OrthoSensor, Inc
1560 Sawgrass Corporate Pkwy, 4th Floor
Sunrise FL, 33323
www.orthosensor.com

ORTHOSENSOR

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 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.

INDICATIONS

The OrthoSensor VERASENSE Knee System device is an intelligent disposable tibial insert trial 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 attaching Shim to the VERASENSE Knee System device, take care and caution to properly slide shim onto device by engaging/snapping components together. 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.
- 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. Contact OrthoSensor for additional data regarding device accuracy.
- Maximum safe allowable load for the VERASENSE Knee System device is 70 lbs per compartment.

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

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- If maximum safe 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.
- 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 load the VERASENSE Knee System device at its edges.
- Do not subject VERASENSE Knee System device or Shims to loads beyond the maximum allowable load.
- 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 orange 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. With the VERASENSE Knee System device now activated, 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.
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.
15. Dispose of VERASENSE Knee System device per institutional guidelines for biohazardous medical waste.

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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)

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			STERILE EO
Device Type:	Type BF			
FCC ID:	XNL-ORTHOSNSR1 XNL-ORTHOSNSR2 XNL-ORTHOSNSR3			
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% 50%, 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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Biomet Orthopedics
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P.O. Box 587
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01-50-0975
Date: 2011-03

Biomet® Knee Joint Replacement Prostheses

ATTENTION OPERATING SURGEON

DESCRIPTION
Biomet manufactures a variety of knee joint replacement prostheses intended for application with or without bone cement. Knee joint replacement components include femoral, tibial, and patellar components. Components are available in a variety of designs and size ranges intended for both primary and revision applications. Specialty components are available including; femoral stems, femoral augments, tibial stems, tibial augments, tibial cement plugs and tibial screws.

MATERIALS

Femoral Components	CoCrMo Alloy/Titanium Alloy
Tibial Plates	CoCrMo Alloy/Titanium Alloy
Tibial Bearings	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Conform Bearings	UHMWPE/CoCrMo Alloy
Patellar Components	UHMWPE/Titanium Alloy/316LVM Stainless Steel
Femoral Stems	Titanium Alloy
Augment Components	Titanium Alloy
Stem Components	Titanium Alloy
Tibial Cement Plugs	UHMWPE
Tibial Screws	Titanium Alloy
Modular Pegs	CoCrMo Alloy

INDICATIONS
1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

The Regenerex™ femoral augments are indicated for use with the Vanguard™ Total Knee System.

The Regenerex™ tibial augments are indicated for use with standard and offset Biomet® Tibial Trays.

Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok™) devices and all-polyethylene patellar components are indicated for cemented application only. Regenerex™ components are intended only for uncemented biologic fixation application.

CONTRAINDICATIONS
Absolute contraindications include: infection, sepsis, and osteomyelitis.
Relative contraindications include: 1) an uncooperative patient or a patient with neurologic disorders who is incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, neuromuscular disease, and/or 8) incomplete or deficient soft tissue surrounding the knee.

Biomet® Microplasty™ Tibial Trays are contraindicated for use with constrained bearings.

WARNINGS
Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments prior to performing surgery.

1. The 23mm Single-Peg Patella components should be used only with an inset mill surgical technique. Product numbers for the 23mm Single-Peg Patella components include the following: 185185, 185186, 185187 and 185188.
2. The shorter titanium locking screws, Catalogue Number 7700015B (Performance Locking Screw), is to be used with the cruciate-retaining and cruciate-supplementing articulating surfaces. The longer P/S Locking Screw, Catalogue Number 7900015B (Performance P/S Locking Screw), is to be used with the P/S cruciate and constrained substituting articulating surface.
3. The locking bar used to secure the tibial plate and tibial-bearing components together must lock securely into place with an audible click at the time of implantation. Disassociation of the locking bar from the modular tibial plate component has been reported. Inadequate seating of the locking bar can cause disassociation of the locking bar from the tibial plate component, requiring revision surgery.
4. The 8mm-polyethylene insert of the modular tibial is not compatible with the AGC™ posterior stabilized and revision AGC™ femoral components. Product numbers for the 8mm-polyethylene insert bearing components include the following: 155508, 155608, 155628, 155648, 155668, 155688, 155708, 155728, and 155748.
5. The all-polyethylene tibial component is designed to be used in treatment of low demand, less active sedentary patients. Patients that will remain active and/or overweight are not candidates for all-polyethylene tibial components.
6. Malalignment or soft tissue imbalance can place inordinate forces on the components, which may cause excessive wear to the patellar or tibial bearing articulating surfaces. Revision surgery may be required to prevent component failure.
7. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.
8. It is the responsibility of the operating surgeon to determine whether there is adequate initial fixation and stability. Stem extension and bone cement are available if additional fixation or stability are needed.
9. The Regenerex™ Tibial Trays require a stem when used with PS components.
10. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

Biomet® joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction, and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation, subluxation and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone, making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity level, 3) a good

nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

PRECAUTIONS

Specialized instruments are designed for Biomet® joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

All trial, packaging, and instrument components must be removed prior to closing the surgical site, do not implant.

POSSIBLE ADVERSE EFFECTS

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis, or osteolysis may be a result of loosening of the implant.
2. Early or late postoperative infection and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, non-union, bone resorption and/or excessive unusual and/or awkward movement and/or activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation, malalignment, malposition, excessive unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Valgus-varus deformity.
13. Transient peroneal palsy secondary to surgical manipulation and increased joint movement has been reported following knee arthroplasty in patients with severe flexion and valgus deformity.
14. Patellar tendon rupture and ligamentous laxity.
15. Interoperative or postoperative bone fracture and/or postoperative pain.

MRI Information

The effects of the MR environment have not been determined for this device. This device has not been tested for heating or migration in the MR environment.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Single Use Only. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

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

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA UK

CE 0086

Symbol Legend


Manufacturer


Date of Manufacture


Do Not Reuse


Caution

Sterilized using Ethylene Oxide

Sterilized using Irradiation

Sterile

Sterilized using Aseptic Processing Techniques

Sterilized using Steam or Dry Heat


Use By


WEEE Device

Catalogue Number

Batch Code

Flammable

Authorized Representative in the European Community