



CASE

Advanced Single-use Surgical Instrument Improves Patient Safety

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Minimally Invasive Procedure

The Danish company LiNA Medical develops and produces instruments for laparoscopic procedures. This surgery is performed with the smallest possible intervention through a small abdominal incision, which means that the patient will recover faster after the operation.

Wide Interest in the Industry

LiNA Medical has just marketed a morcellator, which is a surgical instrument to morcellate and remove the uterus after isolating it. The product line is a new business area for LiNA Medical. 'Our expectations for the success of Xcise are high.

The product has already attracted great interest from surgeons both in Denmark and at the international market', says Henrik Bisgaard Poulsen, Business Unit Manager.

Products for Repeated Use are Time-consuming

The existing products for repeated use require extensive sterilization and preparation processes between each procedure. And in some cases it takes two persons to use the equipment. This is because an external unit is connected to the device for speed adjustment, and a nurse operates this unit during the procedure.

The new disposable product, Xcise, is ready for use straight from the package. The surgeon has full control over the activation/deactivation and is not disturbed by any extra wires. This improves the surgeon's freedom of movement and efficiency tremendously.

Improved Patient Safety

The instrument comes in a sterile package and is ready for use. The guarantee for sharpness and



'The development of Xcise from idea to market launch in just 14 month is an incredibly fast completion that we are very proud of', says Michael Funder, Managing Director at Medicologic.

sterility ensures high precision, which increases the safety for the patient.

Design for Manufacturing

Medicologic faced the challenge of developing a disposable product that performed fully as well as similar products for repeated use, gave the surgeon more freedom of movement and complied with more stringent regulatory requirements.

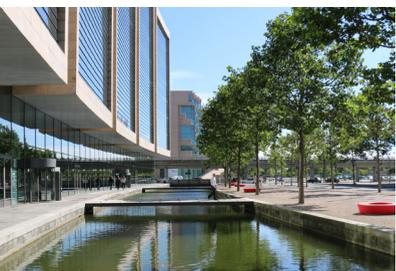
The Development Engineers at Medicologic, point to the choice of design and materials as the most important challenge in order to achieve a combination of low weight, good ergonomics, easy operation and components that were as easy to manufacture as possible. This led to the choice of plastic as the preferred material.

Development for Medical Manufacturing

Medicologic is a consultancy company specialising in medical devices with customers among leading medical manufacturing companies in Denmark. During the past few years we have targeted our services towards the medical device industry. Our expertise ranges from user-driven innovation, design and concept development to maturing for production and regulatory documentation.

CE Marking and FDA Approval

Medicologic has participated in providing documentation on Xcise, and the product obtained CE marking and FDA approval in record time. A merger with the consultancy firm Regulus early 2011 strengthened our regulatory expertise. Medicologic is able to advise customers on development projects right through to marketing approval.



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About Medicologic

Medicologic A/S is a consultancy firm that has advised Danish medical device companies for over a decade on the successful development and validation of medical devices to increase patient safety and to ensure the best possible treatment methods. Our Medical Device Consulting shows that we are meeting market needs and the requirements of the medical device field.

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