ARROW-TREROTOLA™ PTD®

Percutaneous Thrombolytic Device Insertion Poster
ARROW-TREROTOLA™ PTD®
Percutaneous Thrombolytic Device

CATHETER LUMEN SIDEARM
Permits catheter flushing during preparation and use

ARROW-TREROTOLA PTD (5 FR.)

ARROW-TREROTOLA PTD OVER-THE-WIRE (7 FR.)
ARROW-TREROTOLA PTD (5 FR.)
CATHETER LUMEN SIDEARM
Permits catheter flushing during preparation and use

ARROW-TREROTOLA PTD OVER-THE-WIRE (7 FR.)
UNIQUE EXPANDABLE 9 MM FRAGMENTATION BASKET
Conforms to variable diameter walls
Shown to easily remove residual thrombus from dialysis vessel walls

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

Teleflex Incorporated (NASDAQ: TEFX) has annual revenues of approximately $1.5 billion and customers in more than 130 countries.
ARROW-TREROTOLA™ PTD® 5 FR. AND 7 FR. OTW PERCUTANEOUS THROMBOLYTIC DEVICE

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

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

5 FRENCH ARROW-TREROTOLA PTD PRODUCTS

<table>
<thead>
<tr>
<th>PRODUCT #</th>
<th>CATHETER LENGTH (CM)</th>
<th>FRAGMENTATION BASKET (MM)</th>
<th>SHEATH INCLUDED (FR.)</th>
<th>ROTATOR DRIVE UNIT (RPM)</th>
<th>SETS/CASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT-03000-R</td>
<td>–</td>
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<td>PT-65509**</td>
<td>65</td>
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<tr>
<td>PT-45509**</td>
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<td>9</td>
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<tr>
<td>PT-65509-HFC</td>
<td>65</td>
<td>9</td>
<td>2/6 (HF)</td>
<td>3000</td>
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7 FRENCH ARROW-TREROTOLA OVER-THE-WIRE PTD PRODUCTS

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

PTD ACCESSORY COMPONENTS

<table>
<thead>
<tr>
<th>INTRODUCER SHEATHS</th>
<th>SHEATH SIZE (FR.)</th>
<th>SHEATH LENGTH (IN)</th>
<th>TISSUE DILATOR LENGTH (IN)</th>
<th>MAX GUIDEWIRE COMPATIBILITY (IN)</th>
<th>RADIOPAQUE TIP MARKER</th>
<th>LARGE-BORE SIDEARM</th>
<th>COLOR-CODED HUB</th>
<th>SETS/CASE</th>
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</thead>
<tbody>
<tr>
<td>CL-0850S</td>
<td>5</td>
<td>2</td>
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<td>0.038</td>
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<td>CL-0860S</td>
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<td>CL-08605-HF</td>
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<td>0.038</td>
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<td>✓</td>
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<tr>
<td>CL-08705-HF</td>
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<td>5</td>
<td>0.038</td>
<td>✓</td>
<td>✓</td>
<td>Orange</td>
<td>5</td>
</tr>
</tbody>
</table>

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**

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

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9 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.

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**CLINICAL SUMMARY**

<table>
<thead>
<tr>
<th></th>
<th>PTD</th>
<th>PULSE-SPRAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of grafts treated</td>
<td>64</td>
<td>58</td>
</tr>
<tr>
<td>Acute technical success</td>
<td>61/64 (95.3%)</td>
<td>55/58 (94.8%)</td>
</tr>
<tr>
<td>Completed procedures</td>
<td>64</td>
<td>57</td>
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<table>
<thead>
<tr>
<th><strong>MEDIAN TIME (MINUTES) IN COMPLETED PROCEDURES</strong></th>
<th><strong>N</strong></th>
<th><strong>MEDIAN</strong> (<strong>RANGE</strong>)</th>
<th><strong>N</strong></th>
<th><strong>MEDIAN</strong> (<strong>RANGE</strong>)</th>
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</thead>
<tbody>
<tr>
<td>Barnes Jewish</td>
<td>64</td>
<td>75 (25-209)</td>
<td>57</td>
<td>85 (50-273)</td>
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<tr>
<td>Indiana University</td>
<td>15</td>
<td>76 (50-209)</td>
<td>14</td>
<td>81.5 (60-273)</td>
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<tr>
<td>Johns Hopkins</td>
<td>13</td>
<td>58 (30-157)</td>
<td>14</td>
<td>74 (50-172)</td>
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<tr>
<td>Methodist</td>
<td>16</td>
<td>80 (25-171)</td>
<td>13</td>
<td>93 (65-131)</td>
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<tr>
<td>University of Pennsylvania</td>
<td>10</td>
<td>49 (38-92)</td>
<td>6</td>
<td>65.5 (55-103)</td>
</tr>
<tr>
<td>Penn State</td>
<td>10</td>
<td>84 (67-167)</td>
<td>9</td>
<td>94 (65-220)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>85 (85-85)</td>
<td></td>
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</tr>
</tbody>
</table>

| Functional success of residual thrombus (not including treatment of arterial plug) | 58/64 (90.6%) | 51/57 (89.5%) |
| Number of grafts able to dialize at 3 months | 25/61 (41.0%) | 23/55 (41.8%) |

---

1. Excludes one incomplete procedure.
2. Among acute technical success.
3. Acute Technical Success: The establishment of patency at the end of the procedure as defined by the restoration of flow.
4. Functional Success: The ability to dialize 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.

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 1–6 as shown in synthetic graft study1 or 2–7 passes as shown in AV fistula study5.

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/graf 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).

REFERENCES:


**TROUBLESHOOTING TIPS**

**Basket breaks:**

**POTENTIAL PROBLEM**  POSSIBLE SOLUTIONS

IF ANY PART OF THIS SYSTEM FAILS TO WORK, Figure 1

**ACTION DEPENDS ON SITE OF BREAK. IF POSSIBLE,**

**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 stenoses/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.

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**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.

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**TROUBLESHOOTING TIPS**

**5 Fr. PTD**

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**COMBINED 5 FR. & 7 FR. OTW PTD 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 stenoses/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.

---

**POTENTIAL PROBLEM**  **POSSIBLE SOLUTIONS**

| Cable breaks: | Remove device with attached catheter sheath. Remove remaining fractured cable section from introducer sheath. |
| In proximity of rotator | Remove catheter hub assembly. Use snare to grasp basket (not tip) and remove through introducer sheath. |
| In proximity of basket | 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 PR**

- Introducer sheath
  - Catheter basket with second sheath
  - Sheath exits graft

- Repeat clotting graft/fistula - to procedure:

- Clot caught in t

---

**7 Fr. orange car separates from**

---

**Figure 1 – (AV Graft)**
### ARROW-TREROTOLA™ PTD® 5 FR. AND 7 FR. OTW PERCUTANEOUS THROMBOLYTIC DEVICE

**In proximity of rotator**
Remove device with attached catheter sheath.

**Figure 2**

1. **Unlock and slide side arm from slot #1** to **slide side arm forward to cover and spins fragmentation basket. Release** (see Figure 4)

2. **Locked in this position throughout the catheter in place. This arm should remain in locked position and remove from introducer sheath**.

3. **Remove device in compressed position.**

4. **Remove guidewire and aspirate approximately 5 cc of clot through arterial channel and note that a closed system may prevent aspiration.**

5. **Activate rotator while withdrawing through arterial anastomosis until the basket begins to compress.**

### 6. ARTERIAL LIMB THROMBOLYSIS

**Administer local anesthetica 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) into venous limb of graft or fistula. In a graft, advance flexible tip up to, but not beyond arterial anastomosis. NOTE: If assessment reveals venous outflow problems, additional passes may be required to completely macerate thrombus. The number of passes required could range from 1-8 as shown in synthetic graft study3 or 2-7 passes as shown in AV fistula study1.

**Flush catheter with heparinized saline and remove any fibrin from PTB 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.**

### OTW PTD PROCEDURE

**COMBINED 5 FR. & 7 FR.**

#### 1. PATIENT PREPARATION

- **Refer to** below for single sheath procedure to treat arterial limb thrombolysis listed below for sheath (if using the 7 Fr. OTW device, position distal end marked with white line of PTD catheter at site). Administer local anesthesia and place arterial sheath directed toward 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** 5 cc of clot through arterial channel and note that a closed system may prevent aspiration. PRECAUTION: Continued unsuccessful aspiration may collapse arterial graft or fistula. The number of passes required could range from 1-8 as shown in synthetic graft study3 or 2-7 passes as shown in AV fistula study1.

**Flush catheter lumen and remove any fibrin from PTB basket. Check device function.**

### TROUBLESHOOTING TIPS

- With basket in compressed position, insert catheter (over guidewire) or rinse expanded basket in saline. Make sure fibrin has been removed from basket by manually removing it from wires. While advancing through the graft establish thrombus. Re-insert device and repeat passes as necessary.

- Make sure heparin level is adequate by checking activated clotting time (ACT). Administer additional heparin, if necessary.

- Insert catheter assembly into rotator device.

- Deploy fragmentation basket and slowly withdraw catheter sheath to grasp basket (not tip) of device and separate from tip:

  - Gently pinch basket and pull thrombus toward the native vessel:
    - For synthetic graft study 8 or 2 hand. Activate rotator and repeat steps with one pass.

  - Refer to the anastomosis, inflate the balloon and allow backbleeding from the distal 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.

| OBLEM | POSSIBLE SOLUTIONS | POTENTIAL PROBLEM | POSSIBL
<table>
<thead>
<tr>
<th></th>
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</tr>
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<tbody>
<tr>
<td>enthralg</td>
<td>Stop rotator. Move device back and forth until free from entanglement.</td>
<td>Basket deployment failure: Make sure by manual deploying</td>
<td></td>
</tr>
<tr>
<td>ng</td>
<td>Make sure fibrin level is adequate by consistently checking activated clotting time (ACT). Administer additional heparin, if necessary.</td>
<td>Difficulty retracting basket into catheter outer sheath: Clean fibrin force to n retracted introduce continue</td>
<td></td>
</tr>
<tr>
<td>blet</td>
<td>Gently pinch basket and pull thrombus toward the tip of the catheter or rinse expanded basket in saline.</td>
<td>Difficulty aspirating venous clot: Treat arterial may be</td>
<td></td>
</tr>
<tr>
<td>lula</td>
<td>Gudrew she should always be used with 7 Fr. OTW device to ensure stabilization of cannula within basket.</td>
<td>Incomplete maceration of clot: Make add</td>
<td></td>
</tr>
<tr>
<td>spasm due to inadvertent entry into native vessel:</td>
<td>Venous spasm due to inadvertent entry into native vessel: Administer adenosine or local heparin p</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Figure 1**

**Figure 2**

**Figure 3**

**Figure 4**

**Figure 5**

**Figure 6**

**Figure 7a. PLUG REMOVAL PROCEDURE**

- If applicable, use appropriate guidewire (ACT). Administer additional heparin, if necessary. In some cases sheath can be reinserted into graft.

- Aspirate 5-10cc of clot using either sheath and remove from sheath.

- Make sure fibrin has been removed from basket by manually removing it from wires. While advancing through the graft establish thrombus.

- Re-insert device and repeat passes as necessary.

- Make sure heparin level is adequate by checking activated clotting time (ACT). Administer additional heparin, if necessary.

- Insert catheter assembly into rotator device.

- Deploy fragmentation basket and slowly withdraw catheter sheath to grasp basket (not tip) of device and separate from tip:

  - Gently pinch basket and pull thrombus toward the native vessel:
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.)

7b. PLUG REMOVAL PROCEDURE WITH PTD FOR SYNTHETIC AV GRAFTS™

- 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 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.

8. ASSESSMENT AND PROCEDURE WRAP-UP

- Administer nitroglycerin, 100 µg/ml. Give in 1 ml push to relieve spasm or adhere to protocol.

- If fibrin has been removed from basket fly removing it from wires. While basket, activate device for short bursts.

- Re-inspect femoral or brachial sheath for perforation.

- Ensure Tuohy-Borst cap is open and pass guidewire into rotator unit and through the fragmentation basket. Release switch to spins fragmentation basket. Release switch to stop motor.

- Under fluoroscopy, assess any existing central and venous outflow stenosis per appropriate spring-wire guide through graft or fistula.

- If using the 7 Fr. OTW device, advance the venous anastomosis. NOTE: In AV fistula, the PTD catheter should be limited to 30-60 seconds of OTW application.

- Make additional pass through clot at a slower rate.

- While in the compressed basket position, remove any fibrin from PTD basket. Inject a sheath and graft/fistula. Two passes are required, but additional passes may be recommended, but additional passes may be required to completely macerate thrombus.

- Aspirate 5-10cc of clot using either sheath and remove from sheath.

- 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.

- Remove guidewire and aspirate clot.

- Administer additional heparin, if necessary.

- Remove (guidewire if using the 7 Fr. device.)

- Flush catheter lumen through sidearm.

- Achieve hemostasis at both sites per native vessel:

- Venous clot:

- Clean fibrin from basket frequently. Use slight pressure if not using the 7 Fr. OTW device.

- Re-inspect femoral or brachial sheath for perforation.

- With PTD FOR SYNTHETIC AV GRAFTS™

- WITH PTD FOR SYNTHETIC AV GRAFTS™

- WITH BALLOON CATHETER

- Remove catheter assembly from and manually rotate counterclockwise to guide thrombolysis.

- Remove device from patient and do not grip catheter when deploying basket near arterial anastomosis. Risk that basket will jump forward arterial plug to dislodge and embolize catheter to slide backward in you. Avoid over-injecting contrast.

- Use of over-the-wire occlusion is reduce occurrence of AE.

- Remove guidewire and aspirate clot.

- Administer additional heparin, if necessary.

- Remove (guidewire if not using the 7 Fr. device.)

- Flush catheter lumen through sidearm.

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- Use of over-the-wire occlusion is reduce occurrence of AE.
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)

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.

Additional steps:

- 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 Tushy-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.
ARROW-TREROTOLA™ PTD®
Percutaneous Thrombolytic Device Insertion Poster

ARROW-TREROTOLA PTD (5 FR.)
CATHETER LUMEN SIDEARM
Permits catheter flushing during preparation and use

ARROW-TREROTOLA PTD OVER-THE-WIRE (7 FR.)
UNIQUE EXPANDABLE 9 MM FRAGMENTATION BASKET
Conforms to variable diameter walls
Shown to easily remove residual thrombus from dialysis vessel walls

ACTIVATED SPINNING BASKET
Macerates the thrombus

SOFT, FLEXIBLE TIP
Designed to easily maneuver through vessel