Manufactured by

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Distributed by

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

Important Information for the Operating Surgeon

ZIMMER BIOMET PATIENT SPECIFIC INSTRUMENTS[1]

DEVICE DESCRIPTION

The guides set and bone models are patient-specific medical devices, designed to fit or represent the patient's anatomy. They are intended for surgical interventions in orthopaedic procedures for total knee arthroplasty.

The device is an instrument set containing a femur and tibia template(s).

INDICATIONS FOR USE

Pin Placement Guides

The device is intended to be used as a surgical instrument to assist in the intra-operative positioning of total knee replacement components and in guiding the marking of bone before cutting.

The device must be used in conjunction with the compatible prostheses families only: 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, AGC™ Complete Knee system, Zimmer NexGen® CR-Flex, Zimmer NexGen® LPS-Flex, Zimmer NexGen® CR, Zimmer NexGen® LPS, Zimmer Gender Solutions® Natural-Knee® Flex, Zimmer Persona® CR, Zimmer Persona® PS.

The device is single use only.

Cut-Through Guides

The device is intended to be used as a surgical instrument to assist in the intra-operative positioning of total knee replacement components and in guiding the marking of bone before cutting and cutting of the bone.

The device must be used in conjunction with the compatible prostheses families only: 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.

The device is single use only.

MATERIALS

Polyamide

CONTRAINDICATIONS

- Do not use in the case of active infection of the knee joint area.
- The anatomic landmarks necessary for alignment and positioning of the implant must be identifiable on the preoperative scan (MRI or CT).

WARNINGS

- If the device is unable to be used for any reason, the surgeon should be prepared to use conventional instrumentation to perform the procedure.
- The user should be aware of possible allergic reactions to materials used in the guide or model. The patient should be informed on this matter by the user.
- The user should consult the instructions for use and surgical technique of respective implant system and their compatible components for the indications, warnings, precautions, adverse effects and contra-indications.
- These are patient-specific, single use, disposable guides and models.
- Do not attempt to reuse or recondition the guides or models.
- Do not alter the guides or models from their original shape. Debris from the alteration could contaminate the operating region. In addition, altering the size of the guide may lead to an improper fit on the patient's anatomy.
- The device is to be used by a trained physician in the performance of knee replacement surgery.
- It is advised to use the device within 6 months of performing the pre-operative scans (MRI or CT) on which the device is based. If the patient's anatomy has changed significantly since the time of acquisition, the device should not be used, even if the time period of 6 months has not expired.
- The device is provided non-sterile and must be sterilized prior to use.
- The device should be properly cleaned before sterilization.
- Do not use if the device is broken, cracked or when loose powder is present.
- Store the device in a properly cleaned and dry place.
- All trial, packaging and instrument components must be removed prior to closing the surgical site, do not implant.

PRECAUTIONS

- Care should be taken to minimize excessive heat buildup due to friction between the Zimmer Biomet Patient Specific Instruments and other instrumentation, such as drills and/or sawblades. Excessive heat buildup can lead to deformation of the polyamide Zimmer Biomet Patient Specific Instruments.
- Do not place heavy objects on top of the device.
- Device identification must be legible.
- Consult device specific report to identify the planned prostheses to be used.
- Do not use the guides after accidental dropping.

DEVICE IDENTIFIERS

A device identifier is indicated on each guide and model. The device identifier is to be checked for readability and confirmed by the surgeon prior to use in surgery. Confirmation must be done using the device report included in the device package.

POSSIBLE ADVERSE EFFECTS

Infection following the surgical procedure. Introduction of foreign materials can result in an inflammatory response or allergic reaction.

PATENT NOTICE

This product is covered by the following patents: EP2775943, US8,984,731, US9,066,727, US9,579,112, AU2012271895, EP2701615, US8,979,856, US9,339,281

CLEANING AND STERILIZATION

MANUAL CLEANING

1. Rinse the guides and bone models under cold running tap water to remove gross soil. Use a soft bristled brush to remove soil from the surface of the guides and bone models. Use a syringe to flush cylinders and slots.
2. Immerse the guides and bone models in a detergent and allow them to soak for a minimum of 25 minutes. The detergent should be of neutral or alkaline pH (pH 7-11 like ELMA TEC CLEAN N1 detergent).
3. Use a soft bristled brush to remove soil from the surface of the guides and bone models. Use a syringe to flush cylinders and slots.
4. Remove the guides and models from the detergent and rinse them in running RO/DI water.
5. Dry the guides and models using a clean, soft lint-free cloth and filtered pressurized air.

AUTOMATED CLEANING

1. Pre-rinse the guides and bone models under running tap water to remove gross soil.
2. Pre-wash the the guides and bone models under running tap water. Use a soft bristled brush to remove soil from the surface of the guides and bone models. Use a syringe and/or long, narrow soft-bristled brush to flush cylinders and slots.
3. Wash the guides and models using an automatic washer unit. It is recommended to use a detergent (like Enzol) as recommended by the manufacturer of the automatic washer unit.
4. Dry the guides and bone models with hot filtered pressurized air and/or wipe with a soft lint-free cloth.

The instructions 1-4 are summarized in the following table :

Phase	Time (Minutes)
Pre-rinse	≥ 1 minute 30-80°C (86-176°F) Running tap water, clean with tools
Pre-Wash	2 minutes 30-80°C (86-176°F)
Wash	4 to 10 minutes 60-80°C (140-176°F)
Pure water Rinse	≥ 2 minutes 40-80°C (104-176°F)
Drying	Dry using hot filtered air dry > 90°C (194°F) or wipe with soft lint-free cloth

RECOMMENDED STERILIZATION SPECIFICATIONS

The Zimmer Biomet Patient Specific Instruments can be sterilized twice prior to use. Prior to use, sterilize the device using **pre-vacuum steam sterilization**. A single device should be packaged in a medical grade sterilization pouch or wrap which conforms to the recommended specifications for steam sterilization provided in the table below. Only legally marketed, FDA cleared and validated sterilization pouch or wrap should be used by the end-user for packaging the devices during sterilization. Ensure that the pouch is large enough to contain the devices without stressing the seals or tearing the pouch. Use one of the following standard steam sterilization settings:

Type	Temperature	Exposure Time	Dry Time
UK,NL Pre-vacuum Cycle[1,2]	134°C (273°F)	3 minutes	≥ 30 minutes
USA Pre-vacuum Cycle[1,2]	132°C (270°F)	4 minutes	
World Health Organization Prevacuum Cycle[2,3]	134°C (273°F)	18 minutes	

[1]Validated steam sterilization temperature required to achieve a 10^{-6} sterility assurance level (SAL).
[2]In the case local or national specifications for steam sterilization requirements are stricter or more conservative than those listed in this table, please contact Materialise before sterilizing and using the guides.
[3]Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.

[1] The Zimmer Biomet Patient Specific Instruments constitute the Signature and Zimmer PSI brand families

ADDITIONAL INFORMATION

For any additional information, please contact customer service at Materialise :

Phone: 1-800-348-2759 & 574-371-3710

Email: personalizedsolutions@zimmerbiomet.com

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