



We Make Innovation Work

Project Name: OrthoSensor Instrumented Trial
Application: Wireless knee balancing system
Customer: Orthosensor, Inc.
Website: www.orthosensor.com



DELIVERING INTELLIGENT ORTHOPEDICS

BACKGROUND AND PROJECT CHALLENGE

This innovative product is the first Intelligent Orthopedic Device to optimize soft tissue balance and leg alignment during Total Knee Arthroplasty.

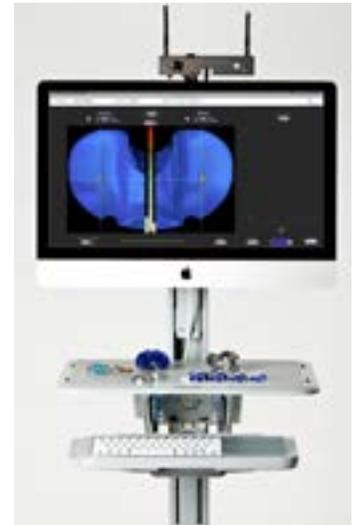
The OrthoSensor Knee Balancer is a low-cost, disposable surgical aid designed to reduce implant failures by addressing their root causes: poor soft tissue balance and misalignment. The device is positioned between the femoral and tibia trials during knee replacement surgery; its custom load sensors transmit load data to a graphic display, enabling surgeons to visualize and quantify joint balance and load. This innovative system allows the surgeon to make informed adjustments to the soft tissues to optimize implant placement.

OrthoSensor contacted PADT during the conceptual stages of product development. PADT has worked closely with OrthoSensor for over 4 years throughout all phases of design development activities and testing. We are proud to see this product achieve commercial success, and are honored to continue working with OrthoSensor as their technology and product line expands.

PROCESS AND SOLUTION

PADT's Medical Device Engineering Team has been instrumental throughout all phases of the product development cycle; from early prototypes, to production of the first clinical devices, and ongoing engineering and process support now that the commercial product has been transferred to a contract manufacturer. The following list provides a very brief summary of our successful collaborative efforts:

Concept Development: PADT was instrumental in developing functional devices suitable for testing and regulatory submissions. Collaborative ef-



Since 2009 PADT has worked closely with Orthosensor on every stage of the product development of their new device.

DISCIPLINES EMPLOYED

- Concept Development
- Quality Control
- Detail Design
- 510(k) Submission Support
- Sterilization & Packaging
- Biocompatibility Design and Test
- Production of Clinical Use Devices
- Design Transfer

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forts between OrthoSensor and PADT ensured that multiple technological and material hurdles were resolved.

Design Planning and Quality Control: OrthoSensor utilized PADT's FDA compliant Quality Control System during the design planning phase. PADT generated all planning documents including the System and User Requirements, Risk Management, and Manufacturing Plans. As OrthoSensor's internal organization grew and developed, PADT's compliant QC System was able to adapt to their internal quality requirements until full QC responsibility was transferred to OrthoSensor.

Detail Design: PADT's engineering involvement grew to include detailed product design and development activities for both the load sensor and wireless data generation system; including stress analysis and simulation testing, ASIC power management testing, device calibration, sensor development and testing, material evaluation, and generation of highly detailed CAD models and production documentation.

Regulatory: PADT and OrthoSensor worked closely throughout the 510(k) submission and approval process, in addition to the regulatory reviews as the product matured.

Sterilization and Packaging: PADT developed the EO sterilization processes and procedures, specified all sterile packaging materials, labels, & production heat sealing equipment, and coordinated the packaging & shipping tests to ensure continued product sterility.

Biocompatibility: PADT specified all patient contacting materials and coordinated the biocompatibility testing as specified by ISO 10993 standards.

Verification Testing: PADT planned, performed, and documented all product verification testing.

Production of Clinical Use Devices: The first clinical use devices were produced and packaged inside PADT's class 10,000 clean room, using PADT generated manufacturing and tracking documentation.

Design Transfer: PADT was instrumental in developing the manufacturing processes when the commercial product was transferred to a contract manufacturer. We have continued to provide ongoing engineering and production support for the OrthoSensor Knee Balancer.

CONCLUSION

The collaborative efforts of the multi-disciplined teams from both PADT and OrthoSensor have advanced this product from concept to commercial success.

PADT Medical is excited for our continued collaborative efforts as OrthoSensor expands its line of intelligent orthopedics.



TESTIMONIAL

"PADT's Design Team was instrumental in working with Orthosensor throughout the design and development activities of the Orthosensor Knee Balance. Their commitment and flexibility to our business needs allowed us to bring our product to market in a significantly shortened period of time."

Juan C Fernandez
Chief Operating Officer
Orthosensor Inc

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