danumed
MEDIZINTECHNIK

danumed Medizintechnik GmbH
Individual solutions in contract development and production

In contract development and production, danumed Medizintechnik realizes individual customer requests quickly and reliably – from first stage of development to the CE-marked product ready for sale.

- We turn your innovative idea into a marketable product
- We develop products both from the technical and regulatory side
- We coordinate the project and all involved partners
- We deliver medical devices manufactured with guaranteed quality

We do all this with the competence and experience of a manufacturer who brings own products onto the market.

For the company Micropos from Sweden, **danumed Medizintechnik** has provided extensive services in contract development and manufacturing, for the production of an **innovative catheter with integrated transmitter unit**, as shown in the following.
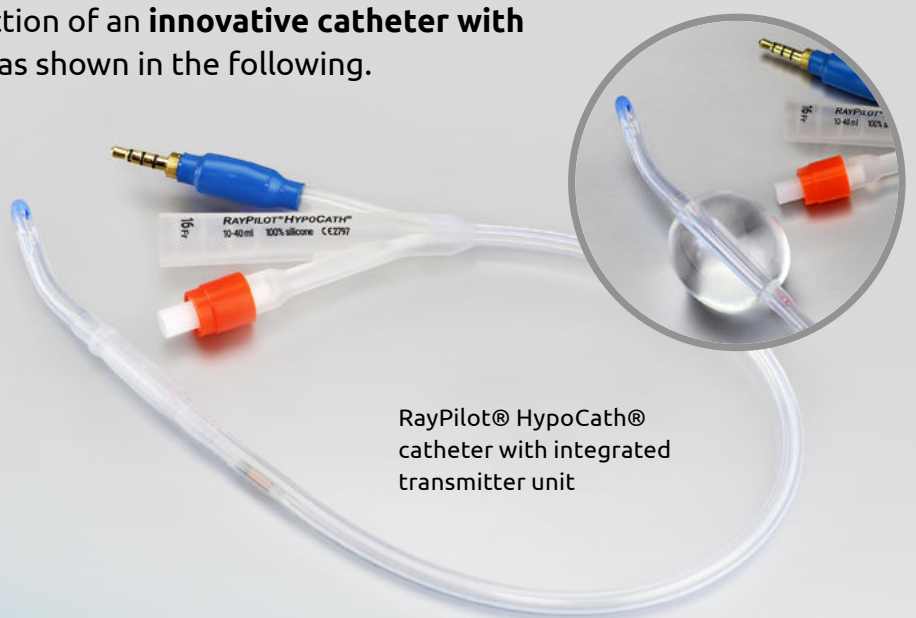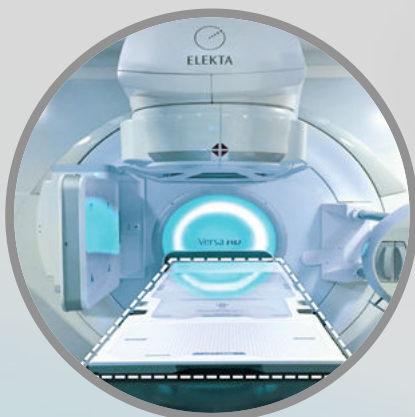
RayPilot® HypoCath® catheter with integrated transmitter unit

The Innovation

Catheter with integrated transmitter unit for easy and high precision prostate tracking – RayPilot® HypoCath® from Micropos Medical, Sweden

Aproximately 3 million men in Europe live with prostate cancer and its common side-effects like impotence, incontinence and rectal bleeding and 450 000 new cases are diagnosed each year.

There are mainly two ways of treating prostate cancer, surgical resection of the prostate and radiotherapy. Due the fact that random and unpredictable prostate motion cannot be detected during the treatment, there is a risk that the radiation will miss the tumor and instead hits the healthy surrounding tissue.

RayPilot HypoCath is an electromagnetic prostate tracking solution to be used during radiotherapy. Increased precision enables higher cure rates, less side effects and a significant shorter period of treatment. Micropos has many years of experience with the RayPilot system, and with the new HypoCath design the tracking solution could be used without surgical intervention.

The RayPilot system consists of three parts:

- RayPilot receiver
- RayPilot software to track and record prostate motion continuously
- RayPilot HypoCath, a Foley catheter with integrated sensor chip (transmitter)

Further information on the product can be found at www.micropos.se.

Our services in this project

Competent and fast contract development and manufacturing of the RayPilot® HypoCath®, from prototypes to CE-marked, ready-to-sell products

Technical Development

- Preparation of the complete specification
- Search and selection of suitable standard components and suitable adaptations
- Definition of all production processes, e.g. insertion of the transmitter into the silicone catheter and sealing of the opening with silicone
- Search and selection of competent and suitable suppliers
- Development and production of prototypes

Regulatory Development

- Comprehensive support for CE marking
- Discussion, definition and implementation of the regulatory strategy
- Organization of the packaging validation and the sterilization validation
- Extensive generation and completion of the technical documentation for the RayPilot HypoCath for submission to the Notified Body, in close cooperation with Micropos, e.g.

- Definition of the structure of the technical documentation (STED file)
- Risk management
- Clinical evaluation
- Validation of packaging and sterilization
- Product testing according to relevant product standards

Project Management

- Coordination of all aspects of the project
- Communication with all parties involved
- Creation of the artwork for product and packaging material
- Preparation of instructions for use with organisation of multilingual content, layout and printing
- Coordination of all packaging and sterilisation aspects with subcontractors
- Organization of sterile packed samples for clinical studies and regulatory purposes

Serial Production

- Transfer of the finished product into serial production
- Coordination of production processes
- Permanent production of CE-marked, sterile packed, marketable products

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INNOVATORS IN ENTERAL CARE