Rotarex™S

Rotational Atherothrombectomy System

Selected Publications

Contents

Lower extremity arteries

Clinical Studies

1. Pan T, Tian SY, Liu Z, Zhang T, Li C, Ji DH.

Combination of Rotarex™S rotational atherothrombectomy and drug-coated balloon angioplasty for femoropopliteal total in-stent occlusion.

Ann Vasc Surg. 2021 Nov 5:S0890-5096(21)00786-X. doi: 10.1016/j.avsg.2021.08.058. Epub ahead of print.

2. Fluck F, Stephan M, Augustin A, Rickert N, Bley TA, Kickuth R.

Percutaneous mechanical thrombectomy in acute and subacute lower-extremity ischemia: impact of adjunctive, solely nonthrombolytic endovascular procedures.

Diagn Interv Radiol. 2021 Jan 18. doi: 10.5152/dir.2021.19403. Epub ahead of print. PMID: 33455896.

3. Migliara B, Cappellari TF, Mirandola M, Griso A, Kolasa K, Zah V, Nicoletti C, Lino M.

Treatment of bypass failure in patients with chronic limb threatening ischemia - open surgery vs. percutaneous mechanical thrombectomy

Vasa. 2020 Aug;49(5):395-402.

4. Wang Q, Zhu RM, Ren HL, Leng R, Zhang WD, Li CM.

Combination of Percutaneous Rotational Thrombectomy and Drug-Coated Balloon for Treatment of Femoropopliteal Artery Nonembolic Occlusion: 12-Month Follow-up.

J Vasc Interv Radiol. 2020 Oct;31(10):1661-1667.

BD

Lower extremity arteries

Clinical Studies

5. Loffroy R, Edriss N, Goyault G, Chabanier A, Pernes JM, Sauguet A, Touil M, Woerly B, Pongas D, Chevallier O, Falvo N, Galland C, Midulla M, Garnier N, Guenfoudi MP, Boulin M, Aho-Gléglé S, Bost S.

Percutaneous mechanical atherothrombectomy using the Rotarex™S device in peripheral artery in-stent restenosis or occlusion: a French retrospective multicenter study on 128 patients.

Quant Imaging Med Surg. 2020 Jan;10(1):283-293.

6. Bosiers M, Deloose K, Callaert J, Peeters P, Verbist J, Van den Eynde W, Maene L, Beelen R, Keirse K, Hendriks J, Wauters J.

Investigating the Rotarex™S Catheter in Femoropopliteal In-Stent Occlusion 6-Month Results in the Robinson (Rotarex Belgian In-Stent Occlusion) Study.

J Cardio Vasc Med 2019, 5: 1-10.

7. Liao CJ, Song SH, Li T, Zhang Y, Zhang WD.

Combination of Rotarex Thrombectomy and Drug-Coated Balloon for the Treatment of Femoropopliteal Artery In-Stent Restenosis.

Ann Vasc Surg. 2019 May 8.
pii: S0890-5096(19)30273-0

8. Liang S, Zhou L, Ye K, Lu X.

Limb Salvage After Percutaneous Mechanical Thrombectomy in Patients with Acute Lower Limb Ischemia: A Retrospective Analysis from Two Institutions.

Ann Vasc Surg. 2019 Jul;58:151-159

9. Latacz P, Simka M, Brzegowy P, Piwowarczyk M, Popiela T.

Mechanical rotational thrombectomy with Rotarex system augmented with drug-eluting balloon angioplasty versus stenting for the treatment of acute thrombotic and critical limb ischaemia in the femoropopliteal segment.

Wideochir Inne Tech Maloinwazyjne. 2019 Apr;14(2):311-319

10. Milnerowicz A, Milnerowicz A, Kuliczkowski W, Protasiewicz M.

Rotational Atherectomy Plus Drug-Coated Balloon Angioplasty for the Treatment of Total In-Stent Occlusions in Iliac and Infrainguinal Arteries.

J Endovasc Ther. 2019 Jun;26(3):316-321

11. Bulvas M, Sommerová Z, Vaněk I, Weiss J.

Prospective Single-Arm Trial of Endovascular Mechanical Debulking as Initial Therapy in Patients With Acute and Subacute Lower Limb Ischemia: One-Year Outcomes.

J Endovasc Ther. 2019 Jun;26(3):291-301

12. Vorwerk D, Triebe S, Ziegler S, Ruppert V.

Percutaneous Mechanical Thromboembolectomy in Acute Lower Limb Ischemia.

Cardiovasc Intervent Radiol. 2019 Feb;42(2):178-185

13. Liu J, Li T, Huang W, Zhao N, Liu H, Zhao H, Wang H.

Percutaneous mechanical thrombectomy using Rotarex catheter in peripheral artery occlusion diseases - Experience from a single center.

Vascular. 2019 Apr;27(2):199-203

14. Freitas B, Steiner S, Bausback Y, Branzan D, Ulrich M, Bräunlich S, Schmidt A, Scheinert D.

Rotarex Mechanical Debulking in Acute and Subacute Arterial Lesions: Single-Center Experience with 525 Patients.

Angiology. 2017 Mar;68(3):233-241.

15. Heller S, Lubanda JC, Varejka P, Chochola M, Prochazka P, Rucka D, Kuchynkova S, Horakova J, Linhart A.

Percutaneous Mechanical Thrombectomy Using Rotarex™S Device in Acute Limb Ischemia in Infrainguinal Occlusions.

Biomed Res Int. 2017;2017:2362769.

Lower extremity arteries

Clinical Studies

16. Kronlage M, Printz I, Vogel B, Blessing E, Müller OJ, Katus HA, Erbel C.
A comparative study on endovascular treatment of (sub)acute critical limb ischemia: mechanical thrombectomy vs thrombolysis.
Drug Des Devel Ther. 2017 Apr 18;11:1233-1241.

17. Scheer F, Lüdtke CW, Kamusella P, Wiggermann P, Vieweg H, Schlöricke E, Lichtenberg M, Andresen R, Wissgott C.
Combination of Rotational Atherothrombectomy and Paclitaxel-Coated Angioplasty for Femoropopliteal Occlusion.
Clin Med Insights Cardiol. 2015 Apr 21;8(Suppl 2):43-8

18. Lichtenberg M, Stahlhoff W, Boese D, Hailer B.
Twelve months outcome after percutaneous mechanical thrombectomy for treatment of acute femoropopliteal bypass occlusion.
Cardiovasc Interv Ther. 2013 Apr;28(2):178-83

19. Wissgott C, Kamusella P, Andresen R.
Recanalization of Acute and Subacute Venous and Synthetic Bypass-Graft Occlusions with a Mechanical Rotational Catheter.
Cardiovasc Intervent Radiol. 2013 Aug;36(4):936-42.

20. Wissgott C, Kamusella P, Andresen R.
Treatment of femoropopliteal stenosis and occlusions with mechanical rotational catheters: comparison of results with the Rotarex and Pathway devices.
J Cardiovasc Surg (Torino). 2012 Apr; 53 (2): 177-86.

21. Wissgott C, Kamusella P, Andresen R.
Treatment of in-stent reocclusions of femoropopliteal arteries with mechanical rotational catheters.
Original text in German. RöFo 2011 Oct; 183(10): 939-44.

22. Wissgott C, Kamusella P, Andresen R.
Treatment of chronic occlusions of the iliac of femoropopliteal arteries with mechanical rotational catheters.
RöFo 2011 Oct; 183(10): 945-951.

23. Laganà D, Carrafiello G, Lumia D, Fontana F, Mangini M, Vizzari F.A, Piffaretti G, Fugazzola C.
Recanalisation of thrombotic arterial occlusions with rotational thrombectomy.
Radiol Med. 2011 Sep;116(6):932-44.

24. Silingardi R, Cataldi V, Moratto R, Azzoni I, Veronesi J, Coppi G.
Mechanical thrombectomy in in-stent restenosis: preliminary experience at the iliac and femoropopliteal arteries with the Rotarex System.
J Cardiovasc Surg (Torino). 2010 Aug; 51(4): 543-50.

25. Wissgott C, Kamusella P, Richter A, Klein-Weigel P, Schink T, Steinkamp HJ.
Treatment of acute femoropopliteal bypass graft occlusion: comparison of mechanical rotational thrombectomy with ultrasound-enhanced lysis.
Original text in German. RöFo 2008 Jun; 180(6): 547-552

26. Zeller T, Frank U, Bürgelin K, Müller C, Flügel P, Horn B, Schwarzwälder U, Neumann FJ.
Early experience with a rotational thrombectomy device for treatment of acute and subacute infra-aortic arterial occlusions.
J Endovasc Ther. 2003 Apr; 10(2): 322-331.

27. Schmitt EM.
Thrombectomy with the Straub- Rotarex-Catheter in acute and subacute occlusions of leg arteries: A Multicentre Study.
Original text in German. Med. Dissertation. Basel 2002

Lower extremity arteries

Case Reports

1. Dinoto E, Ferlito F, Urso F, Pakeliani D, Bajardi G, Pecoraro F.
Mechanical rotational thrombectomy in long femoropopliteal artery and stent occlusion in COVID-19 patient.
Int J Surg Case Rep. 2021 Jun 24;84:106133.

2. Caetano AP, Gomes FV, Bilhim T, Coimbra É, Neves J.
Percutaneous Mechanical Thrombectomy with Rotarex Using the Retrograde Posterior Tibial Artery Approach for Recanalization of Superficial Femoral Artery In-Stent Occlusion.
J Vasc Interv Radiol. 2019 Apr 16. pii: S1051-0443(18)31822-0

3. Kilickesmez O, Oguzkurt L.
Mechanical Thrombectomy with Rotarex System in Buerger's Disease.
J Clin Imaging Sci. 2015; 5: 14.

Upper extremity arteries

Case Reports

1. Silingardi R, Lauricella A, Cataldi V, Njila MK, Coppi G.
Mechanical thrombectomy in proximal subclavian artery in-stent occlusion.
Cardiovasc Interv Ther. 2014 Apr;29(2):140-5.

2. Lichtenberg M, Kaeunicke M, Lukat M, Hailer B.
Retrograde rotational thrombectomy with the Rotarex™ catheter system: treatment option for an acute thrombotic occlusion of a subclavian artery.
Vascular Health and Risk Management Sep 2011(7): 623-627.

3. Zeller T, Frank U, Bürgelin K, Sinn L, Horn B, Schwarzwälder U, Roskamm H, Neumann FJ.
Treatment of acute embolic occlusions of the subclavian and axillary arteries using a rotational thrombectomy device.
Vasa. 2003 May; 32(2): 111-116.

4. Zeller T, Frank U, Bürgelin K, Sinn L, Horn B, Roskamm H.
Acute thrombotic subclavian artery occlusion treated with a new rotational thrombectomy device.
J Endovasc Ther. 2002 Dec; 9(6): 917-921.

Visceral arteries

Clinical Studies

1. Freitas B, Bausback Y, Schuster J, Ulrich M, Bräunlich S, Schmidt A, Scheinert D.
Thrombectomy Devices in the Treatment of Acute Mesenteric Ischemia: Initial Single-Center Experience.
Ann Vasc Surg. 2018 Aug;51:124-131.

Visceral arteries

Case Reports

1. Thurner A, Augustin AM, Götze O, Bley TA, Kickuth R.
Percutaneous mechanical thrombectomy device assisted TIPS recanalization: a feasibility study.
Acta Radiol. 2021 Jul 29:2841851211034041.

2. Zhang Z, Chen X, Li C, Feng H, Yu H, Zhu R.
Percutaneous Mechanical Thrombectomy for Acute Superior Mesenteric Artery Embolism: Preliminary Experience in Five Cases.
Ann Vasc Surg. 2020 Feb;63:186-192.

3. Latacz P, Simka M, Mrowiecki T.
Endovascular embolectomy of the superior mesenteric artery using the Rotarex™ system for the treatment of acute mesenteric ischemia.
Pol Arch Med Wewn. 2016;126 (3): 196-197

4. Kuhelj D, Kavcic P, Popovic P.
Percutaneous mechanical thrombectomy of superior mesenteric artery embolism.
Radiol Oncol. 2013 Jul 30;47(3):239-43. doi: 10.2478/raon-2013-0029. eCollection 2013.

5. Goltz JP, Petritsch B, Spor L, Hahn D, Kickuth R.
Acute thromboembolic occlusion of the superior mesenteric artery following covered stent occlusion in the superior mesenteric artery: endovascular therapy using mechanical rotational thrombectomy.
Vasa. 2012 Sep; 41(5): 375-9.

6. Lichtenberg M, Hailer B.
Recanalisation of an acutely thrombosed aortic stent graft using rotational thrombectomy.
Original text in German, Zeitschrift für Gefässmedizin 2010; 7(2), 16-21.

7. Quateen A, Pech M, Berg T, Bergk A, Podrabsky P, Felix R, Ricke J.
Percutaneous transjugular direct porto-caval shunt in patients with Budd-Chiari syndrome.
Cardiovasc Intervent Radiol. 2006 Jul-Aug; 29(4): 565-70.

8. Loupatatzis C, Stoupis C, Seiler C, Candinas D, Do DD, Triller J.
Use of Mechanical Thrombectomy Device to Recanalize a Subacutely Occluded Aortohepatic Bypass After Orthotopic Liver Transplantation.
Journal of Endovascular Therapy: June 2005, Vol. 12, No.3, pp. 401- 404.

Literature reviews

1. Lichtenberg MKW.
Evolving evidence for limb threatening ischemia treatment with a mechanical thrombectomy approach - we need to think endovascular.
Vasa. 2020 Oct;49(6):433-435.

2. Loffroy R, Falvo N, Galland C, Fréchier L, Ledan F, Midulla M, Chevallier O.
Percutaneous Rotational Mechanical Atherectomy Plus Thrombectomy Using Rotarex S Device in Patients With Acute and Subacute Lower Limb Ischemia: A Review of Safety, Efficacy, and Outcomes.
Front Cardiovasc Med. 2020 Oct 22;7:557420.

3. Bulvas M.
Removal of Peripheral Arterial Occlusive Material with the Rotarex™ S Device: Mechanical Atherothrombectomy.
Surg Technol Int. 2020 May 28;36:225-232.

4. Fluck F, Augustin AM, Bley T, Kickuth R.
Current Treatment Options in Acute Limb Ischemia.
Rofo. 2020 Apr;192(4):319-326.

5. Bulvas M.
Mechanical atherothrombectomy in the treatment of peripheral arterial in-stent occlusions.
Vascular. 2020 Apr;28(2):152-158

6. Lichtenberg M, Korosoglou G.
Atherectomy plus antirestenotic therapy for SFA lesions: evolving evidence for better patency rates in complex lesions.
J Cardiovasc Surg (Torino). 2019 Apr;60(2):205-211

7. Stanek F, Ouhrabkova R, Prochazka D.
Could mechanical thrombectomy replace thrombolysis in the treatment of acute and subacute limb ischemia?
Minerva Cardioangiol. 2019 Jun;67(3):234-245

8. Pongas D, Pernes J-M.
Désobstruction endovasculaire des occlusions artérielles aiguës, sub-aiguës et chroniques - La thrombectomie mécanique par le système ROTAREX™
Original text in French. Cardiologie pratique, 2018, March 15

9. Scheer F, Vieweg H, Wissgott C.
Peripheral Endovascular Thrombectomy.
Original text in German. Interventionelle Radiologie Scan 2015; 03(02): 139-154

10. Bent CL, Sahni VA, Matson MB.
The radiological management of the thrombosed arteriovenous dialysis fistula.
Clin Radiol. 2011 Jan;66(1):1-12.

Unpublished case reports

1. Zhang Z.

Percutaneous Mechanical Thrombectomy of Acute Superior Mesenteric Artery Embolus using the Straub Rotarex™S Catheter

Department of Vascular Surgery, Beijing Friendship Hospital, Capital Medical University, Beijing, China, 2019

2. Jacke C.

Ultrasound-guided mechanical thrombectomy of a moderate External Iliac Artery (EIA)-Stenosis with the mechanical Rotarex™S 8F catheter system in a complex case

Angiology Department, Alfried Krupp Hospital Rüttenscheid, Essen, Germany, 2019

3. Bulvas M.

Mechanical Atherothrombectomy (MATH) in the Treatment of Chronic Occlusions of the Popliteal Artery.

Cardiol Cardiovasc Med 2019; 3 (5): 248-257

4. Beran J.

Recanalization of a short chronic occlusion of the femoral artery using a Rotarex™S 8F catheter.

Institute for Clinical and Experimental Medicine (IKEM) Prague, Czech Republic, 2019

5. Porod J

Recanalization of a thrombosed A-V shunt in the upper left limb using Rotarex™S catheter.

Angio a.s. private clinic in Příbram, Czech Republic, 2019

6. Bulvas M.

Endovascular Debulking in Therapy of Occluded Lower Limb Bypass.

Online Journal of Cardiovascular Research - OJCR, Volume 2 - Issue 1, 2019

7. Bulvas M.

The Rotarex™S catheter in the treatment of peripheral arterial in-stent occlusions.

King`s Vineyards Hospital, Prague, Czech Republic, 2019

8. Bulvas M.

Endovascular Mechanical Atherectomy with Thrombectomy (MATH) using the Rotarex™S as initial therapy of acute lower limb ischemia.

King`s Vineyards Hospital, Prague, Czech Republic, 2019

9. Korosoglou G, Heinrich U.

Removal of thrombotic material in a patient with chronic popliteal artery occlusion with the Rotarex™S debulking device.

GRN Klinik Weinheim, Germany, 2017

10. Pelouze G.A.

Debulking of a recurrent SFA occlusion with the Straub Mechanical endovascular system.

Thoracic and Vascular Surgical Department St John's Hospital, Perpignan, France, 2016

11. Capel Alemán A, Taboada Martín R.

Thromboembolic occlusion in superficial femoral artery treated with Rotarex™S after failed surgical thrombectomy.

Hospital Clínico Universitario Virgen de la Arrixaca Murcia, Spain, 2016

12. Migliara B, Mirandola M, Griso A, Cappellari T. F, Lino M.

Percutaneous mechanical rotational debulking in complex surgical bypass occlusions: clinical cases.

Pederzoli Hospital, Peschiera del Garda, Italy, 2016

Unpublished case reports

13. Kennedy P.

Treatment of a femoral artery occlusion using the Straub Mechanical Thrombectomy Device.

Royal Victoria Hospital Belfast, UK, 2012

14. Peer A, Altshuler A.

Straub Medical's ROTAREX™ thrombectomy device used as an atherectomy device in recanalization of chronic calcified SFA-POP occlusions.

Unit of Interventional Radiology Assaf Harofeh Medical Center Israel, 2012

15. Vorwerk D.

Occluded synthetic dialysis access graft Mechanical thrombectomy using Rotarex™ 8F.

Institute of Diagnostic and Interventional Radiology, Klinikum Ingolstadt, Germany, 2011, Available in English and German

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.

Straub Medical AG, Straubestrasse 12, CH-7323 Wangs, Switzerland.

bd.com

CE 0483