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Signature Personalized Patient Care System - Knee

ATTENTION OPERATING SURGEON

DESCRIPTION
The Signature Personalized Patient Care System includes the Signature Patient-Specific Surgical Guides which are patient specific instruments (guides are considered custom-made per EU definition). The Signature Patient-Specific Surgical Guides are intended to be used as part of the Signature Personalized Patient Care System. It is intended to be used as a guide during the surgical procedure for total and partial knee arthroplasty.

MATERIALS
Polyamide

INDICATIONS FOR USE
Pin Placement Guides
Signature Personalized Patient Care System is intended to be used as a surgical instrument to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The **Signature Personalized Patient Care System** can be used with the following Biomet® Knee Systems and their respective components: Vanguard™ Complete Knee System, Vanguard™ SSK 360, Vanguard™ SSK Revision Knee System, Regenerex™ Primary Tibial System, Offset & Microplasty™ Tibial Systems, Maxim™ Complete Knee System, Ascent™ Total Knee System, and AGC™ Complete Knee system.

Cut-Through Guides
Signature Personalized Patient Care System is intended to be used as a surgical instrument to assist in the positioning of total and partial knee replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The **Signature Personalized Patient Care System** can be used with the following Biomet® Knee Systems and their respective components: Vanguard™ Complete Knee System, Vanguard M™ Unicompartmental Knee System, Vanguard™ SSK 360, Vanguard™ SSK Revision Knee System, Regenerex™ Primary Tibial System, Offset & Microplasty™ Tibial Systems, Maxim™ Complete Knee System, Ascent™ Total Knee System, and AGC™ Complete Knee system.

The **Signature Personalized Patient Care System** is compatible for use with the Oxford® Partial Knee System as approved in P010014/S31.

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

CONTRAINDICATIONS
Active infection is a contraindication for use of this device.

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. Cut-through guides can only be developed using MRI scans.
5. The cutting blade used for the cut-through guide bone cuts should be placed into the slot of the guide prior to turning on the power to the cutting instrument.

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 CT/MRI-scan (CT cannot be used to make cut-through guides), the Signature Guide should not be used.
3. Store it in a properly cleaned and dry place.
4. The guide should be properly cleaned before sterilization.
5. Open, clean and sterilize immediately prior to surgery.
6. Do not use if the Signature Guide is broken, cracked, or when loose powder is present.
7. Do not alter the guide.
8. 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.
9. 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.

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). Use Manufacturer's instructions.

Since Materialise is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Materialise assumes no responsibility for sterilization of product by a hospital even if the general above 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 of the distributor: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968 or the manufacturer.

Kimguard® is the trademark of Kimberly-Clark Health Care.
Enzol® is a registered trademark of Johnson & Johnson Co.
Renu-Klenz™ is a trademark of Steris Corporation.

Symbol Legend

 Manufacturer

 Date of manufacture

 Do not reuse

 Caution, see instructions for use

Non-sterile

 Use by date

Catalogue number

Batch code