Rotarex™ S

Rotational Atherothrombectomy System

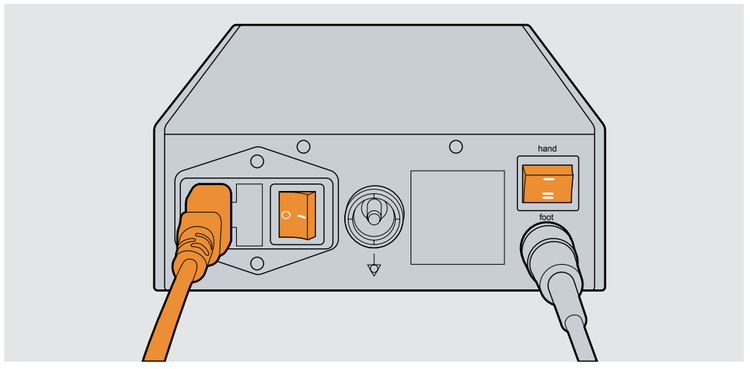
Step-by-Step Guide

Capital Equipment Components

- Drive System (see IFU)
- Catheter Handle/Motor (see IFU)
- Foot-Switch (optional use)
- Power Cord
- Manual

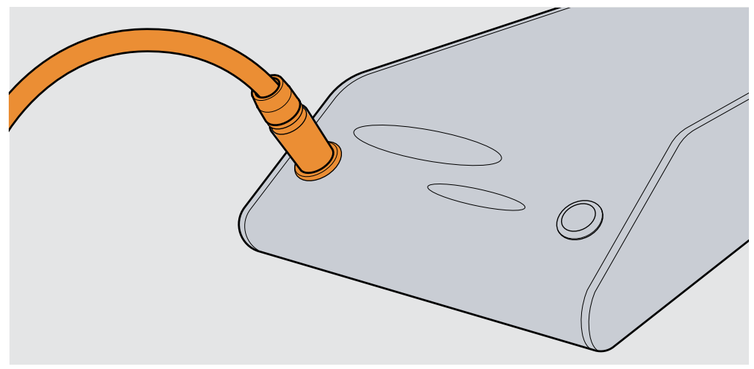
Disposable Kit Components

- Rotarex™ S Catheter
- Collecting Bag
- Guidewire
- Sterile Drape
- Instructions for Use (IFU)



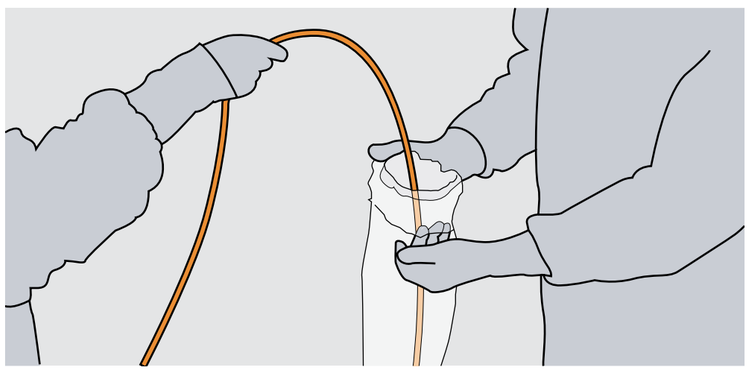
1. Connect Power Cord

Power-switch has to be in the “off” position <0> until the procedure starts. Connect power cord and optional foot-switch, if desired. Choose <hand> or <foot> operation mode as appropriate.



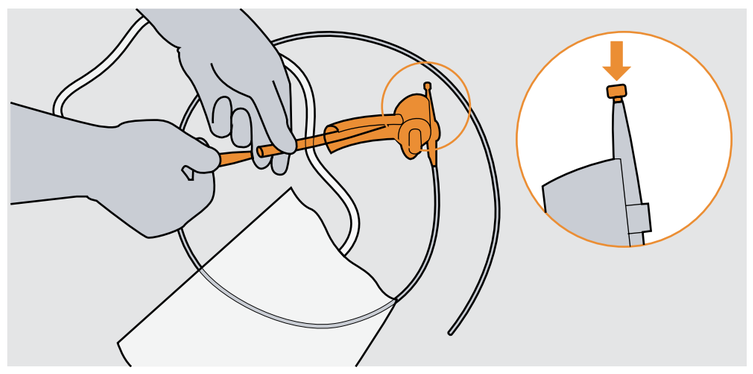
2. Connect Motor to Drive System

Connect the cable from the Motor to the socket of the Drive System, making sure that the red dots (on cable plug and Drive System socket) are aligned



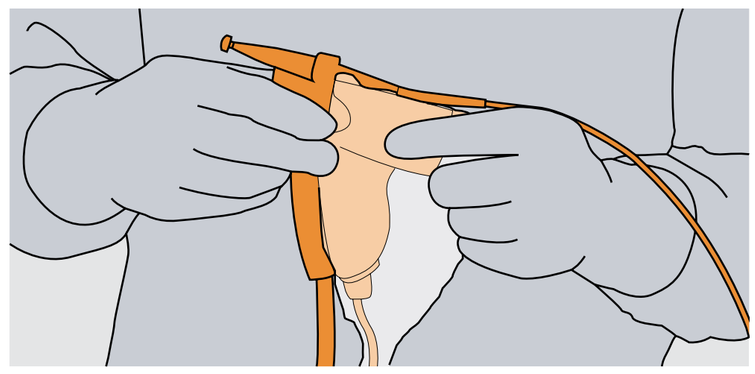
3. Drape Motor & Drive System

Using sterile technique, cover the Motor with the sterile drape and pull over the whole length of the cable. Fix the drape with the adhesive tape on top of the Drive System. Tighten the drape over the Motor housing and wrap the adhesive tape around the cable.



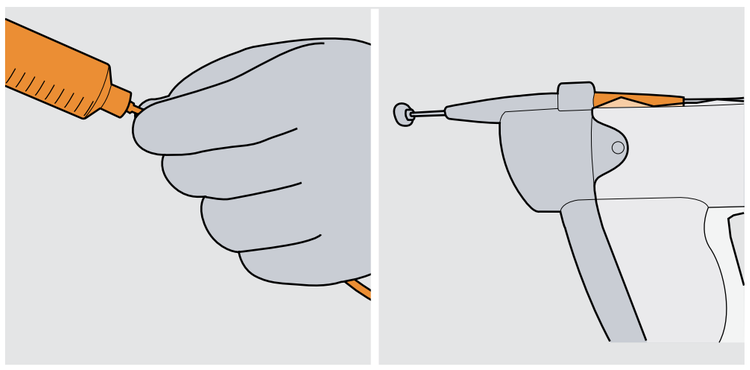
4. Remove Catheter from Packaging & Connect Collecting Bag

Take the catheter out of the sterile packaging. **Note:** *Use both hands to prevent the coiled catheter from unwinding.* Connect the collecting bag to the tube coming out of the catheter housing and press the wire adapter in.



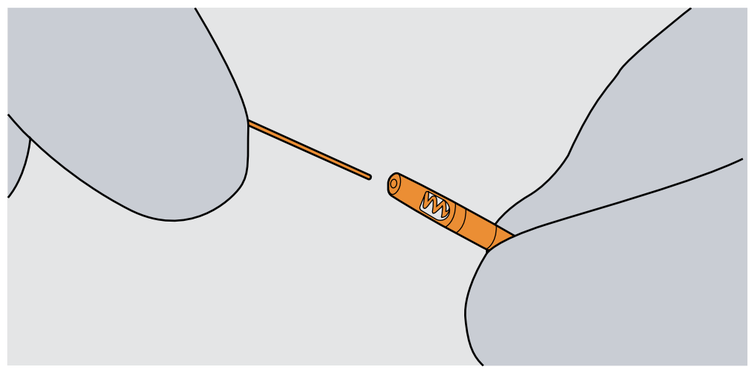
5. Press Catheter onto Motor

Press the catheter onto the Motor. Lateral plates must click into the corresponding structure of the motor housing. Make sure that the catheter locks firmly into position.



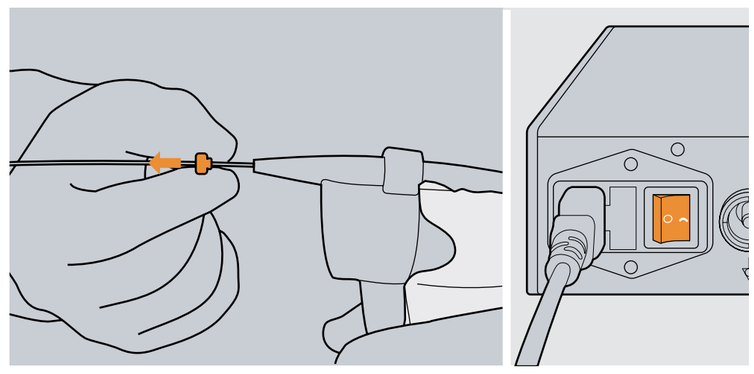
6. Flush Catheter

Flush the catheter lumen completely with a heparinized saline solution by covering the two side windows of the catheter head with your thumb and index finger to avoid liquid spilling out. Ensure the window of the Motor is filled with saline.



7. Insert Guidewire

Insert the guidewire provided into the distal end of the catheter. Push the wire through until it exits the adaptor at the proximal end. Slide the catheter over the wire, through the sheath and into the blood vessel; advancing until the catheter head lies 1 cm proximal to the target occlusion.



8. Close Wire Adapter & Turn on Drive System

Close the wire adapter by pulling it back. Switch on the Drive System (power switch in position “on” (<I>)) and start procedure according to catheter IFU and Drive System Manual.

Rotarex™ S Catheters

Size	Length (cm)	Product Codes	Max Rotational Speed	Max Aspiration Rate	Designed for the treatment of these vessel diameters:
6F	110	80219	60,000 RPM	45 ml/min	3-5 mm
	135	80202			
8F	85	80223	40,000 RPM	75 ml/min	5-8 mm
	110	80224			
10F	85	80277	40,000 RPM	130 ml/min	7-12 mm

Set includes catheter, guidewire, sterile drape, and collecting bag

Rotarex™ S Guidewires

Diameter (in.)	Length (cm)	Flexible Tip (mm)	Hydrophilic Coating (cm)	Product Codes
0.018	220	40	9.5	80270
	270	40	9.5	80271
	320	40	9.5	80272
0.025	220	60	8.5	80304
	270	60	8.5	80305

Drive System

Description	REF Number
Drive System	80300

Rotarex™ S Catheters

Indications for Use: Rotarex™ S catheters in combination with the Straub Medical Drive System (REF SRS-Set/80300) are intended for the percutaneous transluminal removal of thrombotic, thromboembolic and atherothrombotic material from fresh, subacute and chronic occlusions of blood vessels outside the cardiopulmonary, coronary and cerebral circulations; Indicated for: Native blood vessels or vessels fitted with stents, stent grafts or native or artificial bypasses outside the cardiopulmonary, coronary and cerebral circulations.

Contraindications: Patients not suitable for thrombectomy. Vessels of the cardiopulmonary, coronary or cerebral circulations; undersized or oversized vessel diameters; subintimal position of the guidewire – even if only in short segments; use in stents, stent grafts, or vena cava filters if the guidewire has become threaded at any point in the wire mesh / construction of stent, stent graft or the lining of the stent graft; if the introducer sheath, the guide catheter, the guidewire or the Rotarex™S catheter sustains any damage, especially kinking; in the fracture areas of broken stents; if used inside or via narrow vessel radii or in tortuous vessel courses (radius of curvature <2 cm); in severely calcified vessel segments; in aneurysmatically altered vessel segments; in veins; if it is impossible to achieve sufficient anticoagulation and platelet aggregation inhibition.

Warning: Before using the Straub Endovascular System and its components, the user must be entirely familiar with the user manuals of the Straub Medical Drive System and Straub rotational catheters; Only use sheaths that are highly resistant to kinking. If used incorrectly, Rotarex™ S catheters and/or the guidewire used can cause vessel perforation. Insert and operate the catheter over the supplied guidewire of the appropriate length only. During the procedure, unforeseen complications of technical or medical origin may make it necessary to carry out unplanned, emergency additional measures, such as, but not limited to, administration of thrombolytic agents or surgical intervention; The products are for single use and must not be resterilized; Do not use the products after the expiration date; Appropriate testing of the patient’s coagulation status is mandatory. Rotarex™ S catheters may only be used in the indicated diameters of target vessels. The catheter must always be guided via the guidewire, which has been correctly positioned according to the instructions for use. Make sure that the flexible tip of the guidewire is placed as distal as possible to the occluded segment to prevent the flexible tip from being aspirated into the catheter head. The guidewire must lie inside the lumen throughout its course from the introducing sheath to its flexible tip. Do not use the catheter if the guidewire has become threaded in the wire mesh of stent or stent graft or the lining of the stent graft. Do not operate the catheter in the fracture areas of broken stents or stent grafts, despite correct positioning of the guidewire. Monitor the correct position of the guidewire throughout the entire process of catheter use. The catheter must never be kinked at any stage. At no point should the catheter ever be exposed to pressure that is sufficient to compress the tube so that it is pressed against the rotating helix. The catheter lumen must be filled with liquid (heparinised isotonic saline or blood) at all times throughout catheter use in the patient. If resistance is experienced, pull the catheter back a little way into the open(ed) segment with the motor continuing to run so that the ablated material can be processed and carried away. Advancing the catheter too quickly increases the risk of this advancement mobilising more material than can be aspirated and carried away, which can cause distal embolization; Manoeuvring the catheter through areas with very hard, especially heavily calcified plaques, requires special care. .

Cautions: The internal lumen of the introducer sheath must at least correspond to the external diameter of the catheter. At all times monitor the quantity of blood transported into the collecting bag. Effective anticoagulants at a suitable dose have to be administered before the patient is treated with the Straub Endovascular System in order to achieve an activated clotting time (ACT) >250 seconds or equivalent values according to other measuring techniques, throughout use of the catheter. If used correctly, embolizations caused by material detached by the catheter head are very rare. Ensure that the catheter lumen is completely filled with solution when the motor is running. The wire adapter must be in the working position (knob pulled out) during use of the catheter; If there is unlikely to be enough natural flow of blood to the catheter head, the supply of liquid to the catheter head can be guaranteed by providing additional appropriate liquid, such as isotonic saline, via a suitable access, such as the side-port of the introducer sheath being used. If the LEDs go out or the alarm is audible, safe functioning of the catheter is no longer guaranteed. If the activated motor is not kept at the same height as the introducer sheath, or if the section of the catheter located outside the patient’s body is not completely straightened at all times, or if the outlet tube does not run vertically and completely stretched from the catheter into the collecting bag, technical problems such as blockage of the catheter, helix fracture or guidewire fracture may occur; Blood and thrombus fragments in the catheter lumen might clot if the helix has stopped. Therefore, if catheter use is interrupted, the catheter must be rinsed immediately in heparinised isotonic saline.

Precautions: The catheter sets do not contain any parts that need to be maintained or serviced by the end-user. Do not repair or change the configuration of the product. An annual service is recommended for the Straub Medical Drive System (see Straub Medical Drive System user manual)..

Potential Adverse Effects: Embolisms, especially distal thromboembolisms; pulmonary embolisms of all degrees of severity; thromboses, especially recurrent thromboses; re-occlusion; vessel wall injury or valve damage; vessel dissection/perforation/rupture; perforation as a result of mural calcium being torn out of the vessel wall; arteriovenous fistula/pseudo-aneurysm; haematoma, bleeding, haemorrhage; organ perforation; implants such as stents/stent grafts/bypass grafts getting damaged, caught or dislodged; disruption of the catheter and/or guidewire: debris remaining in the body; allergic reactions to catheter material; death; infections or necrosis at the puncture site; allergic reactions; catheter-induced sepsis.

Please consult product labels and instructions for use for all indications, contraindications, hazards, warnings and precautions.

DISCLAIMER: This list is intended to facilitate scientific research on rotational catheter use only. Straub Medical AG assumes no liability for the completeness of this list. The use made of Straub Medical’s products and the indications Straub Medical’s products were used for in the publications of this list might deviate from the intended use and the indication authorized by Straub Medical AG. This list does not constitute and endorsement, approval or acceptance of any use made of Straub Medical’s products and the indications Straub Medical’s products were used for in the publications. This list does not constitute and advertisement or invitation to use Straub Medical’s products

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