Zimmer® PSI Knee System
For Use with the NexGen® Complete Knee System
Surgical Technique
Zimmer PSI Knee Surgical Technique

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**Introduction**

**Overview**

The Zimmer® Patient Specific Knee System consists of: disposable patient specific tibial and femoral instrument guides (also called PSI jigs), optional bone models, and an optional Tibial Rotational Guide (to set the axial rotation of the tibial component), per the available kits listed in the section titled “Zimmer PSI Knee Disposable Kits”. A copy of the approved pre-operative surgical planning is also provided in the Zimmer PSI Knee packaging to be referenced by the surgeon intra-operatively. The bone models are a reconstruction of the patient’s knee joint tibial and femur bones from the medical imaging data, aiding the surgeon in verifying the Zimmer PSI Jigs’ placement intra-operatively, they are required to hold a place in the sterile field prior and during the surgery.

The customized PSI instrument guides are to be used with the given NexGen® implant families as described in the following section, “Indication for Use”. The Zimmer PSI Knee instrument guides are placed on the distal femur and proximal tibia intra-operatively, and have pin holes to allow the surgeon to precisely insert reference pins, in accordance with the pre-operative surgical plan, that set the position of the cut guides.

The PSI Knee Reusable instruments, provided by Zimmer CAS, are listed in the section titled “Reusable Zimmer PSI Knee Instruments”. All other reusable instruments that are part of the applicable standard instrumentation sets, described in the “Intra-Operative Guide” section, are listed with a NexGen or Posterior Referencing Instruments (PRI) identifier.

The scope of this document is to provide information on the surgical technique, cleaning/sterilization methods, as well as the available Zimmer PSI Knee kits. The pre-operative guide and instructions for use of the Zimmer PSI Knee Planner application are provided in the Zimmer PSI Knee Planner Software User Guide 97-5970-035-00.

**Indication for use**

The Zimmer PSI Knee System is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of provided patient radiological images with identifiable placement anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan.

The Zimmer PSI Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona® CR and Persona PS.

The patient specific guide components are intended for single-use only.

**Contraindications**

The Zimmer PSI Knee system should not be used in any of the following situations: in cases with active infections of the knee joint, in cases with Hip-Knee-Ankle (HKA) alignment deformities larger than 15° varus or valgus, in cases where femoral anterior cut first surgical techniques will be used, in cases where 3° Option Fluted or A/P Wedge Stemmed Tibial plates are used, in cases of knee replacement revision surgery, or in cases which are contraindicated for the implant as given by Zimmer.

**Complications**

Possible complications associated with the use of the system may include, but are not limited to: infection, complication due to misplacement of the implants that may potentially lead to dislocation, leg misalignment or knee ligament imbalance. The occurrence of one of these complications may affect the patient’s mobility.
Precautions

The following are general precautions and warnings related to the use of Zimmer PSI instrument guides:

- **Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician**

- Zimmer strongly recommends formal Zimmer PSI Knee System training prior to use of the system. Contact your local Zimmer representative or the Zimmer Institute (1-855-ZSurgeon or 1-855-978-7436) for more information.

- The Zimmer PSI Knee System should not be used to perform surgical procedures other than those specified in this surgical technique.

- The Zimmer PSI Knee System should be used in conjunction with a femur first technique

- The Disposable Zimmer PSI Knee Instruments, including instrument guides and bone models are patient specific and single use and should be discarded after surgery.

- The Disposable Zimmer PSI Knee Instruments and Reusable Zimmer PSI Knee Instruments are provided non-sterile and must be cleaned and sterilized before use per instructions provided in this surgical technique (in the section “Cleaning/Sterilization Methods and Equipment Inventory”). These instructions are also provided with the components, refer to Zimmer PSI Jigs & Bone Models Package Insert (20-8014-043-00).

- The Disposable Zimmer PSI Knee Instruments have a limited shelf life of 6 months after the manufacturing date, as indicated on the package label. Given the potential for patient morphological changes, the surgeon will need to reassess the patient to identify any potential changes prior to surgery. In case of any doubt the Zimmer PSI Knee guides and bone models must not be used.

- The Disposable Zimmer PSI Knee Instruments are to be used with the given implant system per the related pre-operative planning. The implant must be used in accordance with its respective package labeling. The user should refer to the surgical technique published by the implant manufacturer.

- The Disposable Zimmer PSI Knee Instruments can withstand two autoclave sterilizations. Re-sterilization is only permissible when they have not been in contact with the patient or otherwise contaminated.

- The Disposable Zimmer PSI Knee Instruments are designed to fit the patient anatomy as it was at the moment when the patient radiological images were acquired. If the anatomy or condition of the articular surface has changed since the radiological images were acquired, the patient specific instrument should not be used.

- If you experience difficulties with the Zimmer PSI Knee Jigs during surgery, stop using the Jigs and revert to the standard (non-PSI) surgical technique.

**Warning:** Ensure that the delivered Disposable Zimmer PSI Knee Instruments correspond to the intended patient. A copy of the approved surgical plan is provided in the Zimmer PSI Knee packaging. Only use the Disposable Zimmer PSI Knee Instruments if the PSI Case ID marking are both legible on the Zimmer PSI Knee instrument guides and bone models and match the PSI Case ID specific to the intended patient. If the two PSI Case ID markings do not match, DO NOT USE the Disposable Zimmer PSI Knee Instruments on the patient and notify your Zimmer representative.
The PSI Case ID can be either 8 or 15 characters, automatically assigned based on region. The nomenclature in the following table is based off of a fictitious patient with a First Initial: S, the First Two Letters of the Last Name: AM, and Operating Side: Left (L). The Marking on the Guides and Bone Models will be the whole case ID if it’s 8 characters and the first seven digits if it is 15 characters (Fig. 1).

### PSI Case ID with 8 Characters

<table>
<thead>
<tr>
<th>S</th>
<th>AM</th>
<th>1234</th>
<th>L</th>
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<td>First letter of patient first name</td>
<td>First 2 letters of patient last name</td>
<td>Unique number assigned by Zimmer</td>
<td>Operated side (Left/Right)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</table>

### PSI Case ID with 15 Characters

<table>
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<th>L</th>
<th>77</th>
<th>DD</th>
<th>13</th>
<th>US</th>
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</thead>
<tbody>
<tr>
<td>First letter of patient first name</td>
<td>First 2 letters of patient last name</td>
<td>Unique number assigned by Zimmer</td>
<td>Operated side (Left/Right)</td>
<td>Year of patient birthday</td>
<td>Surgeon initial</td>
<td>Year when the case created</td>
<td>Region where the case ID created</td>
</tr>
</tbody>
</table>

**Fig. 1**

PSI Case Identifier

**Warning:** If the Case ID markings do not match the patient, do not use the PSI Knee Instrument Guides and Bone Models on the patient. Notify your Zimmer representative immediately.
Intra-Operative Guide

The Zimmer PSI Knee Instrument Guides, (Jigs), are designed for use with conventional incision as well as the MIS Sub-Vastus, the MIS Mid-Vastus, and the MIS Medial-Parapatellar approaches for the placement of given NexGen implant families defined in the “Indication for Use” section. These surgical approaches are described in the following Zimmer Surgical Techniques:

- **Zimmer MIS Multi-Reference® 4-in-1 Femoral Instrumentation Surgical Technique** (97-5967-002-00)
- **Zimmer NexGen Cr-Flex and LPS-Flex Knees Surgical Technique with Posterior Referencing Instrumentation (PRI)** (97-5905-002-00)
Femur Exposure

- Expose the femur and tibia according to the applicable surgical technique listed under “Intra-Operative Guide”.
- Look at the mating surfaces of the femoral PSI jig on the femoral bone model or on the surgical plan (Fig. 2).
- Remove soft tissues on the bone that could prevent good contact with the PSI jigs, such as the meniscus and fat tissue.
- Do not remove any osteophytes or cartilage from the femur.

Note: If the bone model differs significantly from the actual anatomy in those regions, it is indicated not to use the femoral PSI jig.
Position the Femoral PSI Jig

- Position the PSI jig on the distal femur by first locking on the anterior ridge of the femur and then applying pressure distally to secure the fit. Avoid rotating the jig towards the posterior condyles, as this would cause excessive flexion (Fig. 3).
- Use the visual cues on the jig indicating the mechanical axis entry point, Whiteside’s Line, and the transepicondylar axis to help position the PSI jig and decide if proper alignment is achieved.

Note: If the PSI jig does not have the appropriate snug fit, if there is any doubt on the jig position, or if the marking on the PSI jig does not match the anatomic landmarks, be sure that no soft tissue interferes between the PSI jig and the bone. The positioning of the PSI jig can be double checked on the optional bone model. If the above conditions remain, do not insert pins or drill holes and revert to standard surgical technique. At this point, intramedullary instrumentation should be used.
Pin the Distal Cutting Guide Pin Holes

- Hold the PSI jig in position by hand, and pin the medial and lateral distal cutting guide pin holes on the PSI jig using the standard instrument accessory 3.2mm x 75mm PRI Trocar Tipped Drill Pins (2.5 hex) (00-5901-020-00) with the Legacy® Instrumentation, or the 3.2 Headless Trocar Drill Pin (20-8000-00-16) with the PRI system (Fig. 4). Both pins can be inserted using the Pin/Screw Inserter (00-5901-021-00). Assure accurate placement of the two pins before proceeding.

![Fig. 4](image-url)
Drill 4-in-1 Cutting Guide Pin Holes

- Using the 3.2mm drill bit, available through Zimmer Standard Instrumentation, drill the medial and lateral 4-in-1 pin holes of the PSI jig deep enough to ensure that after the distal cut, the holes are still visible (Fig. 5).

Note: If the drill contacts a trocar pin, DO NOT drill further and remove the pin.

Fig. 5
Resect Distal Femur

- Remove the Femoral PSI jig by sliding it off the pins, leaving the distal cutting guide pins in place (Fig. 6).
- In case the Femoral PSI jig gets locked over the bone during its retrieval, it is recommended to disengage one pin at a time to ease the removal of the PSI jig. If the pins are removed in the process, re-insert them in the pin holes after having removed the jig.

- Secure the NexGen MIS Distal Cut Guide (00-5967-036-00) or the NexGen PRI 0° Captured/Uncaptured Cutting Head (00-5901-064-00), in the holes marked '0' (Fig. 7).

- Check alignment, if desired, and make the cut (Fig. 8).

Instruments

PRI 0° Captured/Uncaptured Cutting Head
00-5901-064-00
Place Anterior Cutting Guide Pins

- Remove the medial and lateral distal 3.2mm x 75mm Trocar Tipped Drill Pins with the PRI Multi Pin Puller (00-5901-022-00).
- For MIS instrumentation: insert two headless pins in the medial and lateral drilled pin holes and move on to the next step (Fig. 9).
- For PRI instrumentation: move on to the next step.
Place 4-in-1 Femoral Finishing Guide

For MIS instrumentation

- Select the applicably sized MIS 4-in-1 Femoral Finishing Guide (silver) or the Flex Femoral Finishing Guide (gold), which coordinates to the surgical plan, both are available from the implant system instrumentation. Place it over the two distal pins, (pins for 4-in-1 guide) (Fig 10).

- Per the standard technique, adjust the M/L positioning for appropriate placement. Secure the Finishing Guide and remove the pins. Verify resections using the Resection Guide (00-5977-084-00), commonly known as the 'angel wing', and make the cuts (Fig. 11). Refer to the Zimmer MIS Multi-Reference 4-in-1 Femoral Instrumentation Surgical Technique for complete instructions (97-5967-002-00).

For the PRI instrumentation

- Attach the PRI Quick Connect Handle (00-5901-034-00) to the appropriate PRI 4-in-1 Flex Femoral Cut Guide (00-5901-043/048-00), in the size per the pre-operation planning. Both are available through standard implant system instrumentation.

- Place the PRI 4-in-1 cut guide on the femur by aligning the 2 pins on the back of the guide with the previously drilled positioning holes (Fig. 12).

- Impact the handle until the guide is flush with the femur. For more stability, secure the 4-in-1 guide with additional 3.2mm pins.

- Refer to the Standard Surgical Technique for PRI for more complete instructions and the next steps (97-5905-008-010).
Position Tibial PSI Jig

- Look at the mating surfaces of the Tibial PSI jig on the tibia bone model or on the pre-operative planning (Fig. 13).
- Remove soft tissues on the bone that could prevent good contact with the PSI jig, such as the meniscus and fatty tissue.
- Do not remove osteophytes or cartilage from the tibia.

- To position the Tibial PSI jig, first ensure good medial contact between the jig and the bone, confirming that the medial side of the jig is properly wrapped around the bone. Then, press the two arms perpendicular on the plateau and then jig as a whole to maintain proper placement and full contact with the bone. Avoid rotating the jig by pressing too strongly anteriorly (Fig. 14).

Note: If the representation of the bone on the planning record or the optional Bone Models significantly differs from the actual anatomy in those regions, it is indicated not to use the Tibial PSI jig.

Note: If the PSI jig does not mate appropriately, or if there is any doubt on the baseplate position or the marking on the PSI jig of the medial third of the tubercle does not match the anatomic landmarks, make sure that no soft tissue interferes between the PSI jig and the bone. The position of the PSI jig can also be double checked on the optional Bone Model. If the above conditions persist, DO NOT insert pins or drill holes and revert to standard surgical technique. Remove the PSI jig from the assembly and set the baseplate orientation and rotation on the tibial cut as per standard surgical technique.
Verify Tibial PSI Jig Alignment

- Insert the PRI Tibia Drop Rod Adaptor (20-8014-014-00) on the PSI jig to help position it correctly. Make sure the drop rod is flush with the PSI jig and is inserted on the proper side by using the left or right laser marking (Fig. 15).

- The Drop Rod Adaptor slot lines up with two landmarks, the PCL insertion point and the medial 1/3 of the tibial tubercle (Fig 16).

- Insert Alignment Rod (00-5785-080-00) through PRI Drop Rod Adaptor to verify alignment of the PSI Guide (Fig. 17). Alignment rod should point towards the center of the malleoli.
Pin Tibia Cut Guide Pin Holes

- Hold the PSI jig in position and pin the medial and lateral tibia cut guide pin holes of the PSI jig using standard instrument accessory 3.2mm x 75mm PRI Trocar Tipped Drill Pins (2.5 hex) (00-5901-020-00) together with the NexGen PRI Pin/Screw Inserter (00-5901-021-00) (Fig. 18).

Note: Avoid applying excessive force on the anterior part of the PSI Tibia jig to prevent adding anterior slope.

Note: The PSI drop rod adaptor is designed to stay in place while pinning the PSI Tibia jig.
Remove Tibial PSI Jig

- Remove the PSI Tibial jig gently by hand to avoid pulling the pins out. Verify that both pins are still placed in the drilled holes (Fig. 19).
- In case the PSI Tibial jig gets locked over the bone during its retrieval, it is recommended to disengage the medial pin first, either by hand if able or with a pin puller. If the jig is still locked, remove the lateral pin. If pins have been removed, re-insert them in the holes after having removed the jig.

Note: Avoid pulling too hard on the jig, as this can damage the drilled pin hole, possibly causing misalignment.
Resect Proximal Tibia

- Align the proper sized Tibial Cut Guide in place on the bone in the holes marked ‘0’, while the pins are still in place (Fig. 20).

- Insert a 3.2 mm Trocar Tipped Drill Pin in the oblique holed to further secure the Captured Cut Guide. (Fig. 21).

- Verify the alignment of the Captured Cut Guide by inserting the PRI Alignment Adapter (00-5901-086-00) (Fig. 22).

- Use a 1.27 mm (.050-inch) oscillating saw blade through the slot on the Captured Cut Guide to resect proximal surface of the tibia (Fig. 23).

Note: The PRI Tibial Cut Guides (00-5901-075-00 and 00-5901-076-00) are used in both NexGen Legacy Standard and PRI instrumentation, is available as part as the implant system instrumentation.
Optional: Install PSI Tibia Rotational Guide on NexGen Sizing Plate Handles

- When using the NexGen Offset Sizing Plate Handle (00-5953-096-00), attach the proper NexGen Tibial Sizing Plate, as per the pre-operative planning, then insert the PSI Tibia Rotational Guide on the Sizing Plate Handle by sliding the open side of the PSI on the handle (Fig. 24).

- Push the PSI Rotational Guide until it clips on the tibial baseplate (Fig. 25).

- When using the NexGen Locking Tibial Tray Provisional Handle (00-5977-096-00), insert the PSI Tibia Rotational Guide on the Sizing Plate Handle by sliding the handle on the open side of the PSI Tibia Rotational Guide. The medial third of the tibial tubercle marking can be used to confirm the correct orientation (Fig. 26).
• Attach the proper NexGen Tibial Sizing Plate, as defined in the preoperative planning. Then, push the PSI Rotational Guide until it clips on the tibial baseplate (Fig. 27).

• Figure 28 shows compatibility between the different tibial implant brand and the two types of handles.

<table>
<thead>
<tr>
<th>Implant Brand</th>
<th>Handle</th>
</tr>
</thead>
<tbody>
<tr>
<td>7° Option Fluted</td>
<td>Straight</td>
</tr>
<tr>
<td>CR Porous Pegged</td>
<td>Straight</td>
</tr>
<tr>
<td>CR Precoat Pegged</td>
<td>Straight</td>
</tr>
<tr>
<td>MIS Modular Precoat Stemmed</td>
<td>Offset</td>
</tr>
<tr>
<td>MIS Precoat Stemmed</td>
<td>Offset</td>
</tr>
<tr>
<td>CR All Poly</td>
<td>Offset</td>
</tr>
<tr>
<td>LPS All Poly</td>
<td>Offset</td>
</tr>
<tr>
<td>Porous Stemmed</td>
<td>Offset</td>
</tr>
<tr>
<td>Precoat Stemmed</td>
<td>Offset</td>
</tr>
<tr>
<td>Option Stemmed</td>
<td>Offset</td>
</tr>
<tr>
<td>TM CR Monoblock</td>
<td>Straight</td>
</tr>
<tr>
<td>TM LPS Monoblock</td>
<td>Straight</td>
</tr>
<tr>
<td>TM Modular</td>
<td>Offset</td>
</tr>
</tbody>
</table>
Set Tibial Rotation

- Slide the PSI Tibial Rotational Guide with the Sizing Plate Handle, as described in the previous step, on the tibial cut guide pins.
- Mate the PSI Rotational Guide on the anterior surface of the tibia to assess the planned rotation and bone cut coverage.
- Use the NexGen 25mm Short-Head Holding Pin (00-5977-056-03) to secure the NexGen tibial baseplate with the PRI Multi Pin Puller (00-5901-022-00) (Fig. 29).

Note: If the PSI jig does not mate appropriately, or if there is any doubt on the baseplate position or the marking on the PSI jig of the medial third of the tubercle does not match the anatomic landmarks, make sure that no soft tissue interferes between the PSI jig and the bone. If the above conditions persist, DO NOT insert pins or drill holes and revert to standard surgical technique. Remove the PSI jig from the assembly and set the baseplate orientation and rotation on the tibial cut as per standard surgical technique.
Verify Overall Alignment

- Insert the drop rod, available through Zimmer standard instrumentation, in either the NexGen Offset Sizing Plate handle (00-5953-096-00) or the NexGen Locking Tibial Tray Provisional Handle (00-5977-096-00) to verify the overall alignment of the leg (Fig. 30).

- When the alignment has been verified, remove the PSI Rotational Guide by pushing on its clipping mechanism and pulling back the PSI Rotational Guide. Remove the handle as per the standard surgical technique.
## Supported Zimmer NexGen Systems

<table>
<thead>
<tr>
<th>Femur</th>
<th>Tibia</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR Option</td>
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<tr>
<td>CR Precoat</td>
<td>CR Precoat Pegged</td>
</tr>
<tr>
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<td>MIS Modular Precoat Stemmed</td>
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<tr>
<td>LPS-Flex Gender Porous</td>
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</table>

- CR Option: C, D, E, F, G
- CR Porous: A, B, C, D, E, F, G, H
- CR Precoat: A, B, C, D, E, F, G, H
- CR-Flex Option: B, C, D, E, F, G, C, D, E, F, G-
- CR-Flex Porous: B, C, D, E, F, G, C, D, E, F, G-
- CR-Flex Precoat: B, C, D, E, F, G, C, D, E, F, G-
- CR-Flex Gender Porous: C, D, E, F, G, C, D, E, F, G-
- CR-Flex Gender Precoat: C, D, E, F, G, C, D, E, F, G-
- LPS Option: A, B, C, D, E, F, G, H
- LPS Precoat: B, C, D, E, F, G
- LPS Porous: B, C, D, E, F, G
- LPS-Flex Option: C, D, E, F, G
- LPS-Flex Porous: A, B, C, D, E, F, G
- LPS-Flex Precoat: A, B, C, D, E, F, G
- LPS-Flex Tivanium: C, D, E, F, G
- LPS-Flex Gender: C, D, E, F, G
- LPS-Flex Gender Porous: C, D, E, F, G

- Fluted 7° Option Stem: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
- CR Porous Pegged: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
- CR Precoat Pegged: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
- MIS Modular Precoat Stemmed: 2, 3, 4, 5, 6, 7, 8
- MIS Precoat Stemmed: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
- Option Stemmed: 3, 4, 5, 6, 7, 8
- Porous Stemmed: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
- Precoat Stemmed: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
- CR TM Monoblock: 3, 4, 5, 6, 7, 8
- LPS TM Monoblock: 3, 4, 5, 6, 7, 8
- TM Modular: 2, 3, 4, 5, 6, 7, 8
- CR All - Poly: 3, 4, 5, 6, 7, 8
- LPS All -Poly: 3, 4, 5, 6, 7, 8
Cleaning/Sterilization Methods And Equipment Inventory

- Disposable Zimmer PSI Knee Instruments are provided non-sterile and are single use. They must be cleaned and sterilized by the end user before the surgery. The Reusable Zimmer PSI Knee Instruments must be cleaned after use and prior to sterilization.
- The instruments should not be sterilized in the protective bag or packaging supplied with them. All sterilizations should be performed using standard and regularly maintained equipment.
- In the case a surgery is re-scheduled or in the case of another issue requiring the Disposable Zimmer PSI Knee Instruments to be re-cleaned and re-sterilized, the Disposable Zimmer PSI Knee Instruments can only be re-cleaned and re-sterilized once for a given patient, if they have not been otherwise contaminated. This is to avoid patient infection and contamination. Validated cleaning methods have not been established for such re-use conditions. Cleaning and Sterilization methods are described below.

Warning: Before every surgery, the user must verify that all jigs (including bone models) and instruments have been cleaned and sterilized.

Cleaning
For cleaning, both the single use Zimmer PSI Knee Jigs (including bone models) and the reusable instruments require manual cleaning steps as follows (additional component-specific cleaning instructions are provided in the next subsections):

1. Pre-soak components in an enzyme solution.
2. Scrub components with a soft bristle brush to remove all visible soil.
3. Use a water jet to flush difficult access areas and closely mated surfaces (see areas labeled “A” in the images in the following tables: “Reusable Zimmer PSI Knee Instruments” and “Disposable Zimmer PSI Knee Instruments”).
4. Ultrasound clean (Sonification) all components in an enzyme solution with a minimum cycle time of 5 minutes.
5. Thoroughly rinse and dry all components.
**Sterilization Parameters**

- All components (disposable and reusable) require steam sterilization before use per the following methods (Fig. 31).

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Temperature¹</th>
<th>Exposure Time²</th>
<th>Minimum Dry Time²</th>
<th>Minimum Cool Time³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum</td>
<td>132°C (270°F)</td>
<td>4 minutes</td>
<td>30 minutes</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

¹ Both the given cycle temperature and time can be increased to 134°C + 3°C (273.2°F + 5.4°F) and 18 minutes according to local requirements outside of the United States such as in the European Union.

² Drying times vary according to load size and should be increased for larger loads

³ Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used.

Cooling process should comply with ANSI/AAMI ST79.

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**Reusable Zimmer PSI Knee Instruments and Additional Specific Cleaning Instructions**

- The table below shows the reusable instruments for *NexGen Zimmer* PSI Jigs Kit. Additional specific cleaning instructions as applicable to each instrument are provided (Fig. 32):

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Instrument</th>
<th>Qty</th>
<th>Sterilization and specific cleaning instructions</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-8014-014-00</td>
<td>PRI Drop Rod Adaptor</td>
<td>1</td>
<td>Autoclave</td>
<td>Re-usable, Provided non-sterile</td>
</tr>
</tbody>
</table>

Note: The *Zimmer PSI NexGen Legacy* jigs Kit must be used together with the Tibia PRI Cut guide (left/right) (00-5901-075/076-00).
Zimmer PSI Knee Disposable Kits

- The table below shows the available Disposable Zimmer PSI Knee Instruments. Additional specific cleaning instructions, as applicable, for each component are provided (Fig. 33):

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Instrument</th>
<th>Qty</th>
<th>Sterilization and specific cleaning instructions</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-8070-003-01</td>
<td><strong>Left</strong> Zimmer PSI Knee NexGen Legacy Jigs</td>
<td>1</td>
<td>Autoclave</td>
<td>Single use, Provided non-sterile</td>
</tr>
<tr>
<td></td>
<td><strong>Left</strong> Zimmer PSI Knee NexGen Legacy Jigs</td>
<td></td>
<td>Additional specific cleaning requirements: Use a water jet to flush difficult access areas (see areas labeled “A”)</td>
<td></td>
</tr>
<tr>
<td>20-8070-003-02</td>
<td><strong>Right</strong> Zimmer PSI Knee NexGen Legacy Jigs</td>
<td>2</td>
<td>Autoclave</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Right</strong> Zimmer PSI Knee NexGen Legacy Jigs</td>
<td></td>
<td>Additional specific cleaning requirements: Use a water jet to flush difficult access areas (see areas labeled “A”)</td>
<td></td>
</tr>
<tr>
<td>20-8070-004-01</td>
<td><strong>Left</strong> Zimmer PSI Knee NexGen Legacy Jigs &amp; Tibia Rotation</td>
<td>1</td>
<td>Autoclave</td>
<td>Single use, Provided non-sterile</td>
</tr>
<tr>
<td></td>
<td><strong>Left</strong> Zimmer PSI Knee NexGen Legacy Jigs &amp; Tibia Rotation</td>
<td></td>
<td>Additional specific cleaning requirements: Use a water jet to flush difficult access areas (see areas labeled “A”)</td>
<td></td>
</tr>
<tr>
<td>20-8070-004-02</td>
<td><strong>Right</strong> Zimmer PSI Knee NexGen Legacy Jigs &amp; Tibia Rotation</td>
<td>1</td>
<td>Autoclave</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Right</strong> Zimmer PSI Knee NexGen Legacy Jigs &amp; Tibia Rotation</td>
<td></td>
<td>Additional specific cleaning requirements: Use a water jet to flush difficult access areas (see areas labeled “A”)</td>
<td></td>
</tr>
</tbody>
</table>

---

**Fig. 33**
<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Instrument</th>
<th>Qty</th>
<th>Sterilization and specific cleaning instructions</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-8070-005-01</td>
<td>Zimmer PSI Knee NexGen Legacy Jigs &amp; Offset Tibia Rotation</td>
<td>1</td>
<td>Autoclave  Additional specific cleaning requirements: Use a water jet to flush difficult access areas (see areas labeled “A”)</td>
<td>Single use, Provided non-sterile</td>
</tr>
<tr>
<td>20-8070-005-02</td>
<td>Right</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-8070-006-01</td>
<td>Zimmer PSI Knee NexGen PRI jigs</td>
<td>1</td>
<td>Autoclave  Additional specific cleaning requirements: Use a water jet to flush difficult access areas (see areas labeled “A”)</td>
<td>Single use, Provided non-sterile</td>
</tr>
<tr>
<td>20-8070-006-02</td>
<td>Right</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catalog No.</td>
<td>Instrument</td>
<td>Qty</td>
<td>Sterilization and specific cleaning instructions</td>
<td>Additional Notes</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------------------------------------</td>
<td>-----</td>
<td>----------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------</td>
</tr>
</tbody>
</table>
| 20-8070-007-01   | Left *Zimmer PSI Knee NexGen PRI Jigs & Tibia Rotation* | 1   | Autoclave  
  Additional specific cleaning requirements: Use a water jet to flush difficult access areas (see areas labeled “A”) | Single use, Provided non-sterile      |
| 20-8070-007-02   | Right                                           |     |                                                                                                              |                                       |
| 20-8070-008-01   | Left *Zimmer PSI NexGen PRI Jigs Kit* (including Offset Tibia Rotational Guide) | 1   | Autoclave  
  Additional specific cleaning requirements: Use a water jet to flush difficult access areas (see areas labeled “A”) | Single use, Provided non-sterile      |
| 20-8070-008-02   | Right                                           |     |                                                                                                              |                                       |

*Fig. 33 (continued)*
<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Instrument</th>
<th>Qty</th>
<th>Sterilization and specific cleaning instructions</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-8070-009-00</td>
<td><em>Zimmer PSI Knee Bone Models</em></td>
<td>1</td>
<td>Autoclave</td>
<td>Single use, Provided non-sterile</td>
</tr>
<tr>
<td>00-5901-020-00*</td>
<td>Headless Trocar Drill Pin, 75mm</td>
<td>2</td>
<td>See package insert for re-sterilization instruction if permissible.</td>
<td>Single use, Provided sterile</td>
</tr>
<tr>
<td>20-8000-000-16</td>
<td>3.2mm Headless Trocar Drill Pin</td>
<td>2</td>
<td>Autoclave</td>
<td>Single use, Provided non-sterile</td>
</tr>
</tbody>
</table>

*The Headless trocar pin (00-5901-020-00) is manufactured by Zimmer (not Zimmer CAS). It should be ordered directly from Zimmer.*

**Warning:** Do not use pins or any other fasteners than those recommended above.

**Fig. 33 (continued)**
Reusable Instruments Ordering

- In order to perform a PSI case, some key reusable instruments have to be part of the kit. For a NexGen case, there are two lines of instruments available:
  - PRI Instrumentation
  - Legacy® Instrumentation (see restriction below)
- The system does not support the NexGen tibial cut guides (00-5997-075-00 and 00-5997-076-00) from the standard Zimmer NexGen instrument set. For cases where NexGen Legacy is to be used, it is important to ensure the NexGen PRI Tibia Cut Guide is provided to use with the PSI Tibial Jig. It is important to read the key remarks of Figure 34.
- A list of instruments that are required for each type of implant is listed in Figure 34, only one of these instruments is required per case for all types of implants. The Zimmer division responsible of supplying the instrument is written in the last row.
- To order a Zimmer instrument, please place your order through DCS.

<table>
<thead>
<tr>
<th>Implant/Instruments</th>
<th>20-8014-014-00 PRI Drop Rod Adaptor</th>
<th>20-8014-015-00 Persona Drop Rod Adaptor</th>
<th>00-5901-021-00 Trocar Screw Pin Driver</th>
<th>00-5901-075-00 PRI 0° Left Cut Guide -or- 00-5901-076-00 PRI 0° Right Cut Guide</th>
<th>00-5901-086-00 PRI alignment adapter*</th>
<th>Key Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>NexGen Legacy</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Do not use NexGen Tibial cut guide</td>
</tr>
<tr>
<td></td>
<td><strong>NexGen Posterior Referencing Tibial Cut Guide shall be used</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NexGen PRI</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Supplier</td>
<td>Zimmer, Warsaw</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*In a NexGen Legacy instrumentation case, the surgeon might want to put the cut guide on the tibia and then verify alignment. Since only the NexGen PRI tibial cutter is used with NexGen Legacy instrumentation, the alignment adapter might be ordered.
Zimmer Contact Information

General Information
Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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Fax: 1 (514) 878-3801
Web site: www.zimmer.com
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Tel: 1 (866) 336-7846

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Please refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.

Contact your Zimmer representative or visit us at www.zimmer.com

The CE mark is valid only if it is also printed on the product label.