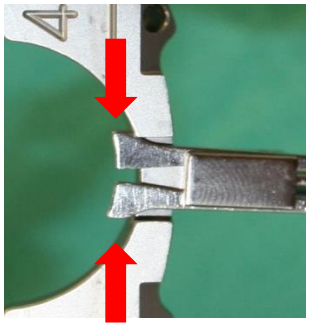
OrthoSensor, Inc.
1855 Griffin Road
Suite A-310
Dania Beach, FL 33004 USA
www.orthosensor.com

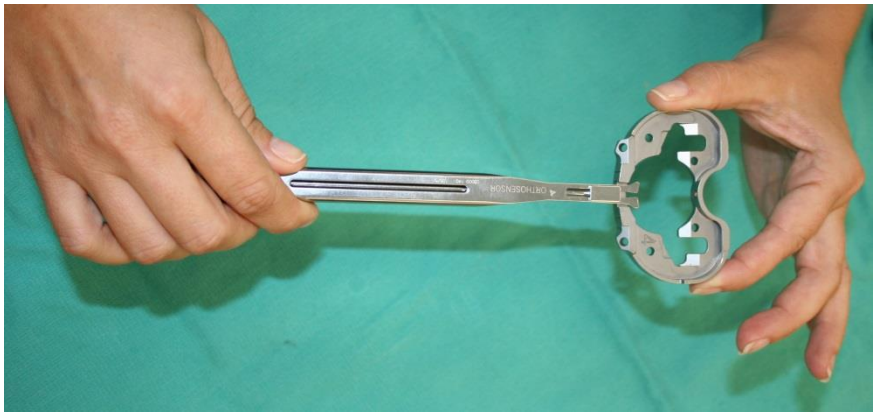
INSTRUCTIONS for VERASENSE HANDLE

The VERASENSE Handle is to be used with the Stryker Triathlon implant system.

1. Determine that the VERASENSE Handle is in good working condition. Rotate the knob and determine that the actuator moves freely.

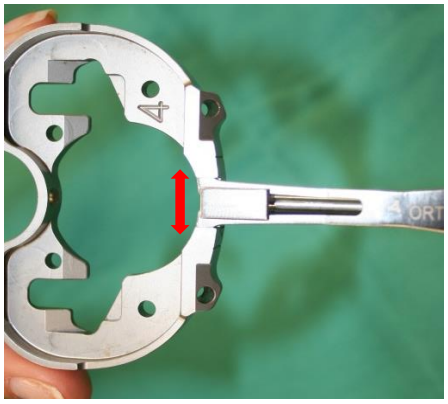


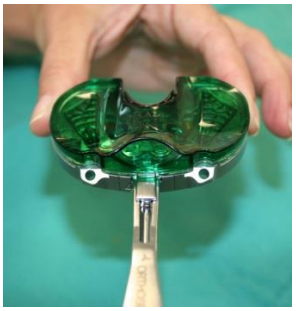
2. Rotate knob counter clockwise until the arms are disengaged.



3. Assemble the distal tip of the VERASENSE Handle into the anterior slot of the Stryker Tibial Tray.

4. Rotate knob clockwise to engage the arms to the tray. Follow Stryker TKA system procedure to insert the Trial Tibia Tray onto the patient. Rotate knob counter clockwise to disengage the handle from the tray.





For further information, contact the OrthoSensor Customer Service Center by phone at +1 954-577-7770
or by e-mail at customerservice@orthosensor.com or go to www.orthosensor.com

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Recommendations for Care and Handling

Description

VERASENSE Handle instrument is composed of stainless steel. This will allow sterilization of the contents to occur in a steam autoclave utilizing sterilization and drying cycle.

Materials

Stainless Steel

Disclaimer

Health care personnel bear the ultimate responsibility for ensuring that conditions essential to safe handling, decontamination, and sterility can be achieved, including conducting the proper testing in the health care facility. Any packaging method or material, including a reusable rigid container system, must be suitable for use in sterilization processing and sterility maintenance in a particular health care facility. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines on the immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, process performance, sterile storage, and aseptic use. OrthoSensor does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by OrthoSensor that should have been properly cleaned and/or sterilized by the end user prior to use.

Warnings and Precautions

- The VERASENSE Handle is NOT sterile and must be thoroughly cleaned and sterilized prior to use.
- The VERASENSE Handle is susceptible to damage for a variety of reasons including prolonged use, misuse, rough or improper handling. Care must be taken to avoid compromising its exacting performances. To minimize damage and risk of injury, the following should be done:
    - Inspect the VERASENSE Handle for damage upon receipt and after each use and cleaning. Incompletely cleaned VERASENSE Handles should be re-cleaned and those in need of repair should be replaced.
    - Only use the VERASENSE Handle for its intended purpose.

Cleaning and Decontamination

1. **Manual pre-cleaning**: The effectiveness of subsequent decontamination processes depends on prior removal of gross soil as it may be impaired by dried or coagulated protein. Gross soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. Care should be taken to avoid splashing and generating aerosols by holding the VERASENSE Handle below the surface of the water in a sink into which water is running and continuously draining. The VERASENSE Handle should not be held under a running tap, as this is likely to result in splashing. Operatives should wear protective equipment including gloves and goggles. Care should be taken to avoid penetrating or cutting injuries. Particular attention should be taken to remove all debris from all cannulations and obscure holes in the VERASENSE Handle.
2. **Disassembly:** Turn the driver nut clockwise until the inner rod of the VERASENSE Handle is disengaged.
3. **Automated cleaning:** The VERASENSE Handle, disassembled as described above, must be decontaminated using an automated washer disinfection unit with thermal disinfection. This should be done using an automated washer disinfector using the validated cleaning cycle shown below in Table 1.

Table 1

Phase	Recirculation Time (minutes)	Temperature	Detergent Type and Concentration
Pre-wash 1	2:00	Cold tap water	N/A
Enzyme Wash	4:00	Hot tap water	Enzol® enzymatic detergent 1 oz/gal
Wash 1	2:00	65.5°C	ValSure® Neutral detergent 1/4 oz/gal
Rinse 1	0:15	Hot tap water	N/A
Drying	6:00	98.8°C	N/A

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Preparation and Assembly

Once cleaning is complete, push the tip of the VERASENSE Handle towards the driver nut while turning the nut counter clockwise in order to re-assemble for future use.

Sterility

Table 2 below shows the recommended minimum steam cycle sterilization parameters that have been validated by OrthoSensor under laboratory conditions for weights up to 25lbs (11kgs). The VERASENSE Handle maybe be autoclaved using a full cycle and must be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI ST46 Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters described below.

Table 2	
Sterilizer Type	Pre-vacuum
Preconditioning Pulses	4
Minimum Temperature	132°C
Full Cycle Time	4 minutes
Minimum Dry Time	30 minutes
Test Article Configuration	Individually wrapped in two layers of 1-ply polypropylene wrap

Since OrthoSensor is not familiar with individual hospital handling procedures, cleaning methods, bio-burden levels, and other conditions, OrthoSensor assumes no responsibility for sterilization of product by a hospital even if the general above guidelines are followed.

Comments regarding OrthoSensor devices or instruments can be direct to Attn: Regulatory Dept. 1855 Griffin Rd. Suite A-310 Dania Beach, FL 33004 USA.

Storage and Shelf Life

A VERASENSE Handle that has been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of the wrapped VERASENSE Handle to prevent damage to the sterile barrier. The health care facility should establish a shelf life for the wrapped VERASENSE Handle based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time, with handling, and whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

Note: The VERASENSE Handle is a reusable instrument with no defined number of maximum uses. The best method to determine whether the instrument can still be used is to carefully inspect and function test the handle before each use.

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Table 3		
Symbols		
Prescription:	By Prescription Only	
Sterility:	Non-sterile	
Manufacturer:	 OrthoSensor, Inc. 1855 Griffin Road Suite A-310 Dania Beach, FL 33004-2200 USA	
Date of Manufacture:		
Caution:		
Documentation:	Consult instructions for use	
Identification::	Batch Code	
	Catalog number	
Authorized Representative in the European Community	Regulatory and Marketing Services-UK, LTD 28 Trinity Road, Nailsea, Somerset BS48 4NU United Kingdom	
Australia Sponsor	PharmaDev Consulting Pty Ltd. Level 12 95 Pitt Street Sydney NSW 2000 Australia	
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