

Medtech Ventures

Hot pick of the month

ORTHOSENSOR

Specialty area(s): Intelligent orthopaedic surgical instruments, implants and analytics

Based in: Sunrise, Florida

Founded in: 2007

No. of employees: 10 full time employees and outsourced product development and contract manufacturing

Total investment received to date: \$27m

Investors: Ziegler Meditech Equity Partners and a number of unnamed strategic investors

Annual hospital charges associated with failure of total joint implants are expected to amount to \$8.6bn by 2015 in the US alone, according to analysts. Many of these early implant failure cases are due to implant malposition, ligament instability and poor limb alignment. Surgeons rely on their experience and training to perform a total joint arthroplasty and until now, they have not had dynamic feedback during surgery to confirm that their “feel” of the joints’ soft tissue balance is optimal.

“Total joint arthroplasty today is more of an art than a science. It is based on feel and the results are very dependent on the subjectivity of the surgeon,” says Jay Pierce, CEO of OrthoSensor, a company that is launching a product in June to help surgeons place knee implants more effectively using intelligent devices that provide quantifiable data and feedback. “Implant failure is primarily driven by poor soft tissue balancing or malalignment of the implant and limb axis. That is a major unmet need which we’re focused on.”

The OrthoSensor Knee Trial is an “intelligent”, disposable trial insert, designed to replace the standard spacer block that is used to balance the knee during implant procedure.

“After the trial prosthesis has been placed, the surgeon will take the knee through a range of motion to determine whether or not effective soft tissue balance and appropriate knee kinematics is achieved,” explains Mr Pierce. “If they put the implant in the patient and one of the ligaments is too tight, the components in that compartment will likely wear down prematurely. If the ligaments are too loose, the patient will experience pain and instability of the knee.”

The OrthoSensor Knee Trial has embedded sensors which pick up pressure or load data on the various compartments of the knee and wirelessly transmit this data in

real-time to a graphic user interface (which can be displayed on any standard computer or tablet, says Mr Pierce). The surgeon can then see on the interface if one compartment of the knee has more pressure than another and adjust this accordingly by realigning the implant, releasing tight ligaments to equalise the intercompartment pressure and optimise the balance in the knee. Once this is achieved, the surgeon can dispose of the OrthoSensor Knee Trial and implant the final prosthesis.

“So for the first time, surgeons will have a quantifiable way of achieving adequate balance,” the CEO tells *Clinica*, adding that another significant advantage to the technology is the lack of a learning curve.



The OrthoSensor Knee Trial in situ

“That’s key about this product. Without changing surgical workflow, the OrthoSensor Knee Trial adds intelligence to the standard instruments and trials used today.”

The knee trial was cleared by the US FDA at the end of 2009, and OrthoSensor has partnered with one of the “largest joint replacement companies” to release its device – customised to the specific geometry of this company’s knee implants – beginning with a limited clinical launch in June.

OrthoSensor’s platform technology integrates microelectronics, sensing technology and radiofrequency telemetry into surgical instruments and implant trials. It has been developed initially for unicompartmental, bicompartamental and total knee replacements and has applications in other joints including the spine, hip, and shoulder.

The firm already has an agreement with a spine implant company and the first spinal

trial is expected to be launched towards the end of 2011, says Mr Pierce. “We’ve been having discussions with many of the implant firms over the last year and selected the first ones for knee and spine and we’re actively looking for application partners for hip as well,” he says, adding that he expects the hip trial insert to come “soon after the spine trial.”

In tandem with its surgical platform, OrthoSensor is developing a platform of intelligent orthopaedic implants that will allow remote monitoring of various parameters specific to the implant in situ and the surrounding bone, such as relative loading and position, material wear, osteolysis, motion, heat, synovial viscosity and implant interface changes.

“With our intelligent orthopaedic implant platform, we’re taking the sensors and electronics that have been built and applied to our disposable surgical tools and we plan to embed them into knee, hip or spine implants,” says Mr Pierce.

“At home, the patient will have a receiver that wirelessly communicates with the microchip in the knee and pulls data out that would alert physicians to the early presence of an infection, for example, or loosening of an implant, and changes in bone density.

OrthoSensor has yet to decide whether to manufacture its own proprietary intelligent implants or, like with its surgical platform, partner with orthopaedic companies and integrate its sensing and telemetry technology into other firm’s devices. “This is a disruptive, marketing-changing technology and we’re keeping our options open. We believe this is an opportunity to change the playing field for orthopaedic implants, and move from mechanics – geometric design and material science on which the market has been largely based – to integrated electronics, using microsensors and wireless telemetry to drive effective placement and ongoing remote monitoring,” says Mr Pierce.

If all goes well, the firm could be launching its first smart implant as early as the end of 2012, the CEO tells *Clinica*.

Jay Pierce, president and CEO.

Tel: +1 954 577 7770

OrthoSensor, Inc. 1560 Sawgrass Corporate Pkwy, 4th Floor, Sunrise, FL 33323, US.

www.orthosensor.com