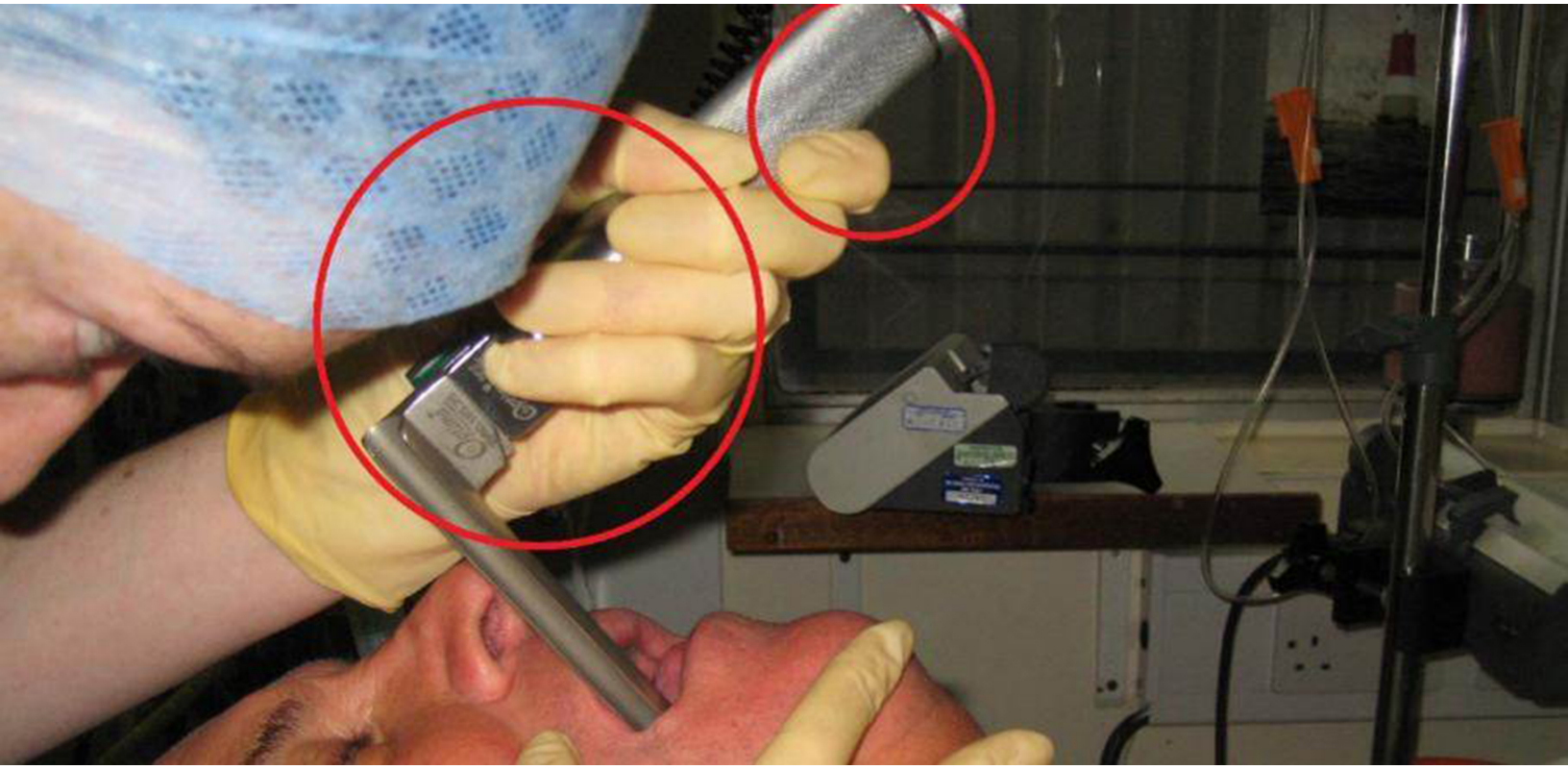
Do you have what it takes to develop surgical products?



By Mike Pratt, Technical Director, IDC China

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Designing medical devices has its own level of challenges with stringent regulatory requirements to ensure the safety of patients, but as Mike Pratt reveals, developing products for surgery creates another level of challenges again. In this Q&A article, he gives his thoughts about the future of surgical product development and the qualities that are needed to be a successful surgical device manufacturer.

Q: What is the main difference between designing regular products and products specifically for use in Surgery?

A: The main difference is lack of access to subject matter; in this case the patient in surgery. So you might have a great idea that you've turned into a prototype, but you can't just take that prototype and test it on a patient. In surgery you have to infer whether things will work, so it's crucial to understand the surgical procedure and how the product will be used, so you can make your own judgment. Having good access to clinicians for helpful feedback and observing the surgical procedure can really help to simplify this process.

Q: How do you go about testing products if you can't test on patients?

A: There are other ways to simulate surgery. Anatomical models can be really useful. For example, when IDC developed a digital laryngoscope for tracheal intubation during anaesthesia, we couldn't just test ideas on patients. We used a realistic model of the head to test the laryngoscope so we could look at the shape, how it interacted with the mouth, throat, trachea and even teeth, as well as control and visibility for the anaesthetist. In a similar way, if you were developing a product for feet, you could get a foot model with bones, cartilage, muscles and blood vessels to help you. The usefulness can be a bit limited in comparison to actually working on a procedure in surgery though.

Anatomical Head Model

Q: Without testing on real patients, how can you be sure it's precise enough and going to be a good solution that will meet all the regulatory standards?

A: When you're looking at a specific surgical procedure, you can normally find out a huge amount of information about the surgical process and techniques. Quite quickly you can become an expert on the process and with surgical products, you certainly get the impression that at this particular moment in time in the world, you may be the only team designing a new product that performs this procedure. So you're probably the team with the best information, because you have the benefit of knowledge about all the products that have gone before, plus all the information gathered in observations from surgery and along with research of the latest technology that you're applying, this makes you a world expert on the product at that time.

Q: What are the difficulties of this type of development at the prototyping stage?

A: The prototyping stage can sometimes take a very long time as you often need special materials, processed in a particular way to develop a surgical prototype. This means you'll need to find specialist suppliers who are able to meet these more specific requirements and this can take a lot longer than with conventional products. To test out an idea or do an iteration, it may take a couple of months instead of just a few weeks for products with more standard materials.

Q: What kind of thing does a design consultancy do to accelerate this process?

A: Over the last ten years there has been a huge advancement in 3D printing. Ten years ago you couldn't get 3D printed metal parts in bio-compatible metals such as titanium. Now this is a useful option for speeding up surgical prototypes. Over the next 5-10 years, the speed of making these parts will be much faster and the accuracy will be greatly improved, so there will be an opportunity to rapidly make miniature surgical components as the norm, even for mass production.

In the future, instead of using a slow CNC machining process, we should be able to use a 3D printer to develop a prototype in a few hours, so this can speed up the development stage. CNC is very labour intensive and slow, but currently provides a good level of precision. This is likely to reverse as 3D printing improves. The requirement to invest in tooling for some manufactured parts may actually disappear as 3D printing evolves. This will undoubtedly speed up development times in the future.

Q: What qualities do manufacturers need in order to move into surgical product development?

A: Time and good funding! Access to the markets is also important, so you can test your ideas. To put a product through a clinical trial takes a lot of investment. Be prepared for a long development, rather than a quick process.

Medical device manufacturers could be a lot more agile. The regulatory processes of medical device companies has created a risk-averse business culture – the need to document the design process can lead organisations into over-documentation and over-analysis which just slows down progress and organisations forget it can be done quickly. The majority of big companies make small incremental changes in a low-risk way. The most successful companies are both smart and rapid. Very innovative products don't normally come from a risk-averse manufacturer. It's a balance; you need to be able to balance risk with innovation.

Q: What are your essential principles of designing surgical products?

A: I try not to see the product like a tool, but more like a beautifully designed, simple product. When designing a product like this, it's not just about function and effectiveness but about the human usability side. These products should look good, feel good, be simple and most importantly, be a joy to use. It has to be desirable to the surgeon to be a success.

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