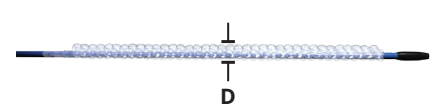
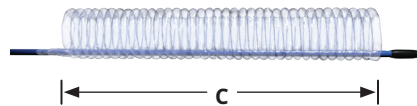
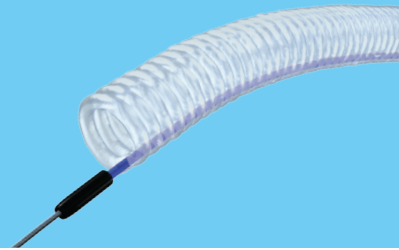


PTCA Procedural Guide

Ringer™ Perfusion Balloon Catheter

The Ringer™ Perfusion Balloon Catheter (PBC) is a rapid exchange catheter with a helical shaped inflatable balloon on the distal end and a wire lumen for delivery over a ≤ 0.014 " guidewire. The semi-compliant balloon, when inflated, approximates a hollow cylinder. Radiopaque markers at the proximal and distal balloon margins allow visualization and accurate positioning of the balloon catheter in the target segment. The catheter shaft has positioning marks located at 95cm (single mark) and 105cm (double mark) from the distal tip.



Balloon O.D. "A"	Balloon I.D. "B"	Balloon Lengths "C"	Crossing Profile "D"
2.5mm	0.039", 1.0mm	20mm	0.052"
3.0mm	0.059", 1.5mm	20mm	0.054"
3.5mm	0.079", 2.0mm	20mm	0.056"
4.0mm	0.099", 2.5mm	20mm	0.058"
4.5mm	0.119", 3.0mm	20mm	0.060"

Guide Compatibility (Delivery and Withdrawal)*

Ringer™ PBC DIAMETER	Minimum Guide Catheter COMPATIBILITY		Minimum GuideLiner™ Catheter COMPATIBILITY		Minimum TrapLiner™ Catheter COMPATIBILITY	
	Delivery	Withdrawal	Delivery	Withdrawal	Delivery	Withdrawal
2.5mm	6F	6F	6F	6F	6F	6F
3.0mm	6F	6F	6F	7F	7F	7F
3.5mm	6F	6F	7F	8F	7F	8F
4.0mm	6F	6F	7F	8F	7F	8F
4.5mm	6F	6F	7F	Not Compatible	8F	Not Compatible

* Data on file at Teleflex. Test data may not be indicative of clinical performance. All values based on bench test averages, n=10.

If resistance is encountered, withdraw the guide extension back into the guide catheter and withdraw the Ringer™ PBC directly into any 6F or larger guide catheter.

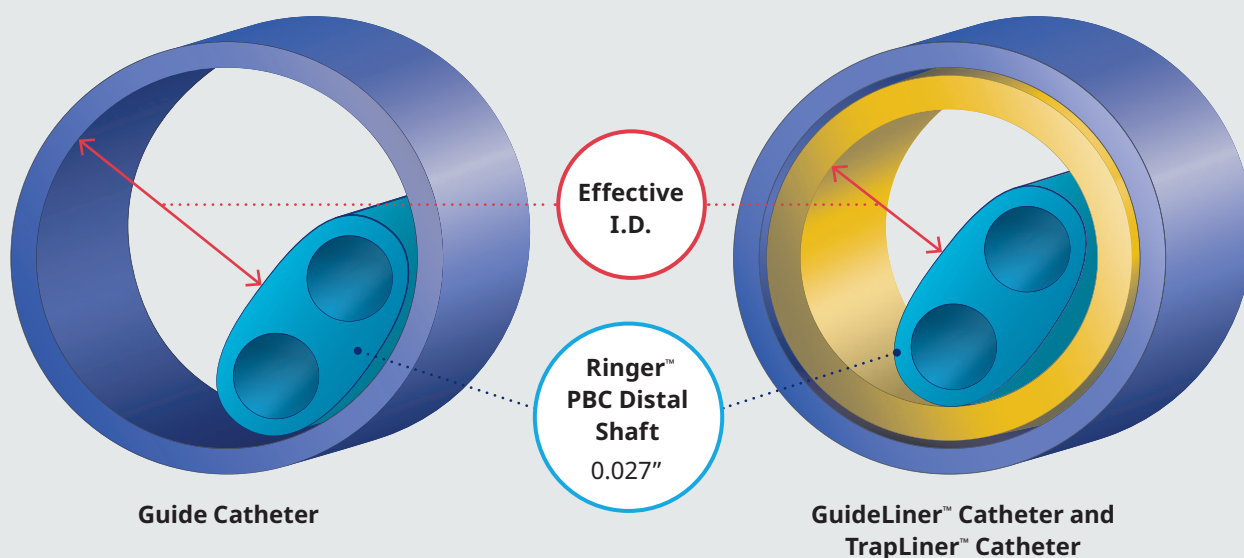
Effective I.D.* and Ringer™ PBC I.D.**

Available space within the guide catheter system with Ringer™ PBC in place depicted below.

Without Guide Extension	6F	7F	8F
Guide Catheter Inner Diameter (I.D.)	0.070"	0.078"	0.088"
Space remaining in Guide System with Ringer™ PBC	0.043"	0.051"	0.061"

With GuideLiner™ Catheter*	5.5F	6F	7F	8F
Guide Catheter Inner Diameter (I.D.)	0.051"	0.056"	0.062"	0.071"
Space remaining in Guide System with Ringer™ PBC	0.024"	0.029"	0.035"	0.044"

With TrapLiner™ Catheter*	6F	7F	8F
TrapLiner™ Catheter Effective I.D.	0.050"	0.053"	0.063"
Space remaining in Guide System with Ringer™ PBC	0.023"	0.026"	0.036"



* Distal Shaft of the Ringer™ PBC is the limiting factor for space remaining in the guide. You must subtract 0.027" from the inner diameter of your guide catheter.

** Data on file at Teleflex. Test data may not be indicative of clinical performance.

Preparation, Handling and Removal Instructions

Refer to the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions. Information in this material is not a substitute for the product Instructions for Use.

- A saline mixture with no greater than 50:50 contrast is recommended.
- Draw and maintain negative pressure on the inflation device until Ringer™ PBC inflation is desired.
- Ringer™ PBC (Nominal = 6; RBP = 8).¹

NOTE: The radiopaque markers are positioned proximal and distal to the outer edges of the balloon.

- Inflate Slowly. Ringer™ PBC inflation time can feel slow (approx. 20 seconds). Ringer™ PBC Balloon reaches 8atm at a low volume.
- When selecting and positioning the Ringer™ PBC, consider the potential for ischemia arising from side branch coverage by the inflated Ringer™ PBC.
- The Ringer™ PBC may facilitate prolonged balloon inflations up to 60 minutes in duration.²
- The crossing profile of the Ringer™ PBC may result in interactions with previously deployed stents resulting in stent deformation or balloon entrapment.
- The device will take up to 30 seconds for complete deflation.

REMINDER: There is no balloon rewrap following deflation of the Ringer™ PBC.

- Once withdrawn into the guide catheter, the Ringer™ PBC should be removed and discarded. The Ringer™ PBC should not be re-advanced into the vasculature after being withdrawn into the guide catheter.

Facilitating Work in the Distal Vessel through the same Guide Catheter

- To continue work in the distal vessel following the inflation of the Ringer™ PBC, insert the guidewire through the same guide catheter as the Ringer™ PBC.
 - Consider a 300cm wire if you are using a microcatheter and don't have the option to trap.
- Advance the guidewire through the center of the Ringer™ PBC and place in the distal vessel.
- You can now use additional devices and continue working through the inflated Ringer™ PBC.
- Following completion of distal vessel work, remove additional devices, then deflate the Ringer™ PBC.
- Withdraw the deflated Ringer™ PBC into the guide catheter and remove.

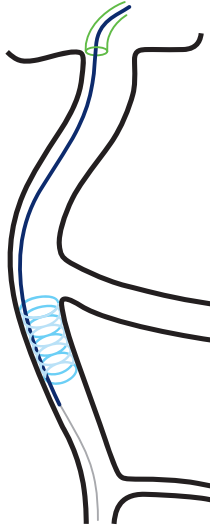
REMINDER: ALL devices need to be removed from the center of the Ringer™ PBC before the Ringer™ PBC can be withdrawn into the guide catheter and removed.

References:

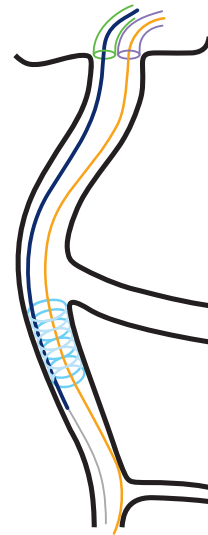
1. To reduce the potential for vessel injury, balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on results of in vitro testing. At least 99.9 percent of the balloons (with 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over-pressurization.
2. Data on file at Teleflex. Benchtop and animal test data may not be indicative of clinical performance.

Delivery of devices **THROUGH** Ringer™ PBC when second access site is required

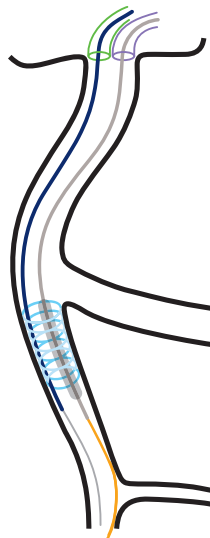
1
Inflate the Ringer™ PBC.
Nominal = 6 atm
RBP = 8 atm



2
If working in the distal vessel following Ringer™ PBC inflation, establish a second access site. Insert a second guide catheter and place a second guidewire through the Ringer™ PBC into the distal vessel.

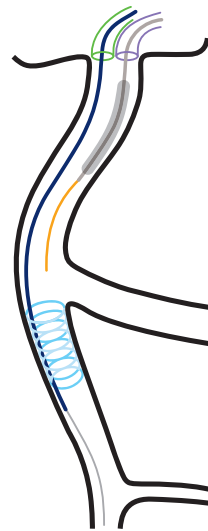


3
Advance the device over the second guidewire through the center of the Ringer™ PBC.



4
Once the distal work is complete, remove the device and associated guidewire.

NOTE: Any devices that were delivered through the lumen of the Ringer™ PBC MUST be removed prior to removal of the Ringer™ PBC.



5
Deflate and withdraw the Ringer™ PBC.



For guidance on when a second access may be necessary, refer to the charts on page 2 showing space remaining within the guide system.

The Ringer™ Perfusion Balloon Catheter (PBC) is indicated for balloon dilatation of coronary artery or coronary bypass graft stenoses where the physician desires distal blood perfusion during balloon inflation for the purpose of improving myocardial perfusion.

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

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