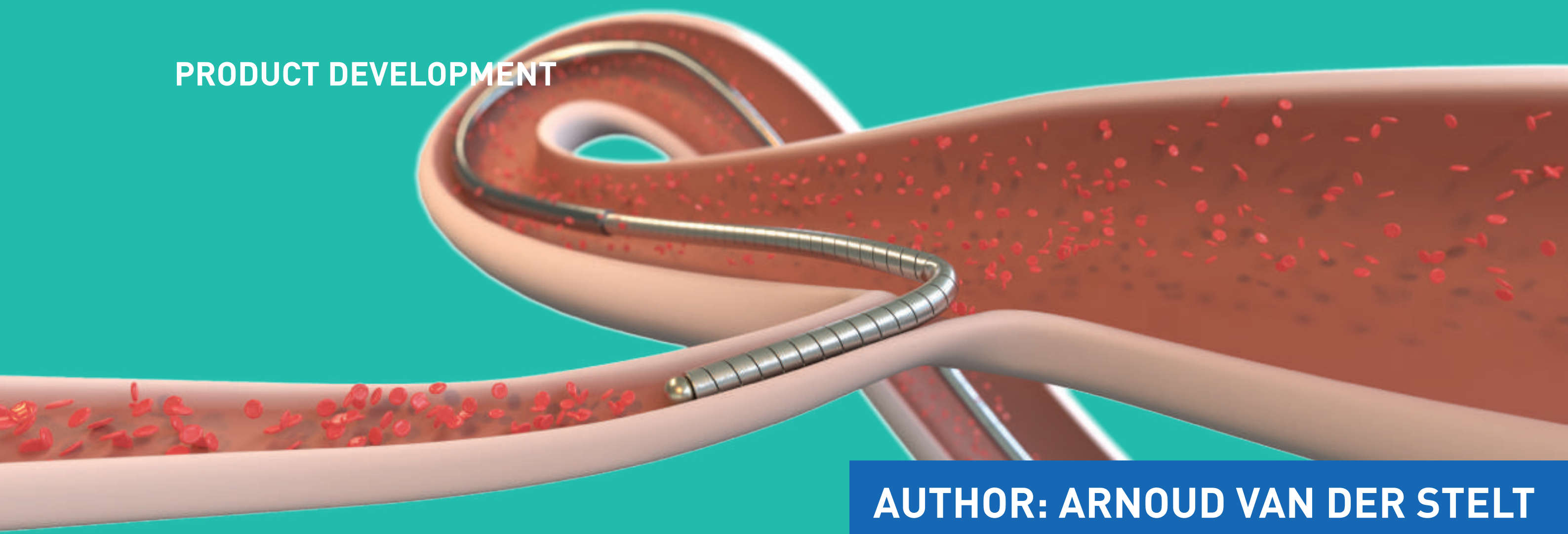
steerable guidewire of 0.33 mm ø.

PRODUCT DEVELOPMENT



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Goal

Memory Metal Holland BV (MMH) introduced a technological solution for creating medical steerable guidewires. The distal end of a guidewire can be shaped mechanically with an actuation mechanism at the other end of the guidewire. Such steerable guidewires will have a major benefit for navigating guidewires through the human body during operation. By shaping the distal end inside the body, it can easier take turns when reaching complex junctions. This behavior has multiple advantages such as better steerability, reduction of the amount of used wires, decrease of operation time and thus saving lives.

Figure 1. Physician looking at a real-time X-ray image to navigate a guidewire through a body.

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The first MMH design required improvement to show its full potential on steerability. The guidewire of initially several centimeters long and a diameter of 0.33 mm had limited shaping capabilities while the tip rotated and bended simultaneously. Moreover, there was insufficient insight on specific behavior of the concept. Demcon multiphysics successfully supported with comprehensive simulations to explain some unknown features of the design. This was the starting point from a fruitful collaboration between Demcon and MMH.

We set our common goal to develop a steerable guidewire of more than 1.5 m length which is capable to shape its distal end by bending and rotating independently from each other, employing a suitable controller.

Approach

Different concepts were proposed in brainstorm sessions to realize a tip which purely bends in-plane or revolves purely around its own axis. Other requirements like safety, costs, ergonomics and biocompatibility were also included in these designs.

Subsequently, most promising concepts were virtually tested with our comprehensive FEM simulations on bending shape, rotation behavior, tip load, support stiffness, force actuation and maximum stresses. Production followed and the designs were experimentally validated. The validation showed that we are capable in using the simulations accurately for virtual prototyping of guidewires.

A similar approach was used for developing the controller, elongation of the guidewire and combining the bending and rotation tip in a fully integrated design.

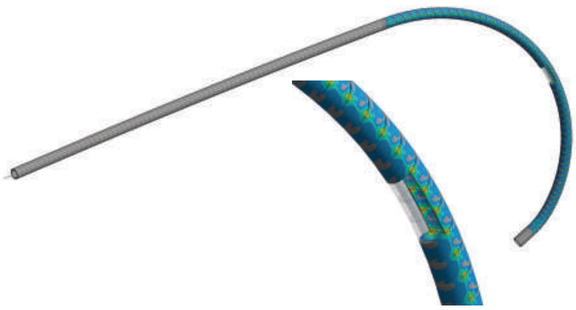

Figure 2. Stress and bending shape predicted by FEM simulations during actuation of the guidewire.

Result

A 1.5 m long variant of a steerable guidewire including a controller was realized and patented. It is a platform ready for engineering further towards a specific medical application, like neurovascular surgery, cardiology, gastroenterology or radiology.

In this way, active endovascular access can be realized, and more lives can be saved.

Relevant patents can be found under:
EP3344323B1, EP3578221A2, US 10,441,746, US 11,241,557, US 2022/0143362, Pending N2032588

www.demcon.com/redwire

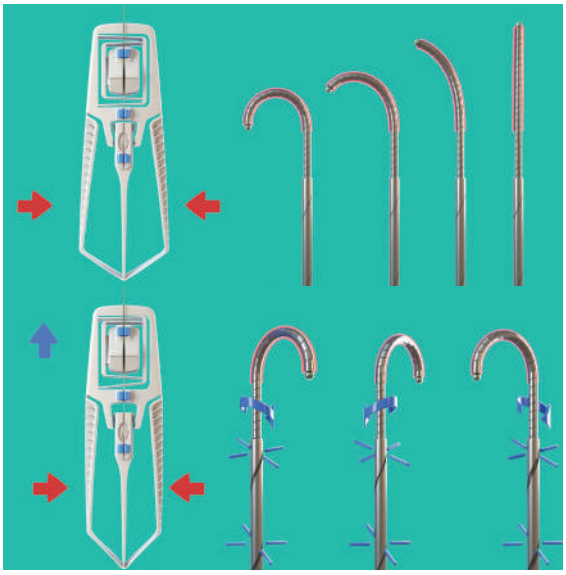

Figure 3. The steerable guidewire with controller. The tip is able to bend and rotate, independently from each other.

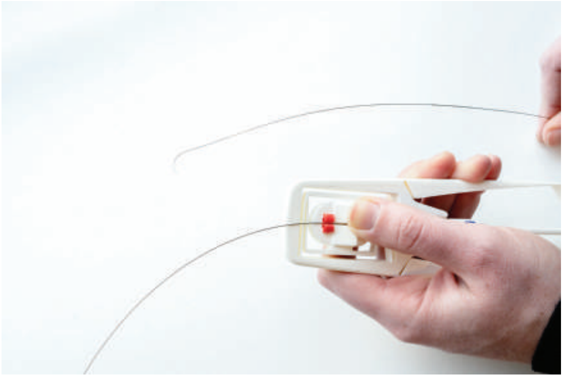

Figure 4. The steerable guidewire with controller.