



ALLIANCE
pour le génie
BIOLOGIQUE
ET MÉDICAL

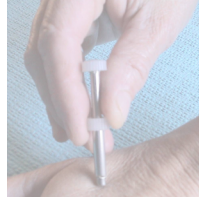
2008
INNOVATIVE MEDICAL
TECHNOLOGIES
Award

Spirotome



MedInvents NV is a European creator of medical devices that have never been built before. The company was founded in 2004 by medical doctors that felt the need to improve research on high quality biopsy instruments for the early detection of cancer and other diseases for all patients irrespective of their social situation worldwide. Patient comfort during the procedure and tissue quality were the main characteristic goals to pursue. After proper patenting of the innovations, the ISO 9001-2000 and ISO 13485 certifications of good manufacturing practice were obtained in 2006. CE and FDA approval for applications in the breast were granted in 2006. In April 2008, the application range was extended by the CE and FDA to almost all soft tissues. Commercial activities were launched in 2007 with registration procedures in most countries. Distribution is worldwide with focus on markets in France, Benelux and Germany. The manufacturing process is being automated. R&D continues to be one of the main activities with 9 new products in the research portfolio. Numerous clinical studies are underway to ensure sustained improvements in technology and guarantee the future of the company.

The Spirotome is one of the leading products of MedInvents NV. The device is made to harvest large samples of high quality from soft tissues in the body and is built on the pioneering concept of a cutting helix on a cutting cannula. The main parts are a cannula, receiving needle with helix and release element (all in one set). The system is available in different sizes (8 to 14 Gauge) and in different formats according to the needs of the physician and the type of clinical procedure. Basically, the sample is harvested by turning the helix into the diseased area under clinical, radiological, ultrasound, CT or MRI guidance. The cannula turns subsequently over the helix to free the sample from the surroundings. The major improvement over existing devices is that the sample is harvested in a direct and frontal way. This feature has major advantages over the traditional tru-cut (shooting) and the (vacuum assisted) biopsy instruments. First, the full core sample is of high quality (see figure). For the same diameter of needle a sample of double size can be obtained. The procedure is **pain free** since the movements of the system are in the anaesthesia tract (no lateral uptake). The procedure is finished within 10 minutes and the costs of one procedure can be substantially reduced. The concept can be applied in various clinical situations: dermatology, gynaecology, interventional radiology, oncology, surgery, etc. and can be mounted on other innovative technologies like robots, stereotactic tables, stereotactic frames etc. for optimal guidance. The technique is **safe** since there is no need for ballistics that cause cell spreading or vacuum that cause bleedings. The Spirotome has an automated version, the Coramate, that operates the needles completely computerized for maximal safety.



Comparison with tru-cut Spirotome set

Skin procedure

Keyboard of the Coramate

The operator has now a third option in the choice of the right biopsy system and can use the same technology for a variety of clinical applications. The patient is the absolute winner since the procedure gives maximal comfort. The laboratory has enough tissue in one piece to make correct diagnoses and to extend diagnostic procedures with molecular biology. The health care system can save on the costs making this procedure available to everybody. The Spirotome concept proves that innovation not necessarily means higher costs and risks but that simplicity remains the cornerstone of good clinical practice.

The Spirotome fills a gap in tissue acquisition through an new concept of fixing the tissue in a helix before cutting. Traditionally the problem of transdermal sampling is to get the soft tissue into the needle before cutting. With the tru-cut systems, widely available, the tissue is captured through speed. Therefore the cutting cannula shoots over the receiving needle. While this technique gets (small – up to 1 mm) samples from cancers, other (normal) tissues like fat are seldom taken up. Cancers starts in normal tissues and very small cancers (below 1 cm) are not always captured. By the shooting of the needles cancer cells may dangerously spread into the neighbouring tissues. The large core biopsy devices (2 to 4 mm diameter) need vacuum to get the tissue into the needle before cutting. This vacuum technology is highly expensive and takes tissue from the side necessitating multiple samples to be taken. The Spirotome makes use of the helix to capture the tissue before cutting. The helix is positioned under radiological guidance to guarantee representativity of the sample. The cutting is done like scissors by rotating the cutting cannula over the sharp edges of the helix. Hereby the core of the sample remains untouched by the procedure. The quality of the stainless steel ensures sharp edges. The manual handling and the possible reuse of the system makes the procedure the least expensive large core method on the market.

Because the Spirotome is an instrument with a completely new design many new applications are now at reach of the clinician that were impossible or hard to perform up until now. With this in mind there is a substantial market to consider with economical advantages that were never obtained before. The aspect of low costs make that an answer is give to the global increase in cancer cases. Developing countries adopt very fast the Western way of life thereby increasing the risk of Western type of cancers. The need for affordable biopsy systems is worldwide. The territory for the commercial requests of the Spirotome is virtually global. Because the Spirotome concept can be used in many clinical departments the commercial interests goes to many specialties of medicine. It is safe to say that the hospital now has a device that can be shared by all departments that regularly perform biopsies. There is an increasing need to have large core biopsies before any treatment is initiated. Large core biopsies are necessary to supply the laboratories of pathology, molecular biology and tissue banks with enough tissue to compose a complete modern diagnosis. The Spirotome has been proven safe and pain free making patients and doctors less afraid of large core biopsy procedures. This will commercially translate in a more frequent use of large core biopsies for patients and indications that now are out of reach.

It is estimated that world-wide some 5 M biopsies are taken yearly with the traditional techniques. The market potential of the Spirotome and related products is considered increasing since increasingly more patients should obtain a (large) core biopsy. MedInvents estimates a market share of 3 per cent in the first 2 years that will increase to 10 per cent and more in the coming years.

The end user of the Spirotome and related products can be divided in 4 groups: the patient, the operator, the pathologist and the health care system.

The patient was the target of the developmental process. An affordable representative biopsy with maximal comfort has been confirmed in the clinical testing of the products. Patients testimonies indicate that the technology decreases fear and pain to minimal levels. The procedure is simple and fast, resulting that it can be done in the office, at the bed side, consultation room reducing the time to wait for an appointment. Altogether, major improvement in patient comfort has been established.

The operator has now the tools to accurately target the diseased site by virtue of a direct and frontal access. The imaging of the helix in the target proofs adequate representativity. This increase in representativity makes less false diagnose and reduces repeated calls for the patient.

The pathologist, molecular biologist, and researchers will obtain more high quality tissue making the diagnosis more precise before any treatment is installed. Since cancer survival relies on accurate diagnosis and treatment, the clinical approach can now be more targeted to the more specified type of malignant disease.

The health care system in each country is under financial pressure. Most innovations increase the financial burden resulting in priority choices in diagnosis and treatment. The Spirotome project creates a substantial decrease of costs despite the increase in quality of care.

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