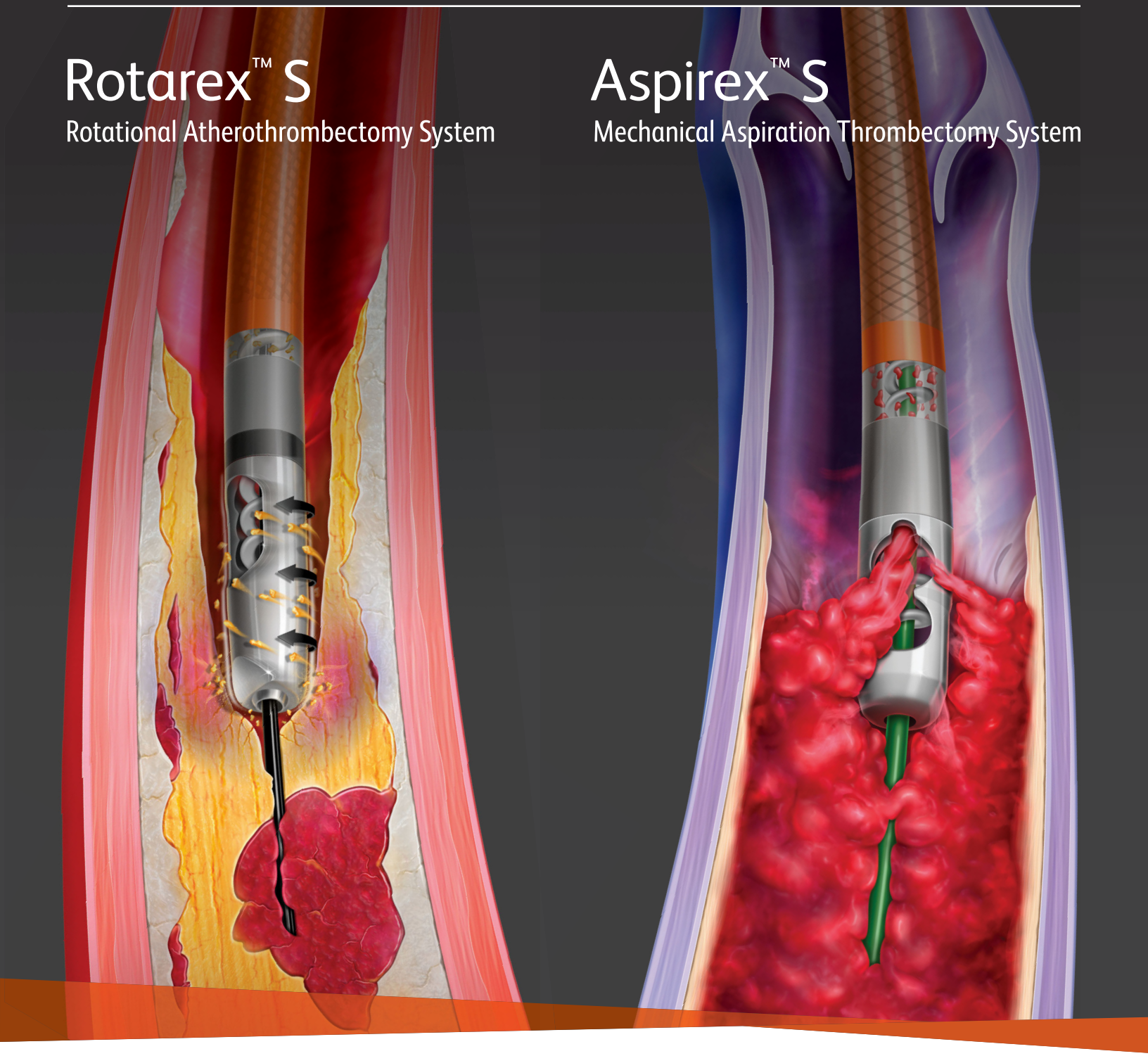
Effective Debulking in Occluded Arteries & Veins

Rotarex™ S

Rotational Atherothrombectomy System

Aspirex™ S

Mechanical Aspiration Thrombectomy System



BD

The Atherothrombectomy System For Occluded Arteries

One Device for Multiple Indications

1 **Efficient debulking for acute to chronic arterial occlusions**

- Native vessels
- Stents (in-stent reocclusion)
- Native and artificial bypasses
- Dialysis access

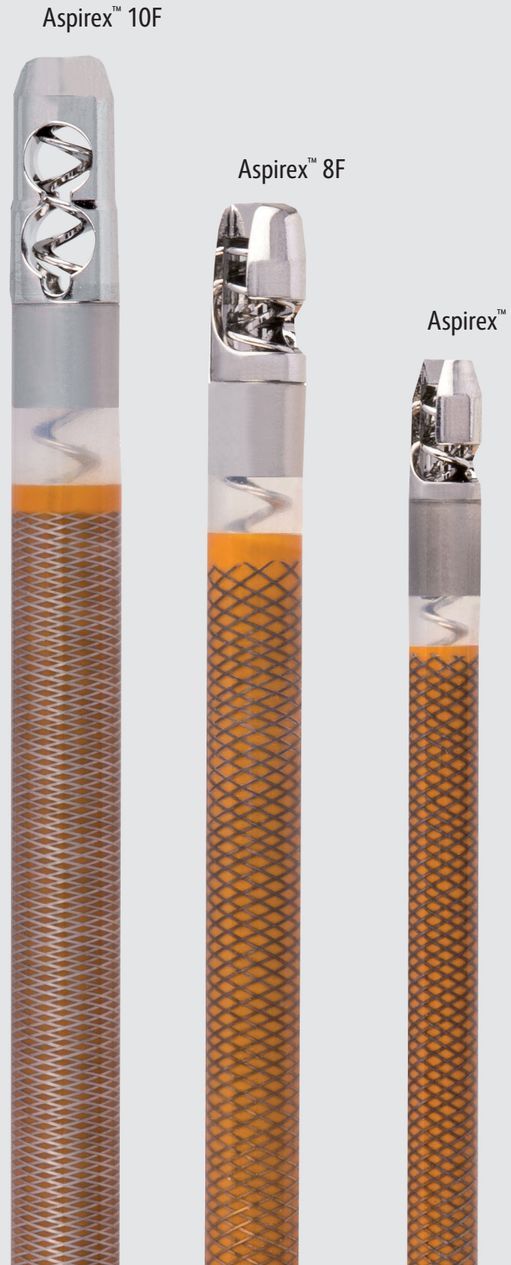
Four functions in one device

- **Detachment** of the occluding material form the vessel (up to 1 cm/sec)
- **Aspiration** of detached material into the catheter head
- **Fragmentation** of the aspirated material
- **Transportation** out of the patient's body

Rotarex™ S

Rotational Atherothrombectomy System

The Thrombectomy System with Continuous Aspiration



One Device for Many Indications

Efficient thrombectomy in acute venous occlusions

- Veins
- Arteries
- Dialysis access

Three functions in one device

- **Aspiration** of fresh thrombus and emboli
- **Fragmentation** of aspirated material
- **Transportation** out of the patient's body

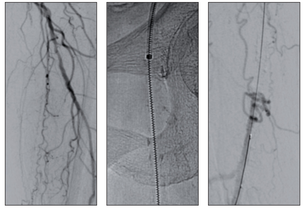
Aspirex™ S

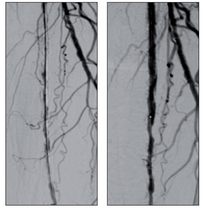
Mechanical Aspiration Thrombectomy System

CTO Left SFA + DCB
8F Rotarex™ S*

Dr. Sven Bräunlich, Diakoniekrankenhaus, Halle, Germany

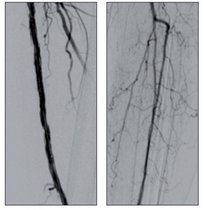
70-year old patient with a claudication for one year of the left calf, walking distance of 100 meters. Puncture of the right groin provided a cross-over approach to the SFA occlusion which was recanalized with a wire intraluminally. Several passes with the Rotarex™ S 8F Catheter followed by two DCB demonstrated restored flow. The patient remains symptom-free after 12 months.



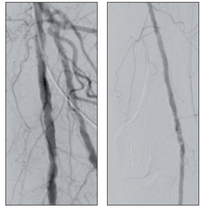


First passage

Second passage



After DCB



Result after 12 months

Rotarex™ S

Rotational Atherothrombectomy System

* Data on file at Straub Medical AG

Intelligent Design with Simple and Safe Operation

Drive System

5

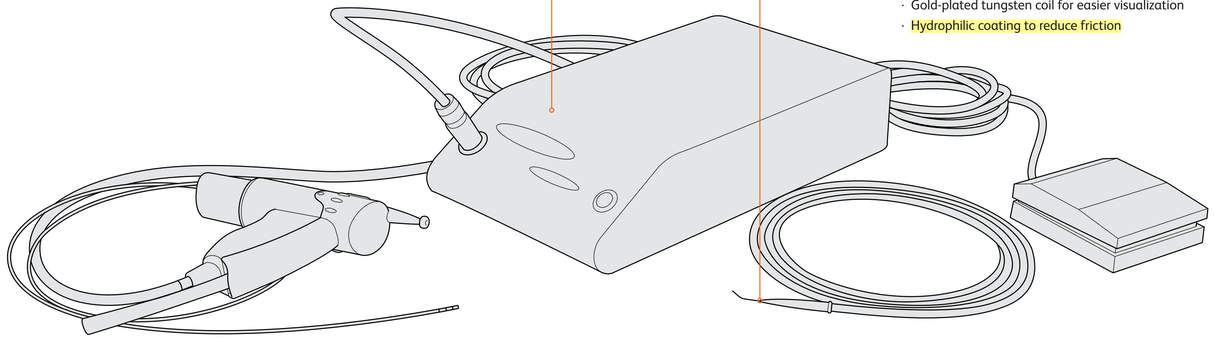
Simple and safe operation

The system for all Rotarex™ S and Aspirex™ S Catheters

- Simple set up
- Hand or footswitch operated

2

- Magnetic coupling to catheter
- Robust and safe



Dedicated Wire for Secure Catheter Function

Guidewire

4

Dedicated wire for secure catheter function

Shaft:

- Nitinol core with PTFE coating

Tip:

- Flexible and angled to facilitate lesion crossing
- Gold-plated tungsten coil for easier visualization
- Hydrophilic coating to reduce friction

Recanalization of an acute iliofemoral deep vein thrombosis using the Aspirex™ S 10F catheter*

Dr. Michael Lichtenberg, Karolinen Hospital, Arnsberg, Germany

41-year-old female with acute painful swelling of the left lower calf for two days. CT venography shows a descending thrombus from distal inferior vena cava to the level of the left external iliac vein (*Figure 1*).

Intervention

Access was gained through an antegrade puncture of the femoral vein under ultrasound guidance with a 10F sheath, 5000 units of heparin were administered. The first venogram demonstrated complete thrombotic occlusion of the left iliac vein (*Figure 2*). The external and common iliac veins were passed with an angled 5F catheter over a stiff guide wire. The guide wire was then exchanged to a 0.025" guide wire provided for performing mechanical thrombectomy with the 10F Aspirex™ S Catheter. After 3 passes with the Aspirex™ S Catheter a quite effective outflow of the iliac vein (*Figure 3*) was restored.

Following thrombectomy, venography demonstrated a high-grade stenosis of the proximal common iliac vein, a site typical for May-Thurner syndrome. Pre-dilatation of the stenosis with a 14 x 60 mm PTA balloon was followed by stent implantation with a 16 x 20 mm self-expanding venous stent. Post-dilatation venogram showed optimal stent deployment and wall apposition (*Figure 4*).

Post-intervention, vitamin K antagonist was prescribed as an anticoagulation therapy for a period of 6 months. At the 3-month clinical follow-up the patient presented symptom-free. Venous outflow was shown to be patent on the treated side with no in-stent restenosis seen on duplex ultrasound.

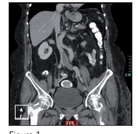


Figure 1

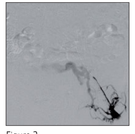


Figure 2

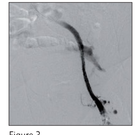


Figure 3

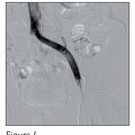


Figure 4

Aspirex™ S

Mechanical Aspiration Thrombectomy System

* Data on file at Straub Medical AG

Rotarex™ S

Rotational Atherothrombectomy System

Rotarex™ S Set

Size	Length (cm)	REF Number
6F	110	80219
	135	80202
8F	85	80223
	110	80224
10F	85	80277

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

Drive System

Description	REF Number
Drive System	80300

Rotarex™ S Rotational Atherothrombectomy System

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.

Straub Medical AG
Straubstrasse 12
CH-7323 Wangs
Switzerland

Phone: +41 81 720 04 60
Fax: +41 81 720 04 61
Email: info@straubmedical.com
Internet: www.straubmedical.com

Aspirex™ S

Mechanical Aspiration Thrombectomy System

Aspirex™ S Set

Size	Length (cm)	REF Number
6F	110	80226
	135	80227
8F	85	80229
	110	80230
10F	110	80232

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

Guidewire

Diameter (in.)	Length (cm)	Flex Tip (mm)	Hydrophilic Coating (cm)	REF Number
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

All guidewires have an angled tip configuration and come in packs of 5.

Aspirex™ S Mechanical Aspiration Thrombectomy System

Indications for Use: Aspirex™ S catheters in combination with the Straub Medical Drive System (REF SRS-Set/80300) are intended for the percutaneous transluminal removal of fresh thrombotic or thromboembolic material from 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: Vessels of the cardiopulmonary, coronary or cerebral circulations; undersized or oversized vessel diameters; 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 vena cava filter or the lining of the stent graft; in the fracture areas of broken stents; in patients with haemodynamic instability or shock; in patients with severe coagulatory disorders; if used inside or via narrow vessel radii or in tortuous vessel courses (radius of curvature <2 cm); 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, Aspirex™ 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. Aspirex™ 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. 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.

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. 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.

CE 0483

bd.com

BD