



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								
EXAMPLE: SAM1234L				Printed on guides and bone models: SAM1234L				
	S	AM	1234	L	-	-	-	-
	First letter of patient first name	First 2 letters of patient last name	Unique number assigned by Zimmer	Operated side (Left/Right)	-	-	-	-

PSI Case ID with 15 Characters								
EXAMPLE: SAM123L77DD13US				Printed on guides and bone models: SAM123L				
	S	AM	123	L	77	DD	13	US
	First letter of patient first name	First 2 letters of patient last name	Unique number assigned by Zimmer	Operated side (Left/Right)	Year of patient birthday	Surgeon initial	Year when the case created	Region where the case ID created

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.

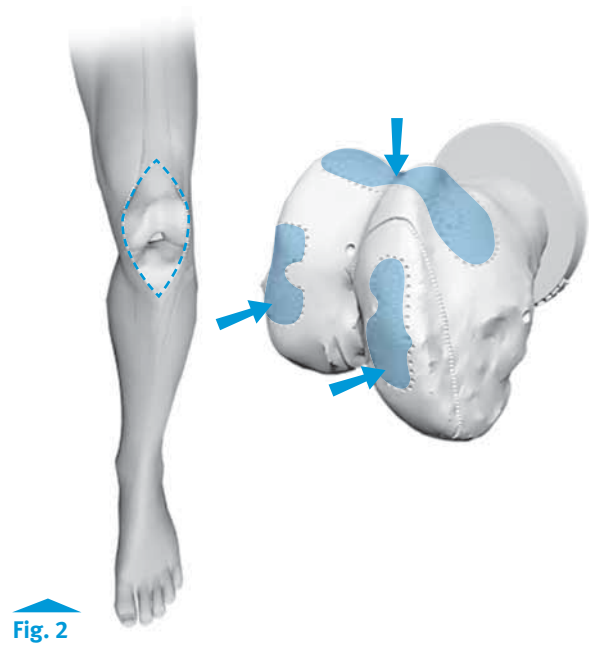


Fig. 2

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.

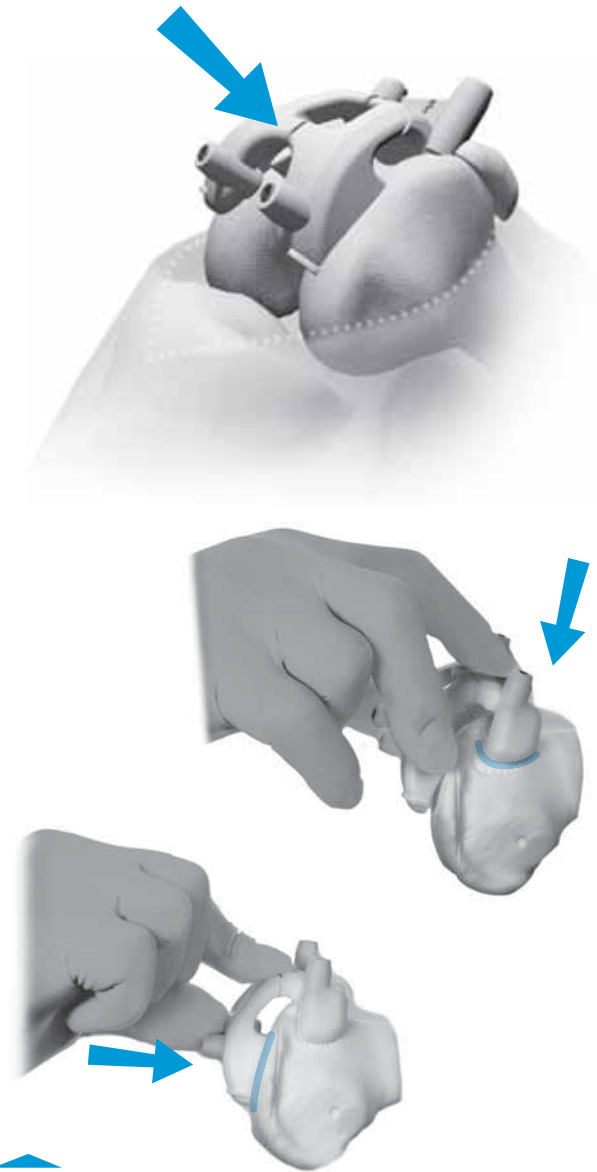


Fig. 3

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

Instruments



3.2 x 75mm
Trocar Tipped
Drill Pin (2.5 hex)
00-5901-020-00

- OR -



3.2 x 75mm
Headless Trocar
Drill Pin
20-8000-000-16



Pin/Screw
Inserter
00-5901-021-00

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.

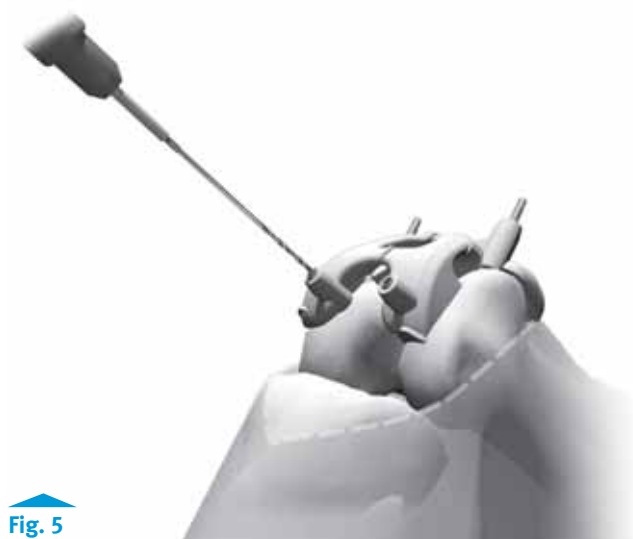


Fig. 5

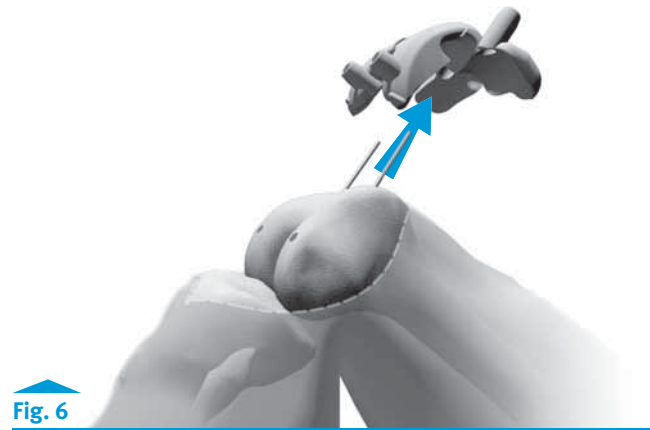
Instruments



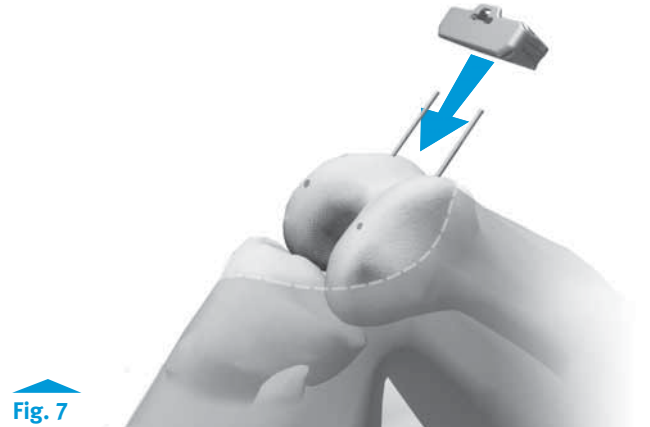
3.2mm Drill
00-5120-085-00

Resect Distal Femur

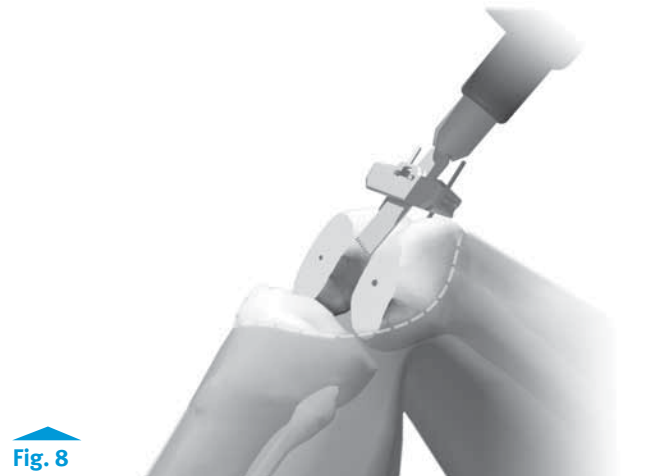
- Remove the Femoral PSI jig by sliding it off the pins, leaving the distal cutting guide pins in place (Fig. 6).
- In case the Femoral PSI jig gets locked over the bone during its retrieval, it is recommended to disengage one pin at a time to ease the removal of the PSI jig. If the pins are removed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



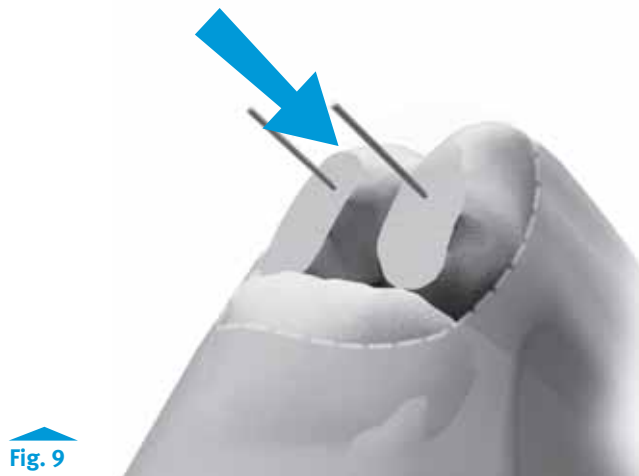
Instruments



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.



Instruments



Multi Pin Puller
00-5901-022-00

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).



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).

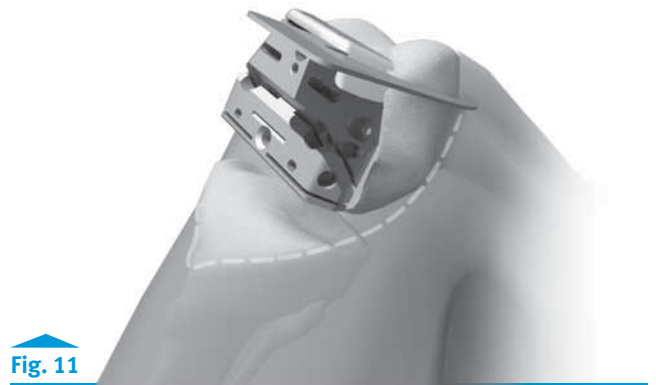


Fig. 11

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).



Fig. 12

Instruments



Quick Connect
Handle
00-5901-034-00



MIS 4-in-1 Femoral
Finishing Guide
00-5983-033/037-00



MIS 4-in-1 Flex
Femoral Finishing
Guide
00-5983-
043/047-00



PRI 4-in-1 Flex
Femoral Cut
Guide
00-5901-
043/048-00

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.

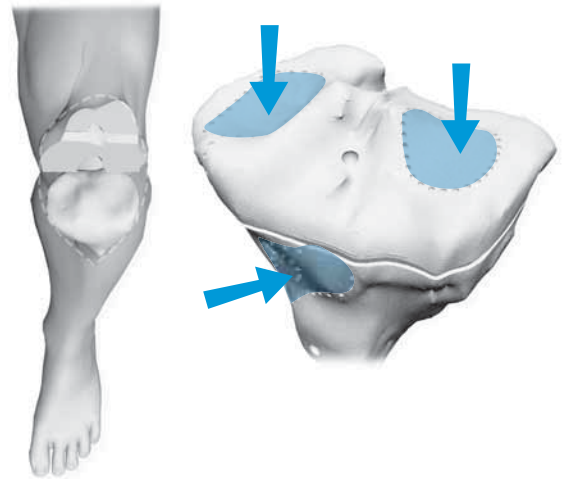


Fig. 13

- 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.

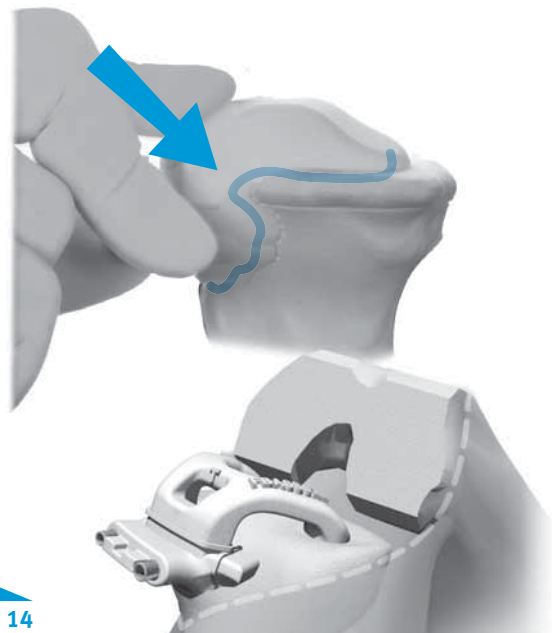


Fig. 14

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).

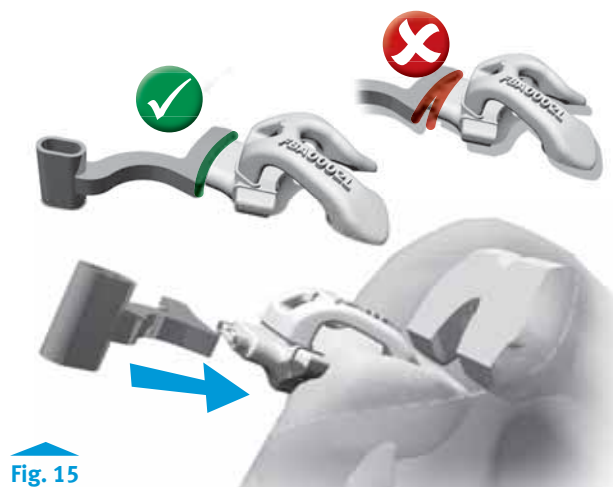
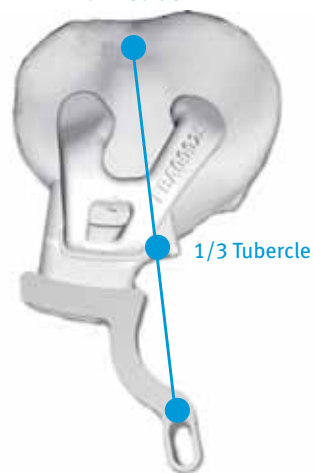


Fig. 15

- 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).

PCL Insertion

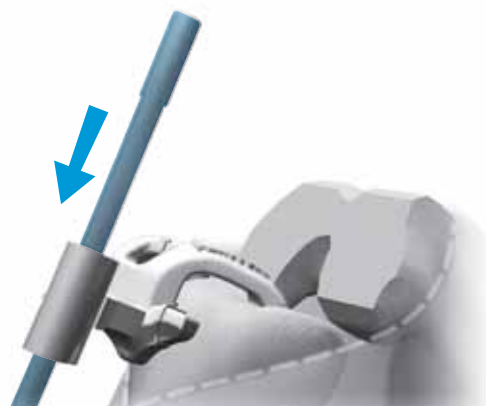


1/3 Tubercle

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.

Fig. 17



Instruments



PSI PRI Tibia Drop
Rod Adaptor
20-8014-014-00

Alignment Rod
00-5785-080-00

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.



Instruments



3.2 x 75mm
Trocar Tipped
Drill Pin (2.5 hex)
00-5901-020-00



Pin/Screw
Inserter
00-5901-021-00

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.

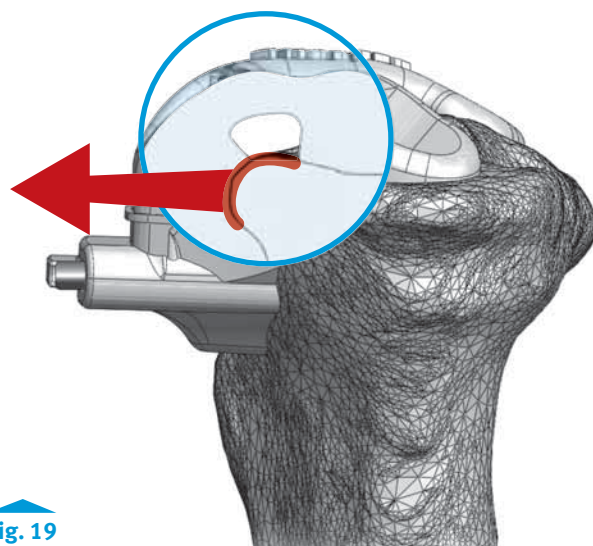


Fig. 19

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 hole to further secure the Captured Cut Guide. (Fig. 21).



- Verify the alignment of the Captured Cut Guide by inserting the PRI Alignment Adaptor (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.



Instruments



Alignment
Adaptor
00-5901-086-00



Tibial Cut Guide,
0°, Left
00-5901-075-00



Tibial Cut Guide,
0°, Right
00-5901-076-00

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).



Fig. 24

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



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).



Fig. 26

Instruments



NexGen Locking
Tibial Tray
Provisional Handle
00-5977-096-00



NexGen Offset
Sizing Plate Handle
00-5953-096-00

- 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**).

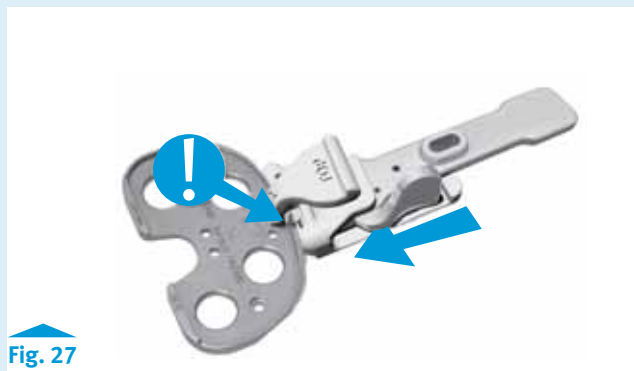


Fig. 27

- **Figure 28** shows compatibility between the different tibial implant brand and the two types of handles

Implant/Sizing Plate Handle compatibility

Implant Brand	Handle
7° Option Fluted	Straight
CR Porous Pegged	Straight
CR Precoat Pegged	Straight
MIS Modular Precoat Stemmed	Offset
MIS Precoat Stemmed	Offset
CR All Poly	Offset
LPS All Poly	Offset
Porous Stemmed	Offset
Precoat Stemmed	Offset
Option Stemmed	Offset
TM CR Monoblock	Straight
TM LPS Monoblock	Straight
TM Modular	Offset

Fig. 28

Instruments



NexGen Locking
Tibial Tray
Provisional Handle
00-5977-096-00



NexGen Offset
Sizing Plate Handle
00-5953-096-00

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.

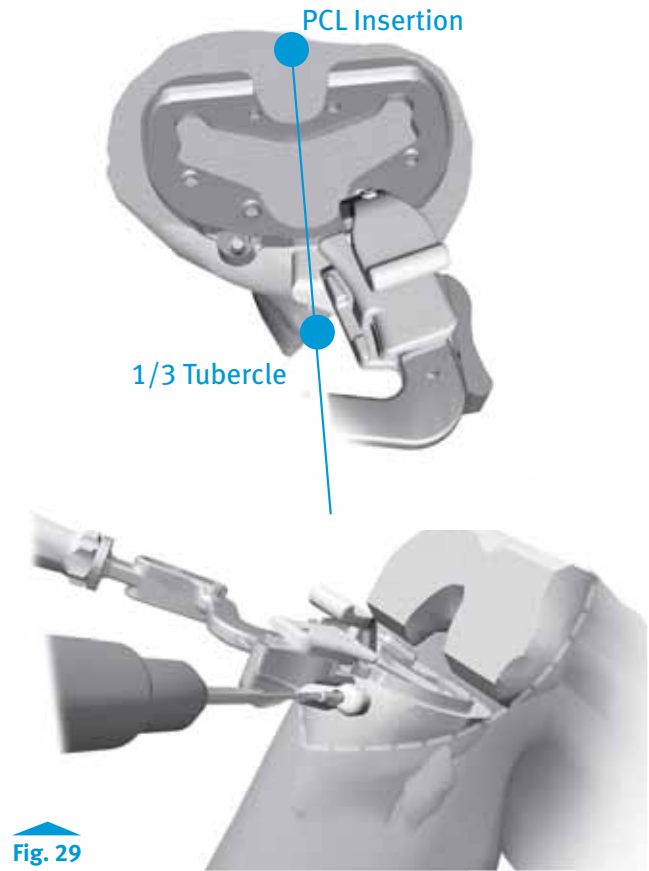


Fig. 29

Instruments



25mm Shorthead
Holding Pin[™]
00-5977-056-03



Multi Pin Puller
00-5901-022-00

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.



Fig. 30

Instruments



NexGen Locking
Tibial Tray
Provisional Handle
00-5977-096-00



NexGen Offset
Sizing Plate Handle
00-5953-096-00



PSI PRI Tibia
Rod Adaptor
20-8014-014-00

Supported Zimmer NexGen Systems

	Femur
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 Titanium	C, D, E, F, G
LPS-Flex Gender	C, D, E, F, G
LPS-Flex Gender Porous	C, D, E, F, G

	Tibia
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).

Steam Sterilization (Autoclave)

Cycle Type	Temperature ¹	Exposure Time ¹	Minimum Dry Time ²	Minimum Cool Time ³
Pre-Vacuum	132°C (270°F)	4 minutes	30 minutes	30 minutes

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.

Fig. 31

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):

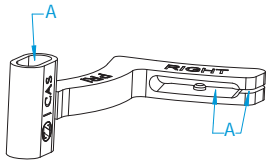
Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8014-014-00	PRI Drop Rod Adaptor 	1	Autoclave Additional specific cleaning requirements : Use a water jet to flush difficult access areas (see areas labeled "A")	Re-usable, Provided non-sterile

Fig. 32

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**):

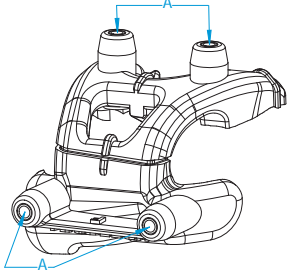

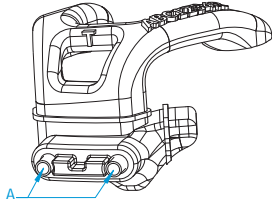
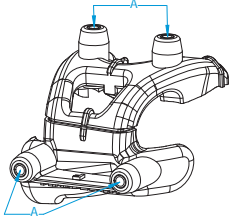

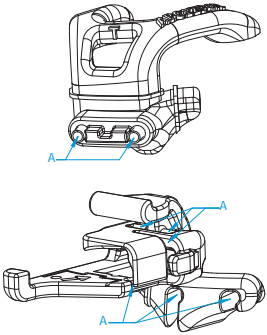
Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8070-003-01 Left	<i>Zimmer PSI Knee NexGen Legacy</i> Jigs 	1	Autoclave Additional specific cleaning requirements : Use a water jet to flush difficult access areas (see areas labeled "A")	Single use, Provided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

Fig. 33

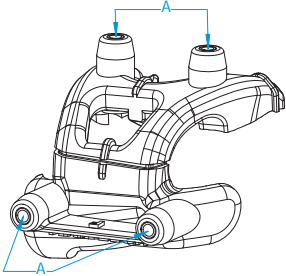

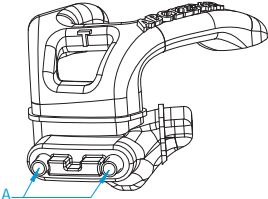
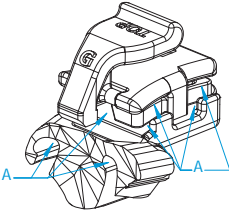
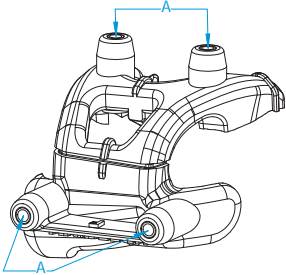

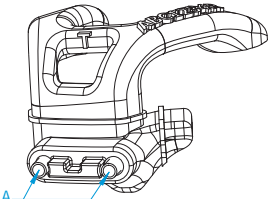
Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8070-005-01 Left	<p>Zimmer PSI Knee NexGen Legacy Jigs & Offset Tibia Rotation</p> 	1	<p>Autoclave</p> <p>Additional specific cleaning requirements : Use a water jet to flush difficult access areas (see areas labeled "A")</p>	<p>Single use, Provided non-sterile</p> 
20-8070-005-02 Right	 	1		
20-8070-006-01 Left	<p>Zimmer PSI Knee NexGen PRI Jigs</p> 	1	<p>Autoclave</p> <p>Additional specific cleaning requirements : Use a water jet to flush difficult access areas (see areas labeled "A")</p>	<p>Single use, Provided non-sterile</p> 
20-8070-006-02 Right		1		

Fig. 33 (continued)

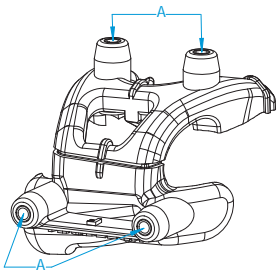

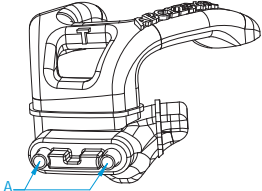
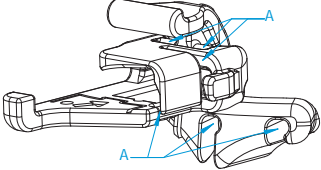
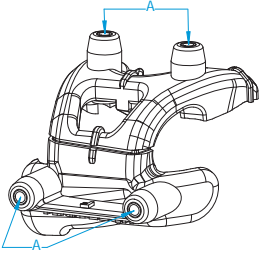

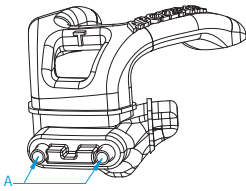
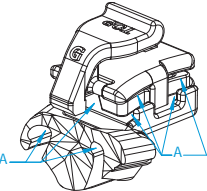



Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8070-007-01 Left	<i>Zimmer PSI Knee NexGen</i> PRI Jigs & Tibia Rotation 	1	Autoclave Additional specific cleaning requirements : Use a water jet to flush difficult access areas (see areas labeled "A")	Single use, Provided non-sterile 
20-8070-007-02 Right	 			
20-8070-008-01 Left	<i>Zimmer PSI NexGen PRI Jigs Kit</i> (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)

Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8070-009-00	Zimmer PSI Knee Bone Models	1	Autoclave	Single use, Provided non-sterile 
Standard Instrumentation Pins:				
00-5901-020-00*	Headless Trocar Drill Pin, 75mm	2	See package insert for re-sterilization instruction if permissible.	Single use, Provided sterile 
- or -				
20-8000-000-16	3.2mm Headless Trocar Drill Pin	2	Autoclave	Single use, Provided non-sterile 

*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.



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

Fig. 34

* 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.

Manufacturer

Zimmer CAS

75, Queen Street, Suite 3300
Montreal (Quebec) H3C 2N6
CANADA

Tel: 1 (514) 395-8883

Fax: 1 (514) 878-3801

Web site: www.zimmer.com

Email: ZimmerPSI@zimmercas.com

Customer Support

Tel: 1 (866) 336-7846

European Community (EC) Representative

Zimmer U.K. Ltd.

9 Lancaster Place
South Marston Park
Swindon, SN3 4FP, UK



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