

RESEARCH ARTICLE

ROSES, the only RObotic System for any Endovascular Surgery, Including the Control of an Animated Catheter Characterized by the Presence of two Controlled Curvatures

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Abstract

The paper presents ROSES, its robotic components, the different devices, not necessarily sterile, and its disposables, suitable for any endovascular procedure, both actually performed and presently not assisted by any robotic system, and open in the future for new application yet to come, such as what will be allowed by the new animated catheter. In fact, this is due to the mechanical configuration of the robotic actuators based on a peculiar gear train which presents a big passage hole which allows both the passage of big catheters and

even hemostasis valves, as well as full control of very small catheters and guide wires. The system measures forces opposed by the body showing their value both numerically and analogically without the need of any special tool, measures length of penetration of each catheter and guide wires recording their value. Thus, it may become in future, connected to a workstation that will register in real time also the fluoroscopic images, a kind of black box of endovascular surgeries, separating completely doctor and nurses from the patient, using also cameras and microphones to replace the physical contact with the patient.

Key Words: *Robotic endovascular surgery; Application to any procedure heart, brain, legs; Initial catheter; Measure of the forces opposed by the body without accessories; Measure of depth of penetration; Black box of endovascular surgery*

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Introduction

Least Invasive Surgery such as laparoscopy, orthopedic or spine surgery [1-5] enormously helps patients reducing risks of a surgery, while speeding their recovery, thus reducing overall costs. Robots in this field [6-10] play a major role almost in every sector, but strangely enough non jet on endovascular Surgery. This is due to a series of problems, such as high price, limited number of robots available, often designed for only one application, like CorPath by Corindus [11-16] and by Robocath [17] for angioplasty, and Magellan by Hansen Medical [18-21] for endovascular surgery. On the other hand, the progress of the fluoroscopic systems, that have considerably reduced the intensity of radiation even improving images have partially reduced ionization risks, which are in any event present [22-28]. Also, the special aprons cover almost completely the doctor's body, but for the hands, they are very heavy and cause spine problems [29-31]. On the other hand, the doctors feel that they can do a much better job acting directly on the catheters, forgetting that robotic systems like ours, measure quantitatively the forces opposed and can register the length of advancement that they cannot evaluate, even allowing them to measure the length of a stenosis before picking up the right stent. As a consequence of this, their diffusion is still low, as reported by Fichtinger *et al.* [32] in a very interesting paper. Another paper, reference [33], observes that almost all these robots are of the master-slave-type systems and are unable to conduct autonomous work. This is definitely true, but even a bright slave can supply information that the operator cannot deduce by his hand's motion, if not in a very approximate way. Our system is already ready to provide this information. Moreover, now the idea of working in the brain to remove thrombus or stop aneurysms certainly requires high ionized radiation, which is unbearable

without the use of a system that separates doctors and patients. Moreover, CorPath and Robocath are characterized by disposables that are large in size and even contain the motors to command catheter and guide wire motion, plus the force sensor if required. Our disposables instead are simple mechanical devices, while motors are in the robotic actuator and there is only one sensor in fixed position that collects all information. Our system has been described in four previous articles [34-37], but this is full of new things, since many derive from the last PCT [38] recently presented.

Brief description of our Robotic Actuators (RA)

The base of the robotic actuators is a gear train composed of a main gear that together with a second disk fixed to it forms the rotating frame that holds in between one or two hollow gears with internal tothing being all separated by ball bearings that keep the train aligned. Planets meshing with the internal tothing of the hollow gear are fixed on shafts that exit from the main gear or the associated rotating disk surmounted by bevel gears or faceted shafts to transmit motion. The train is also kept in position by three shafts placed at 120° holding external idle gears that participate in stabilizing the system. An external motor for each gear of the train transmits the required motion through a combination of bevel and spur gears. Clearly when the main gear rotates, if one wants the secondary shafts to maintain the position, all gears must rotate at the same speed. If the main gear is stopped, then the motion of the secondary shafts is free, while if the main gear moves, to give commands to the secondary gears it is necessary to algebraically add or subtract the motion required from that of the main gear. From this base, RA with two, three, five and six motors are generated, piling up two gear trains for RA5 and RA6.

The shafts coming out of the system are then used to drive the disposables, which are inserted into the central sterile passage, 36 mm wide. In one case a special two motor RA presents the disposable inside the gear train to save space, and this is used as proximal RA. Figure 1 shows a robotic actuator seen from the top, with the final disk and the second gear train eliminated in order to show the internal mechanisms of the first gear train. All this is protected by various patent applications, quoting a PCT for all other applications [39].

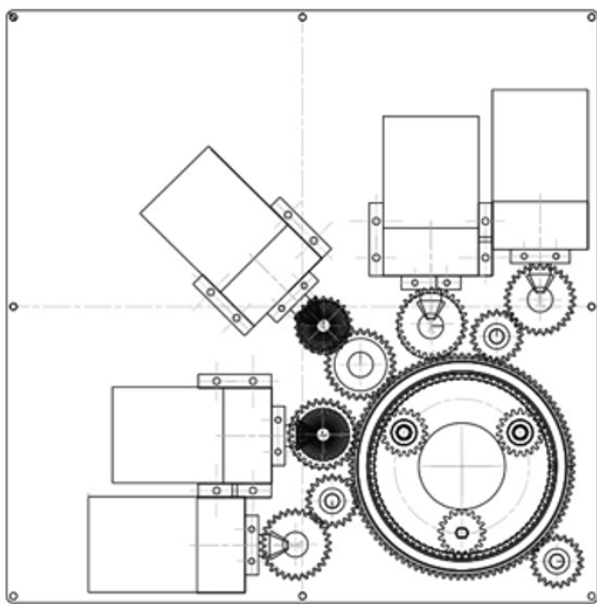


Figure 1) View from the top of the base of the RA.

The Robotic Cart with Force Measuring System

The Robotic Cart (RC) bearing the force measuring system is basically a bar, inclined toward the patient, surmounted by a rail on which three or four slides hold a RA each for the first two or three slides, while the last holds the motors that, through a worm gear, move the second or third RA, while the first is fixed, by a lateral bar, to the motors. The slide supporting the motors is then connected with a wire to the force measuring system that, being the bar slightly inclined toward the patient, feels the g component of whatever is placed on the rail. Consequently, if something moves inside a RA

or between the various RA, the g component is constant. This can change as a reduction only if something external opposed the advancement of what is coming out of the system, that is to say, that this system feels the forces opposed by the patient body to catheter penetration. Figure 2 shows a sketch of the system. We will discuss later on how it works when we talk about programs. This is protected by an Italian patent obtained and a European patent application [40,41].

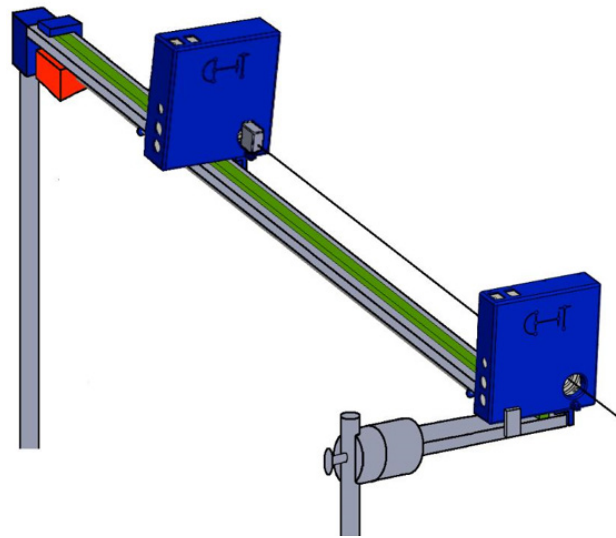


Figure 2) The Robotic Cart with two RA, one motor (red) and at the end the force sensor (box also in blue).

The Disposable for Standard Catheters and Guide Wires

The first disposable designed for the new RA was in reality designed to develop ROSINA (Robotic System for Intubation) [42], work performed during the COVID period to separate doctors from patients during intubation. But it was late since the anti-COVID suits did a very good job. Nevertheless, this effort paid in giving us the lines to follow in the development of all disposables. Remembering that up to that moment we were working with an RA having a sterile passage of only 7 mm in diameter, the angioplasty disposables were much thinner and thus flexible, and this would cause, if the torque to be transmitted to the disposable exceeded a certain value, teeth jump with disturbing noise.

Moreover, we understood that in order to be able in future to position a catheter for TAVI, which had been requested by Prof. Massetti, it was necessary to remove the initial catheter leaving in place the guide wire, while the passage through the RA had to be sterile, and only way to do this was to divide the disposable in an upper and a lower portion that could be eliminated without the need to eliminate what was present in the RA passage. Finally, we ended up with a much stronger disposable of the same length as the previous, but wider and with teeth that would eliminate lateral deformation, canceling teeth jump. The difference between disposables for guide wires and catheters lies only in the position of the bevel gear (left for catheters, right for guide-wire) and in the shape of the friction wheels. Figure 3 shows an image of the disposable for big size catheters, bearing a screw on the top to control pressure, while for normal size catheters, from 4 to 10 French, two springs allow automatic adjustment.



Figure 3) *The first edition of a disposable for big catheter, from which all the others derive.*

The Disposable for Angioplasty

In this case, the bevel gears are present on both sides, and the disposable is completely different on the two sides, where on the left side there are four friction wheels, the lower ones rotating of the same amount thanks to an idle gear meshing with two spur gears placed between the bevel gear and the friction wheel on the motorized shaft, and laterally with respect to the friction wheel but aligned with the other spur gears,

both surmounted by two small friction wheels, free to rotate. On the wire side, a friction wheel identical to the catheter side is motorized, while two more friction wheels are positioned to contact a big radius friction wheel placed on the cover, in order to force the wire to describe a kind of double curvature, in order to transmit torque to the thin wire used as guide-wire in angioplasty. Figure 4 shows a picture of the disposable CAD model where the side wall is transparent to show the inner mechanisms.

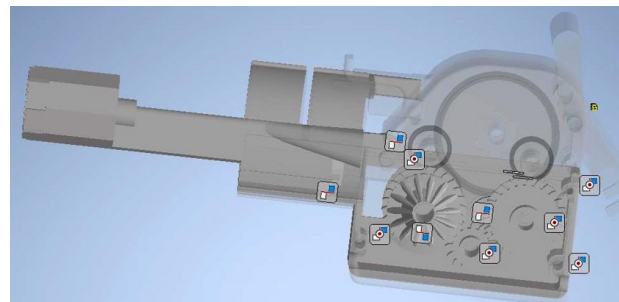


Figure 4) *Angioplasty disposable*

The Special Rotating Hemostasis Valve

Reasoning with Prof. De Rosa, we understood that since in the previous model of angioplasty disposable we had sometimes problems with the rotation of the guide wire, that seemed slow and somehow impeded in turning about its axis, we had to find a remedy. In fact, since both catheter and guide-wire were mounted on the same disposable, at the end of which they would enter the hemostasis valve, being in angioplasty the guide internal to the catheter only for a few centimeters near the catheter tip, then almost always in our system catheter and guide wire had separate access into the valve. This is caused when rotating the disposable, being the valve fixed, the wire would wrap around the catheter in the short region between friction wheels and the valve. Thus, the idea came to use a valve that could rotate with the disposable, which is presented in Figure 5. Note that there

is a change with respect to previously published work, since this valve, whose inner portion is common to other producers, can be adjusted in the friction as opposed to the advancement of guides and catheters, by rotating an element that approaches the fixed tube inside the valve to the silicon valve turning on an inner threaded portion. Since this could also turn when the disposable turns, then a locking slider has been added to the valve, to keep the desired friction opposed by the valve. This element is indicated by an arrow.

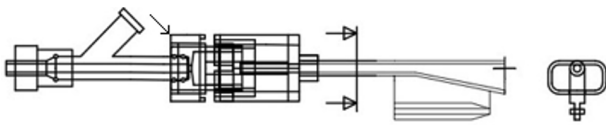


Figure 5) *The new rotating hemostasis valve.*

To hold this in position there are two different supports, one fixed for a RA with only three motors, that requires the first catheter to be inserted manually, and a second fixed to the rotating frame of a second gear train, thus using a RA5 in distal position with a RA2 in proximal, which allows also to guide from console the introduction of the first catheter. In both cases a kind of cap blocks the final component of the hemostasis valve. Figure 6 presents the valve support and relative cap in the rotating edition.

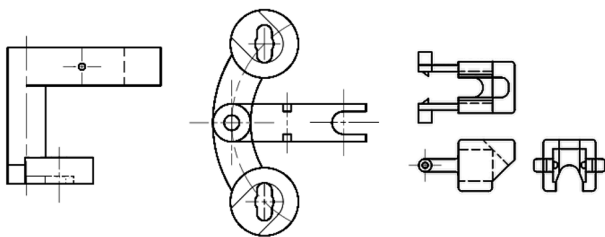


Figure 6) *The rotating support for the hemostasis valve and its closing cap.*

The Disposable for Guide Wires with a Movable Core

Since at the beginning our animated catheters

would not be immediately registered, since catheters have a longer approval path with respect to electromechanical devices that never enter in contact with the human body, we figured that it was better to develop disposables for guide wires with movable core of the two types currently in use, the one that allows the core to move freely inside the wire, and the second with the core fixed at the tip, using again both bevel gears coming out of the main gear of the RA. Naturally, this implies that in this case first we need to use joysticks bearing three analog controls, secondly, the three controls of the joystick dedicated to the guide wire must control the three motors of the gear train.

Starting with the first one, the idea is to place on the right the usual pair of friction wheels, while on the left we will use a big external wheel around which the core will be wrapped, surrounding this big external wheel with a cover delimiting a toroidal passage in which the core will be hosted. Naturally, this rather big wheel must not interfere with the bevel gear, that will transmit motion to it. Thus, the guide wire must pass first on the right side, then its tail introduced in a small hole aligned with the toroidal cavity. The big wheel will present an empty short sector from which a hole inclined and in which a threaded insert is present to block the tip of the wire tail. To force the wire tip entering this cavity a small mechanism kept in position by a spring (missing in the image), is to be pushed to bend the tip the right amount. Finally, another threaded insert allows blocking the body of the wire. Similarly in the case of the core fixed to the tip this time no external wheel, but a rack that is moved by two gears, with an idle gear in between. This is shown in Figures 7 and 8.

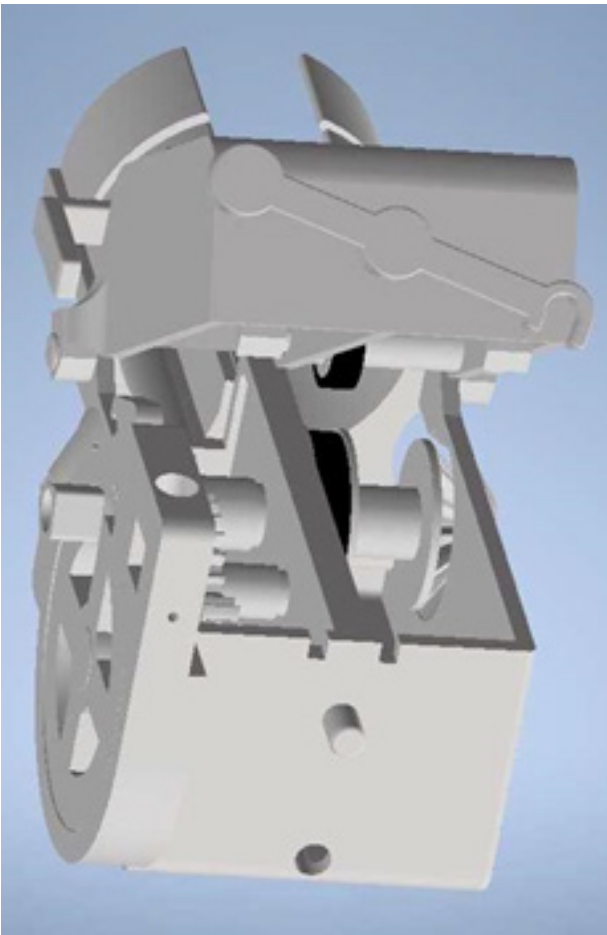


Figure 7) The CAD model.

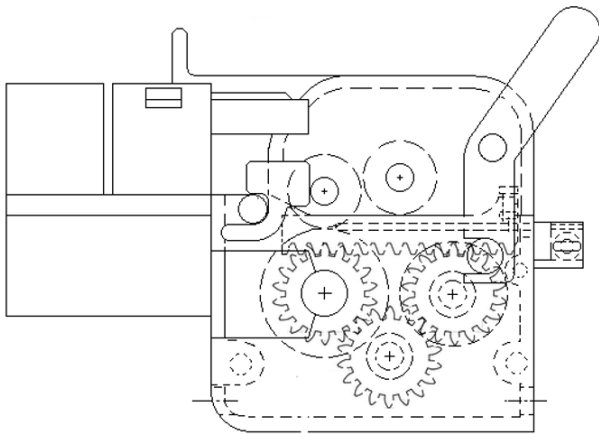


Figure 8) CAD model not available as image, but already finished.

The Device to Control Motion of the Animated Catheters

Before starting to describe this device, let's first present the new five lumen catheter (Figure 9), of which four are very small, about 1,5 French, and close in pairs on opposite sides with respect to the bigger central lumen. Two different series of wedge-shaped cuts are produced on

one side only near the tip in correspondence of one of the pairs of small lumens, while in a different position are present wedge-shaped cuts on both sides, in order to bend the catheter in two directions. Wires are present inside the small lumens, two fixed near the tip placed on opposite sides with respect to the central one, while the other two are fixed at the beginning of the series of symmetrical wedge cuts. As a consequence, this catheter may assume different shapes as shown for example in Figure 10.

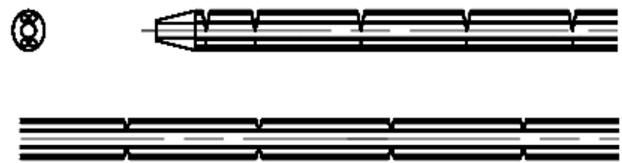


Figure 9) Cross section, tip and central portion configuration of possible cuts.

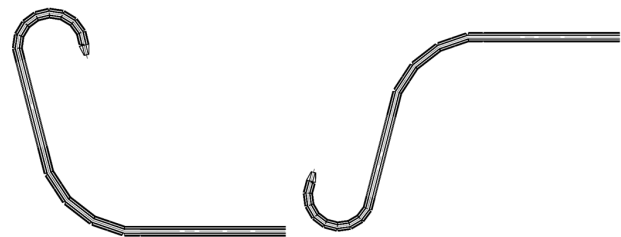


Figure 10) Few examples of possible shapes assumed by the animated catheter.

Before passing to describe the controlling mechanism of this catheter, we should alert that this mechanism requires the use of an RA with six motors since it needs two complete gear trains each with three gears, the first three for the disposables, the second to follow rotation as requested by the operator, while catheter advancement is produced by the 2 motors proximal RA with internal disposable, synchronized with the advancement of the RA6 produced by the RC. Thus, there will be two shafts with faceted ends exiting from the rotating frame of the second-gear train. On these shafts two longer shafts are connected, bringing the command to the catheter connector, which contains two very small drums on which

the wires inside the small lumens are wrapped, leaving a minimum slack between the two cables to compensate for catheter configuration changes. Finally, the transmission of the rotations to the drums is obtained with two pairs of bevel gears. This is presented in Figure 11.

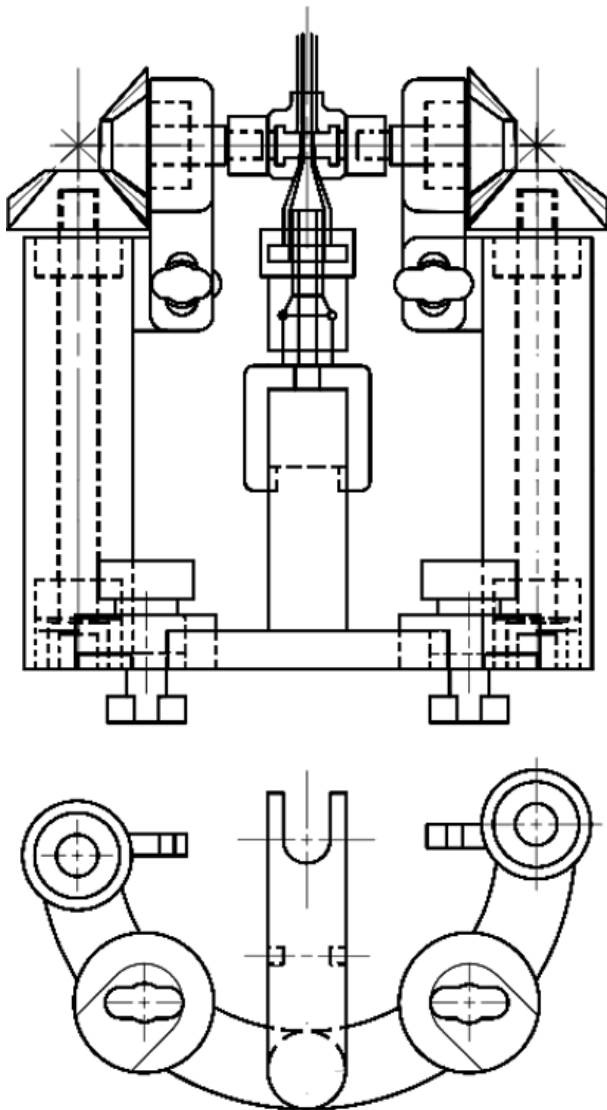


Figure 11) *The controlling mechanism of the two degrees of freedom animated catheter.*

The Hardware Configuration and Software Programs

The hardware configuration is very simple, basically only commercial microcontrollers boards are used adding specially designed interface boards of our design, of only three types, one for the console, one for each group of three motors, so that for instance RA5 and RA6

have two of these boards with its microcontroller, and a third board commands the two possible motors of the RC while continuously reading the force sensor output. Each microcontroller has a name that identifies the type of RA on which it is mounted, and all transmit via cable using advanced standard protocols.

But the real problem is the software, which not only must give the right commands to each motor, as it has been said considering the possible rotation of the entire gear train, but different programs are needed depending on the task to be performed. For instance, for the introduction of the first catheter, the left joystick will command advancement and rotation of the catheter, but while rotations will be transmitted to the RA2 and to the second train of RA5, advancements to RA2 and to the RC. With the right joystick as usual rotation and advancement will be commanded as usual, while the core motion will be commanded rotating the button on top of the joy, actuating the motor that in angioplasty commands the advancement of catheters. Once reached the position, RA2, RC and the second stage of RA5 will be stopped, while the left joy will command catheter advancement on this first train of RA5, while the right will command advancement of the guide wire and the rotation of the disposable, that is to say of both plus the hemostasis valve.

Another example may be commanding the positioning of a TAVI using our two degrees of animation catheter. Catheter mounted on RA6 with the previously described device, more or less standard guide wire mounted on a suitable disposable, eventually adapted if there is some maneuver to accomplish once positioned to make it rigid, but if this is needed our disposable for movable core will do it. Naturally the joysticks will bear four linear

controls each in this case, which is simple to do. Then as before advancement of the catheter controlled on RA2 and RC, rotation RA2 and RA6 second stage, shape control RA6 second stage. Once the position is reached and also the guide wire is in position, the RC pulls back the catheter while advancing the guide wire that must stay in position. Once the catheter is out of the patient, the guide il blocked with a clamp fixed in front of RA2, then the disposable for the guide wire and the mechanism to command the animated catheter are eliminated, and the catheter eliminated detaching the bevel gears from the connector so that everything passes through the sterile hole, and the TAVI catheter inserted in the tail of the guide, and driven into the patient by RA2, eventually changing the upper component. Once the TAVI catheter has reached the right position, we can activate the TAVI, and pull the TAVI catheter and guide-wire once their job is finished.

Discussion

At this point it should be clear that ROSES is the only system able to separate the patient from the doctor during the entire process, since it is also able to guide the initial catheter, passing immediately after to any endovascular procedure, for which it is required only to select the right program and disposables, which should be a great advantage.

Remember also that thanks to the possibility of recording lengths of penetration and forces opposed in every moment of the procedure, by adding a workstation and registering in real-time data from the console and images we will end up building the first black box of the endovascular surgeries. This is a great advantage for safety reasons.

Conclusion

Presently we are working in the preparation of all devices and documents for the initial registration phase, and soon we will start working with the doctors to simulate each surgery using model of the human vessels, some printed from CAT data on transparent plastic. Then we will start once obtained the permission the patient trials in several different hospitals, in Italy, Europe, and hopefully USA and Canada. Certainly, we are aware that we should also try to find systems to remotely control radio-opaque liquid injection as well as pumps to inflate balloons, but some of these should be already available, and in case we will study remote control for these.

But we are also ready to develop new disposables for new procedures, such as ablation, and our system will also allow entering the skull with catheters and guide-wires, which is only possible if the control is fully remote.

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