OrthoSensor, Inc.
1855 Griffin Road
Suite A-310
Dania Beach, FL 33004-2200
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ORTHOSENSOR VERASENSE™ KNEE SYSTEM INSTRUCTIONS FOR USE

DESCRIPTION

The OrthoSensor™ VERASENSE™ Knee System provides a means to dynamically balance the knee during Total Knee Arthroplasty (TKA).

The VERASENSE Knee System device is an intelligent disposable tibial insert that measures dynamic loads in the medial and lateral compartments of the knee and angular positional information (IE; alignment, varus/valgus, posterior and anterior slope positioning) after insertion into the space between the tibia and the femur. It wirelessly transmits the measured load data to the OrthoSensor LinkStation for surgeon visualization. Individual VERASENSE™ devices are packaged sterile, for single patient use with a Shim Set for thickness adjustments.

The OrthoSensor LinkStation and VERASENSE Knee System Software Application are required for use of the VERASENSE Knee System device. The LinkStation contains a computer and all peripheral equipment required to display the measured load data by providing a graphical and numerical presentation of the loads in both the medial and lateral compartments of the knee.

VERASENSE Knee System devices are implant system specific due to variations in implant design. The following catalog numbers are specific for the Knee System Family:

- OrthoSensor™ VERASENSE™ Knee System for BIOMET® VANGUARD® Complete Knee System:
  - BMT-VGCR63, BMT-VGCR71, BMT-VGCR79, BMT-VGPS63, BMT-VGPS71, BMT-VGPS79
- OrthoSensor™ VERASENSE™ Knee System for Mako RESTORIS® PKA Implants
  - 170740
- OrthoSensor™ VERASENSE™ Knee System for STRYKER® TRIATHLON® Knee System
  - SYK-TRCR02, SYK-TRCR03, SYK-TRCR04, SYK-TRCR05, SYK-TRCR06, SYK-TRCR07, SYR-TRPS02, SYR-TRPS03, SYR-TRPS04, SYR-TRPS05, SYR-TRPS06, SYR-TRPS07
- OrthoSensor™ VERASENSE™ Knee System for Zimmer® NexGen® Knee Replacement System
  - ZMR-NGCRCH34, ZMR-NGCRCH56, ZMR-NGCRCH70, ZMR-NGPSCD34, ZMR-NGPSEF34, ZMR-NGPSEF56

INDICATIONS

The OrthoSensor VERASENSE Knee System device is a tool for the adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE Knee System device is sterile, for single patient use.

CONTRAINDICATIONS

- Any active or suspected latent infection in or about the knee joint.
- Refer to Knee System IFU for additional contraindications.

PRECAUTIONS

- Read and follow instructions for proper use and interpretation of force data displayed.
- Strict adherence to the indications, contraindications, precautions and user/patient safety for this product is essential.
- Refer to appropriate Knee System IFU for additional precautions.
- Data from the VERASENSE Knee System is for reference purposes only and should not be the sole basis for surgical decisions.
- VERASENSE Knee System device internal components are non-sterile. Immediately discontinue use of device if any cracks, damage, or internal fluid is observed. Failure to observe these warnings may expose patient to non-sterile material.
- The Verasense™ Knee System device consists of sophisticated calibrated internal microelectronics. Avoid direct impact with mallet or other instruments when possible.
- Handle VERASENSE™ Knee System device with care when inserting, adjusting shim size or removing from tibial tray.
- Do not forcibly impact femoral implant trial onto the VERASENSE Knee System device placed in tibial tray.
- Do not attempt to use the VERASENSE Knee System device without selection and use of proper shim and appropriate sized tibial tray.
- When detaching a Shim from the VERASENSE Knee System device, detach anterior lip first, do not pry off posterior edge.

USER/PATIENT SAFETY

- VERASENSE Knee System device and Shim Sets are supplied as single-use sterile. Do not reuse or re-sterilize.

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For further information, contact the OrthoSensor Customer Service Center by phone at 888-756-7846 or by e-mail at customerservice@orthosensor.com or go to www.orthosensor.com.

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- If VERASENSE Knee System device or Shim Set packaging is open or damaged, do not use and immediately return to OrthoSensor.
- Do not use VERASENSE Knee System device after the expiration date on the package labeling.
- Do not use the VERASENSE Knee System device in a tibial tray without a Shim attached.
- The measurement load range of the VERASENSE Knee System device is 5 to 40 pounds per condyle.
- Maximum allowable load for the VERASENSE Knee System device is 70 lbs per compartment.
- If the physician perceives a difference between the loads displayed on the screen and the physical feel, the physician should either replace the device or continue the procedure using their standard instrumented trial technique and best clinical judgment.
- Do not impact / hit the VERASENSE Knee System device or any objects in contact with the device as this may result in damage to its exterior casing.
- Do not use a prying device during surgical procedure while the VERASENSE Knee System device is in place as this may result in damage to the exterior of the device.
- The VERASENSE Knee System device contains non-sterile, non-medical grade internal components. If the device housing is damaged or cracked during the procedure, take appropriate steps to promote patient safety.
- Do not disassemble or otherwise modify the VERASENSE Knee System device or Shims.
- Do not use VERASENSE Knee System device if it appears to be functioning improperly.
- Observe all warnings and alarms generated by the OrthoSensor LinkStation.
- Federal law restricts this device to sale by or on the order of a licensed physician.

INSTRUCTIONS

1. Determine the specific size VERASENSE Knee System device required. Remove pouched Shims and device from the box and put on the shelf of the OrthoSensor LinkStation. DO NOT OPEN POUCH SEALS.
2. Record VERASENSE Knee System device serial number (S/N) onto patient and hospital records as required.
3. To activate the VERASENSE Knee System device:
    a. Locate the VERASENSE icon on the screen of the LinkStation and double click the icon to activate the VERASENSE Software Application.
    b. With the product still in the sealed pouches, place the device directly over the magnet on LinkStation shelf; an LED light will illuminate on the articulating surface of the device. Do not move the device until you observe the following:
        i. LED turns off after approximately four (4) seconds.
        ii. VERASENSE Knee System User Software launches.
        iii. Initialization progress bar appears and completes.
        iv. Prompt to select left or right leg appears
    c. Device may now be removed from magnet.
4. The VERASENSE Knee System Software will automatically prompt selection of left or right leg. Select appropriate leg.
5. Zero Device
    a. Follow on screen instructions to zero the VERASENSE Knee System device.
6. Upon completion of the device initiation process as prompted on the LinkStation, pass the sealed pouches to the nurses within the sterile field of the OR.
7. Open double sealed pouches per hospital protocol (VERASENSE Knee System device and Shim Set.)
8. With device and Shims removed from the pouches, apply designated Shim to underside of device.

    Note: Once the product is removed from the pouch, the application of the initial shim, if applicable, relates to devices without mounted shims (Mako, Stryker and Zimmer). For the Biomet family, the 10mm shim is already mounted.

9. To remove the Shim, or exchange for another size, simply unsnap the anterior lip of the attached Shim and replace.
10. With the VERASENSE Knee System device and Shim attached, physician should manually compress / apply load to the device and verify the response on the User Interface prior to placing VERASENSE Knee System device into the tibial tray.
11. Confirm that the VERASENSE Knee System device with Shim is fully seated when placed in the tibial tray.
12. Flex the joint throughout its full range of motion to ensure appropriate response on the User Interface.
13. Proceed with total knee replacement process per physician / hospital protocol.
14. Upon completion of the procedure, deactivate the VERASENSE Knee System Software Application by pressing the Power Button on the User Interface.

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15. Dispose of VERASENSE Knee System device per institutional guidelines for biohazardous medical waste.

    Note: If maximum allowable load of 70 lbs is reached in either compartment, the VERASENSE Knee System device must be removed from the knee joint and "re-zero'd" by holding down the "CONTROL" key and pressing the letter "Z" key on the OrthoSensor LinkStation keyboard to recalibrate the device.

VERASENSE™ TROUBLESHOOTING

Issue	Cause	Solution
VERASENSE Device LED does not light up	VERASENSE Device batteries are dead	Discard VERASENSE Device and replace
VERASENSE Device not transmitting data to LinkStation	VERASENSE Device is out of wireless range	Move LinkStation closer to VERASENSE Device
		Move LinkStation to achieve an unobstructed line-of-sight to the VERASENSE Device field of use
	VERASENSE Device is powered off	Activate with LinkStation magnet
	VERASENSE Device batteries are low	Discard VERASENSE Device and replace
VERASENSE Device breakage	VERASENSE Device loaded beyond limit	VERASENSE Device internal components are non-sterile and non-medical grade. Ensure patient safety. Discard Device and replace
Lag in reported data	Software latency	Maintain knee position until data settles (approximately 5 seconds)

Note: Should any of the issues above arise please contact Orthosensor Customer service at (888) 756-7846 for return or replacement assistance.

VERASENSE™ KNEE SYSTEM DEVICE SPECIFICATIONS

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2.) These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment.
- Consult OrthoSensor for help.

This device complies with Part 95 of the FCC rules. This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Modification of this device may void the user's authority to operate the equipment under the FCC rules above.

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Model:	VERASENSE™ Knee System			
Quantity:	1			
Type:	Single Procedure Only. Do not re-sterilize			
Sterile:	Ethylene Oxide			
Device Type:	Type BF			
FCC ID:	XNL-ORTHOSNSR1 XNL-ORTHOSNSR2 XNL-ORTHOSNSR3 XNL-ORTHOSNSR5 XNL-ORTHOSNSR6			
Operating Range:	6.5 ft [2m] Unobstructed			
Mode of Operation:	Temporary (single-use)			
Power Supply:	Internally powered at less than 3.3 VDC			
Battery Life:	40 minutes (approximate)			
Temperature:	**Operation**	15°C ~ 37°C	**Storage**	0°C ~ 50°C
Relative Humidity:		30% ~ 100%, submersion		10% ~ 80 %, non-condensing
Atm Pressure:		470-1060 hPa		360-1060 hPa
Rx Only:	U.S. Federal Law restricts this product to sale by or on the order of a physician			

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