Camaro ™

Support Catheter

Instructions for Use

STERILE EO

CAUTION: RX Only Federal (USA) law restricts this device to sale by or on the order of a physician.

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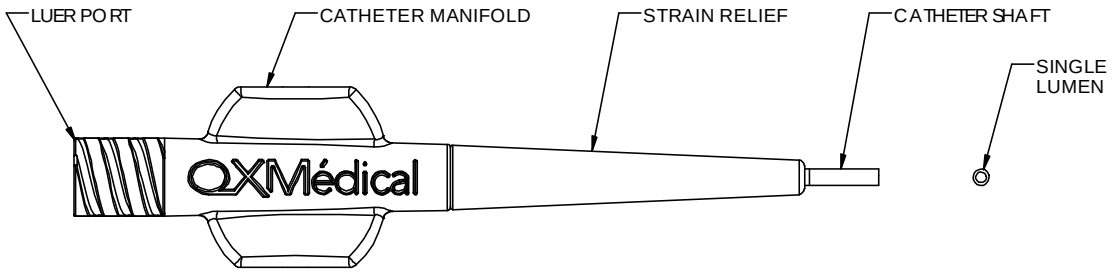
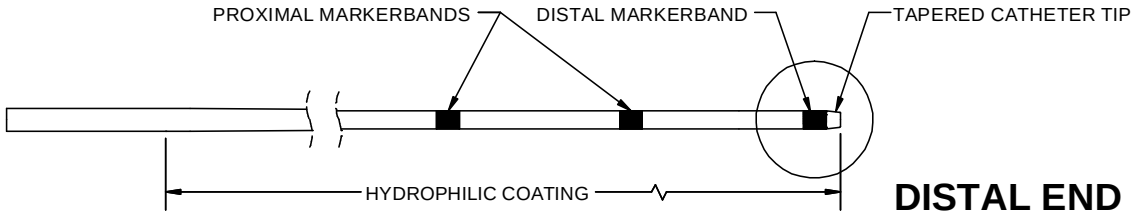
1. DEVICE DESCRIPTION

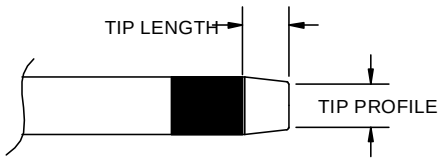
The Support Catheter is an over-the-wire (OTW) single-lumen catheter with an atraumatic tapered tip. The catheter system is offered in fifteen (15) size models that are 0.014", 0.018", and 0.035" guidewire compatible with working lengths of 65 cm, 90 cm, 135 cm, 150 cm and 180 cm. The distal catheter shaft has three (3) radiopaque markers that aid in positioning the catheter and estimating distances. The distal outer portion of the catheter has a hydrophilic coating. The proximal end of the catheter has a manifold with a female luer connection to communicate with the catheter lumen. The lumen is used to pass the catheter over the appropriate guidewire (as listed in Table 1) or for infusion. The catheter guidewire size and length are printed on the strain relief. The catheter is compatible with sheaths and guiding catheters as outlined in Table 1.

PROXIMAL END





DISTAL END



TIP DETAIL

CAUTION: Only physicians trained in vascular surgery, interventional radiology or cardiology, and who have completed training or have experience with interventional procedures and associated devices should consider using this device.

CAUTION: Read the entire Instructions for Use manual prior to using the device.

TABLE 1: CATHETER SPECIFICATIONS										
MODEL	**Max. Guidewire Diameter (inches)**	**Effective Length (cm)**	**Markerband Spacing (mm)**	**Proximal Shaft Diameter (inches)**	**Distal Shaft Diameter (inches)**	**Tip Profile (inches)**	**Tip Length (mm)**	**Min. Guiding Catheter (Fr)**	**Min Sheath (Fr)**	**Hydrophilic Coating Length (cm)**
0.014 x 65cm	0.014	65	15	0.039	0.0265	0.0195	1.25	5	4	40
0.014 x 90cm	0.014	90	15	0.039	0.0265	0.0195	1.25	5	4	40
0.014 x 135cm	0.014	135	15	0.039	0.0265	0.0195	1.25	5	4	80
0.014 x 150cm	0.014	150	15	0.039	0.0265	0.0195	1.25	5	4	80
0.014 x 180cm	0.014	180	15	0.039	0.0265	0.0195	1.25	5	4	80
0.018 x 65cm	0.018	65	15	0.044	0.0305	0.0235	1.25	5	4	40
0.018 x 90cm	0.018	90	15	0.044	0.0305	0.0235	1.25	5	4	40
0.018 x 135cm	0.018	135	15	0.044	0.0305	0.0235	1.25	5	4	80
0.018 x 150cm	0.018	150	15	0.044	0.0305	0.0235	1.25	5	4	80
0.018 x 180cm	0.018	180	15	0.044	0.0305	0.0235	1.25	5	4	80
0. 035 x 65cm	0.035	65	50	0.062	0.0505	0.0405	1.25	6	5	40
0. 035 x 90cm	0.035	90	50	0.062	0.0505	0.0405	1.25	6	5	40
0. 035 x 135cm	0.035	135	50	0.062	0.0505	0.0405	1.25	6	5	80
0. 035 x 150cm	0.035	150	50	0.062	0.0505	0.0405	1.25	6	5	80
0. 035 x 180cm	0.035	180	50	0.062	0.0505	0.0405	1.25	6	5	80

2. INDICATIONS FOR USE

The Support Catheter is intended for use during coronary and peripheral interventional procedures to guide and support guidewires, traverse discrete portions of the vasculature, allow for guidewire exchanges and provide a conduit for infusion of saline solution, diagnostic contrast agents and therapeutic agents.

3. WARNINGS

- The Support Catheter is supplied STERILE and for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and of compromised device performance.
- The catheter should only be manipulated while observing under fluoroscopy.

- If resistance is encountered at any time during the insertion procedure, do not force passage or torque the catheter. Resistance may cause damage to device or vessel. Carefully withdraw the catheter.
- The catheter should only be advanced or withdrawn over a guidewire.
- Do not exceed the maximum infusion pressure of 300 psi.
- This device has not been evaluated for use in the neurovasculature.

4. PRECAUTIONS

- Preparations should be made and a trained vascular surgical team available in the event conversion to open surgery is required.
- Carefully inspect the package and catheter prior to use to verify no damage occurred during shipment. Do not use if the package or catheter is damaged since the sterility or integrity of the device may be compromised and thus increasing the risk of patient infection and device malfunction.
- To avoid damage to hydrophilic coating, do not wipe the catheter surface with dry gauze.
- Do not attempt to pass the catheter through a smaller sized sheath or guiding catheter than indicated in Table 1. Damage to the device may occur.
- Only use guidewires of the recommended diameter and length indicated in Table 1.
- To avoid kinking and damaging the catheter, advance slowly in small increments until the proximal end of the guidewire emerges from the catheter.
- To avoid damage to the catheter or vessel, do not advance or withdraw the device without a guidewire in place.
- Do not exceed the maximum recommended infusion pressure of 300 PSI. Higher pressures may cause damage to the catheter and vessels. Refer to Table 2 for flow rates of the catheter.
- Catheter should not be advanced into a vessel having a diameter smaller than the catheter outer diameter. Damage to the device or vessel may occur.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations.
- Use the catheter prior to the "Use by" date specified on the package.

5. POTENTIAL COMPLICATIONS/ADVERSE EFFECTS

Complications may occur with the use of any support catheter or during any catheterization procedure. Therefore, only physicians trained in vascular surgery, interventional radiology or cardiology, and who have completed training or have experience with support catheters and associated devices should consider using this device. Possible complications associated with this type of procedure include but are not limited to the following:

- Access site complications
- Acute or total occlusion of the vessel

- Arterial dissection
- Arterial spasm
- Arterial thrombosis
- Catheter fracture with tip separation and distal embolization
- Death
- Distal embolization (air, blood clots or plaque)
- Hemorrhage or hematoma
- Hypo/hypertension
- Intimal disruption
- Local or systemic infection including sepsis
- Myocardial infarction
- Perforation and vessel rupture
- Surgical intervention
- Thrombus formation/thrombosis

6. PACKAGING, STERILIZATION AND STORAGE

The device has been sterilized using ethylene oxide (EO) and is supplied sterile and non-pyrogenic. The package label indicates the Use By date.

Do not use the device after the Use By date. The device sterility and integrity may be compromised and possibly result in patient infection and/or device malfunction.

The device should be stored in cool, dry and dark place. Use device prior to the **Use By** date on the package label.

7. RECOMMENDED ITEMS

Each Support Catheter package includes the following:

- Single-use sterile disposable catheter contained in a coiled storage tube.

Materials required but not provided are:

- 10 cc syringe (filled with sterile heparinized saline)
- One-Way or Three-Way stopcock
- Appropriately sized exchange guidewire (refer to Table 1)
- Appropriately sized sheath or guiding catheter (refer to Table 1)
- Additional Support Catheters
- Sterile, heparinized saline (for flushing catheter)

8. DEVICE PREPARATION

8.1 Carefully inspect the package and catheter prior to use to verify no damage occurred during shipment. Do not use catheter if either the catheter or packaging is damaged or compromised.

8.2 If the packaging is free of damage, carefully open the pouch and introduce the sterile hoop (with catheter) to the sterile field using sterile techniques.

8.3 Carefully disengage the catheter manifold from the clip connector and withdraw the catheter from the hoop. Carefully inspect the catheter for any signs of damage. If damaged, please discard and use another catheter.

8.4 The device is coated with a lubricious hydrophilic coating. Prior to inserting the catheter, activate the coating by immersing the catheter in normal saline for approximately 30 seconds, or wiping down the catheter shaft with a saturated gauze or sponge. Do not wipe the catheter surface with dry gauze.

8.5 Prepare the catheter by removing the air in the central lumen. Connect a 10 cc syringe filled with heparinized saline to the luer hub and flush out the lumen. While flushing the catheter, visually inspect the catheter for any signs of damage or leakage. If any damage or leakage is observed, discard and use a new device.

9. DEVICE USAGE

9.1 Using standard techniques, place the sheath/guiding catheter and guidewire.

9.2 Place the prepared Support Catheter over the previously inserted guidewire by threading the end of the guidewire through the tip of the catheter. Advance the catheter over the guidewire. Refer to Table 1 for guidance regarding appropriate catheter selection along with sheath, guiding catheter and guidewire sizing.

9.3 The catheter can be introduced percutaneously through the sheath or guiding catheter. Do not attempt to pass the device through a smaller sized sheath than indicated in Table 1.

9.4 Using fluoroscopic imaging, carefully advance the catheter to the desired location in the vasculature. If resistance is encountered at any time during the insertion procedure, do not force passage or torque the device. The markerbands on the distal end of the catheter will provide visual guidance.

9.5 Using fluoroscopic imaging manipulate the guidewire and catheter in order to achieve the desired position. Do not torque the catheter. Also, do not advance or withdraw the catheter without the guidewire in place and extending beyond the distal end of the catheter.

9.6 When removing the catheter, use fluoroscopic imaging and make sure to maintain guidewire position.

Guidewire Exchange

When exchanging guidewires, maintain the catheter position and carefully withdraw the guidewire under fluoroscopic imaging. Without moving the catheter, insert new guidewire through the proximal hub and advance under fluoroscopic imaging. Do not advance or withdraw the catheter without the guidewire in place and extending beyond the distal end of the catheter.

Catheter Infusion

To use the catheter for infusion, maintain the catheter position and carefully withdraw the guidewire under fluoroscopic imaging. Attach infusion device (syringe, power injector, etc.) and use as directed. If required, a 1-way or 3-way stopcock may be used for additional fluid control. Ensure that the stopcocks are properly rated for the desired infusion pressure. Do not exceed 300 PSI inlet infusion pressure. Approximate flow rates for the catheter are outlined in Table 2. Once the infusions are complete, detach infusion device and remove any stopcocks that may have been used. Reinsert guidewire prior to advancing or withdrawing the catheter.

TABLE 2: CATHETER FLOW RATES

MODEL	Saline		Contrast*	
	150 psi	300 psi	150 psi	300 psi
0.014" x 65cm	1.3 ml/s	1.7 ml/s	0.7 ml/s	1.2 ml/s
0.014" x 90cm	1.0 ml/s	1.3 ml/s	0.6 ml/s	1.1 ml/s
0.014" x 135cm	0.8 ml/s	1.3 ml/s	0.4 ml/s	0.8 ml/s
0.014" x 150cm	0.8 ml/s	1.3 ml/s	0.3 ml/s	0.8 ml/s
0.014" x 180cm	0.8 ml/s	1.2 ml/s	0.3 ml/s	0.6 ml/s
0.018" x 65cm	1.9 ml/s	2.6 ml/s	1.4 ml/s	2.3 ml/s
0.018" x 90cm	1.6 ml/s	2.2 ml/s	1.2 ml/s	1.9 ml/s
0.018" x 135cm	1.3 ml/s	1.9 ml/s	0.8 ml/s	1.4 ml/s
0.018" x 150cm	1.3 ml/s	1.9 ml/s	0.8 ml/s	1.3 ml/s
0.018" x 180cm	1.3 ml/s	1.8 ml/s	0.6 ml/s	1.1 ml/s
0.035" x 65cm	7.8 ml/s	11.0 ml/s	6.7 ml/s	9.4 ml/s
0.035" x 90cm	5.8 ml/s	8.3 ml/s	5.8 ml/s	8.3 ml/s
0.035" x 135cm	5.4 ml/s	8.0 ml/s	4.9 ml/s	6.9 ml/s
0.035" x 150cm	5.2 ml/s	7.7 ml/s	4.7 ml/s	6.6 ml/s
0.035" x 180cm	5.1 ml/s	7.3 ml/s	4.2 ml/s	6.2 ml/s

* 75% - 25%: Conray® 43 contrast/sterile saline mix

10. DISPOSAL

After use, this product is a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable hospital, local, state and federal laws and regulations.

11. REUSE PRECAUTION STATEMENT

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

SYMBOL	LANGUAGE
	English
MD	Medical Device
	Maximum Guide Wire
	Length
	Minimum Sheath
Ø	Maximum Diameter
REF	Catalogue Number
LOT	Batch Code
	Use By
	**Caution** Attention, See Instructions for Use
	Consult Instructions for Use
	Do Not Reuse
	Do Not Resterilize
	Do not use if package is damaged
	Non-pyrogenic
STERILE EO	Sterilized by Ethylene Oxide
	Store in cool dry place
	Manufacturer
	Distributor

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