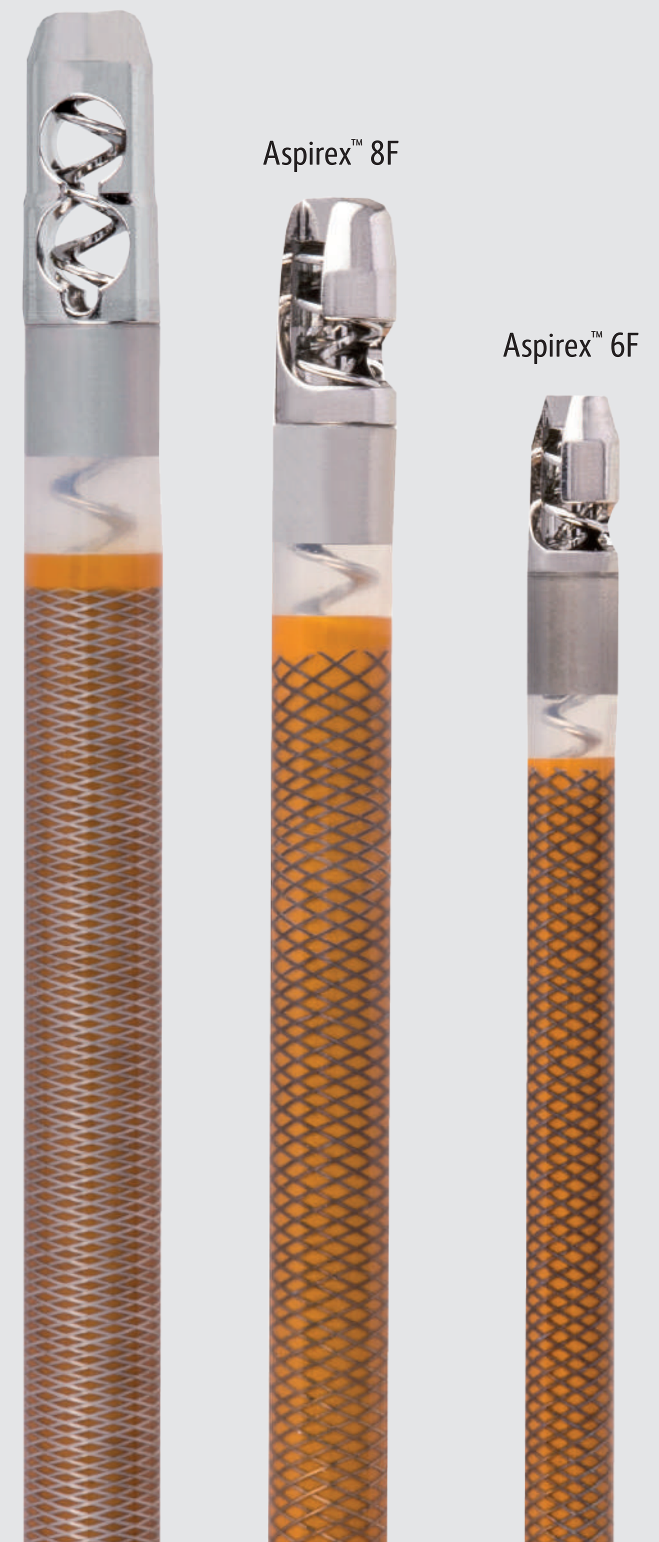
The thrombectomy system with continuous aspiration



One device for many indications

Efficient thrombectomy in acute venous occlusions

- Native vessels
- Stents (in-stent reocclusion)
- Native and artificial bypasses
- Stent grafts

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

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 Endovascular System

Indication 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 by passes outside the cardiopulmonary, coronary and cerebral circulations. **Contraindications:** · In patients not suitable for thrombectomy · In the cardiopulmonary, coronary or cerebral circulations · In vessels that are undersized or oversized for the device used · **Warnings:** · Do not use in anatomical locations with persistent vasospasm · The Rotarex™S family of catheters may only be used with the BD supplied guidewire with which they are packaged · The catheter must always be guided via the supplied guidewire, which has been correctly positioned according to the instructions for use. Do not use the catheter without the supplied guidewire or over the supplied guidewire which is incorrectly placed · If the supplied guidewire is in a subintimal position of any length, reposition and ensure it is intraluminal before proceeding · Do not use the catheter if the supplied guidewire has become threaded or entangled in the wire mesh of a stent, stent graft or the lining of a stent graft · Position the flexible tip of the supplied guidewire as far distally as possible from the vessel occlusion being treated to avoid the tip being aspirated into the rotating helix. Recommended distance is at least 10 cm. Operators should take care that manipulations of the catheter do not alter the desired position of the supplied guidewire. · Do not use inside or via narrow vessel radii or in tortuous vessel courses (bending radius of catheter shaft < 2 cm) · Do not use in calcified vessel segments with presence of radiopacities on both sides of the arterial wall and extending more than 1 cm of length prior to contrast injection or digital subtraction angiography · Do not use this device at or near locations with pre-existing damage to the vessel wall from prior surgery, aneurysms, or other disease. · Remove catheter and supplied guidewire from patient before employing magnetic resonance imaging (MRI) or using a defibrillator · Do not use Rotarex™S Atherectomy Catheters when product damage is evident, whose packaging is damaged, or where the sterilisation expiration date has passed · This device is intended for use only by suitably qualified medical personnel experienced in the diagnosis and treatment of peripheral vascular disease by percutaneous methods · This device may only be used in conjunction with the Drive System · This device is supplied sterile for single-use only. Do not reprocess or resterilise. Resterilisation or reconditioning may severely impair the function of the device · Risk of distal embolisation is greatly increased if the operator attempts to advance the catheter faster than the recommendations in these instructions, especially near the distal end of the occlusion · Failure to ensure sufficient blood flow to the catheter head could result in vessel collapse · Monitor the blood flow to the collecting bag continuously throughout the procedure · Do not operate near fractured areas of broken stents or stent grafts. If a protruding stent strut penetrates into the side window of the catheter head, the stent, stent graft or vessel may become severely damaged, destroyed and/or dislodged, or the catheter head may become entrapped in the stent or stent graft in such a manner that the catheter and the stent or stent graft must be surgically recovered · This device should only be used under adequate visual monitoring with suitable radiographic techniques. **Precautions:** · This device does not contain any parts that can be maintained or serviced by the end-user. Do not repair or change the configuration of the device · Use of the device through a kinked or damaged introducer or where the catheter itself has become kinked or bent, may cause erratic function and/or device failure · Catheters must not be allowed to operate "dry" and must be primed and flushed using heparinised saline before and during use per the instructions in this IFU. Throughout catheter use, always ensure there is a sufficient blood flow to the catheter head. Allowing the catheter to operate without heparinised saline solution priming and flushing or without adequate amounts of aspirated blood, will cause the device to operate erratically and/or cease functioning · Failure to manipulate the catheter slowly in a back and forth motion as described in these instructions may result in fracture of the helix and/or supplied guidewire · Insufficient blood flow through the catheter may result in intra-catheter clotting, slow or absent therapeutic function, fracture of the helix and/or supplied guidewire, and/or overheating of the catheter · The guidewire adaptor must be in the working position (pulled back) when the motor is active · When active, the handle of the Rotarex™S Catheter and the portion of the catheter outside the patient's body must be kept at he same height as the introducer sheath and straight at all times with the outlet tube to the collecting bag hanging vertically below the motor in a straight line. Failure to position the catheter and outlet tube in this manner may result in catheter blockage, helix fracture and/or supplied guidewire fracture · If the supplied guidewire begins to rotate with the helix, which may occur if the helix and supplied guidewire become bonded with fibrin, the procedure must be immediately stopped; the catheter thoroughly flushed and the supplied guidewire changed. **Potential Adverse Effects:** Potential adverse events include, but are not limited to: · Embolisation, especially distal embolisation · Pulmonary embolisms of all degrees of severity · Thrombosis · Reocclusion · Vessel wall injury · Vessel dissection / perforation / rupture · Perforation as a result of mural calcium being torn out of the vessel wall · Arteriovenous fistula / pseudo-aneurysm · Hematoma, bleeding, hemorrhage · Organ perforation · Implants such as stents / stent grafts / bypass grafts getting damaged, caught or dislodged · Disruption of the catheter: debris remaining in the body · Allergic reactions, including allergic reactions to device components · Infections or necrosis at the puncture site · Catheter-induced sepsis · Death

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use

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 resterilised; Do not use the products after the expiration date; Appropriate testing of the patient's coagulation status is mandatory. Aspirex 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 embolisation. **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 ad-ministered 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, embolisations 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/pseudoaneurysm; 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 inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.

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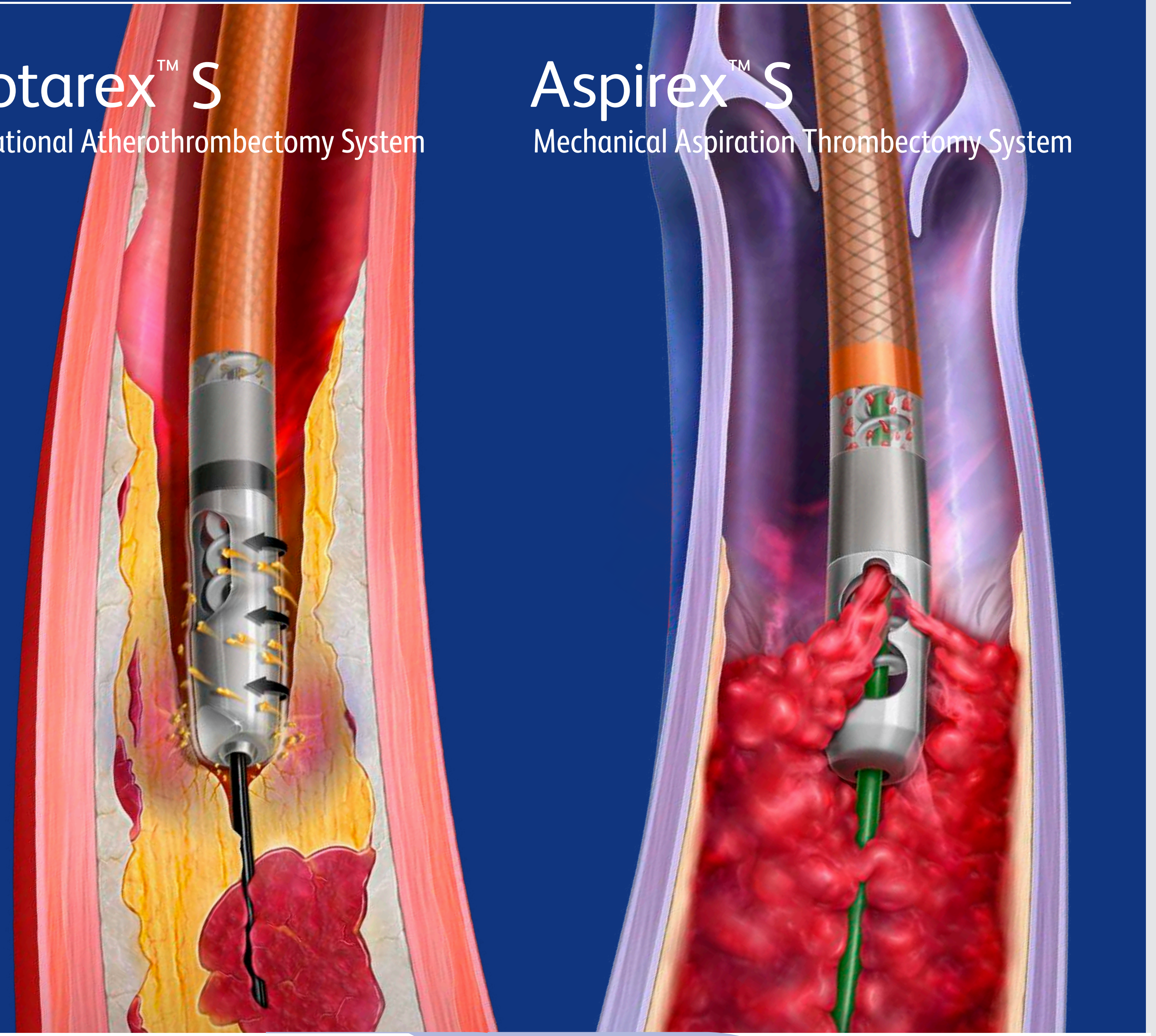
BD

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

Efficient debulking for acute to chronic arterial occlusions

- Native lesions
- In-stent restenosis
- Stent grafts
- Native or artificial bypass

Four functions in one device

- **Detachment** of the occluding material from 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

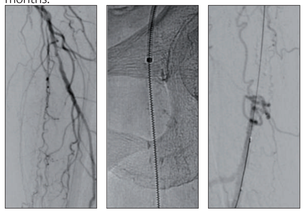
Rotational Atherothrombectomy System

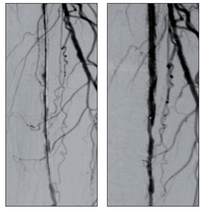
CASE REPORT

CTO Left SFA + DCB
8F Rotarex™ S*

Dr. Sven Bräunlich, Diakoniekrankenhaus, Halle, Germany

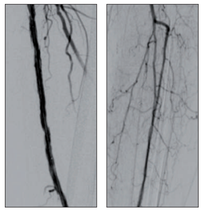
70-year old patient with a claudication for one year of the left calf, walking distance of 100 meters. Puncture of the right groin provided a cross-over approach to the SFA occlusion which was recanalised with a wire intraluminally. Several passes with the Rotarex™ S 8F Catheter followed by two DCB demonstrated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



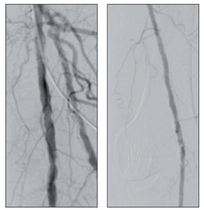


First passage

Second passage



After DCB



Result after 12 months

Rotarex™ S

Rotational Atherothrombectomy System

* Data on file at Straub Medical AG

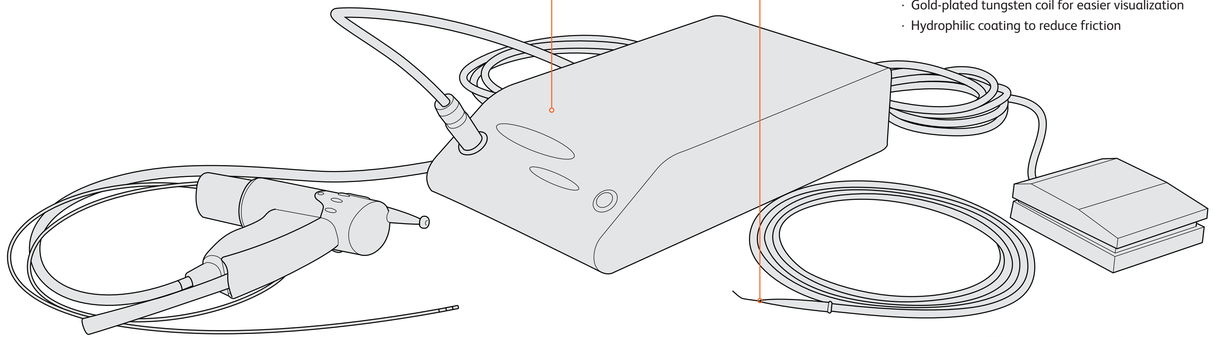
Intelligent design with simple operation

Drive system

Simple operation

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

- Simple set up
- Hand or footswitch operated
- Magnetic coupling to catheter
- Robust



Dedicated wire for secure catheter function

Guidewire

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

CASE REPORT

Recanalisation 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*).

* Data on file at Straub Medical AG

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.

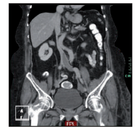


Figure 1

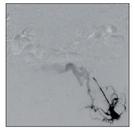


Figure 2

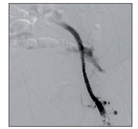


Figure 3

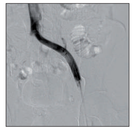


Figure 4

Aspirex™ S

Mechanical Aspiration Thrombectomy System