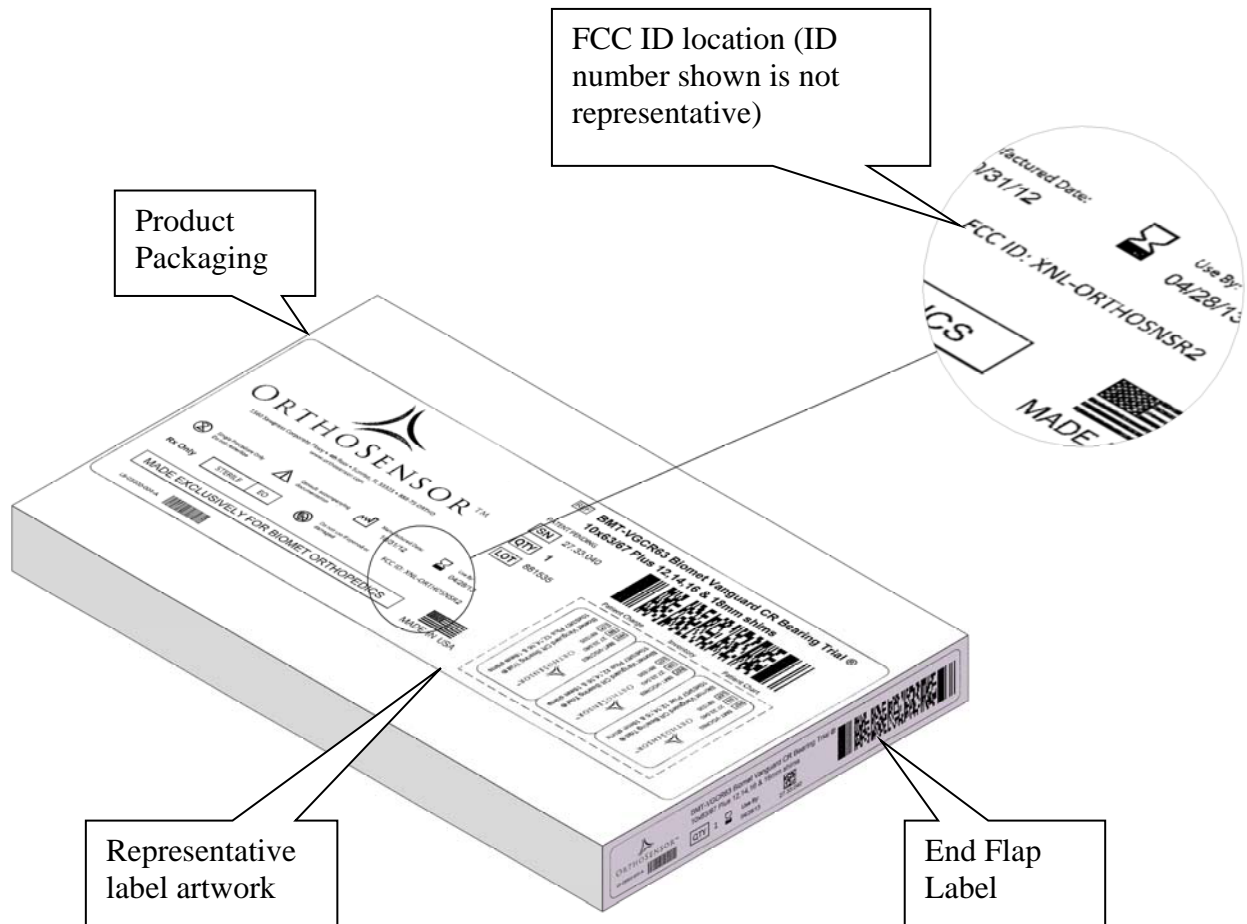


1855 Griffin Road, Ste A-310, Dania Beach, FL 33004-2200  
Telephone: 954-577-7770, Fax: 954.577.7343

**FCC LABEL ID LOCATION**

The VERASENSE is contained within the below product box until immediately before use.  
The FCC ID is indicated on the label attached to the product packaging.



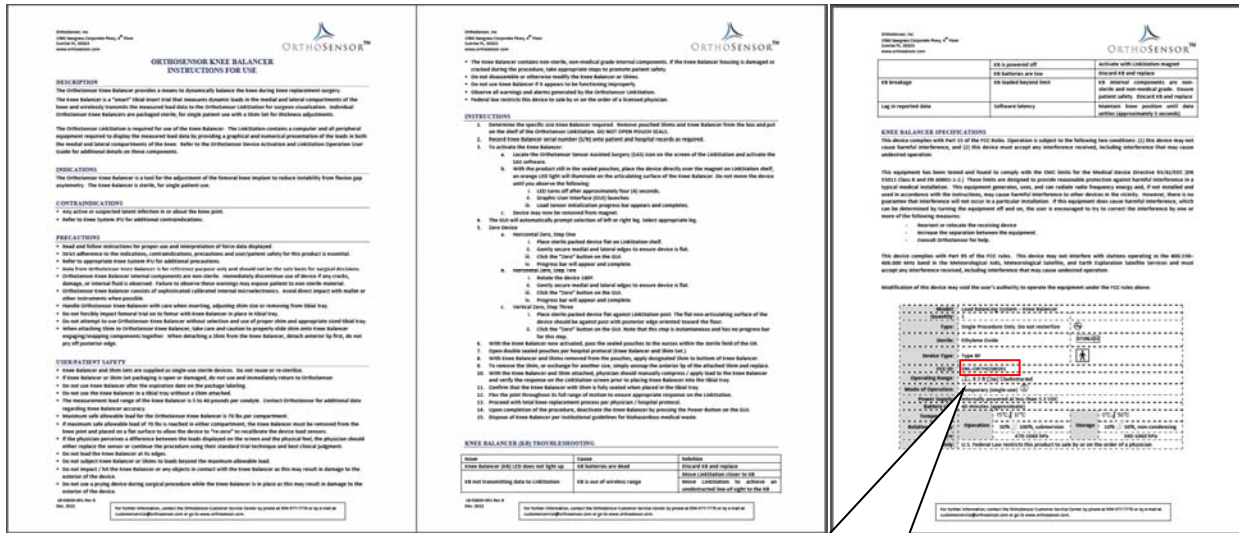


# ORTHOSENSOR

DELIVERING INTELLIGENT ORTHOPEDICS

1855 Griffin Road, Ste A-310, Dania Beach, FL 33004-2200  
 Telephone: 954-577-7770, Fax: 954.577.7343

The FCC ID can be seen in the indicated table from the IFU (instructions for use).  
 This document is included in the VERASENSE product box.



**ORTHOSENSOR KNEE BALANCE INSTRUCTIONS FOR USE**

**DESCRIPTION**

The Knee Balance is a "smart" closed loop real-time feedback system that provides real-time feedback to the user and continuously adjusts the measured load data to the OrthoSensor calibration for optimal performance. Individual OrthoSensor knee balances are packaged sterile, for single patient use with the knee brace adjustment.

The OrthoSensor calibration is required for use of the Knee Balance. The calibration contains computer and algorithmic components required to display the measured load data to the OrthoSensor calibration for optimal performance. Individual OrthoSensor knee balances are packaged sterile, for single patient use with the knee brace adjustment.

The OrthoSensor knee balance is used for the adjustment of the femoral brace to reduce instability from knee joint instability. The knee balance is sterile, for single patient use.

**CONTRAINDICATIONS**

- Do not use on compromised knee without an orthopedic knee brace.
- Refer to knee brace IFU for additional contraindications.

**PRECAUTIONS**

- Read and follow instructions for proper use and interpretation of force data displayed.
- Do not use on the knee without the calibration, contraindications, precautions, and user safety for this product is essential.
- Refer to appropriate knee brace IFU for additional precautions.
- Do not use OrthoSensor knee balance in an environment where the user is not trained for use of the device.
- OrthoSensor knee balance internal components are not sterile. Immediately discontinue use of device if any cracks, damage, or unusual fluid is observed. Failure to observe these warnings may expose patient to non-sterile material.
- OrthoSensor knee balance consists of non-sterile calibrations and internal components. Avoid direct impact with metal or other instruments when possible.
- Handle OrthoSensor knee balance with care when handling, adjusting, or removing from knee brace.
- Do not handle repeat femoral trial or brace with knee balance in place in OR/ORI.
- Do not attempt to use OrthoSensor knee balance without calibration and use of proper sterilization and appropriate disinfection.
- When attaching knee brace to OrthoSensor knee balance, take care and caution to properly slide into knee brace mounting/docking components together. When attaching a knee brace to the knee balance, attach femoral brace IFU, do not pry off femoral brace.

**THERAPEUTIC SAFETY**

- Knee balance and knee brace are supplied as single use sterile device. Do not reuse or re-sterilize.
- If knee balance or knee brace is damaged or exposed to damage, do not use and immediately return to OrthoSensor.
- Do not use knee balance after the expiration date on the package labeling.
- Do not use the knee balance in a trial run without a knee brace.
- The measurement load range of the knee balance is 1 to 40 pounds per cycle. Contact OrthoSensor for additional data regarding knee balance accuracy.
- Measurement with allowable load for the OrthoSensor knee balance is 10 lbs per component.
- Measurement with allowable load of 10 lbs is reached in either component, the knee balance must be removed from the knee joint and placed in the knee brace to allow the device to "re-learn" to recalibrate the device load sensor.
- Do not use knee balance after the expiration date on the package labeling.
- Do not perform procedures or adjustments to the knee balance on the knee brace or femoral brace. The procedure should allow repair the knee brace or continue the procedure using their standard trial technique and best clinical judgment.
- Do not modify the knee balance at all stages.
- Do not subject knee balance or device to loads beyond the maximum allowable load.
- Do not repair, fix the knee balance or any other component of the knee balance as this may result in damage to the exterior of the device.
- Do not use a spring device during surgical procedure while the knee balance is in place as this may result in damage to the exterior of the device.

**NEE BALANCE (KNEE) FROM SHIPPING**

Case	Case	Balance
NEE BALANCE (KNEE) FROM SHIPPING	NEE BALANCE (KNEE) FROM SHIPPING	NEE BALANCE (KNEE) FROM SHIPPING
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**FCC ID location (ID number shown is not representative)**