Trans-Arterial Micro Perfusion (TAMP™)
DELIVERING THERAPY WHERE IT MATTERS™

RenovoCath®

Instructions for Use

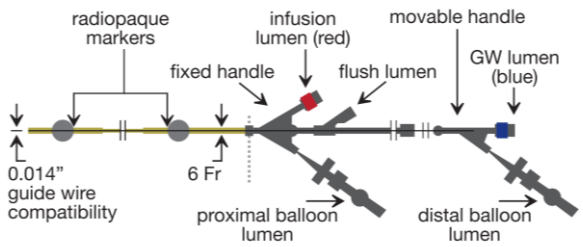

Figure 1: RenovoCath® Device Components

Caution: Federal law restricts this device to sale by or on the order of a physician.
This device should be used only by trained physicians familiar with interventional radiological procedures.

INSTRUCTIONS FOR USE

Please read instructions prior to using this product, with careful attention to caution symbols. This product is sterile and non-pyrogenic. Sterilized using ethylene oxide gas. Single use ONLY. Do not re-sterilize or reuse.

DEVICE DESCRIPTION

The RenovoCath® device includes the components shown in Figure 1. The device is a multi-lumen, dual-balloon catheter having a two-part handle that is designed for targeted delivery of fluids, including radiopaque material and therapeutic agents, to selected sites in the peripheral vascular system. The inflation of the proximal occlusion balloon and of the distal occlusion balloon may isolate the selected site prior to the infusion of fluids into the same site. The two balloons are inflated independently using diagnostic contrast agents delivered via two separate inflation lumens (Distal Balloon Lumen and Proximal Balloon Lumen). The two-part handle consists of a Fixed Handle and a Movable Handle. The distance between the proximal occlusion balloon and the distal occlusion balloon is controlled by the physician within a range of values (15mm to 109mm, measured between the radiopaque marker bands) by changing the position of the Movable Handle, which controls the distal balloon, relative to the Fixed Handle, which controls the proximal balloon and is stationary. Radiopaque markers are located between the two balloons to allow for identification of targeted site and position adjustment under fluoroscopic guidance.
The radiopaque markers are internal to the balloons and designate the total occluded area by identifying the region between the distal and proximal balloons. Physician-specified infusion fluid is delivered through the infusion lumen (Infusion Lumen, red color). An additional lumen provides for guide wire entry (Guide wire Lumen, blue color).
The last lumen is for flushing the catheter prior to use (Flush Lumen).

COMPATIBILITY

The RenovoCath device is intended to be used with 6 Fr guide sheaths and 7 Fr guide catheters (neither is shown). The device is compatible with 0.014" guide wires (also not shown) for positioning the catheter in the desired region. The effective length is 75cm to 85cm (adjustable).

INDICATIONS FOR USE

The RenovoCath device is intended for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. The RenovoCath device is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. The RenovoCath device is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath device is intended for use in arteries from 3mm in diameter for vessel entry and to occlude vessels ranging between 3mm to 11mm in diameter.
The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the respective agent manufacturer.

Table 1: Balloon Compliance

Inflation Volume (cc) Average	Vessel Diameter (mm)
0.10	3
0.10	4
0.14	5
0.19	6
0.28	7
0.39	8
0.56	9
0.69	10
0.99	11

Note: Maximum volume tested is 1.07cc

HOW SUPPLIED

Contents: One (1) RenovoCath device
Storage: Store in a dry, cool dark place.
Sterile: Sterilized with Ethylene Oxide gas.
Single-use only. Do not re-sterilize.

CONTRAINDICATIONS

- It is the responsibility of the physician to determine whether any physical impairment, including any vascular abnormality or reaction to contrast medium, of the patient would contraindicate the use of this device.
- The RenovoCath device is not intended for use in coronary and intracranial arteries.
- The RenovoCath device is not intended for embolic protection or as an aspiration catheter.

WARNINGS

- The device is intended for one time use only. Do not re-sterilize, reuse or reprocess. Reuse, reprocessing or re-sterilization can result in compromised device performance or contamination, which in turn may result in patient injury, illness or death.
- Do not attempt to use the device if its package has been opened or damaged.
- Verify vessel dimensions prior to inflation to ensure they do not exceed the maximum balloon diameter.
- Use only recommended balloon inflation medium of diluted contrast medium solution by volume. Never use air to inflate the balloons.
- Do not exceed maximum listed balloon inflation volume as this may cause the balloon to rupture.
- The RenovoCath device should only be used with a 0.014" guide wire.
- Use the catheter prior to the "Use Before" date specified on the package label.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.

PRECAUTIONS

- This device should be used only by trained physicians familiar with the principles, applications and risk associated with percutaneous interventional radiological procedures. General technical requirements for catheter insertion should be observed at all times.
- Precautions should be taken to reduce the possibility of thrombosis formation, such as limiting treatment time.
- Use of heparin (or other approved antithrombotic agents) is recommended during the procedure.

- Manipulation of the device inside the body should only be performed under fluoroscopic visualization.
- If flow through the catheter becomes restricted, do not attempt to clear by increasing infusion pressure.
- Before retrieving the RenovoCath device through the guide catheter or sheath, confirm via fluoroscopy that balloons are fully deflated.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel at the desired site of occlusion.

POTENTIAL ADVERSE EVENTS

Adverse events that may result from a catheter procedure include vessel perforation or dissection, vessel spasm, damage or trauma; hemorrhage; hematoma, pain or tenderness at puncture site; vascular thrombosis; drug reactions; allergic reaction to contrast medium; infection; hemodynamic changes; aneurysm; air embolism; arrhythmia; limb necrosis, respiratory failure, neutropenia, and death.

INSPECTION PRIOR TO USE

Prior to use, carefully handle and thoroughly evaluate the catheter to verify that neither the sterile packaging nor the device has been damaged. Inspect the catheter for bends, kinks or other damage. Carefully evacuate air from all systems and thoroughly inspect all connections for leakage.

THE TAMP™ DRUG-DELIVERY PROCEDURE

CATHETER PREPARATION

1. Always handle the RenovoCath device carefully and avoid sharply bending or kinking as this could damage the device and impair its function. Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked as this may result in the shaft breaking. Instead, prepare a new catheter.

2. Remove stylet from the guide wire lumen (blue). The stylet (a wire inserted into the catheter) maintains rigidity during shipping.
3. Fill a standard 3cc syringe with normal saline.
4. Attach the syringe to the guide wire lumen (blue) and flush with normal saline.

Note: The RenovoCath device should only be used with a 0.014" guide wire.

5. Re-fill syringe with normal saline and attach syringe to the flush lumen of the catheter.
6. Gently inject saline through the flush lumen.
7. Refill syringe with normal saline and flush the infusion lumen (red) with saline.
8. Insert a long 0.014" guide wire through the catheter tip. Move the catheter over the guide wire until the wire exits the guide wire lumen, at which time it can be secured.
9. Remove the clip, which prevents accidental movement of the balloons.
10. In small motions, from the handle, gently extend and retract catheter and re-flush the flush lumen as needed to facilitate smooth balloon distance adjustment.

BALLOON PREPARATION

11. In a small container, prepare approximately 30 cc of diluted contrast (70% saline/30% contrast).
12. Fill a standard 1.0 cc syringe with diluted contrast. Verify balloon stopcocks are tightly connected and attach the syringe to the distal balloon stopcock. Inject a small volume of diluted contrast into the balloon to verify its inflation and integrity.
13. Aspirate the contrast with the 1.0 cc syringe and close the stopcock.
14. Disconnect the 1.0 syringe and attach a 10 cc syringe half-filled with diluted contrast. Pull a vacuum with the 10 cc syringe while maintaining the syringe tip and distal catheter tip in a downward position to remove any residual air from the balloon. Hold vacuum pressure for 20-30 seconds while air is removed. Release the syringe plunger to allow diluted contrast passively into the distal balloon.
15. Repeat step 14 as necessary to ensure proper evacuation of air from the catheter shaft and balloon.
16. Set the stopcock valve of the distal balloon to the OFF position.
17. Remove the 10 cc syringe.
18. Fill a 1.0 cc luer lock syringe with diluted contrast and connect to the stopcock on the distal balloon.
19. Repeat steps 12-18, this time at the proximal balloon.
20. Set the catheter aside, keeping the distal end hydrated with saline until ready for use.

INSERTION AND POSITIONING

21. Introduce an off-the-shelf 6 Fr guide sheath (or, 7 Fr guide catheter) using standard technique.
22. Introduce the RenovoCath device over a 0.014" guide wire.
23. With the distal end of the guide wire secured, carefully adjust the position of the distal occlusion balloon relative to the proximal occlusion balloon by pulling apart the Movable Handle relative to the Fixed Handle until balloons' distance is at the minimum.
24. Re-flush the flush port as necessary, detach syringe and put an end cap or closed one-way valve on the flush port.
25. With the guide wire secured, introduce the RenovoCath device into the vasculature using standard technique over the guide wire. Under fluoroscopy, guide the catheter into position within the selected vessel.
26. Maintain balloons at minimum distance until the proximal balloon is positioned where intended into the vasculature. Then, adjust the position of the distal occlusion balloon relative to the proximal occlusion balloon by advancing the Movable Handle relative to the Fixed Handle, as necessary.

NOTE: Radiopaque marker bands identify the region between the distal and the proximal balloons.

27. Set the stopcock valve to the Distal Balloon Lumen in the OPEN position.
28. Set the stopcock valve to the Proximal Balloon Lumen in the OPEN position.

NOTE: Determine the vessel size in the treatment segment using standard practices. Refer to Table 1 for guidance on the amount of inflation fluid to achieve a balloon diameter.

29. Using the 1cc (or less) luer lock syringe slowly inflate distal and proximal occlusion balloons, 0.2cc at a time while waiting to allow for any delay in inflation.
30. Position and diameter of the balloons must be monitored under fluoroscopy during inflation. Do not advance or withdraw the Movable Handle while inflating the balloons. Do not exceed maximum listed balloon inflation volume.
31. Once the appropriate balloon diameter for vessel occlusion is achieved, set the stopcock valve to the OFF position on both the distal and proximal balloons to maintain balloon inflation diameter. Confirm occlusion of the vessel by angiography.

FLUID DELIVERY

NOTE: Selection of the desired infusion material is at the discretion of the physician.

32. While maintaining proximal and distal balloon inflation, infuse the selected vascular site by injecting the desired material through the infusion lumen (red). Flush the infusion lumen as needed.

NOTE: Do not use excessive force to depress plunger. Do not exceed 16mL/min of flow rate when delivering fluid.

NOTE: Selection of the desired infusion material is at the discretion of the physician with possible

consideration to viscosity of the infusion material (testing was done for solution of saline with up to 40% Glycerol).

CATHETER REMOVAL

33. At the completion of the infusion cycle, always under fluoroscopic control, deflate each balloon completely with a vacuum using a 20cc syringe or larger and confirm reestablishment of flow.
34. Manipulate the position of the Movable Handle relative to the Fixed Handle so that the distal radiopaque marker is close to the proximal radiopaque marker.
35. Under fluoroscopic control retract the catheter from the guide sheath.
36. When treatment is complete, remove the catheter and guide sheath using standard removal procedures.
37. Dispose of contaminated device, components and packaging materials using standard hospital procedures for bio-hazardous waste.

The RenovoCath device has not been tested for prolonged use in the vascular system.

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Symbol Definitions

	Prescription Only
	Reference number
	Lot / Batch number
	Use by Date
	Manufacturer
	Contents sterile unless enclosed package has been opened or damaged. Sterilization by ethylene oxide
	Keep dry
	Consult Instructions for Use
	Do not re-use, use only once
	Do not resterilize
	Caution
	Non-pyrogenic
	Do not use if package is damaged