or ligament calcifications, postpartum symphysis diastasis and skeletal dysplasia, neoplasms or other disorders that affect pelvic anatomy and bony landmark recognition.

Active infection is a contraindication for use of this device.

The Signature Guides are contraindicated for use with flanged acetabular components.

WARNINGS
1. The user should be aware of possible allergic reactions to materials used in the guide. The patient should be informed on this matter by the user.
2. The guide's patient specific identifiers are to be checked for readability and confirmed by the surgeon before use.
3. Device is single use only. Do not attempt to re-clean or re-sterilize this product for other than its originally-intended patient. After use, this product may be a potential biohazard.
4. Surgeon must ensure that the guide is placed appropriately or malalignment can occur.

PRECAUTIONS
1. The Signature Guide is for single use only. The guide is not reusable.
2. If the patient's anatomy has changed significantly since the time of the MRI-scan, the Signature Guide should not be used.
3. Acetabular guides can only be developed using MRI scans.
4. Store it in a properly cleaned and dry place.
5. The guide should be properly cleaned before sterilization.
6. Open, clean and sterilize immediately prior to surgery.
7. Do not use if the Signature Guide is broken, cracked, or when loose powder is present.
8. Do not alter the guide.
9. Do not bend or reconfigure pins or alignment devices.
10. The surgeon should be familiar with the package insert and appropriate surgical technique(s) specific to the joint replacement implants utilized in conjunction with the Signature Guides.
11. Care should be taken when drilling the pins to ensure that placement pins do not perforate the pelvis which could cause internal soft tissue damage.
12. Do not reuse guides or use them in patients for which they are not intended.
13. All trial, packaging, and instrument components must be removed prior to closing the surgical site; do not implant.

POSSIBLE ADVERSE EFFECTS
1. Infection following the procedure.
2. Introduction of foreign materials can result in an inflammatory response or allergic reaction.
3. Wound dehiscence.
4. Nerve damage.
5. Perforation of pelvic wall causing bone or soft tissue damage.

See also Possible Adverse Effects associated with total hip replacement in general and those associated with the hip replacement system utilized in conjunction with the Signature Guides.

STERILITY AND CLEANING
-Guides and bone models are provided in Non-Sterile condition and must be sterilized prior to surgery.

Guides must be cleaned until visibly clean prior to sterilization. Visible soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. It is recommended that the instruments be decontaminated using an automatic washer-disinfection unit utilizing thermal disinfection. This should preferably be of the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. The following table outlines a validated automated cleaning method for use.

Phase	Time (Minutes)	Temperature & Water Quality	Detergent & Concentration
Pre-Wash	2:00	95°F (35°C) Tap Water	None
Detergent Wash	6:00	158°F (70°C) Tap Water	Enzol® 1oz./gallon
Wash	4:00	158°F (70°C) Tap Water	Renu-Klenz™ ¼ oz./gallon
Rinse	2:00	158°F (70°C) Tap Water	None
Drying	7:00	239°F (115°C)	None

- The following tables outline sterilization parameters for use.

Dynamic-Air-Removal Sterilization
US Parameters Temperature: 270°F (132°C) 4 Minute exposure time 30 Minute drying time Single Wrapped*
Parameters for non-US countries Temperatures: 132°C (270°F) to 140°C (284°F) 3 Minute exposure time minimum 30 Minute drying time minimum Single or Double Wrapped or unwrapped
Gravity Displacement Sterilizer
Parameters for non-US countries Temperatures: 132°C (270°F) to 140°C (284°F) 10 Minute exposure time minimum 30 Minute drying time minimum Single or Double Wrapped or unwrapped
Sterrad 100S – Short Cycle US Parameters Cycle temperature: 113°F - 131°F (45° C - 55°C) Cycle Time: Approximately 55 minutes (short cycle) Double or Single Wrapped or unwrapped
Parameters for non-US countries Cycle temperature: 113°F - 131°F (45°C - 55°C) Cycle Time: Approximately 55 minutes (short cycle) Single or Double Wrapped or unwrapped

*Wraps used during the steam sterilization process are to be FDA cleared wraps (e.g., Kimguard® Sterilization Wrap; 510K #K082554).

Since Biomet is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Biomet assumes no responsibility for sterilization of product by a hospital even if the above general guidelines are followed.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA UK

Symbol Legend

 Manufacturer

 Date of manufacture

 Do not reuse

 Caution, see instructions for use

Sterilized using ethylene oxide

Sterilized using irradiation

Sterile

Sterilized using aseptic processing techniques

Sterilized using steam or dry heat

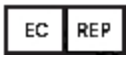
 Use by date

 WEEE device

Catalogue number

Batch code

Flammable



Authorized representative in the European Community

Non-Sterile