

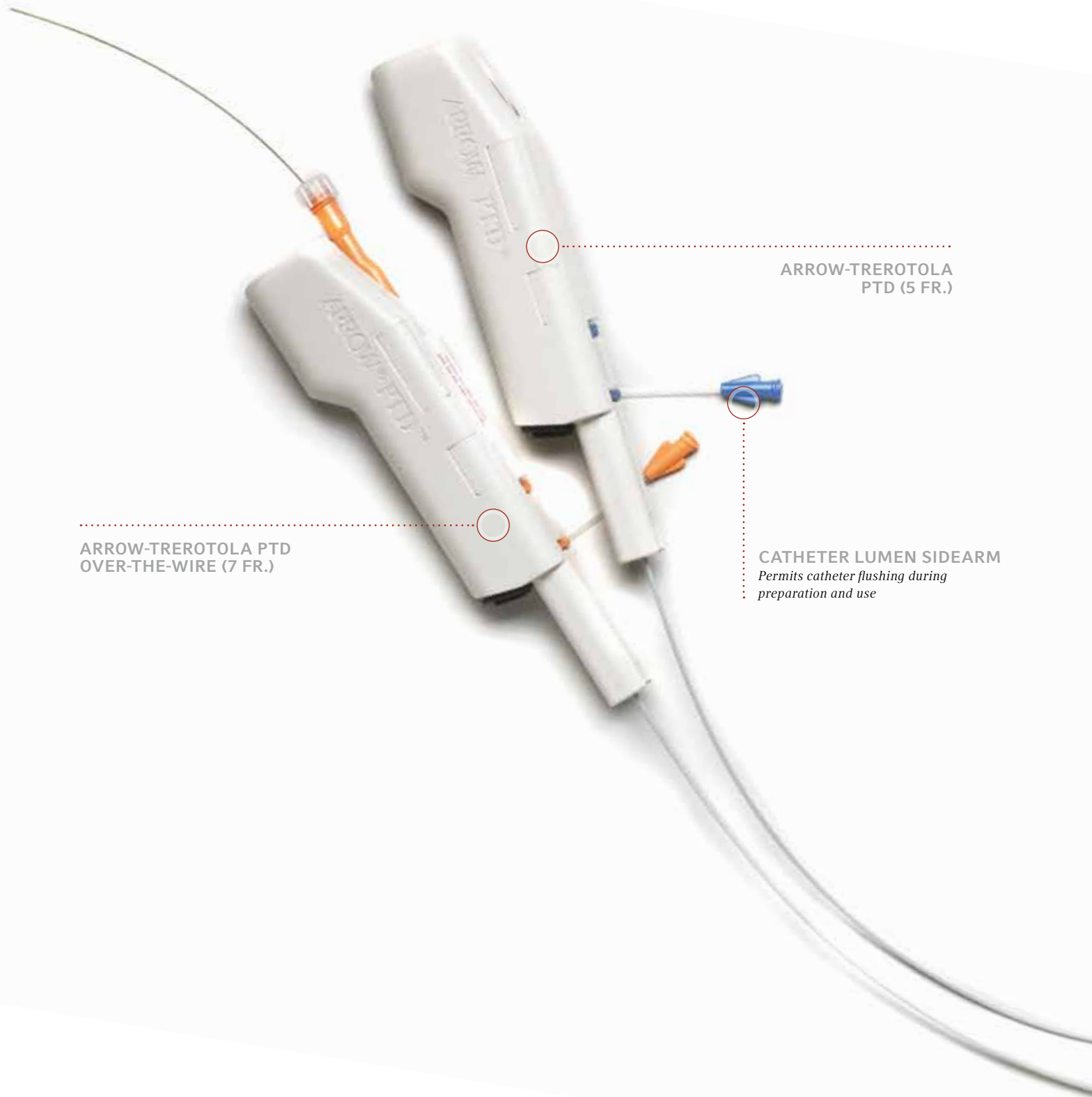
**ARROW-TREROTOLA™ PTD®**

Percutaneous Thrombolytic Device Insertion Poster



# ARROW-TREROTOLA™ PTD®

Percutaneous Thrombolytic Device



ARROW-TREROTOLA PTD  
OVER-THE-WIRE (7 FR.)

ARROW-TREROTOLA  
PTD (5 FR.)

CATHETER LUMEN SIDEARM  
*Permits catheter flushing during  
preparation and use*



**ACTIVATED SPINNING BASKET**  
*Macerates the thrombus*

**SOFT, FLEXIBLE TIP**  
*Designed to easily maneuver through vessel*

**UNIQUE EXPANDABLE 9 MM FRAGMENTATION BASKET**  
*Conforms to variable diameter walls*  
*Shown to easily remove residual thrombus from dialysis vessel walls<sup>6</sup>*

# ARROW-TREROTOLA™ PTD® 5 FR. AND 7 FR. OTW

## 5 FRENCH ARROW-TREROTOLA PTD PRODUCTS

PRODUCT #	CATHETER LENGTH (CM)	FRAGMENTATION BASKET (MM)	SHEATH INCLUDED (FR.)	ROTATOR DRIVE UNIT (RPM)	SETS/CASE
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)	TISSUE DILATOR LENGTH (IN)	MAX 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	✓	✓	Green	5
CL-08705-HF	7	2	5	0.038	✓	✓	Orange	5

Does not contain natural rubber latex.

### Each product includes:

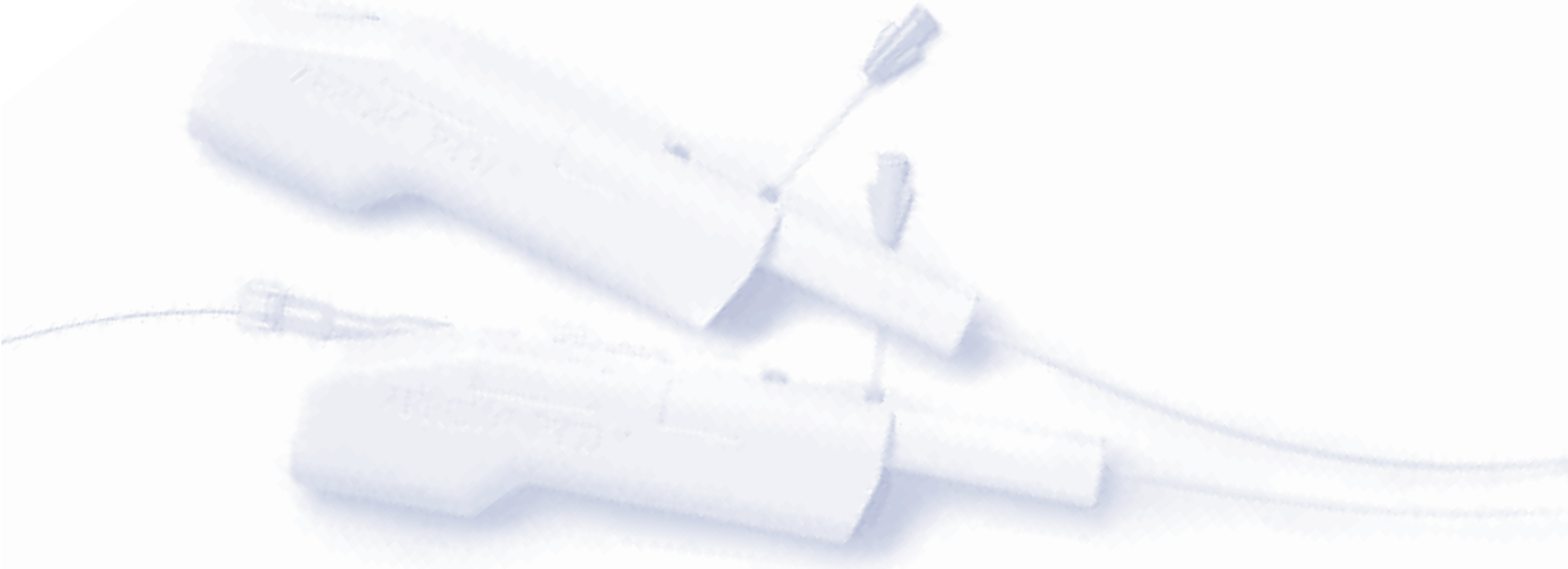
One Radiopaque Polyurethane Sheath with Integral Side Port/Hemostasis Valve  
One Vessel Dilator with SnapLock™ feature

\* 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.

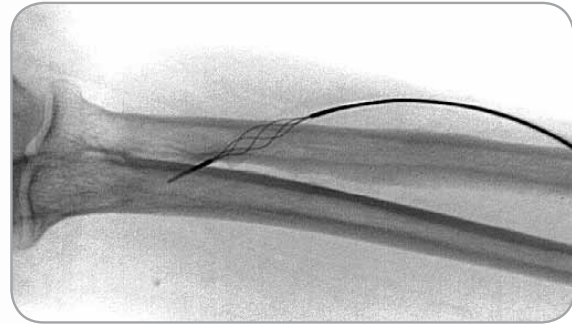


# PERCUTANEOUS THROMBOLYTIC DEVICE

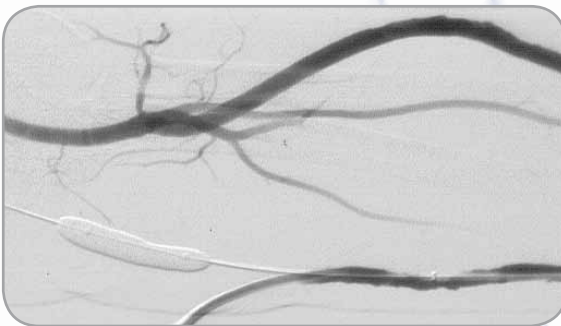
## X-RAY TESTIMONIALS-AV SYNTHETIC GRAFT



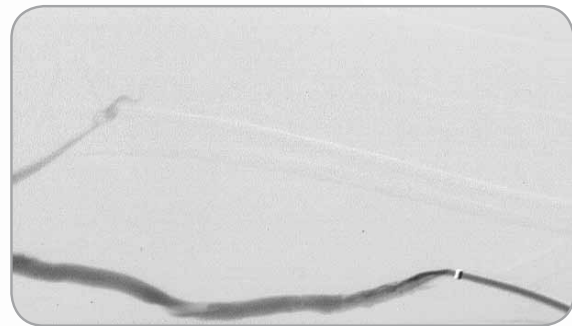
Spot radiograph shows clotted forearm loop graft.



Spot radiograph shows PTD treating arterial limb of graft.



Completed fistulogram after using PTD shows patient graft with no residual clot.



Completed fistulogram of the venous outflow after using PTD and performing angioplasty of venous stenosis shows patient graft and no residual clot.

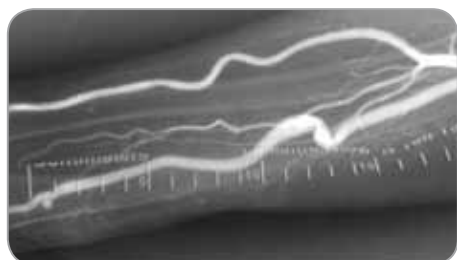
### SUMMARY OF STUDIES TO SUPPORT THE SAFETY OF PTD IN VESSELS

AUTHOR	TYPE	BRIEF DESCRIPTION OF STUDY	RESULTS
McLennan G, Trerotola SO, et al <sup>2</sup>	Animal	Effects of mechanical thrombolytic device on canine vein valves (n=51 valves)	80% exhibited no change in valve reflux function after PTD use. 77% exhibited insignificant change in reflux time.
McLennan G, Rhodes CA, et al <sup>3</sup>	Animal	Effects of mechanical thrombolytic device with stranded stainless steel basket on venous endothelium of rabbits (n=30 rabbits)	Stranded stainless steel does not cause significantly more endothelial loss as compared to surgical gold-standard Fogarty balloon catheters.
Rocek M, Peregrin JH, et al <sup>3</sup>	Human	Effects of mechanical thrombolytic device in native fistulas (n=10 patients)	90% clinical success, 70% 3 mo. Primary patency, 60% 6 mo. Primary patency.
Rocek M, Peregrin JH, et al <sup>b</sup> (abstract)	Human	Effects of mechanical thrombolytic device in synthetic grafts and native fistulas (n=25 patients)	83.3% 12 months patency.

<sup>a</sup> McLennan G, Rhodes CA, et al. Venous endothelial effects of a mechanical thrombolytic device using a stranded stainless steel basket. (unpublished study)

<sup>b</sup> Rocek M, Peregrin JH, et al. The Arrow-Trerotola percutaneous thrombolytic device and declotting of graft and native fistula occlusions: (results and one year follow-up. Abstract.)

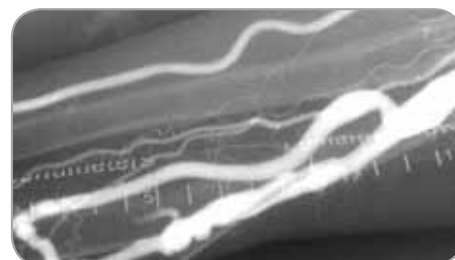
## X-RAY TESTIMONIALS-AV FISTULA



Spot radiograph from arteriogram shows thrombosed



Spot radiograph shows over-the-wire PTD treating clot in cephalic vein.



Completed fistulogram after using over-the-wire PTD shows patent fistula with no residual clot.

### CLINICAL SUMMARY<sup>g</sup>

	PTD			PULSE-SPRAY		
Number of grafts treated	64			58		
Acute technical success <sup>e</sup>	61/64 (95.3%)			55/58 (94.8%)		
Completed procedures	64			57		
MEDIAN TIME (MINUTES) IN COMPLETED PROCEDURES	N	MEDIAN	(RANGE)	N	MEDIAN	(RANGE)
Barnes Jewish	64	75	(25-209)	57	85	(50-273)
Indiana University	15	76	(50-209)	14	81.5	(60-273)
Johns Hopkins	13	58	(30-157)	14	74	(50-172)
Methodist	16	80	(25-171)	13	93	(65-131)
University of Pennsylvania	10	49	(38-92)	6	65.5	(55-103)
Penn State	10	84	(67-167)	9	94	(65-220)
				1	85	(85-85)
Functional success <sup>f</sup>						
Number of grafts requiring adjunctive therapy for residual thrombus (not including treatment of the arterial plug)	58/64 (90.6%) 29/64 (45.3%)			51/57 (89.5%) 43/47 (75.4%)		
Number of grafts able to dialyze at 3 months <sup>d</sup>	25/61 (41.0%)			23/55 (41.8%)		

<sup>c</sup> Excludes one incomplete procedure.

<sup>d</sup> Among acute technical success.

<sup>e</sup> Acute Technical Success: The establishment of patency at the end of the procedure as defined by the restoration of flow.

<sup>f</sup> Functional Success: The ability to dialyze through the graft post procedure.

## WARNINGS:

Prior to use, read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.

Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.

Practitioners must be aware of potential complications associated with percutaneous dialysis graft thrombolysis including hemorrhage, symptomatic pulmonary embolism, arterial embolization, allergic reaction to contrast, and pseudoaneurysm.

The PTD® device is not for use in stents.

Caution should be used when dislodging the plug at the arterial anastomosis to minimize the risk of arterial embolization. For the OTW device, caution should be used when declotting synthetic dialysis grafts and AV fistulas.

Due to lack of excretion associated with hemodialysis patients use of contrast should be kept to a minimum throughout this procedure.

Potential fatigue failure of PTD torque cable and fragmentation basket may occur with prolonged activation of PTD device. A withdrawal rate of 1–2 cm/second is recommended when sharp radii are encountered (i.e. radius of loop graft, radii < 3 cm).

Do not advance PTD catheter forward during activation.

Due to the risk of exposure of HIV (Human Immunodeficiency Virus) or other bloodborne pathogens, health care workers should routinely use universal blood and body fluid precautions in the care of all patients.

## REFERENCES:

1. Lajvardi A, Trerotola SO, Strandberg JD, Samphilipo MA, Magee C. Evaluation of venous injury caused by a percutaneous mechanical thrombolytic device. *Cardiovascular Interventional Radiology*. 1995; 18: 172-178.
2. McLennan G, Trerotola SO, Davidson D, Rhodes AC, et al. The Effects of a Mechanical Thrombolytic Device on Normal Canine Vein Valves. *JVIR*. 2001;12:89-94.
3. Rocek M, Peregrin, JH, Lastovickova J, Krajickova D, et al. Mechanical Thrombolysis of Thrombosed Hemodialysis Native Fistulas with use of the Arrow-Trerotola Percutaneous Thrombolytic Device: Our Preliminary Experience. *JVIR*. 2000;11:1153-1158.
4. Swan TL, Smyth SH, Ruffenach SJ, Berman SS, Pond GD. Pulmonary embolism following hemodialysis access thrombolysis/thrombectomy. *JVIR*. 1995;6:683-686.
5. Trerotola SO, Johnson MS, Schauwecker DS, Davidson DD, Filo, RS, et al. Pulmonary emboli from pulse-spray and mechanical thrombolysis: evaluation with an animal dialysis graft model. *Radiology*. 1996;200:169-176.

## PRECAUTIONS:

During native fistula declotting, an appropriate guidewire should be used with the OTW device. Excessive vessel tortuosity (i.e. tight stenosis alternate with broader segments of vessel or sharp angle of anastomosis) may significantly complicate the thrombectomy procedure. Due to tortuosity, if a guidewire cannot be advanced in the vessel or a guidewire cannot cross the clot, then an alternative procedure should be explored.

Arterial and venous sheath tips should not overlap.

Keep the exposed portion of the PTD catheter straight at all times during the procedure.

Continued unsuccessful aspiration may collapse sheath and graft/fistula. Two passes are recommended but additional passes may be required to completely macerate thrombus. The number of passes required could range from 1–8 as shown in synthetic graft study<sup>8</sup> or 2–7 passes as shown in AV fistula study<sup>3</sup>.

Do not use unit if the rotator does not activate immediately when the ON/OFF switch is depressed, and deactivate immediately when the ON/OFF switch is released.

If assessment reveals venous outflow stenosis greater than 10 cm long, untreatable central venous stenoses/occlusions, or any large pseudoaneurysm, treatment of graft should be re-evaluated and alternative treatments should be considered.

Immediately release activation switch on rotator device if an audible change in pitch becomes apparent. This will prevent rotator strain and further decrease the chance of basket breakage.

## CONTRAINDICATIONS:

The PTD devices are not recommended in the presence of hemodialysis s access site/graft infections. They are not recommended for use in venous outflow stenosis greater than 10 cm long and large pseudo aneurysm.

The non-OTW PTD is also contraindicated for untreatable central venous stenosis/occlusion.

The OTW PTD is also contraindicated for use in native vessels smaller than 6 mm in diameter and immature AV fistulas (fistulas that have not been used for at least one hemodialysis treatment).

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.
7. Trerotola SO, Lund GB, Scheel Jr PJ, Savader SJ, Venbrux AC, Osterman Jr FA. Thrombosed dialysis access grafts: percutaneous mechanical declotting without urokinase. *Radiology*. 1994;191:721-726.
8. Trerotola SO, Vesely TM, Lund GB, et al. Treatment of thrombosed hemodialysis access grafts: Arrow-Trerotola percutaneous thrombolytic device versus pulse-spray thrombolysis. *Radiology*. 1998;206:403-414.
9. Winkler TA, Trerotola SO, Davidson DD, Milgrom ML. Study of thrombus from thrombosed hemodialysis access grafts. *Radiology*. 1995;197:461-465.
10. Lazzaro CR, Trerotola SO, Shah H, Namyslowski J, Moresco K, Patel N. Modified use of the Arrow-Trerotola Percutaneous Thrombolytic Device for treatment of thrombosed hemodialysis access grafts. *JVIR*. 1999;10:1025-1031.
11. Trerotola SO, Johnson MS, Shah H, Namyslowski J, Filo RS. Incidence and management of arterial emboli from hemodialysis graft surgical thrombectomy. *JVIR*. 1997; 8:557-562.



## 5 Fr. PTD

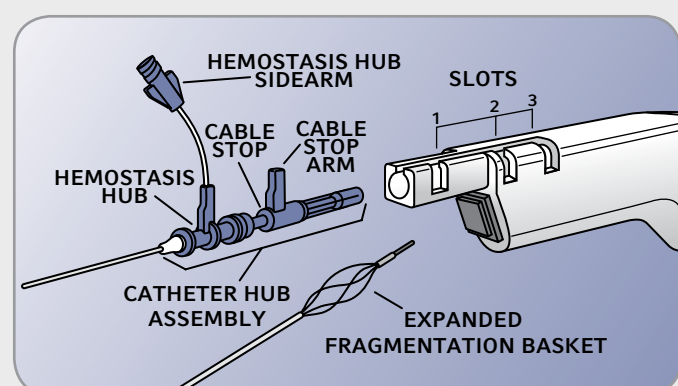


Figure 1

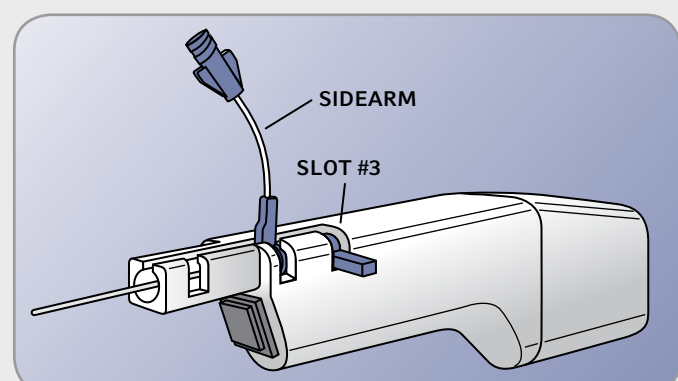


Figure 2

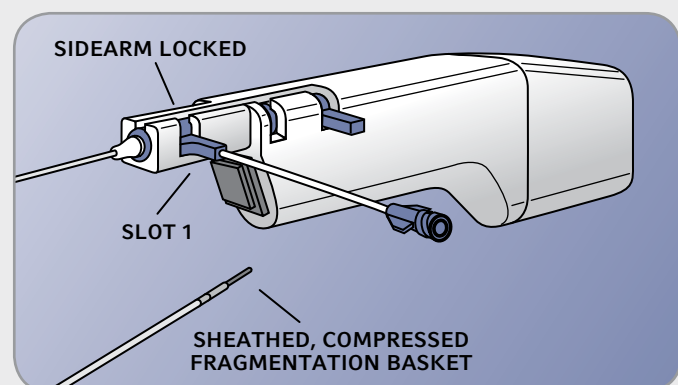


Figure 3

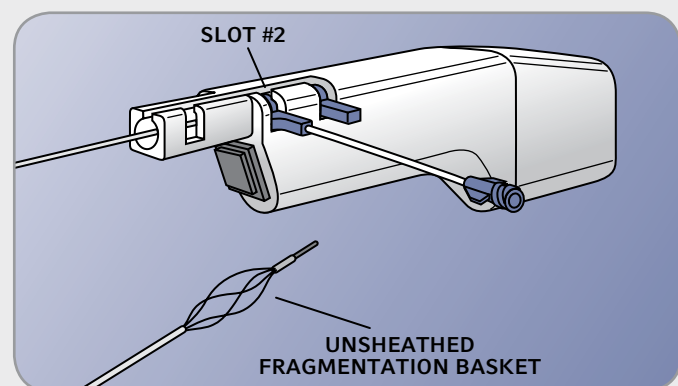


Figure 4

## ROTATOR ASSEMBLY PROCEDURE

- ▶ Flush catheter lumen through sidearm.
- ▶ Verify function of rotator drive unit by pressing ON/OFF switch.
- ▶ Insert catheter into rotator. (see Figure 1)
- ▶ Turn arm on cable stop into slot #3 to lock catheter in place. This arm should remain locked in this position throughout the entire procedure.
- ▶ Slide side arm forward to cover and compress fragmentation basket. Lock into compressed position by inserting side arm into slot #1. (see Figure 3)
- ▶ Unlock and slide side arm from slot #1 to slot #2. Lock into deployed position by inserting side arm into slot #2. (see Figure 4)
- ▶ Depress ON/OFF switch to ensure unit spins fragmentation basket. Release switch to stop motor.

**IF ANY PART OF THIS SYSTEM FAILS TO WORK, REPLACE THE MALFUNCTIONING PART AND RETEST.**

## COMBINED 5 FR. & 7 FR. OTW PTD PROCEDURE INSTRUCTIONS

### 1. PATIENT PREPARATION

- ▶ Pre-medicate, prep, and drape patient per hospital protocol.

### 2. INTRODUCER SHEATH PLACEMENT

- ▶ Refer to Figures A-D below for sheath placement techniques. Puncture sites should be at least 10 cm apart. Sheath tips should not overlap.
- ▶ Administer local anesthesia and place venous introducer sheath directed toward the venous anastomosis. NOTE: In AV fistula, the venous sheath placement can be optional depending on the clot burden in vessel. If a venous sheath is used, it should be placed in venous limb of fistula and directed toward central venous outflow. NOTE: If no venous sheath is used in AV fistula, then go to ARTERIAL LIMB THROMBOLYSIS listed below for single sheath procedure to treat AV fistula.

### 3. PATIENT ASSESSMENT

- ▶ Under fluoroscopy, assess any existing central and venous outflow stenosis per institutional protocol. In an AV fistula, if there are large thrombosed aneurysms, a cuff could be considered.

NOTE: If assessment reveals venous outflow stenosis greater than 10 cm long, untreatable central venous stenosis/occlusions, or any large pseudoaneurysm, treatment of graft should be re-evaluated and alternative treatments should be considered.

### 4. ANTICOAGULATION

- ▶ If graft or fistula is salvageable, administer heparin (or other appropriate anticoagulant) intravenously or adhere to hospital protocol.

### 5. VENOUS LIMB THROMBOSIS

- ▶ If using the 7 Fr. OTW device, advance appropriate spring-wire guide through venous sheath into venous limb of graft or fistula.

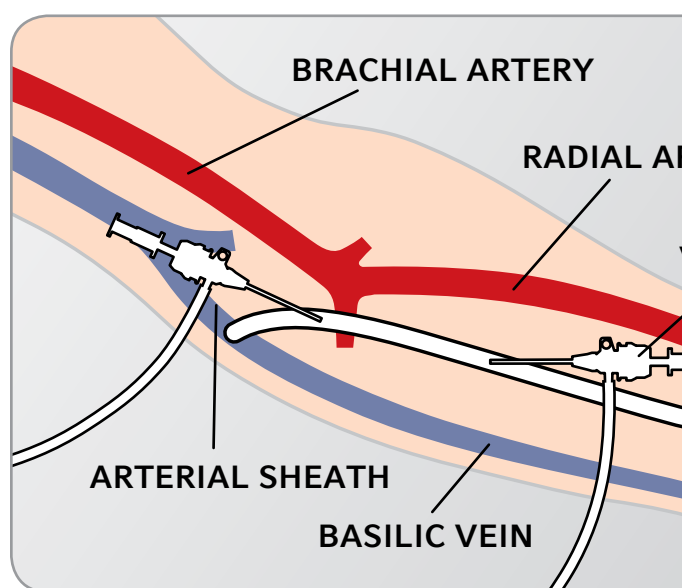


Figure A - (AV Graft)

## TROUBLESHOOTING TIPS

### POTENTIAL PROBLEM

#### Cable breaks:

In proximity of rotator

### POSSIBLE SOLUTIONS

Remove device with attached catheter sheath. Remove remaining fractured cable section from introducer sheath.

In proximity of basket

Remove catheter hub assembly. Use snare to grasp basket (not tip) and remove through introducer sheath.

#### Basket breaks:

Action depends on site of break. If possible, remove device through introducer sheath. If pulling back will cause broken wire to catch on graft/fistula wall, use snare through opposite sheath to grasp basket (not tip) of device and remove.

### POTENTIAL PROBLEM

#### Introducer sheath

Catheter basket with second sheath. Sheath exits graft.

#### Repeat clotting graft/fistula - low procedure:

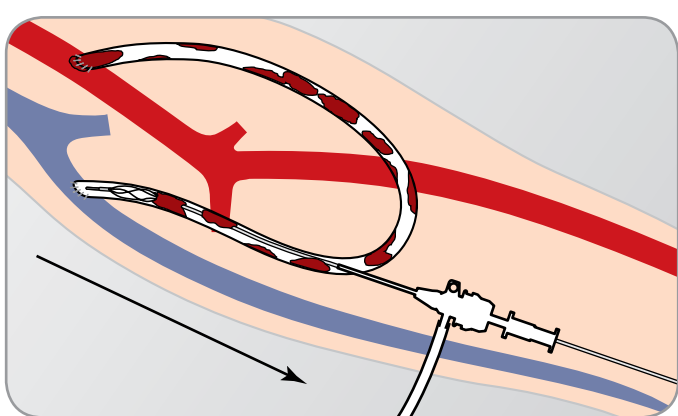
Clot caught in basket

7 Fr. orange catheter separates from



# W PERCUTANEOUS THROMBOLYTIC DEVICE

- ▶ With basket in compressed position, insert catheter (over guidewire if using the 7 Fr. OTW device) into venous limb of graft or fistula. In a graft, advance flexible tip up to, but not beyond the venous anastomosis. In a fistula, advance the tip up to the central-most extent of the clot and expose PTD basket by sliding the sidearm from slot #1 into slot #2. (see Figures 3 and 4)
- ▶ Activate the on/off switch, and slowly withdraw the deployed rotating basket along graft or vessel to macerate the adherent clot. **WARNING:** Potential fatigue failure of the PTD torque cable and fragmentation basket may occur with prolonged activation of the device. The cumulative activation time of the PTD catheter should be limited to 30-60 seconds in tight curves. A rapid withdrawal rate of 1-2 cm/second is recommended when tight curves are encountered (i.e. radius of loop graft or vessel < 3 cm).



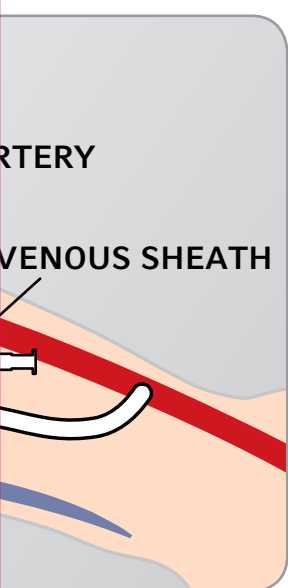
- ▶ Release switch when basket reaches tip of introducer sheath.
- ▶ Move the PTD basket into the compressed position and remove from introducer sheath (leaving the guidewire in place if using the 7 Fr. OTW device). Flush catheter lumen and manually remove fibrin from the PTD basket. Re-insert device and repeat passes as necessary.
- ▶ Remove (guidewire if using the 7 Fr. OTW device and) catheter with basket in compressed position. If possible, aspirate approx. 5cc of clot via the venous sheath and note that a closed system may prevent aspiration.

**PRECAUTION:** Continued unsuccessful aspiration may collapse venous sheath and graft/fistula. Two passes are recommended, but additional passes may be required to completely macerate thrombus. The number of passes required could range from 1-8 as shown in synthetic graft study<sup>8</sup> or 2-7 passes as shown in AV fistula study<sup>3</sup>.

- ▶ Flush catheter with heparinized saline and remove any fibrin from PTD basket. Inject a small amount of contrast to ensure adequate thrombolysis of venous limb. **AVOID OVER-INJECTION OF CONTRAST TO MINIMIZE THE RISK OF ARTERIAL EMBOLIZATION.**

## 6. ARTERIAL LIMB THROMBOLYSIS

- ▶ Administer local anesthesia and place arterial sheath directed toward arterial anastomosis.
- ▶ (If using the 7 Fr. OTW device, position spring-wire guide through arterial sheath into graft or fistula.) With catheter basket in compressed position, insert catheter (over guidewire if using the 7 Fr. OTW device) through sheath and into arterial limb of graft or fistula keeping exposed PTD catheter straight at all times.
- ▶ Advance flexible tip of PTD basket up to, but not beyond arterial anastomosis. Expose PTD basket by moving sidearm from slot #1 to slot #2, but do not grip outer catheter when deploying basket near arterial anastomosis. If catheter is held, the fragmentation basket may jump forward and cause arterial plug to dislodge and embolize. Allow catheter to slide backward in your hand. Activate rotator and repeat steps with two passes.
- ▶ Remove device in compressed position.
- ▶ Remove guidewire and aspirate approximately 5cc of clot through arterial sheath and note that a closed system may prevent aspiration. **PRECAUTION:** Continued unsuccessful aspiration may collapse arterial sheath and graft/fistula. Two passes are recommended, but additional passes may be required to completely macerate thrombus. The number of passes required could range from 1-8 as shown in synthetic graft<sup>8</sup> study or 2-7 passes as shown in AV fistula study<sup>3</sup>.
- ▶ Flush catheter lumen and remove any fibrin from PTD basket. Check device function.



Option 1

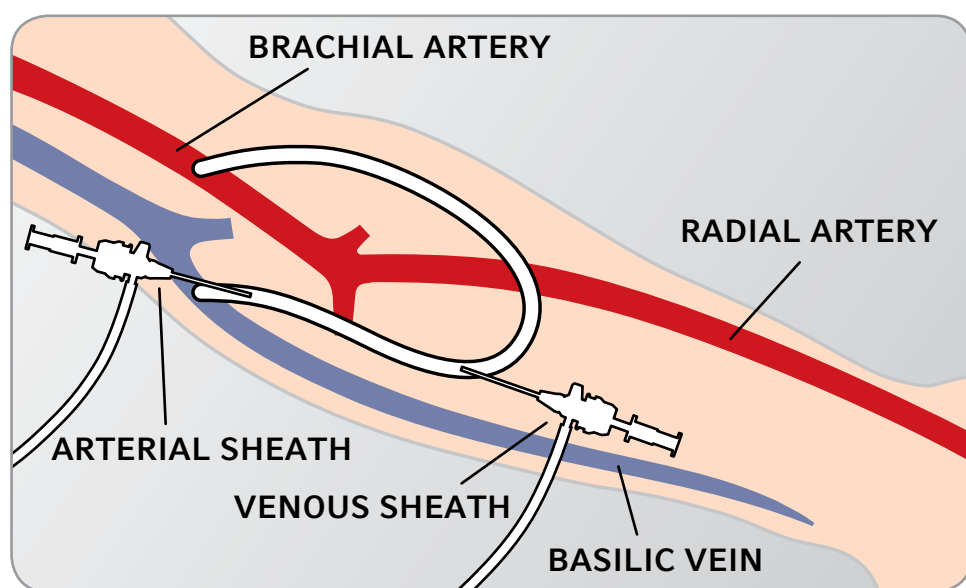


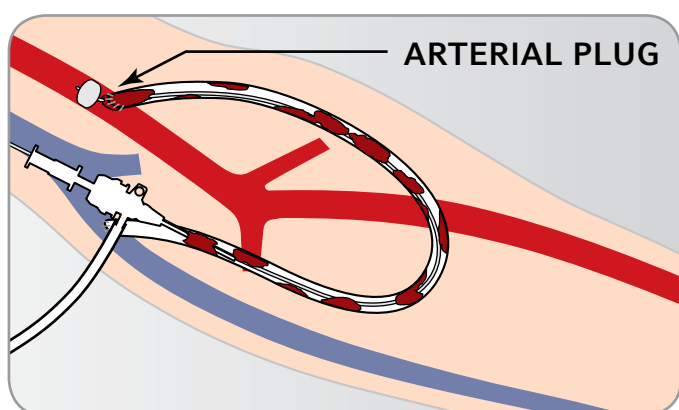
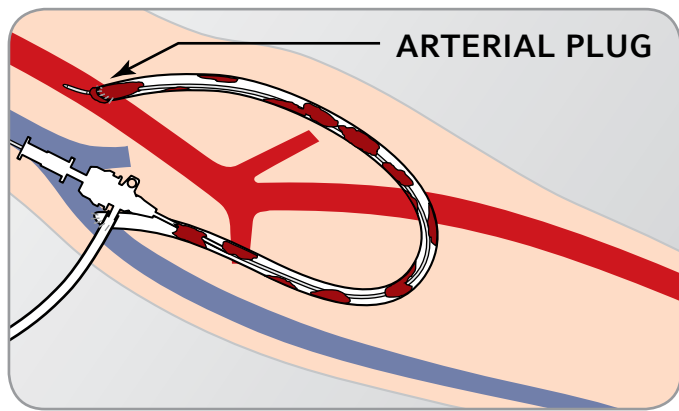
Figure B - (AV Graft)

Option 2

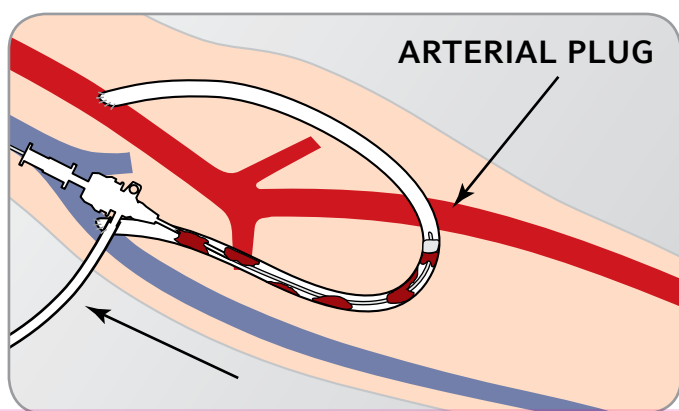
PROBLEM	POSSIBLE SOLUTIONS	POTENTIAL PROBLEM	POSSIBLE SOLUTIONS
<b>Access problems:</b> Entangled catheter Catheter not advancing	Stop rotator. Move device back and forth until free from sheath. In some cases sheath can be reinserted into graft over PTD catheter.	<b>Basket deployment failure:</b>	Make sure by manually deploying
<b>Clotting</b>	Make sure heparin level is adequate by consistently checking activated clotting time (ACT). Administer additional heparin, if necessary.	<b>Difficulty retracting basket into catheter outer sheath:</b>	Clean fibrin force to retract introduced continuously
<b>Clot aspiration:</b>	Gently pinch basket and pull thrombus toward the tip of the catheter or rinse expanded basket in saline.	<b>Difficulty aspirating venous clot:</b>	Treat arterial may be possible
<b>Cannula tip:</b>	Guidewire should always be used with 7 Fr. OTW device to ensure stabilization of cannula within basket.	<b>Incomplete maceration of clot:</b>	Make additional passes
		<b>Venous spasm due to inadvertent entry into native vessel:</b>	Administer aliquots of hospital protocol

**7a. PLUG REMOVAL PROCEDURE WITH BALLOON CATHETER (advance to 7b. for alternate plug removal procedure using the PTD)**

- ▶ If applicable, use appropriate guidewire and pass balloon catheter through arterial sheath and carefully feed past the arterial anastomosis of graft or fistula.

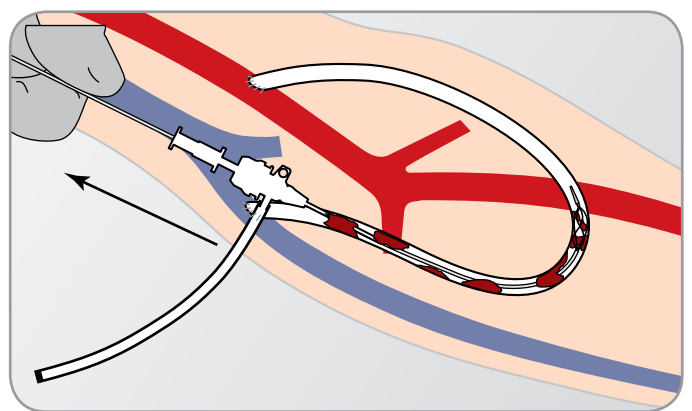


- ▶ Inflate balloon and pull arterial plug into middle of the arterial limb of graft or fistula.



- ▶ Deflate balloon and remove catheter. (remove wire if not using the 7 Fr. device.)

- ▶ Re-insert PTD catheter (over guidewire if using the 7 Fr. OTW device) back into the arterial limb. Expose PTD basket and activate rotator to macerate arterial plug using contrast to guide thrombolysis.



- ▶ (Remove guidewire if using the 7 Fr. OTW device) place PTD into compressed position and remove from sheath.
- ▶ Aspirate 5-10cc of clot using either sheath and inject contrast to assess degree of thrombus removal. Treat residual thrombus using PTD via both sheaths as needed.

**7b. PLUG REMOVAL PROCEDURE WITH PTD FOR SYNTHETIC AV GRAFTS<sup>10</sup>**

- ▶ This procedure has been evaluated in 6 mm forearm loop grafts with brachial artery anastomosis. PRECAUTION: This technique may not be applicable to straight forearm loop grafts with radial artery anastomosis or tapered grafts.
- ▶ (Re-insert guidewire if using the 7 Fr. OTW device).
- ▶ While in the compressed basket position, advance the flexible tip through the arterial anastomosis and into the inflow artery, but DO NOT ACTIVATE WHILE THE BASKET IS WITHIN THE INFLOW ARTERY.

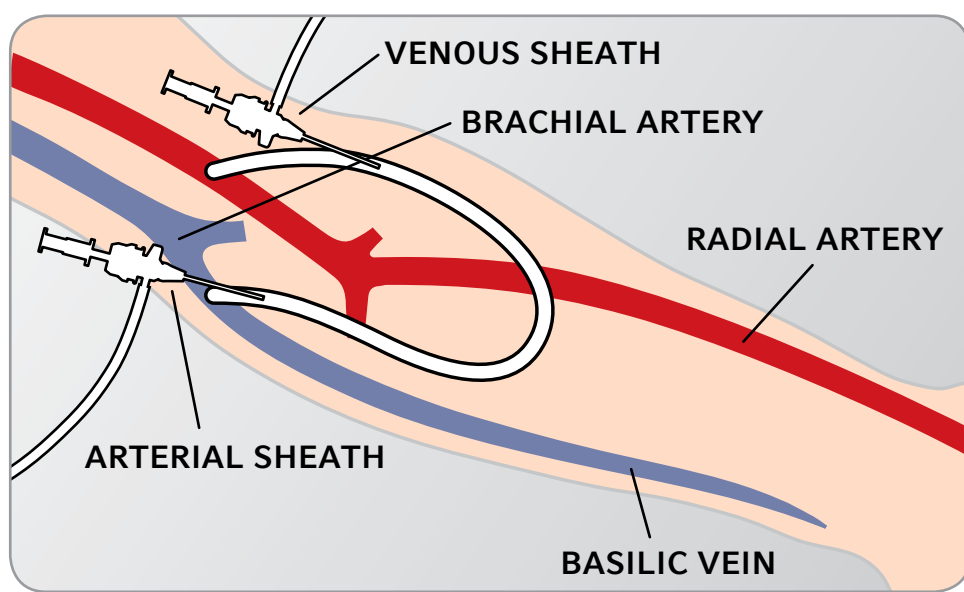
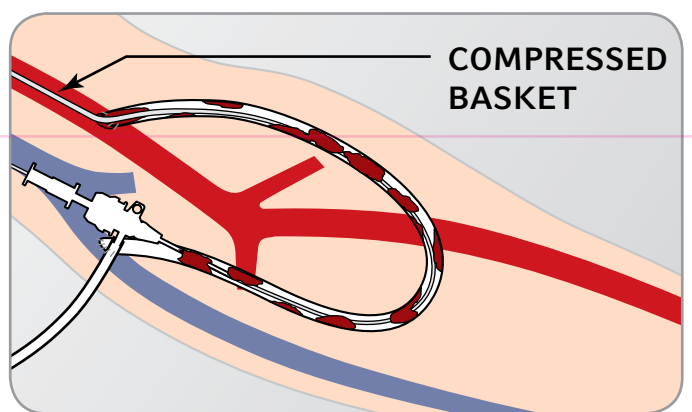


Figure C – (AV Graft)

Option 3



Figure D – (AV Fistula)

**POTENTIAL SOLUTIONS**

If fibrin has been removed from basket manually, remove it from wires. While pulling basket, activate device for short bursts.

Remove fibrin from basket frequently. Use slight pressure to resheath device. If device still cannot be pulled into outer sheath, remove device via the inner sheath and remove fibrin before reinserting procedure.

Use arterial side of graft and venous aspiration if possible.

Make additional pass through clot at a slower rate.

Use nitroglycerin, 100 µg/ml. Give in 1 ml bolus IV push to relieve spasm or adhere to protocol.

**POTENTIAL PROBLEM**

**Intact basket gets stuck:**

**Cable stretching:**

**Arterial Embolization (AE) contributing factors:**

- Holding catheter when near arterial plug
- Over-injecting contrast before clot is macerated
- Arterial plug treatment with occlusion balloon

**POSSIBLE SOLUTIONS**

Remove catheter assembly from patient and manually rotate counterclockwise basket. Manually resheath basket.

Remove device from patient and resheath.

Do not grip catheter when deploying basket near arterial anastomosis. There is a risk that basket will jump forward and dislodge arterial plug to dislodge and embolize catheter to slide backward in you. Avoid over-injecting contrast.

Use of over-the-wire occlusion balloon to reduce occurrence of AE.



## 7 Fr. OTW PTD

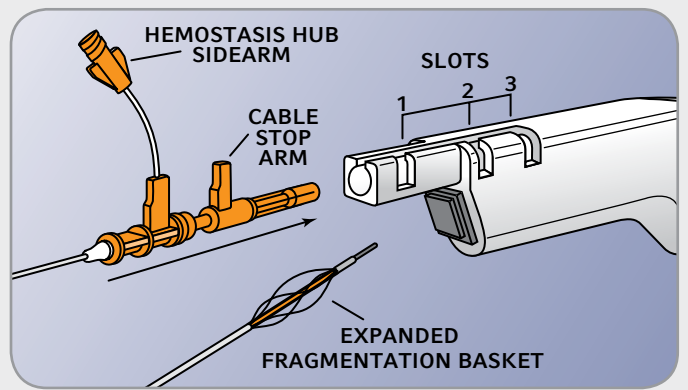


Figure 1

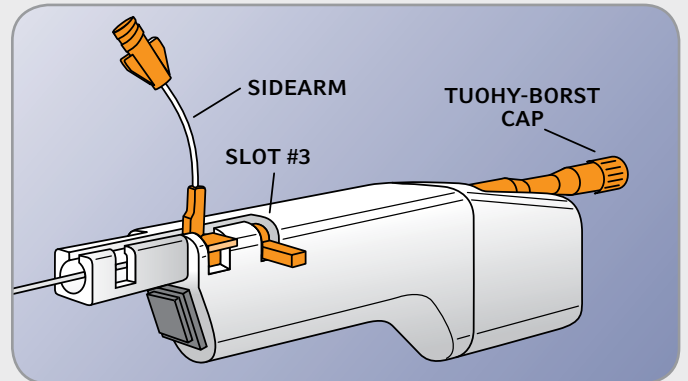


Figure 2

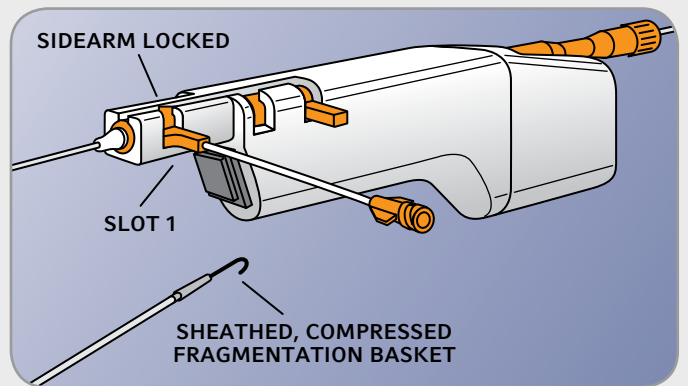


Figure 3

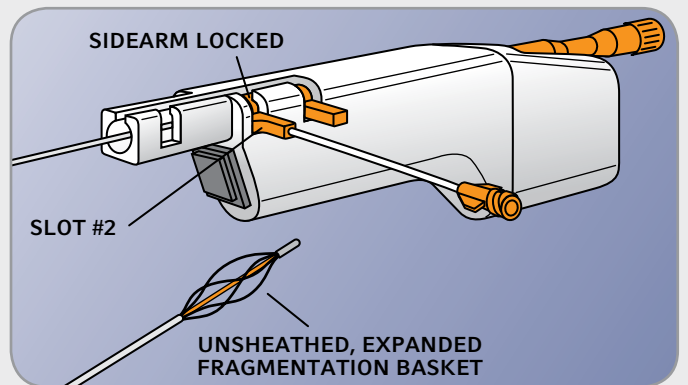


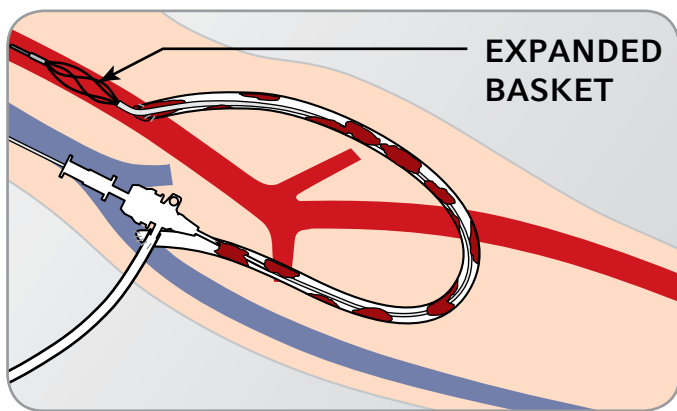
Figure 4

## ROTATOR ASSEMBLY PROCEDURE

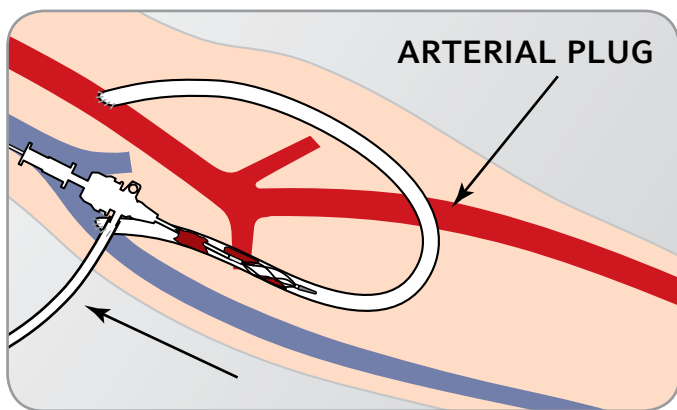
- ▶ Flush catheter lumen through sidearm.
- ▶ Verify function of rotator device unit by pressing ON/OFF switch.
- ▶ Insert catheter assembly into rotator device. (see Figure 1)
- ▶ Turn arm on cable stop into slot #3 to lock catheter into place. This arm should remain locked in this position throughout the entire procedure. (see Figure 2)
- ▶ Compress and cover PTD basket by locking sidearm into slot #1. Expose PTD basket by moving sidearm into slot #2. (see Figure 3 & 4)
- ▶ Depress ON/OFF switch to ensure unit spins fragmentation basket. Release switch to stop motor.
- ▶ Ensure Tuohy-Borst cap is open and pass guidewire into rotator unit and through the flexible tip.

**IF ANY PART OF THIS SYSTEM FAILS TO WORK, REPLACE THE MALFUNCTIONING PART AND RETEST.**

- ▶ Deploy fragmentation basket and slowly withdraw expanded basket into the arterial anastomosis until the basket begins to compress.



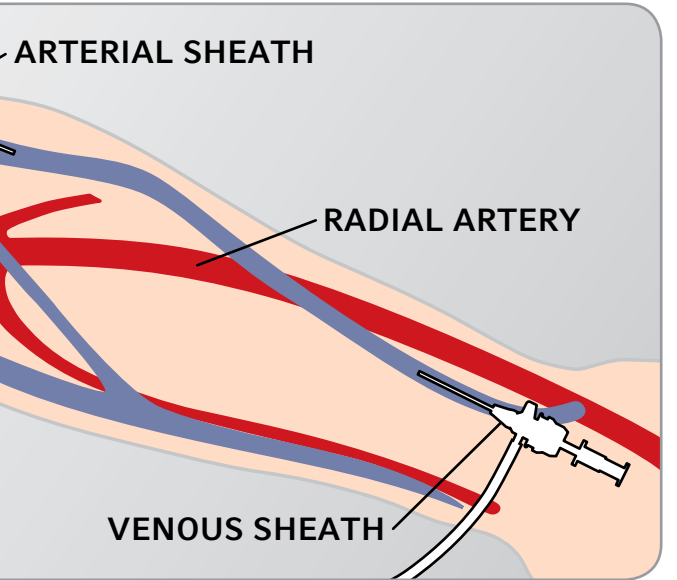
- ▶ Activate rotator while withdrawing through the graft/fistula. Move device to compressed position when you have reached the sheath tip, (leaving guidewire in place if used). Remove from sheath, flush catheter, and clean fibrin from PTD basket.
- ▶ Repeat passes in above steps as necessary.



- ▶ (Remove guidewire if using the 7 Fr. OTW device).
- ▶ Aspirate 5-10cc of clot using either sheath.

## 8. ASSESSMENT AND PROCEDURE WRAP-UP

- ▶ Inject contrast to assess degree of thrombus removal. Treat residual thrombus using PTD via both sheaths as needed.
- ▶ Remove blood pressure cuff or tourniquet if used. When thrombus removal is complete, any underlying disease or stenosis should be treated with balloon angioplasty per hospital protocol.
- ▶ Perform final fistulogram. Remove sheaths, verifying entire length has been withdrawn. Achieve hemostasis at both sites per hospital protocol.



## TREATMENT OF SYMPTOMATIC ARTERIAL EMBOLIZATION<sup>11</sup>

### Mechanical techniques:

1. Treat with backbleeding - place an embolectomy catheter in artery proximal to the anastomosis, inflate the balloon and allow backbleeding from the distal artery to carry embolus back into graft.
2. Use an over-the-wire balloon (e.g. wedge catheter) to mobilize embolus.
3. Thromboaspiration.

If mechanical techniques fail, thrombolysis or surgical thrombectomy may be alternatives. Asymptomatic emboli may not need treatment.

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