

ORTHOsoft[®] Knee 2.3 Universal

For Persona[®] Knee Implants and Vanguard[®] Complete
Knee System

User Manual Addendum



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Persona and Vanguard Implant Geometry

1.1 Persona Implant Geometry

Persona Knee Implants can now be navigated.

Four implant lines which cover all Persona Knee Implant sizes have been integrated into the Implant selector of the Surgeon Profile:

- Persona CR Anterior Referencing
- Persona CR Posterior Referencing
- Persona PS Anterior Referencing
- Persona PS Posterior Referencing

The user needs to make an appropriate selection according to the implant type (CR or PS) and the reference technique (anterior or posterior) being used.

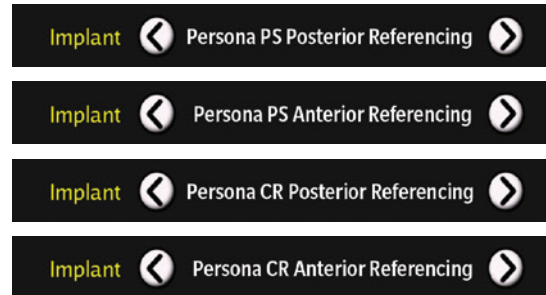


Figure 1
The Persona Implants in the Implant selector of the Surgeon Profile

1.2 Vanguard Implant Geometry

The Vanguard Knee System* features two knee implant options so that surgeons may select an implant specifically suited to each patient's unique needs :

- Cruciate retaining (CR) knee, which has three bearing options :
 - CR – Three degree posterior slope
 - CR Lipped – enhanced posterior lip
 - Anterior Stabilized – ultracongruent deep dish design
- Posterior stabilized (PS) knee which has two bearing options:
 - PS – substitutes for PCL – no constraint
 - PS+ - rotational and varus/valgus constraint

*Vanguard XP® Knee not supported

Warning: Make sure to select the appropriate implant line as values and implant representation displayed by the system are dependent on the selection made. Implant geometries are different for each implant line.



Figure 2
The Vanguard Implant in the Implant selector of the Surgeon Profile

Persona and Vanguard Drill Guides

2.1 Persona Drill Guides

Four drill guides are provided to support different workflows as configured through the Surgeon Profile parameters.

There are two drill guides, one for anterior referencing (P/N 20-8000-010-65) and one for posterior referencing (P/N 20-8000-010-67), that are compatible with the validation tool.

Note: The CAS Short Posterior Condyles Digitizer (P/N 20-8000-010-09) cannot be used with the anterior referencing drill guide.

There are two drill guides, one for anterior referencing (P/N 20-8000-010-61) and one for posterior referencing (P/N 20-8000-010-63), that are compatible with the ORTHOsoft Tensor if the user wants to perform gap balancing using the tensor.

2.2 Vanguard Drill Guides

Two drill guides are provided to support different workflows as configured through the Surgeon Profile parameters.

There is one Vanguard Drill Guide (M/N 108.095 P/N 20-8000-080-10), for posterior referencing, that is compatible with Validation Tool.

There is one Vanguard A/P Drill Guide (M/N 108.096 P/N 20-8000-080-11) for posterior referencing, that is compatible with ORTHOsoft Tensor.

Warning: Make sure to use the appropriate drill guide according to the referencing technique used.

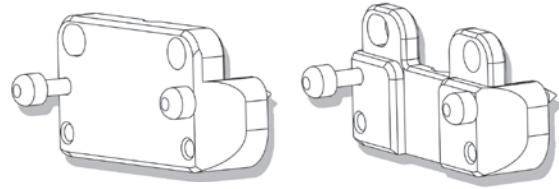


Figure 3
Persona Drill Guides compatible with the validation tool

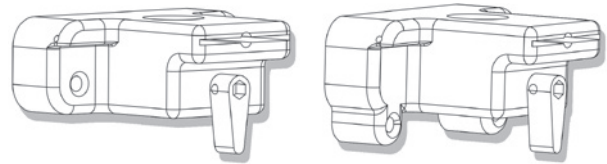


Figure 4
Persona Drill Guides compatible with the ORTHOsoft Tensor

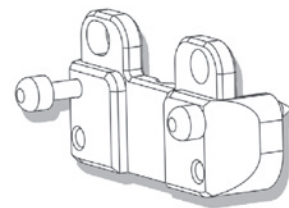


Figure 5
Vanguard Drill Guide compatible with the validation tool

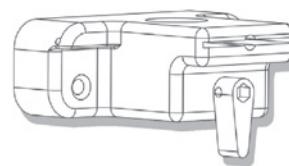


Figure 6
Vanguard A/P Drill Guide compatible with the ORTHOsoft Tensor

Cleaning and Sterilization

Reusable instruments must be cleaned after use prior to sterilization. They should not be sterilized in the protective bag or packaging supplied with them. All sterilizations should be performed using standard and regularly maintained equipment.

For cleaning, reusable instruments require manual cleaning steps as follows. All multi-component instruments must be disassembled. Every instrument must be pre-soaked for 10 minutes in an enzyme solution followed by scrubbing with a soft bristle brush to remove all visible soil. Use a water jet to flush difficult to access areas and closely mated surfaces. For threaded interfaces, screw/unscrew components while flushing the areas. Ultrasound cleaning (Sonication) in an enzyme solution is recommended thereafter in all cases to complete the cleaning steps, with minimum cycle times of 5 minutes and, for those instruments with difficult to access areas, cycle times of at least 10 minutes.

Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

Screws and other mechanisms should be checked and lubricated as required with a medical grade surgical lubricant. The above instructions that are instrument type dependent are indicated in Table 3.1 as applicable to each instrument.

The methodology, "Combination Cleaning and Disinfection Instructions", described in the Reprocessing Manual, available at <http://www.zimmerbiomet.com>, is also applicable.

Warning: The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/ disinfector. A washer/ disinfector with approved efficacy (e.g. CE mark, FDA approval, and validation according to ISO 15883) should be used.

Typical US Automated Washer/Disinfector Cycle for Surgical Instruments

Step Description

1	2 minutes prewash with cold tap water
2	20 seconds enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 seconds cold tap water rinse (x2)
5	2 minutes detergent wash with hot tap water (64-66°C/146-150°F)
6	15 seconds hot tap water rinse
7	2 minutes thermal rinse (80-93°C/170-200°F)
8	10 seconds purified water rinse with optional lubricant (64-66°C/146-150°F)
9	7 to 30 minutes hot air drying (116°C/240°F)

Typical European Automated Washer/Disinfector Cycle for Surgical Instruments

Step Description

1	5 minutes prewash with cold tap water
2	10 minutes alkaline cleaning agent wash at 55°C
3	2 minute rinse with neutralizer
4	1 minute rinse with cold tap water
5	Disinfection at 93°C with hot purified water until A0 3000 is reached (approx. 10 minutes)
6	40 minutes hot air drying at 110°C

3.1 Sterilization Parameters

The following parameters are given for reference. Refer to the package insert included in each instrument package for more details or updates.

Steam Sterilization (Autoclave)

Cycle type	Temperature	Time
Pre-Vacuum	132°C (270°F)	4 minutes

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 as in the European Union.

ⓘ Warning: Before every surgery the user must:

1. Verify that all instruments have been sterilized.
2. Verify that the instruments are in good condition to perform the operation. If any signs of fatigue or deterioration are noticed, do not use the Zimmer CAS Surgical Navigation System and contact the technical support.

ⓘ Warning: All instruments are delivered with a package insert, which indicates the applicable cleaning and sterilization specifications. The specifications given on the inserts take precedence over the ones included in this text.

Specific cleaning and sterilization requirements for the Persona A-Ref A/P Drill Guide (P/N 20-8000-010-61), the Persona P-Ref A/P Drill Guide (P/N 20-8000-010-63) and the Vanguard A/P Drill Guide (M/N 108.096 P/N 20-8000-080-11) are applied as follows :

- Requires water jet to flush difficult to access areas
- Screw/unscrew components while flushing the area
- Screw/mechanism should be checked and lubricated as required

Specific cleaning requirements for the Drill Guide Persona A-Ref (P/N 20-8000-010-65), the Drill Guide Persona P-Ref (P/N 20-8000-010-67) and the Vanguard Drill Guide (M/N 108.095 P/N 20-8000-080-10) are applied as follows :

- Requires water jet to flush difficult to access areas
- Requires a minimum 10 minutes ultrasonic cleaning cycle in an enzymatic solution

General Information

Caution

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

Warnings

The warnings included in this guide are intended for trained Navitrack® Navigation System users.

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