



Cork, Ireland

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OrthoXel Announce World's First Patient Surgical Implantation of the Apex Tibial Nailing System

OrthoXel, an innovative new orthopaedic trauma company, pioneering the use of enhanced fracture fixation to stimulate callus formation with the goal to reduce healing time, is delighted to announce that following FDA 510k clearance and European CE mark approval, the first patient in Cork University Hospital Trauma Center has had the Apex Tibial Nail implanted.

The patient, a 42 year-old female, presented with a spiral mid-shaft tibial fracture and was treated by Professor James Harty, Consultant Orthopaedic Surgeon and Head of the Department of Orthopaedics at Cork University Hospital. Prof. Harty successfully completed the world's first clinical use of the Apex Tibial Nailing System in Cork University Hospital on Saturday 3rd March.

Professor James Harty, Consultant Orthopaedic Surgeon, Cork University Hospital – "It was a major milestone to use the Apex Tibial Nailing System from OrthoXel in a live trauma case. As was expected, the surgical procedure was smooth and uncomplicated and barring any extenuating circumstances, I expect the patient recovery to be full and swift."

Professor Hannah Dailey, Chief Scientific Officer, OrthoXel – "This implant is the first of a clinical trial running at Cork University Hospital, Ireland that has been designed with an innovative approach to outcomes assessment. OrthoXel is currently seeking potential research partners to replicate or initiate a similar clinical investigation in the USA. Relevantly qualified orthopaedic clinical investigators or institutions can contact OrthoXel direct via the [website](#) or meet us at AAOS 2018 this week in New Orleans at Booth 7041."

About the Apex Tibial Nailing System

The Apex Tibial Nailing system offers surgeons the greatest range of locking options of any intramedullary nail on the market, allowing tailored patient care with a simple and intuitive surgical procedure. The Apex system's revolutionary micromotion locking mode allows controlled axial movement with exceptional torsional stability, providing the ideal conditions for callus formation. Research shows that controlled small axial movements along the length of the bone help to accelerate healing, while twisting movements slow down healing.

The Apex system has a unique design featuring the first-ever implementation of this controlled micromotion in an intramedullary nailing platform, all with no changes to the established evidence-based reamed insertion technique. The Apex system also provides additional locking modes so the surgeon can customize the fixation to suit the needs of the patient, including: standard cross-locking, true rigid fixation with multiple proximal screw clamping to generate a substantially rigid construct, and dynamization locking with unparalleled built-in torsional stability. The state of the art reusable implantation kit allows fast and reliable nail implantation in any locking mode.

No other intramedullary nail currently on the market in the US or the EU gives surgeons the freedom to choose this ideal combination of flexibility and stability for their patients.

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About OrthoXel

Founded in 2014, OrthoXel is the only orthopaedic trauma company focused exclusively on improving patient outcomes through enhanced fixation to stimulate callus formation, with the aim of reducing healing time when OrthoXel intramedullary nails are implanted.

The novel Apex Tibial Nailing system is patent protected and the first technology that OrthoXel will commercialize for treatment of tibial fractures followed by a second device for femoral fractures.

For more information visit: www.orthoxel.net

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