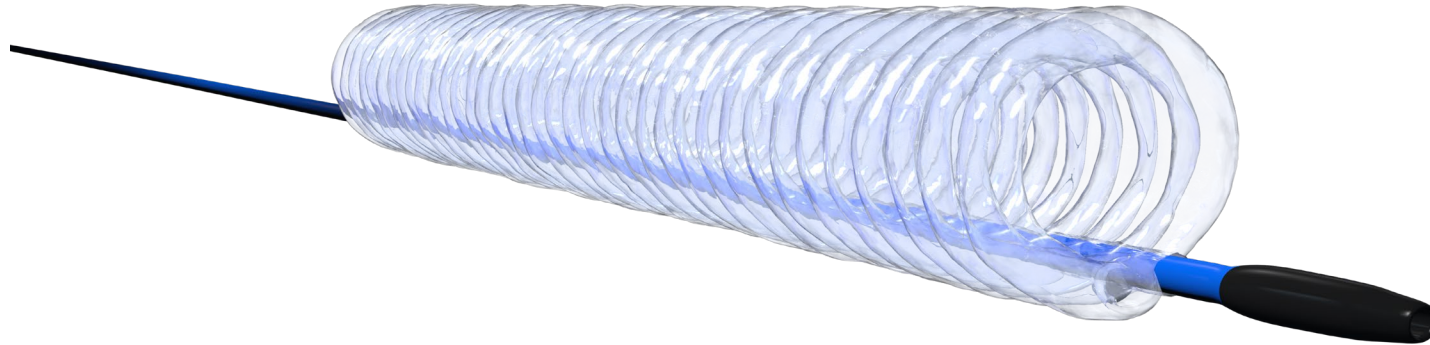


Intraoperative Control of Coronary Artery Hemorrhage using Rapid Exchange Catheter with Helical Perfusion Balloon

Ringer™ Perfusion Balloon Catheter



Coronary Artery Perforation (CAP)

- Infrequent but life-threatening complication of percutaneous coronary intervention (PCI) that typically results from iatrogenic barotrauma.
- Incidence of perforation approximately 0.4% in *all-comer* PCI cohorts.

Source: Mikhail, P., Howden, N., Monjur, M., Jeyaprakash, P., Said, C., Bland, A., Collison, D., McCartney, P., Adamson, C., Morrow, A., Carrick, D., McEntegart, M., & Ford, T. J. (2022). Coronary perforation incidence, outcomes and temporal trends (COPIT): a systematic review and meta-analysis. *Open Heart*, 9(2), e002076. <https://doi.org/10.1136/openhrt-2022-002076>

Current Coronary Artery Perforation Management - step-by-step

1. Immediately inflate PTCA balloon inflation across the perforation to stop ongoing hemorrhage into the pericardial space (“blocking balloon”).
2. If needed, stabilize the patient’s hemodynamics.
3. If practical, engage surgical, anesthesia and additional cardiology support.
4. If necessary, perform pericardiocentesis.
5. Consider definitive treatment options : covered stent, surgical repair of perforation or prolonged balloon inflation if tolerated. Execute on chosen option.

Procedural Steps for Ringer™ Perfusion Balloon Catheter (PBC)

- **Initial Response (see previous slide)**
 - Blocking balloon as tolerated/resuscitate/pericardiocentesis as necessary
- **Ringer™ PBC Device Preparation**
 - Select appropriately sized Ringer™ (2.5–4.5 mm × 20 mm), prep as with any PTCA balloon
 - Ensure guide compatibility— any 6F, 7F and 8F guide systems used in PCI
- **Deliver the Ringer™ PBC**
 - Minimize time from blocking balloon deflation and removal to Ringer™ PBC delivery and inflation
 - Ringer™ PBC is delivered over any ≤ 0.014 " coronary guidewire under fluoroscopy
 - Using radiopaque markers, position Ringer™ PBC to span perforation segment and inflate (nominal 6 atm)
 - Confirm control of hemorrhage and coronary blood flow; adjust Ringer™ PBC position or size as required
- **Consider Definitive Options**
 - The perfusion function of the Ringer™ PBC allows it to remain inflated up to 60 minutes
 - With hemorrhage controlled and patient stabilized, reconsider/consult regarding options for definitive therapy
 - Inflated Ringer™ PBC allows for delivery of additional therapies through the central lumen over a second wire
 - If surgery is chosen, the Ringer™ PBC may be left inflated until patient is on cardiopulmonary bypass
- **Deflation and Removal**
 - Allow for complete balloon deflation before removal through guide catheter
 - Determine if hemorrhage has stopped; if not, reinflate Ringer™ PBC and reconsider covered stent or surgery

Delivery of Covered Stent **THROUGH** RINGER™ Balloon

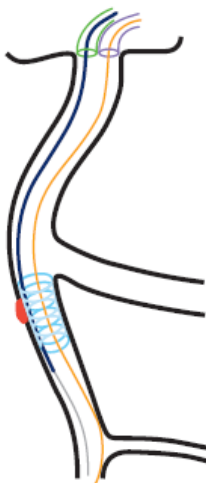
1

Following detection of perforation, prep RINGER™ balloon



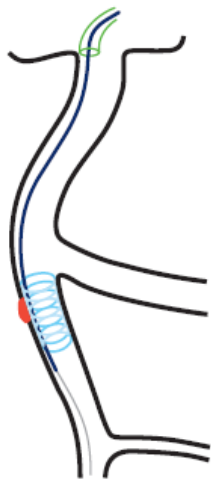
3

Establish second access, set up ping pong guide catheter and place second guidewire through RINGER™ balloon into distal vessel



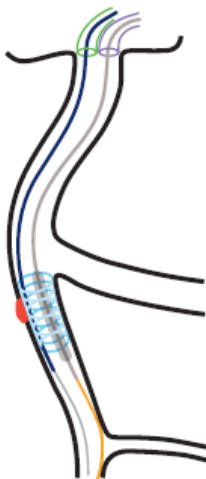
2

Manage perforation with RINGER™ balloon
Nominal = 6
RBP = 8



4

Advance covered stent over second guidewire through the center of the RINGER™ balloon

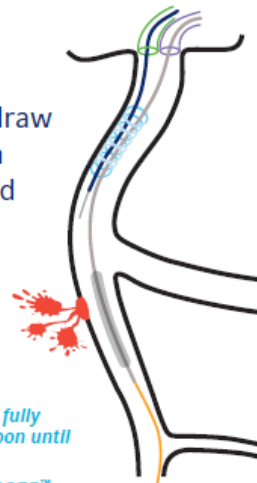


5

Deflate and withdraw RINGER™ balloon and the associated guidewire proximal to the perforation

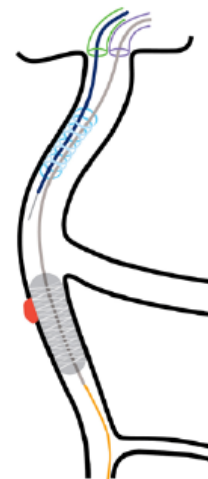
*NOTE: When delivering a covered stent **THROUGH** a RINGER™ balloon, you are unable to fully remove the RINGER™ balloon until the end of the procedure*

NOTE: In order to pull RINGER™ balloon proximal to perforation, you will need enough proximal clearance length in the vessel. OR another potential option for ostial lesions is to pull back both guide catheters into aortic root.



6

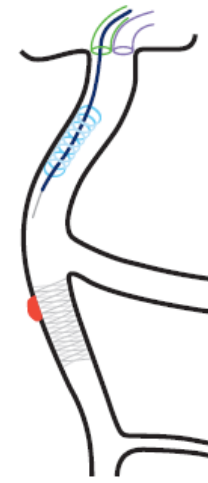
Position and deploy covered stent



7

Remove covered stent delivery balloon and associated guidewire

*NOTE: This **MUST** be done before the RINGER™ balloon can be removed*



8

Following confirmation of resolved perforation, remove RINGER™ balloon and associated guidewire



Delivery of Covered Stent **AROUND** RINGER™ Balloon

1

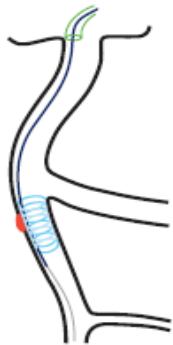
Following detection of perforation, prep RINGER™ balloon



2

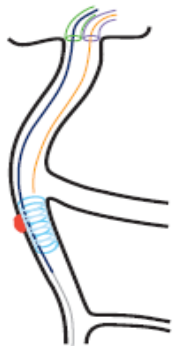
Manage perforation with RINGER™ balloon

Nominal = 6
RBP = 8



3

Establish second access, set up ping pong guide catheter and place second guidewire proximal to the RINGER™ balloon



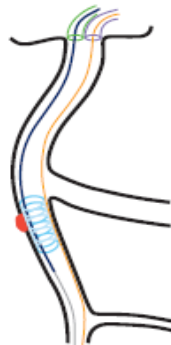
4

Deflate RINGER™ balloon and advance second guidewire around RINGER™ balloon into distal vessel



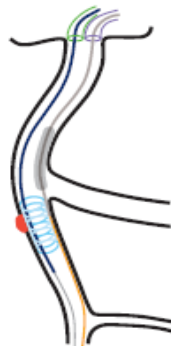
5

Inflate RINGER™ balloon to re-establish perforation management



6

Advance covered stent proximal to RINGER™ balloon, over the second guidewire



Delivery of Covered Stent **AROUND** RINGER™ Balloon, (continued)

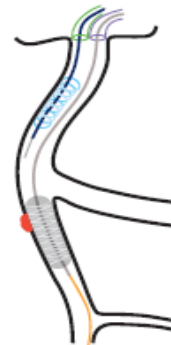
7

Deflate and withdraw RINGER™ balloon and the associated guidewire proximal to the perforation



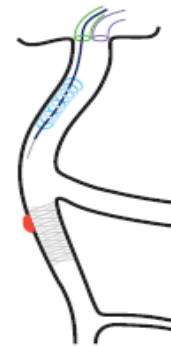
8

Position and deploy covered stent



9

Remove covered stent delivery balloon and associated guidewire



10

Following confirmation of resolved perforation, remove RINGER™ balloon and associated guidewire



How will medical coders recognize the Ringer™ PBC?

Documentation of Ringer™ Perfusion Balloon Catheter use may be included in:

- (i) the physician-generated PCI procedure report
- (ii) the cardiac catheterization procedure log (nurse or technician generated)

- Ringer™ Perfusion Balloon Catheter
- Ringer™ Balloon Catheter
- Ringer™ Catheter
- Ringer™ Balloon
- Balloon Tamponade
- Balloon Catheter
- Perfusion Balloon
- Perfusion Balloon Catheter
- Autoperfusion Balloon
- Perforation Balloon