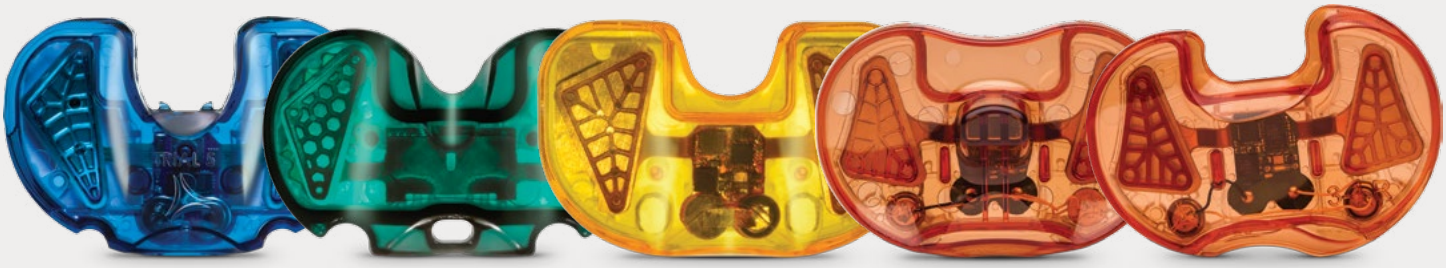
VERASENSE™
ORTHOSENSOR®



FREQUENTLY ASKED QUESTIONS AND ANSWERS

1. What is VERASENSE?

VERASENSE™ is the orthopaedic industry's first Sensor-Assisted disposable medical device used in primary and revision Total Knee Arthroplasty (TKA) procedures* that transmits compartmental load data wirelessly. It enables surgeons to make informed decisions on soft tissue balance, tibio-femoral congruency** and implant position with the goal of improving joint performance, knee kinetics and patient satisfaction.

2. What is Kinetics?

Kinetics is the study of force and motion; whereas, kinematics is solely focused on the study of motion and does not take into account any forces that act upon the body in motion. Knee kinematics has improved with implant design and alignment technologies over the last few decades, but these techniques have not provided actionable information regarding soft tissue tension and gap balance. VERASENSE enables kinetic analysis of the knee quantifying the forces applied to the joint from the soft tissue tension through the full range of motion.

3. What does VERASENSE solve?

Patient satisfaction closely correlates with post-operative function.[1] In a multi-center study, use of VERASENSE has been shown to reduce post-op pain and to improve activity and patient satisfaction scores with statistical significance. In fact, 97% of patients whose knees were balanced using VERASENSE reported they were satisfied to very satisfied at 1-year post-op. This compares favorably to peer-reviewed publications that show an average of 81% patient satisfaction after a TKA procedure. That's a 16% improvement in patient satisfaction for balanced knees – the first significant, notable increase of patient-reported satisfaction in over 30 years.[1,2]

* The characteristics of the clinical use of VERASENSE are similar for primary and revision TKA for the supported knee implant families and sizes.
** For Reference Only.

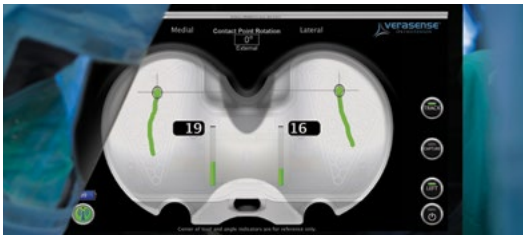
4. Why is VERASENSE needed?

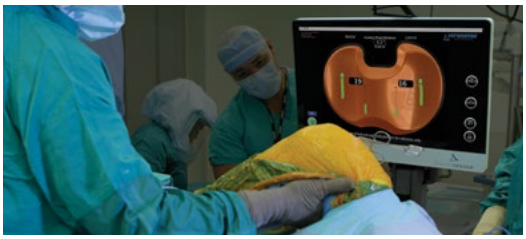
Improper soft tissue balance complications (e.g. instability, aseptic loosening, polyethylene wear) and mal-alignment cause approximately 40% of all pre-mature implant failures,[3,4,5,6] burdening patients, providers, hospitals and payors with high cost revision surgeries. The importance of proper ligament balance, implant position and limb alignment to maximize implant survivorship is well understood in clinical peer-reviewed literature. Decisions concerning these factors have varied based on an individual surgeon's judgment, experience and skill. Before VERASENSE, surgeons lacked a quantifiable instrument and data to optimize their soft tissue balance and knee kinetics.

VERASENSE advances soft tissue management from a feel-based art to a quantifiable science. Without VERASENSE, surgeons must continue to rely on their "best judgment," thereby increasing post-op risk of pain, imbalance and instability – all of which can lead to premature implant failure. VERASENSE provides surgeons, hospitals and other health care stakeholders access to real-time data to maximize patient care, measure evidence-based clinical outcomes, improve care pathways, potentially lower the delivery of TKA costs and potentially improve musculo-skeletal health.[1,2]

5. What are the benefits of adding VERASENSE to your TKA procedures?

You can't change what you can't measure. VERASENSE helps quantify proper implant congruence** and soft-tissue balance by reducing technical variability and outliers that can add to the TKA revision burden.[1,2] Proper soft tissue balance may also reduce the incidence of post-operative stiffness, which often leads to manipulation under anesthesia (MUA).[7,8] In a multi-center study, patients with quantifiably balanced knees exhibited less pain, improved function, increased activity levels and higher patient satisfaction.[1,2] Such improvements in efficiency and higher quality of care are becoming important hospital, CMS, payor and patient performance measures.



6. Is VERASENSE US-FDA Cleared?

Yes. VERASENSE is cleared for commercial use by the US-FDA under 510(k) numbers K090474, K130380 and K131767.

7. Is VERASENSE an implantable?

No. VERASENSE is used intra-operatively during a TKA procedure. Upon use, the device is discarded and replaced with a permanent total knee replacement system component.

8. What physician groups do you expect to use VERASENSE?

Orthopaedic surgeons performing primary and revision TKA* will benefit from use of VERASENSE.

9. Is VERASENSE compatible with all Total Knee Systems?

At present, VERASENSE is compatible for use with Smith & Nephew® JOURNEY®II and LEGION®, Stryker® Triathlon®, Zimmer Biomet NexGen® and Vanguard.®

10. Is VERASENSE sterile?

Yes. VERASENSE comes in sterile packaging with a two-year shelf line and is intended for single-use.

11. Does VERASENSE change a surgical workflow or add complexity and time to a TKA procedure?

No, VERASENSE was designed to fit seamlessly within a standard TKA surgical workflow, integrating intelligent microelectronics into a replica of the standard tibial trial insert.[9]

12. What kind of training and ongoing support is required to adopt and use VERASENSE?

VERASENSE is a disposable, easy-to-adopt device for the operating room staff. A typical in-service training with review of simple instructions for use usually requires no more than a 10-15 minute meeting with OR staff. OrthoSensor provides additional ongoing clinical educational opportunities through Surgical Customer Site Visits (CSVs), Bioskills labs, visiting expert surgeon Grand Rounds education and various surgical educational multimedia.

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13. How can VERASENSE enhance your Orthopaedic Service Line Initiatives?

Sensor-Assisted Surgery enables healthcare providers to deliver a high-tech innovation that improves clinical outcomes, streamlines care pathways and ultimately improves patient satisfaction.[1,2] First mover advantage with Sensor-Assisted Surgery technology has the potential of increasing patient interest and physician referrals while developing a strategic private pay constituent audience. OrthoSensor offers several turn-key Direct-to-Patient education and marketing resources that can be incorporated into your Orthopaedic Service Line patient outreach and marketing strategies.

14. Does use of VERASENSE require the purchase of capital equipment?

No. VERASENSE is a single-use, disposable device. The use of LinkStation software, software upgrades, hardware, service and warranties are included in the purchase price of each disposable device.

15. What are the space and storage requirements for the LinkStation used with VERASENSE?

The LinkStation provides surgeons with visibility to the intra-operative data provided by VERASENSE. The LinkStation is attached to a movable (wheeled) hospital-grade stand with a minimum footprint of approximately 2’ x 1.5’.

16. Who manufactures VERASENSE?

VERASENSE is manufactured by OrthoSensor, Inc., the pioneer and leader in Sensor-Assisted Technology in Orthopaedics. OrthoSensor has a robust patent portfolio directed to the integration of sensors into instruments and future implant technologies for various musculoskeletal applications.

17. Who should I contact for more information about VERASENSE?

Your local OrthoSensor sales representative or the following key contacts can answer any additional questions you may have or provide additional data specific to your hospital’s needs:

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