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**Project title:** Systematic process design for the fabrication of nanomodified fiber-based implants for use in ablation therapy (ProNano)

**Partner:** Institute of Applied Medical Engineering, RWTH Aachen University

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**Funding agency:** AiF/IGF

## Mission Statement

Cancer is the second most common cause of death in Germany. The tumor often infiltrates hollow organs, such as trachea, the esophagus or the bile duct, narrowing their lumen. This can lead to a life-threatening situation. If possible, the tumor is removed surgically. However, tumor tissue ingrowth, so-called restenosis, often causes a re-closure of the hollow organ. Currently, conventional metal stents or plastic tubes are applied to widen the occluded hollow organs have the disadvantage that they cannot prevent a re-closure in the long term. The treatment of hollow organ tumors can be achieved by their local overheating, so-called hyperthermia, induced by magnetic actuation of nanomodified hybrid stents. The hybrid stent has then a "self-cleaning" feature.

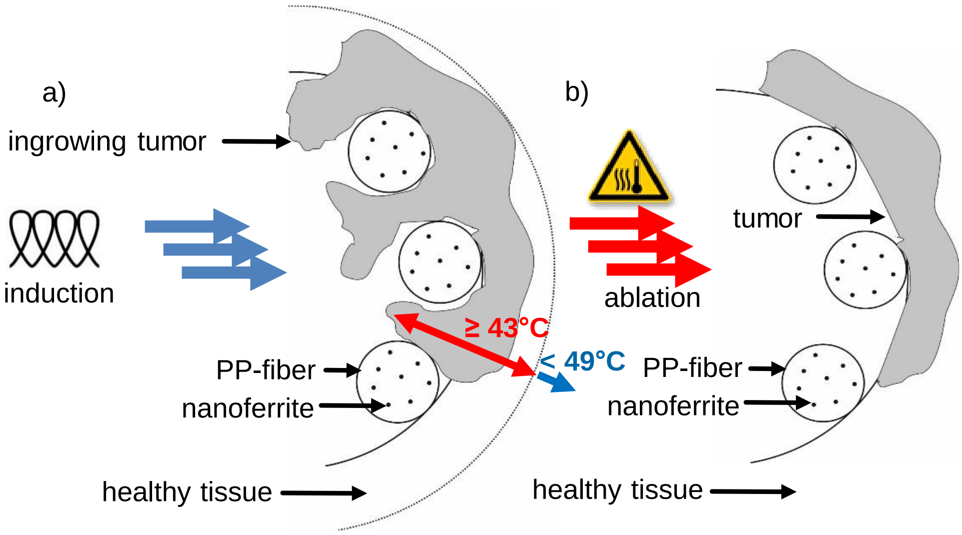


*Figure 1 a) Tumor tissue infiltrates into a hollow organ (e.g. the trachea). By means of magnetic actuation of the hybrid fibers, the tumor is locally overheated and destroyed and b) thus the hollow organ is reopened.*

Irreversible tumor cell damage generally occurs at a temperature of at least 43 °C. The hyperthermia treatment makes use of the fact that tumor tissue reacts more sensitively to higher temperature than healthy normal tissue.

Magnetic hyperthermia is enabled by using a polymer hybrid stent with incorporated magnetic nanoparticles (MNP) which is activated in an alternating magnetic field (AMF) to release therapeutically effective heat in a controlled manner. This heat dissipates into the surroundings, e. g. tumor. Heatable polymer stents with adjustable surface saturation temperature are currently not available in both medical and engineering fields. In this project, a technology for the production of nanomodified fiber-based stents for use as hyperthermia agents and permanent retention in the body was developed. These stents consist of polypropylene (PP) fibers with incorporated iron oxide MNP.
For MNP production, the synthesis route of co-precipitation of iron ions by a base in an aqueous solution was used. By adjusting kinetic factors of the synthesis parameters, it was possible to optimize the properties of the MNP to reach a high heating performance. The MNP properties such as core size, hydrodynamic size, surface charge, composition, magnetic properties and iron concentration were determined.

The MNP were further processed into spinnable compounds. A good distribution of MNP agglomerates of small size (100 - 200 nm) was achieved and analyzed by transmission electron microscopy. A reduced heating efficiency of MNP as a result of the processing compared to immobilized MNP was not observed.
With these compounds, a stable melt spinning process for nanomodified fibers with a nominal MNP concentration of up to 20 wt% at laboratory scale and up to 16 wt% at pilot scale could be established. Winding speeds of up to 1780 m/min were realized. The tensile strength of the nanomodified fibers reached a fineness-related tensile force of approx. 30 cN/tex at a maximum draw ratio of 4.5. In addition to these fibers, which are to be regarded as a platform technology, thicker fibers adapted specifically to the application “hyperthermia stent” were produced.

For both fiber systems, textile-technological processability was demonstrated within the framework of demonstrator production by means of machine circular braiding. Functional demonstrators were also produced for nominal MNP concentrations of 0, 2, 4, 8, 16 and 20 wt%, both as tracheal stents and as bile duct stents. These were characterized in an in vitro test setup (see Figure 2) with regard to their heating efficiency. A therapeutically effective saturation temperature of 43 °C was achieved for specific MNP concentration and magnetic field parameters. A successful manufacturing process of magnetic heatable stents could be established.

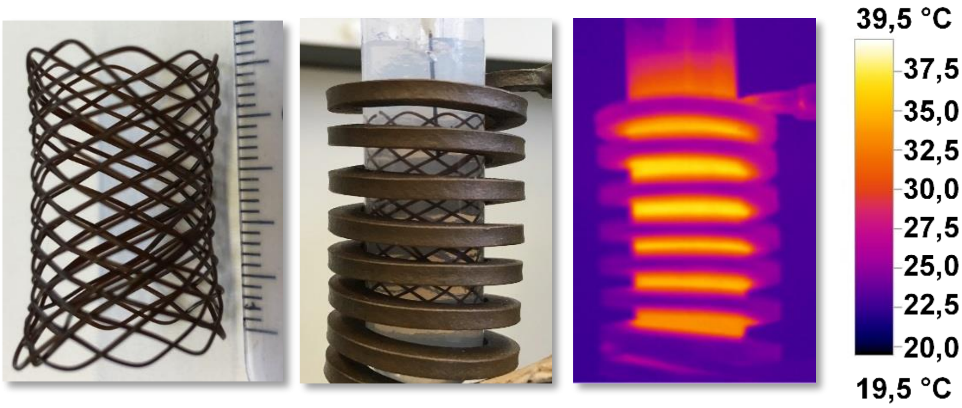


*Figure 2 Left: Nanomodified hyperthermia stent. Center: Stent in agarose gel inside the water-cooled copper coil. Right: IR-camera image of the stent in the test setup during magnetic actuation.*

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