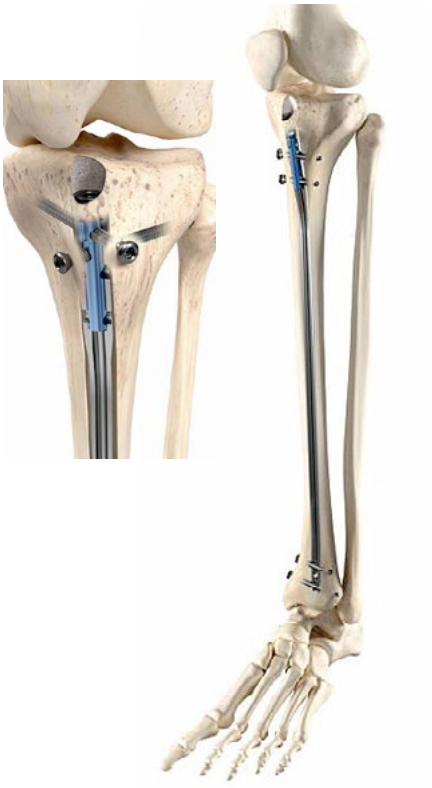
CLINICAL EVALUATION STUDY

Health Innovation Hub Ireland

Cork based medical device company, OrthoXel is a specialist orthopaedic trauma company, which uses innovative engineering design to evolve the next generation fracture fixation devices. Its innovative orthopaedic trauma devices are inspired by surgeons and are focussed on delivering superior patient outcomes.

OrthoXel's products include the Apex Tibial Nailing System and the Apex Femoral Nailing System, both of which are CE marked and FDA cleared.



About Health Innovation Hub Ireland

Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health and is supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise. We offer companies the opportunity for pilot and clinical evaluation studies and we provide the health service access to innovative products, services and devices that they may not otherwise be exposed to.

HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways and outcomes. We assess all concepts for healthcare innovation from those on the frontline – from clinician to porter. We encourage healthcare professionals to get in touch with HIHI if they have an idea or solution to how something in your job might work better.

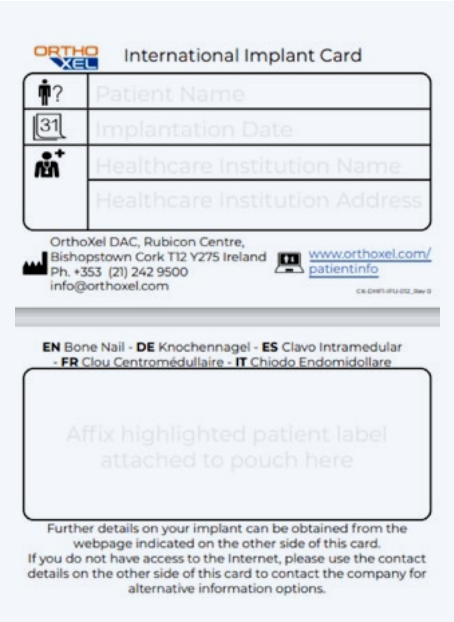
The Healthcare Challenge

While OrthoXel's Apex products are already CE marked, the company must now comply with the new EU 2017/745 **Medical Device Regulation** (MDR). To continue sales in the EU, the MDR requirement for implantable medical device manufacturers to provide an **Implant Card** shall be met. Implant cards provide patients easy access to all relevant information concerning the device with which they have been implanted. Implant Cards, labels and Instructions for Use (IFUs) must be ergonomically tested with the intended users to satisfy MDR requirements. This requires companies to engage with the community to test their cards, labels and IFUs with qualified persons.

The Healthcare Solution

As part of its risk management in designing and producing their Implant Card, OrthoXel first identified who will be responsible for completing the Implant Cards in a hospital. They then carried out ergonomic usability test with some of these identified healthcare professionals in a real world setting to ensure that the card, label and Instructions for Use are sufficient to complete the implant card correctly by the intended user. OrthoXel designed an International Implant Card, adhesive labels and Instructions for Use for its Apex Tibial Nailing System in line with the guidance document MDCG 2019-8 v2.

Ergonomic usability testing was carried out in South Infirmary Victoria University Hospital (SIVUH) in Cork. OrthoXel provided the nurses with all the materials in original packaging as they would receive it if a patient were to be implanted with an Apex Tibial Nailing System medical device in their hospital. The feedback from these theatre nurses during this human factor testing led OrthoXel to revise its labels and Instructions for Use. A second round of usability testing was then carried out in SIVUH with the revised materials to ensure compliance with MDR.



HIHI Role

OrthoXel approached HIHI to assist it in carrying out the human factor usability testing of the completion of its Implant Card in compliance with the MDR. HIHI first identified that orthopaedic theatre nurses are the healthcare professionals responsible for completing the Implant Card in this case. Through its clinical network and the HSE clinical staff assigned to HIHI, HIHI identified orthopaedic theatre nurses and facilitated two rounds of ergonomic usability testing. HIHI provided clinical liaison and project management expertise throughout the project to ensure that this testing was carried out in line with OrthoXel's tight timeline.

Outcome Report

Like many other medical device companies, OrthoXel still holds valid CE certificates that comply with the Medical Devices Directive (MDD 93/42/EEC). These devices can continue to be placed on the European market until their certificate expires or 26th May 2024 whichever is the sooner. After this date the company must comply with the new EU 2017/745 MDR. An important change in MDR is that patients are now to be provided with an Implant Card containing accurate information about their particular medical device. This allows patients access to safety-related information and to identify their needs in certain situations such as security checks or emergency rooms.

HIHI supported OrthoXel in conducting human factor usability testing of the completion of its Implant Card. With HIHI's support, OrthoXel is now confident that the Implant Card, labels and Instructions for Use are fit for purpose by the intended user. The results of the usability testing will form part of OrthoXel's application for approval under MDR.

Testimonial

"OrthoXel contacted Health Innovation Hub Ireland (HIHI) in November 2021 with an urgent project related to the new EU Medical Device Regulations, under which OrthoXel as a manufacturer of implantable medical devices are required to provide patients with an implant card. The project was to identify which specific healthcare professionals would be responsible for completing the card and evaluate clarity of the associated Instructions for Use. The team were excellent in responding and promptly identified and sourced the relevant healthcare professionals. HIHI also completed the project within extremely tight timelines. We were very happy with the results and would strongly recommend HIHI to other medical device manufacturers looking for support."

Alanna Carty,
Commercial Director, OrthoXel

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