OrthoSensor, Inc
1560 Sawgrass Corporate Pkwy, 4th Floor
Sunrise FL, 33326
www.orthosensor.com

ORTHOSENSOR LOAD BALANCING SYSTEM
LOAD SENSOR INSTRUCTIONS FOR USE

DESCRIPTION

The OrthoSensor Load Balancing System (LBS) provides a means to dynamically balance the knee during knee replacement surgery intra-operatively.

The OrthoSensor Load Sensor (LS) is made exclusively for use with the Stryker Orthopaedics Knee Trial for Triathlon™ system with special authorization from OrthoSensor. The device is approved for early validation testing only. Therefore, the information reported by the OrthoSensor System shall not be used to affect patient outcome.

The Load Sensor measures the forces between the tibia and the femur. It wirelessly transmits measured force data to the Link Station positioned outside the sterile field. The Load Sensor replaces the standard trial tibial insert, it is provided sterile, for single patient use. A Shim Set is included for thickness adjustments.

Additional Load Balancing System components include:

- Link Station: The Link Station houses a computer and all peripheral equipment required to interpret and display the force data. The Link Station provides a graphical and numerical presentation of the forces in one or both of the knee compartments.

- Receiver: The Receiver is incorporated into the Link Station; it receives the wireless transmissions from the Load Sensor and communicates the data to the computer.

Refer to the OrthoSensor Link Station Instructions for Use for additional details on these components.

INDICATIONS

The OrthoSensor Load Balancing System (LBS) is a tool for the adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry.

CONTRAINDICATIONS

- Any active or suspected latent infection in or about the knee joint.
- Refer to Stryker Orthopaedics Triathlon 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 warnings for this product is essential.
- Refer to Stryker Orthopaedics Triathlon Knee System IFU for additional precautions.

USER/PATIENT SAFETY

- The Load Sensor and Shim Set are supplied as single-use sterile devices. If Load Sensor or Shim Set packaging are open or damaged, do not use and immediately return to OrthoSensor.
- Impact or excessive loading of the Load Sensor may result in a failure of the Load Sensor housing, exposing the patient to non-sterile and non-biocompatible internal components.
- Load Sensor and Shim Sets are single use only. Do not reuse or resterilze.
- Load range of the Load Sensor is 5 to 40 pounds per condyle.
- Maximum safe allowable load for the OrthoSensor Load Sensor is 70 lbs per condyle.
- Refer to the Device History File for Load Sensor accuracy data.
- Do not load the Load Sensor at its edges.

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- The Load Sensor contains non-sterile, non-medical grade internal components. If the Load Sensor housing is damaged or cracked during procedure, take appropriate steps to promote patient safety.
- Do not disassemble the Load Sensor.
- Do not use Load Sensor if it appears not to be functioning properly.
- Observe all warnings and alarms generated by the OrthoSensor Link Station.
- Do not subject Load Sensor or Shims to sudden impact.
- Federal law restricts this device to sale by or on the order of a licensed physician

INSTRUCTIONS

1. Prior to start of procedure, turn Orthosensor Link Station on. Ensure that the station is plugged into a standard 110V outlet. Then locate the power button, which is located along the left lower rear side of the monitor and press the button. Upon startup, the system will upload to the main screen.
2. Determine specific size load sensor. Remove pouched shims and load sensor from the box and set atop of the shelf on the Orthosensor Link Station. DO NOT OPEN POUCH SEALS.
3. Record Load Sensor serial number (S/N) onto patient and hospital records as required.
4. To activate the Load Sensor:
    a. Locate the magnet on the right rear side of the retractable keyboard / mouse tray.
    b. With the product still in the sealed pouches, place the center rear section of the device over the magnet; a red light will illuminate; continue to hold in place until the red light turns off.
5. Once the unit is activated, locate the TKA load balancing icon on the screen of the smart system and activate the software.
6. Upon activation of software scan the label barcode attached to the Load Sensor outer pouch.
7. The software will now enter the active display mode.
8. Open double sealed pouches per hospital protocol (Load Sensor and Shim Set).
9. If required, snap a shim onto the base of the Load Sensor before implanting into the Tibia tray. Shim size to be determined by the physician.
    a. To remove the shim or exchange for another size, simply unsnap the installed shim and replace.
10. The physician should manually compress / apply load to the device and verify it's response on the Link Station screen prior to placing Load Sensor into the tibia tray.
11. Confirm that the load sensor module is fully seated when installed onto the tibial tray.
12. Flex the joint throughout its full range of motion five times (5X) to ensure appropriate response on the Link Station.
13. Perform knee surgery with the Load Sensor in conjunction with the instructions displayed on the Link Station, and per the requirements of the Stryker Orthopaedics Triathlon Knee System. Due to the early verification status of the Load Sensor do not use the data to affect patient outcome.
    a. The load range of the Load Sensor is 5 to 40 pounds per condyle.
    b. The maximum safe allowable load for the OrthoSensor Load Sensor is 70 lbs per condyle.
14. Dispose of Load Sensor per institutional guidelines for biohazardous medical waste.

LOAD SENSOR (LS) TROUBLESHOOTING

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

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LOAD SENSOR 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 limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a hospital 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 radio communications. 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 antenna
- Increase the separation between the equipment and transmitter.
- 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 of operate the equipment under the FCC rules above.

Patent Pending

Model:	Load Balancing System – Load Sensor			
Quantity:	1			
Type:	Single Procedure Only. Do not resterilize			
Sterile:	Ethylene Oxide			
Device Type:	Type BF			
FCC ID:	XNL-ORTHOSNSR1			
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 (approximately):	40 minutes			
Temperature:	Operation	15°C ⁄ 37°C	Storage	15°C ⁄ 37°C
Rx Only	U.S. Federal Law restricts this product to sale by or on the order of a physician			

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.