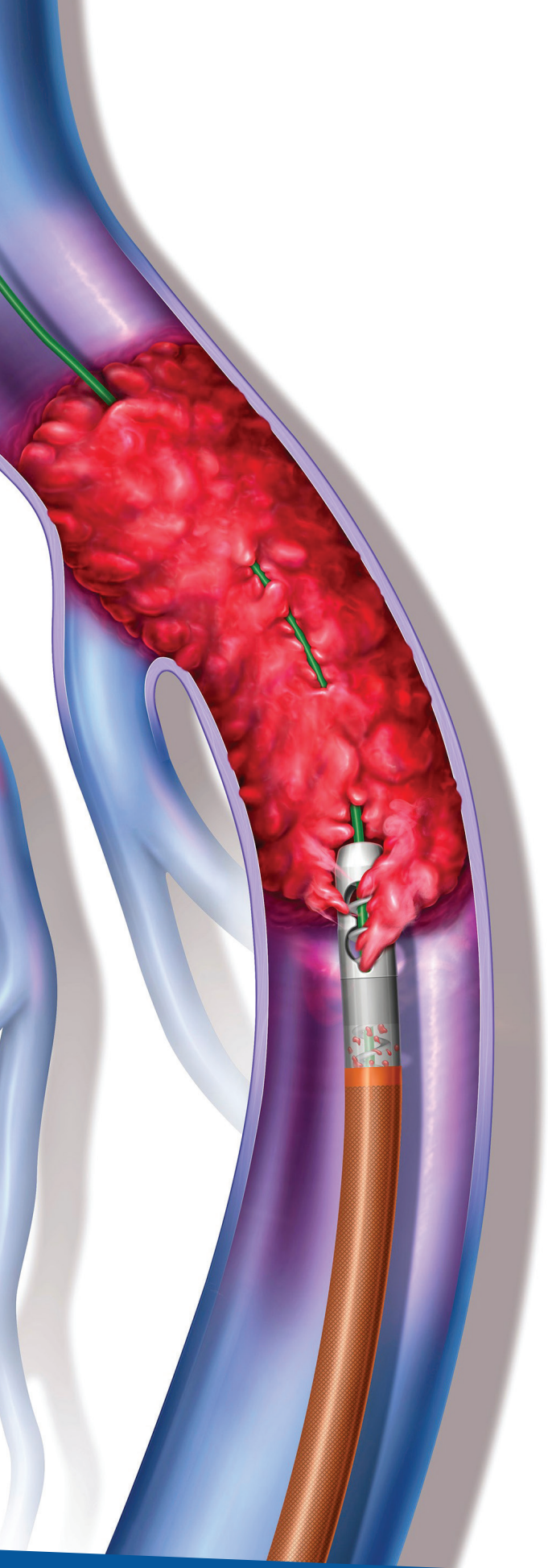


Aspirex™S

Mechanical Aspiration Thrombectomy System

Effective debulking in occluded arteries and veins

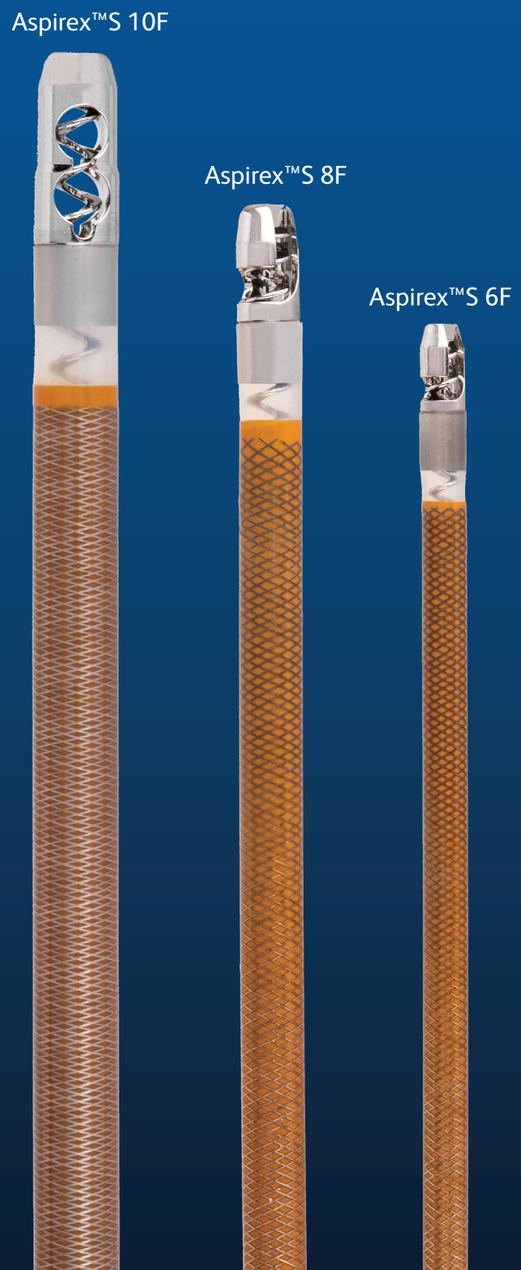
BD

The Thrombectomy System with continuous aspiration

One device for many indications[1]

Efficient thrombectomy in fresh venous or arterial occlusions

- native vessels
- vessels fitted with stents
- stent grafts
- native or artificial bypass



Three functions in one device

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

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Small footprint, **simple to set up**

- **No warm-up, infusion, or repeated catheter clean-out required[2]**
- **Plug-and-play capital component**

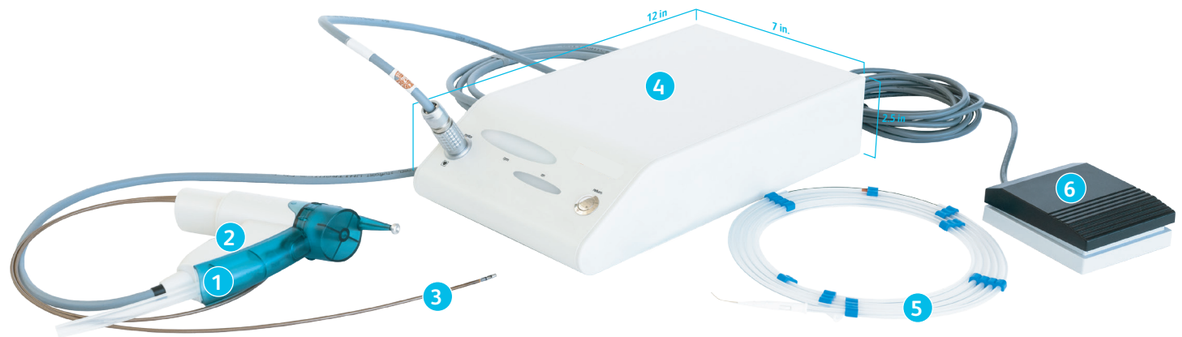
Catheter set includes:

- Catheter
- Guidewire
- Sterile Drape
- Collecting Bag

Sterile drape

Collecting bag

High volume collecting bag allows for uninterrupted removal of aspirated material



1 Ergonomic handle

- Easy to use handle designed for single operator control
- Disposable catheter simply clips to reusable portion of the handle

2 Switch

- Operates the catheter helix roatation
- Magnetic coupling facilitates ease of use while in the sterile environment

3 Catheter

- Designed in a variety of sizes to manage a range of vessel diameters
- No defined limitation on treatable lesion length

4 Drive system

- System is auto-aspirating, without the need for a separate pump

5 Guidewire

- Nitinol core shaft with Polytetrafluoroethylene coating for catheter support
- Hydrophilically-coated, flexible, angled tip to enable lesion crossing
- Gold-plated tungsten coil to enhance visualisation under fluoroscopy

6 Optional foot switch

- Facilitates single- or multiple-operator scenarios

Recanalisation of an acute iliofemoral deep vein thrombosis using the Aspirex™S 10F Catheter[3]

Dr. Michael Lichtenberg,
Chief Medical Officer,
Karolinen Hospital, Arnsberg, Germany

41 year old female with
left iliac vein occlusion

2-day swelling of
the left lower calf

Effective debulking in occluded arteries and veins
Aspirex™S Mechanical Aspiration Thrombectomy System

Intervention

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 distal external iliac vein (Figure 1).

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 an 0.025" guide wire provided for performing mechanical thrombectomy with the 10F Aspirex™S Mechanical Aspiration Thrombectomy System catheter. After 3 passes with the Aspirex™S Mechanical Aspiration Thrombectomy System Catheter a quite effective outflow of the iliac vein (Figure 3) was restored.

Following thrombectomy, venography demonstrated a high-grade stenosis of the left proximal Vena iliaca communis at the typical May-Thurner point. 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. After dilatation a final angiogram showed optimal stent deployment and wall apposition (Figure 4).

Post-intervention, vitamin K antagonist was prescribed as an anticoagulation therapy for at least 6 months. A 3 month follow-up examination showed still a patent outflow situation on the left leg and significant improvement of complaints. Venous outflow was shown to be patent on the treated side with no in-stent restenosis seen on duplex ultrasound.[3]

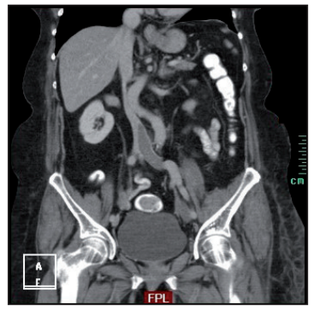


Figure 1

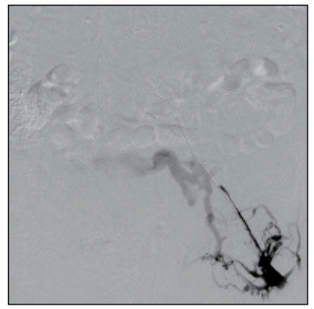


Figure 2

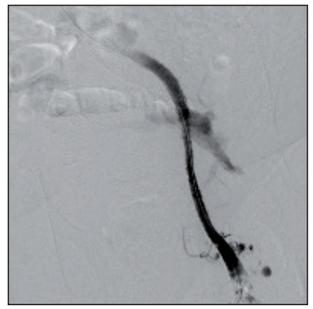


Figure 3

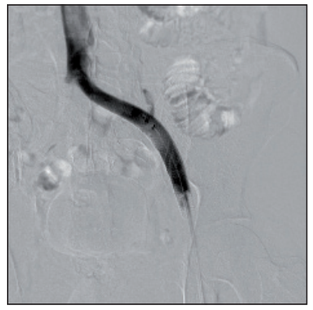


Figure 4

Aspirex™S
Mechanical Aspiration Thrombectomy System

Aspirex™S Mechanical Aspiration Thrombectomy System

Ordering information

Aspirex™ S Mechanical Aspiration Thrombectomy System Catheter Set

Order code	Length (cm)	Device size and minimum sheath required (F)
80226	110	6
80227	135	6
80229	85	8
80230	110	8
80232	110	10

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

Guidewires

Order code	Length (cm)	Diameter (in.)	Flex Tip (mm)	Hydrophilic Coating (cm)
80270	220	0.018	40	9.5
80271	270		40	9.5
80272	320		40	9.5
80305	270	0.025	60	8.5

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

Drive system

Order code
80300

Aspirex™S

Mechanical Aspiration Thrombectomy System

Aspirex™S Mechanical Aspiration Thrombectomy System

1. Straub Medical AG Aspirex™S. Instructions for Use. ZE11121 B1
2. Straub Medical AG Drive System. Instructions for Use. ZE11407 A5
3. Straub Medical. 2022. Case Reports. Accessed on February 15, 2022, at http://www.straubmedical.com/userdata/Produkte/Aspirex/case-report-dvt-treatment-dr-lichtenberg.pdf

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™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 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, 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 inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.

Becton Dickinson Pty Ltd T/A Bard Australia Pty Ltd. Customer Service: 1800 257 232.