The Key to Collaborative Surgical Product Development

Case Study

Ogle Models and Prototypes - with a strong reputation for applying its experience and know-how to medical device development projects - was privileged to become involved in the design and development of two completely new surgical instruments.

The expertise the company has in this area directly affected the style, functionality and manufacturability of the two new instruments developed specifically for contemporary total knee arthroplasty (or, in layman's terms, total knee replacement).

ogle
models+prototypes

www.oglemodels.com
info@oglemodels.com
+44 (0)1462 682 661

For contemporary total knee arthroplasty, like many surgical procedures, the instruments used by the medical staff are based on concepts that have been approved and in use for many years, resulting in excessive patient invasion during surgery, discomfort for the surgeons themselves and rising costs in production. However, advances in product design strategies, new materials and progressive technologies are all being adopted within the medical device field to overcome these issues.

DePuy Orthopaedic, a member of the Johnson & Johnson family of companies, develops and manufactures surgical instruments and is one organisation leading the way in evolving product development processes for surgical instruments.This policy originated in 2006 when InnovationRCA (Royal College of Art, London) ran a creative workshop with DePuy design and engineering staff. This ultimately resulted in the establishment of a new design unit at the Helen Hamlyn Centre at the RCA. One part of the unit's remit is to generate new design ideas for existing instruments and surgical systems that are less invasive, easier to use and less costly to make.

The success of this policy is evident in the products that are now emerging onto the market from DePuy, with its Sigma system of high performance instruments for knee surgery including the two aforementioned instruments. These instruments were initially developed by Maja Kecman and Lisa Stroux; graduates of RCA Industrial Design Engineering, as part of their work as Helen Hamlyn Research Associates at the RCA.

After intensive research with surgeons inside and outside of hospitals, the design work began in earnest. After the first iteration, the designers recognized that they needed further expertise to bring these products to life for visual models and later for functional testing. It was at this stage that Ogle Models and Prototypes became involved in the project, with Steve Willmott,Technical Director at Ogle, leading the team.

Commenting on Ogle's collaboration on this concept, Steve Willmott said: "I had previously worked with Maja Kecman, supplying a model for her during her final year as a student at the RCA. I expected great things of her and I have not been disappointed. Working on the development of this medical device has been a stimulating and engaging challenge that has resulted in a product that will benefit innumerable patients in the years ahead. Being able to work with such talented designers is a privilege and I was delighted to bring the model making expertise for which Ogle is renowned to the project with such great success."

The original brief that Ogle received was direct from the RCA to produce a visual RP model using Stereolithography (SLA) to achieve highly detailed and accurate parts. The model was created using a combination of different materials to meet initial requirements.To achieve part rigidity,Accura 55 was the material of choice, but where some flexibility was necessitated, Accura 25 was used. Some component parts also required visual clarity and for these SL 7870 material was applied. In terms of the accuracy, the model parts were built to maintain ±0.1 mm. However closer tolerances of ±0.05mm were required for some of the small mechanism parts - specifically the setting controls - and this was achieved quickly and easily by Steve and his team.

At this point, although the parts physically worked, there was no specific requirement for functional metal parts or medical grade materials. However, as the project progressed, DePuy engineers became more heavily involved in the project and recognized the valuable input that Ogle offered. Development continued between the RCA designers,Ogle and DePuy over a two- year period to achieve optimum products.Ogle's input resulted in more practical designs that could be produced with the correct specifications,which finally lead to functional iterations of the surgical instruments that were used in trials on cadavers.

Through each of the product iterations, the team at Ogle was able to guide the development in terms of process and material selection due to its exceptional experience in this area. With a wide range of processes and materials at its disposal - all based in-house at the company's state-of-the-art facility - the most appropriate process could be used to achieve the required results. 3D Printing and additive manufacturing using both the SLA and selective laser sintering (SLS) processes were pivotal to the product development program.As the project progressed, some parts were vacuum cast from SLA masters to achieve the desired results for the cutting guides, which were made in stainless steel and subsequently machined.

Both of the surgical instruments that resulted from this project utilized improvements in many different areas of design, technology and materials (notably plastics). Each instrument also significantly contributes to reduced surgery times for contemporary total knee arthroplasty as well as a reduction in manufacturing costs. Furthermore, feedback has shown that the instruments can be customized to the surgeon's individual way of working and improve accuracy through simplified controls.

The two instruments developed as part of DePuy's Sigma range are both vital instruments within the entire Sigma system for knee arthroplasty surgery.

The instrument shown here illustrates the clamp in the model's left hand, which fits around the ankle, with the other end to be fitted up against the shin-bone. Adjustments can be made to align the cut for the surgeon, which is made through the slot in the stainless steel part at the top of the device.

Developing new surgical instruments is not a fast-moving activity - from the inception of the initial concept through to the operating room can often take many years of development, testing and dedication. However, the rewards for seeing it through often bring great benefits to both patients and surgeons that go way beyond financial gains. Bringing on board experts in the medical product development program - experts such as Ogle Models and Prototypes - can reduce the lead time significantly and arrive at the optimum solution much sooner.