



Zimmer, Inc.
1800 West Center Street
Warsaw, IN 46580 USA
1-800-348-2759 (USA)
+1-574-372-4999



Materialise
innovators you can count on

Materialise, NV
Technologielaan 15
3001 Leuven
Belgium

EN

Materialise NV (manufacturer) states that the custom-made medical device with the product specifications and the product identification as mentioned in this document are in accordance to the essential requirements of Annex I of the Medical Device Directive 93/42/EEC.

Though all necessary precautions were taken to ensure that an accurate and good device was made, Materialise NV does not take any medical responsibility. The delivered device should always be examined before use.

Important Information for the Operating Surgeon **ZIMMER® PATIENT SPECIFIC INSTRUMENTS**

DESCRIPTION OF ZIMMER PATIENT SPECIFIC INSTRUMENTS

Zimmer Patient Specific Instruments (Zimmer PSI) are designed to be used to implant the following selected Zimmer knee prostheses:

- ***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***
- ***Zimmer Persona™ Trabecular Metal™***
- ***Zimmer Unicompartmental High Flex Knee System***

The *Zimmer PSI* must only be used in conjunction with the implants listed above. Consult the prosthesis labeling and instructions for use for specific patient indications, contraindications, associated risks, information for use, warnings and precautions. *Zimmer Patient Specific Instruments* is an instrument set containing a femur and/or tibia template(s).

INDICATIONS FOR USE

Total Knee Replacement

The ***Zimmer Patient Specific Instruments 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 ***Zimmer Patient Specific Instruments System*** is to be used with *Zimmer NexGen CR-Flex* fixed bearing, *Zimmer NexGen CR* fixed bearing, *Zimmer NexGen LPS-Flex* fixed bearing, *Zimmer NexGen LPS* fixed bearing, *Zimmer Gender Solutions Natural – Knee Flex* fixed bearing, *Zimmer Persona CR* fixed bearing, *Zimmer Persona PS* fixed bearing and *Zimmer Persona Trabecular Metal* prostheses families only.

Unicompartmental Knee Replacement

The ***Zimmer Patient Specific Instruments System*** is intended to be used as a surgical instrument to assist in the positioning of Unicompartmental Knee Replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting of the bone provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The ***Zimmer Patient Specific Instruments System*** is to be used with *Zimmer Unicompartmental High Flex Knee System* prostheses families only.

The ***Zimmer Patient Specific Instruments*** are intended for single use only.

MATERIALS

Polyamide

CONTRAINDICATIONS

Do not use in the case of active infection of the knee joint area.

WARNINGS

- *Zimmer PSI* are patient specific, single use, disposable devices.
- Do not attempt to reuse or recondition.
- Do not alter *Zimmer PSI* in any way.
- *Zimmer PSI* are to be used by a trained physician in the performance of knee replacement surgery.

- It is advised to use *Zimmer PSI* within 6 months of performing the CT scans on which they are based. If the patient's anatomy has changed significantly since the time of the CT-scan, the device should not be used, even if the time period of 6 months has not expired.
- *Zimmer PSI* should be properly cleaned before sterilization. Do not use if the *Zimmer PSI* are broken, cracked, or when loose powder is present.
- *Zimmer PSI* in this package are provided non-sterile.
- *Zimmer PSI* in this package must be sterilized prior to use.

PRECAUTIONS

- Care should be taken to minimize excessive heat buildup due to friction between the *Zimmer PSI* and other instrumentation, such as drills. Excessive heat buildup can lead to deformation of the polyamide *Zimmer PSI*.
- Do not place heavy instruments on top of the *Zimmer PSI*.
- Markings on *Zimmer PSI* used for indicating anatomical dimensions and case information must be legible. These include lines indicating anatomical directions, identifiers with case information such as implant size, patient and surgeon information. Notify your Zimmer representative if the markings are not legible or if the identifiers do not correspond to the intended patient or surgeon.
- Consult the *Zimmer PSI* labeling in order to determine the correct Zimmer knee prostheses that are to be used.

ZIMMER PSI IDENTIFIERS

Identifier indicated on femur template:

- Patient's first initial and first 4 letters of last name (e.g. **JSMIT**).
- Patient's month and year of birth, left or right knee, and femur implant size (e.g. **0209LG**).
- Surgeon's first and last name initials (e.g. **DB**).

Identifier indicated on tibia template:

- Patient's first initial and first 4 letters of last name (e.g. **JSMIT**).
- Patient's month and year of birth, left or right knee, and tibia implant size (e.g. **0209L2**).
- Surgeon's first and last name initials (e.g. **DB**).
- To assure a unique identifier for each patient the last letter of the patient's last name in the identifier will be replaced by a digit (0 ... 9) in case patients with identical patient information are created (e.g. **JSM11**).

POSSIBLE ADVERSE EFFECTS

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

CLEANING

Whenever possible, an automatic washer unit (according to ISO 15883) and ultrasonic cleaning equipment should be used to clean the *Zimmer PSI*. If an automatic washer unit is not available, manual cleaning can be used.

Manual cleaning

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

Automated cleaning

1. Rinse the *Zimmer PSI* under running tap water to remove gross soil. Use a soft bristled brush to remove soil from the surface of the *Zimmer PSI*. Use a syringe and/or long, narrow soft-bristled brush to flush cylinders and slots.
2. When available, clean the *Zimmer PSI* ultrasonically at the temperature and with a specially formulated detergent recommended by the manufacturer of the ultrasonic cleaning equipment. The detergent should be of neutral or near neutral pH (pH 7-11). Follow the manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners and medical equipment. After ultrasonic cleaning, rinse the *Zimmer PSI* using RO or DI water. Use a syringe to flush cylinders and slots.
3. Wash the *Zimmer PSI* using an automatic washer unit. It is recommended to use a detergent as recommended by the manufacturer of the automatic washer unit.

Pre-rinse	Pre-Wash (1-4)	Enzyme Wash	Wash 1	Rinse 1 (1-4)	Thermal Rinse	Pure water Rinse	Drying
1 minute minimum 30°C - 80°C Running tap water, clean with tools	2 minutes 30°C - 80°C	None	4 to 10 minutes @ 60-80°C The detergent should be of neutral or near neutral pH (pH 7-11).	None	None	2 minute minimum @ 40-80°C	hot filtered air dry (>90°C) or wipe with soft lint-free cloth

4. Dry the *Zimmer* PSI using a clean, soft lint-free cloth and/or filtered pressurized air.

RECOMMENDED STERILIZATION SPECIFICATIONS

Zimmer PSI **can be sterilized twice prior to use**. The devices are intended for single use only and should only be used once. Sterilize the device using **steam sterilization** before use. Single devices 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. 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:

Steam Sterilization

Type	Temperature	Exposure Time	Minimum Dry Time
UK Pre-vacuum/Pulsating Vacuum ¹	134°C (273°F)	3 minutes	30 minutes
Pre-vacuum/Pulsating Vacuum	132°C (270°F)	4 minutes	
Pre-vacuum/Pulsating Vacuum ^{1,2}	134°C (273°F)	18 minutes	

¹ This cycle is not for use in the United States.

² This cycle has not been validated for prion inactivation in the US.

ADDITIONAL INFORMATION

For any additional information, please contact your *Zimmer* representative and/or the *Zimmer* customer service.

This is version 6 of the document and has been issued in May 2016.

Note: NexGen, Gender Solutions, Natural-Knee, Persona, Trabecular Metal, *Zimmer* and the *Zimmer* logo are trademarks of *Zimmer*, Inc.

Materialise and the Materialise logo are trademarks of Materialise NV