

Arrow[®] Arrow-Trerotola[™] PTD[®] Percutaneous Thrombolytic Device



A proven mechanical thrombectomy technology available for dialysis access

To achieve fast, easy removal of thrombus from both dialysis native AV fistulae and synthetic graft walls, depend on the Arrow-Trerotola™ PTD[®] from Teleflex.

Simple

Easy to assemble. Easy to operate. Because the Arrow-Trerotola PTD comes complete with mechanical thrombectomy catheter, hand-held disposable rotator drive unit and introducer sheath, there is no bulky, expensive capital equipment to purchase.

Catheter Lumen Sidearm

• Permits catheter flushing during preparation and use

Activated Spinning Basket

• Macerates the thrombus

Introducer Sheath and Large-Bore Sidearm Assembly

• Simplifies thrombus removal

Short Procedure Time

• Patient can immediately return to dialysis²

Safe

The Arrow-Trerotola PTD conforms to AV graft and AV fistulae walls, which enables you to remove clots with minimal risk of wall damage, and without the use of thrombolytics.⁵

Proven

Addresses key benchmarks for effective outcomes, including KDOQI guidelines for both immediate and three-month fistula and graft patency and functionality rates. The only mechanical thrombectomy device indicated to pull the arterial plug.³

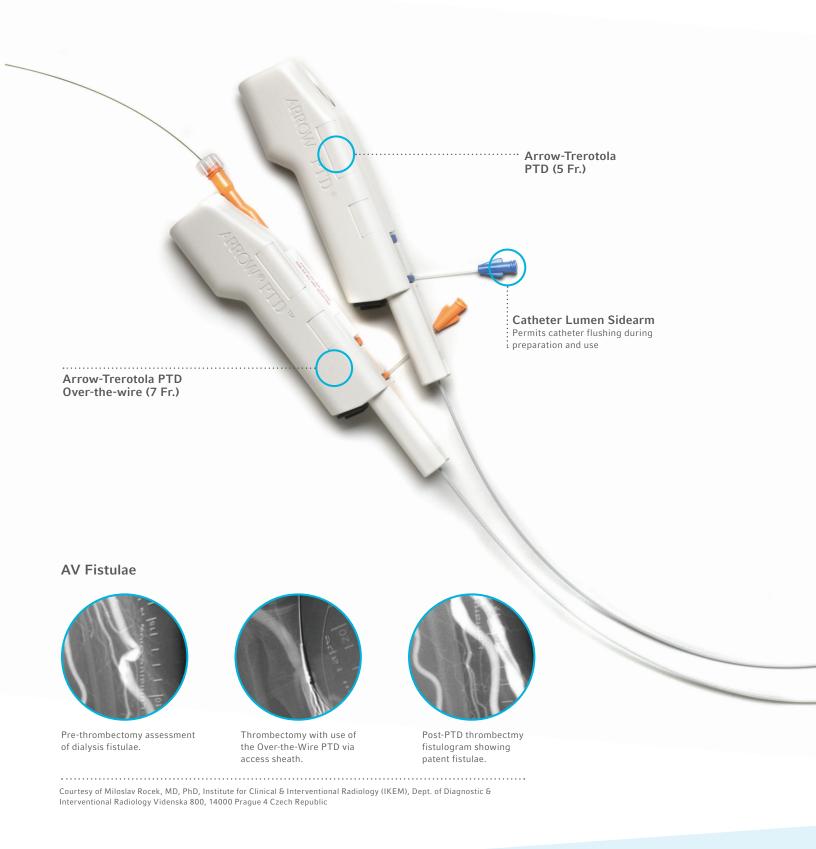
Dialysis Access

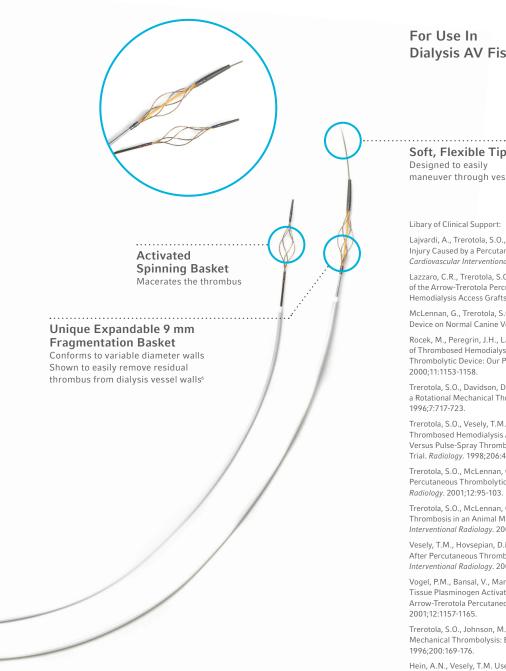
STUDIES	TECHNICAL PATENCY RATE	3-MONTH PRIMARY PATENCY RATE
KDOQI Guideline ¹	85%	40%
PTD vs. PSPMT ³	95%	39%
Modified Technique ³	100%	42%
Use of PTD and Native Fistulae ⁴	100%	70%

AV Synthetic Graft



PTD device in use in a forearm-loop synthetic graft.





Dialysis AV Fistulae and Synthetic Grafts.

Soft, Flexible Tip maneuver through vessel

Lajvardi, A., Trerotola, S.O., Strandberg, J.D., Samphilipo, M.A., Magee, C. Evaluation of Venous Injury Caused by a Percutaneous Mechanical Thrombolytic Device. Cardiovascular Interventional Radiology. 1995;18:172-178.

Lazzaro, C.R., Trerotola, S.O., Shah, H., Namyslowski, J., Moresco, K., Patel, N. Modified Use of the Arrow-Trerotola Percutaneous Thrombolytic Device for the Treatment of Thrombosed Hemodialysis Access Grafts. Journal of Vascular Interventional Radiology. 1999;10:1015-1031.

McLennan, G., Trerotola, S.O., Davidson, D. et al. The Effects of a Mechanical Thrombolytic Device on Normal Canine Vein Valves. Journal of Vascular Interventional Radiology. 2001;12:89-94.

Rocek, M., Peregrin, J.H., Lasovickova, J., Krajickova, D., Slaviokova, M. Mechanical Thrombolysis of Thrombosed Hemodialysis Native Fistulas With Use of the Arrow-Trerotola Percutaneous Thrombolytic Device: Our Preliminary Experience. Journal of Vascular Interventional Radiology.

Trerotola, S.O., Davidson, D.D., Filo, R.S., Dreesen, R.G., Forney, M. Preclinical In Vivo Testing of a Rotational Mechanical Thrombolytic Device. Journal of Vascular Interventional Radiology.

Trerotola, S.O., Vesely, T.M., Lund, G.B., Soulen, M.C., Ehrman, K.O., Cardella, J.F. Treatment of Thrombosed Hemodialysis Access Grafts: Arrow-Trerotola Percutaneous Thrombolytic Device Versus Pulse-Spray Thrombolysis. Arrow-Trerotola Percutaneous Thrombolytic Device Clinical Trial. Radiology. 1998;206:403-414.

Trerotola, S.O., McLennan, G., Davidson D., et al. Preclinical In Vivo Testing of the Arrow-Trerotola Percutaneous Thrombolytic Device for Venous Thrombosis. Journal of Vascular Interventional

Trerotola, S.O., McLennan, G., Eclavea, A.C. et al. Mechanical Thrombolysis of Venous Thrombosis in an Animal Model With Use of Temporary Caval Filtration. Journal of Vascular Interventional Radiology. 2001;12:1075-1085.

Vesely, T.M., Hovsepian, D.M., Darcy, M.D., Brown, D.B., Pilgram, T. K. Angioscopic Observations After Percutaneous Thrombectomy of Thrombosed Hemodialysis Grafts. Journal of Vascular Interventional Radiology. 2000;11:971-977.

Vogel, P.M., Bansal, V., Marshall, M.W. Thrombosed Hemodialysis Grafts: Lyse and Wait With Tissue Plasminogen Activator or Urokinase Compared to Mechanical Thrombolysis With the Arrow-Trerotola Percutaneous Thrombolytic Device. Journal of Vascular Interventional Radiology.

Trerotola, S.O., Johnson, M.S., Schauwecker, D.S. et al. Pulmonary Emboli From Pulse-Spray and Mechanical Thrombolysis: Evaluation With an Animal Dialysis-Graft Model. Radiology.

Hein, A.N., Vesely, T.M. Use of the Percutaneous Thrombolytic Device for the Treatment of Thrombosed Pseudoaneurysms During Mechanical Thrombectomy of Hemodialysis Grafts. Journal of Vascular Interventional Radiology. 2002;13:201-204.

Ordering Information

5 French Arrow-Trerotola™ PTD[®] Products

ITEM NUMBER	CATHETER LENGTH (CM)	FRAGMENTATION BASKET (MM)	SHEATH INCLUDED (FR.)	ROTATOR DRIVE UNIT (RPM)	CASE QTY
PT-03000-R	-	-	-	3000	1
PT-65509*	65	9	-	-	1
PT-45509**	65	9	2/6	-	1
PT-65509-HFC	65	9	2/6 (HF)	3000	1

7 French Arrow-Trerotola Over-the-Wire PTD Products

product #	CATHETER LENGTH (CM)	FRAGMENTATION BASKET (MM)	TIP-TO-CUFF INSERTION LENGTH (CM)	SHEATH INCLUDED (FR.)	ROTATOR DRIVE UNIT (RPM)	SETS/CASE
PT-03009-RW	-	-	-	-	3000	1
PT-65709-W ***	65	9	0.025	-	-	1
PT-65709-WC	65	9	0.025	2/7	3000	1
PT-65709-HFWC	65	9	0.025	2/7 (HF)	3000	1
PT-12709-WC	120	9	0.025	2/7	3000	1

PTD Accessory Components

INTRODUCER SHEATHS	SHEATH SIZE (FR.)	SHEATH LENGTH (IN)	VESSEL DILATOR LENGTH (IN)	GUIDEWIRE COMPATIBILITY (IN)	RADIOPAQUE TIP MARKER	LARGE-BORE SIDEARM	COLOR CODED HUB	SETS/CASE
CL-08505	5	2	5	0.038			Gray	10
CL-08605	6	2	5	0.038			Green	10
CL-08605-HF	6	2	5	0.038	\checkmark	~	Green	5
CL-08705-HF	7	2	5	0.038	\checkmark	~	Orange	5

Does not contain natural rubber latex.

Each product includes:

One Radiopaque Polyurethane Sheath with Integral Side Port/Hemostasis Valve

One Vessel Dilator with SnapLock™ feature

*When ordering this component, the PT-03000-R and CL-08605-HF must also be ordered.

**When ordering this component, the PT-03000-R must also be ordered.

***When ordering this component, the PT-03009-RW and CL-08705-HF must also be ordered.

Caution: U.S. federal law limits this device to sale by or on order of a physician. Contents of unopened, undamaged package are sterile. Disposable. Refer to package insert for current warnings, indications, contraindications, precautions and Instructions for Use.

References:

1. NNKF-K/DOQI Clinical Practice Guidelines for Vascular Access: Update 2000. American Journal of Kidney Disease. 2000;37:137-181.

- 2. Trerotola, S.O., Vesely, T.M., Lund, G.B., Soulen, M.C., Ehrman, K.O., Cardella, J.F. Treatment of Thrombosed Hemodialysis Access Grafts: Arrow-Trerotola Percutaneous Thrombolytic Device Versus Pulse-Spray Thrombolysis. Arrow-Trerotola Percutaneous Thrombolytic Device Clinical Trial. *Radiology*. 1998;206:403-414.
- 3. Lazzaro, C.R., Trerotola, S.O., Shah, H., Namyslowski, J., Moresco, K., Patel, N. Modified Use of the Arrow-Trerotola Percutaneous Thrombolytic Device for the Treatment of Thrombosed Hemodialysis Access Grafts. Journal of Vascular Interventional Radiology. 1999;10:1025-1031.
- 4. Rocek, M., et. al. Mechanical Thrombolysis of Thrombosed Hemodialysis Native Fistulas With Use of the Arrow-Trerotola Percutaneous Thrombolytic Device: Our Preliminary Experience. Journal of Vascular Interventional Radiology. 2000;11:1153-1158.

5. Lajvardi, A., Trerotola, S.O., Strandberg, J.D., Samphilipo, M.A., Magee, C. Evaluation of Venous Injury Caused by a Percutaneous Mechanical Thrombolytic Device. Cardiovascular Interventional Radiology. 1995;18:172-178.

6. Trerotola SO, Johnson MS, Shah H, Namyslowski J. Backbleeding technique for treatment of arterial emboli resulting from dialysis graft thrombolysis. JVIR. 1998;9:141-143.

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow[®], Deknatel[®], Hudson RCI[®], LMA[®], Pilling[®], Rüsch[®] and Weck[®] – trusted brands united by a common sense of purpose.

Corporate Office

Phone +1 610 225 6800, 550 E. Swedesford Road, Suite 400, Wayne, PA 19087, USA

Regional Offices

United States: Phone +1 919 544 8000, Toll Free 866 246 6990, cs@teleflex.com, 3015 Carrington Mill Boulevard, Morrisville, NC 27560, USA

Latin America: Phone +1 919 433 4999, la.cs@teleflex.com, 3015 Carrington Mill Boulevard, Morrisville, NC 27560, USA

International: Phone +353 (0)9 06 46 08 00, orders.intl@teleflex.com, Teleflex Medical Europe Ltd., IDA Business and Technology Park, Dublin Road, Athlone, Co Westmeath, Ireland

Australia/New Zealand 1300 360 226 Austria +43 (0)1 402 47 72 Belgium +32 (0)2 333 24 60 Canada +1 (0) 905 943 9000 China (Shanghai) +86 (0)21 6163 0965 China (Beijing) +86 (0)10 6418 5699 Czech Republic +420 (0)495 759 111 France +33 (0)5 62 18 79 40 Germany +49 (0)7151 406 0 Greece +30 210 67 77 717 India +91 (0)44 2836 5040 Italy +39 0362 58 911 Japan +81 (0)3 6632 3600 Korea +82 2 536 7550 Mexico +52 55 5002 3500 Netherlands +31 (0)88 00 215 00 Portugal +351 22 541 90 85 Singapore (SEA non-direct sales countries) +65 6439 3000 Slovak Republic +421 (0)3377 254 28 South Africa +27 (0)11 807 4887 Spain +34 918 300 451 Switzerland +41 (0)31 818 40 90 United Kingdom +44 (0)1494 53 27 61

For more information, please visit teleflex.com.

Rx only

Teleflex, the Teleflex logo, Arrow, Arrow-Trerotola, and PTD are trademarks or registered trademarks of Teleflex Incorporated or its affiliates, in the U.S. and/or other countries. All other trademarks are trademarks of their respective owners. Information in this document is not a substitute for the product Instructions for Use. The products in this document may not be available in all countries. Please contact your local representative. Revised: 10/2017. Subject to technical changes without further notice.

© 2017 Teleflex Incorporated. All rights reserved. MC-002441 Rev 0.1

