



AGENT™ Drug-Coated Balloon Preparation Guide

Step-by-step instructions on how to prepare AGENT DCB

1

Verify Lesion and Vessel Preparation.

Ensure lesion is pre-dilated and vessel is ready for drug transfer.

CAUTION: A DCB is designed only to deliver a therapeutic drug dose to the lesion and should NOT be used to prep the lesion.

2

Select the Correct Balloon Size.

Choose balloon diameter and length based on vessel measurements.

RECOMMENDATION: 1:1 balloon to vessel sizing.

3

Prepare the Device: Critical Handling Information.

Do not touch, do not wipe, do not bend and do not wet the balloon.

4

Flush and Prepare the Delivery System.

Flush catheter system with saline, avoiding balloon contact, as you may damage the coating or cause premature drug release.

5

Removal of Balloon Protector.

Pull out the mandrel and balloon protector together from the distal end.

CAUTION: Do not touch the drug with your gloves when removing the protector.

6

Insert and Position the Balloon.

Advance over guidewire and confirm position under fluoroscopy.

CAUTION: Take care when passing balloon through the hemostatic valve to prevent damage to the drug coating.

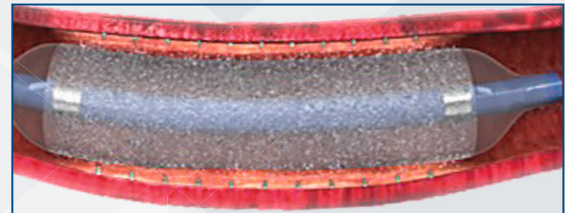
7

Inflate for Drug Transfer.

Inflate at nominal pressure for at least 30 seconds.

CAUTION: There is no delivery time limitation, but if you remove a DCB balloon from the patient prior to inflation, please do not reuse. DCB coatings start activating once in contact with the blood, and will be more prone to damage and drug loss if removed. Please select a new device.

CAUTION: Only use a DCB for one time inflation. Do not reuse on a second lesion as the therapeutic dose is designed for the first inflation transfer only.



8

Remove the Device Carefully.

Deflate completely and withdraw slowly.



Safety Tips:

- Do not touch or wet the balloon before insertion.
- Avoid over-tightening hemostatic valves.
- Use only once and dispose properly after use.



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