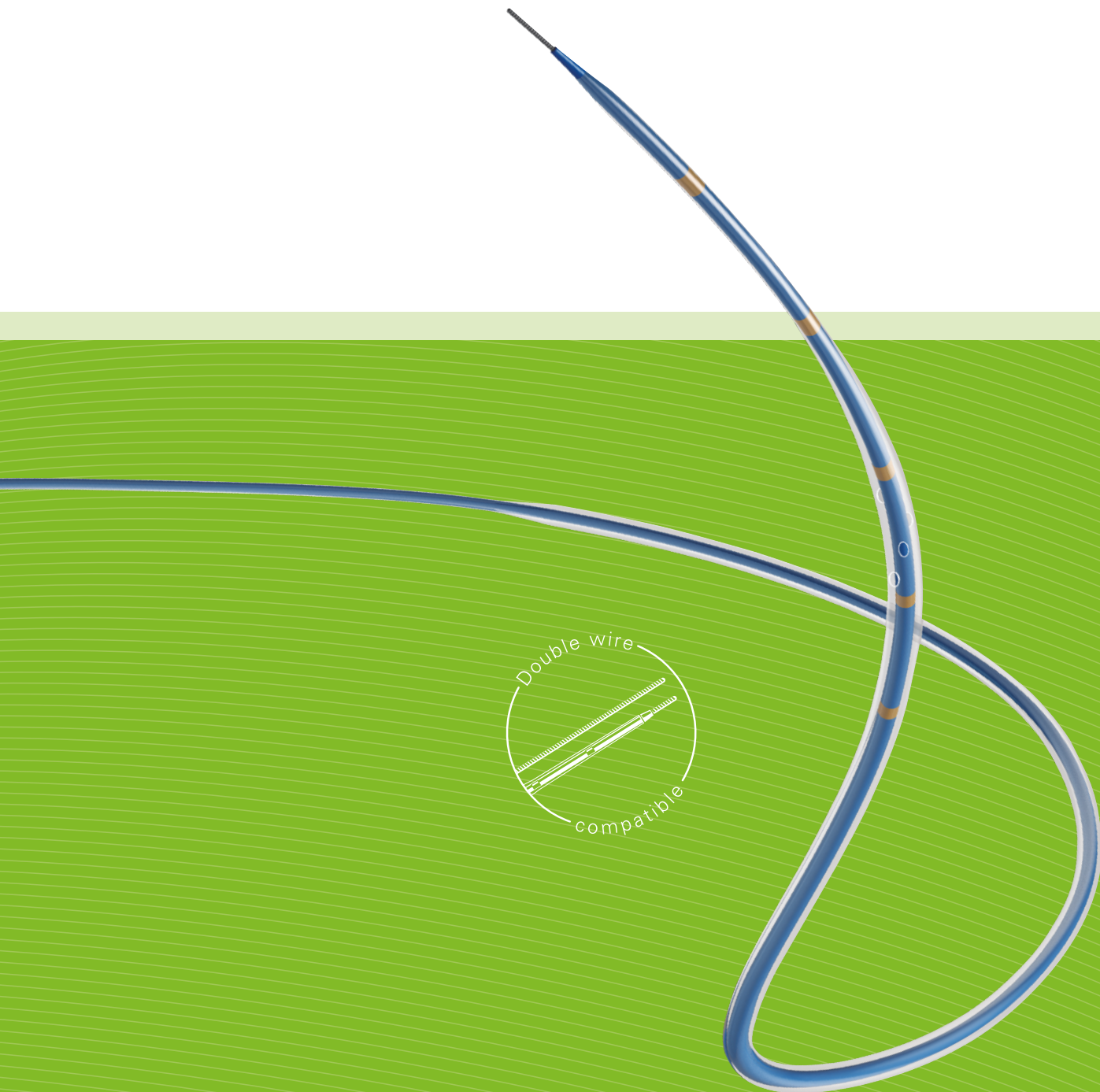


Amicath® II

Dilatation and perfusion coronary catheter

**Designed for safer and easier
primary angioplasty in AMI**





Amicath® II

Dilatation and perfusion coronary catheter

Amicath® II is especially indicated in AMI patients with acute total occlusion, suitable for percutaneous transluminal coronary angioplasty (PTCA)

INDICATIONS FOR USE

- Predilatation of the stenotic part of the total acute occlusion up to a diameter of 1.30 mm.
- Visualization of the distal artery state to the total acute occlusion.
- Pharmacological administration for local treatment.
 - Prevents no reflow phenomenon.
 - Improves microcirculation.
 - Disaggregates thrombotic load.
- *In situ* lesion localization and length estimation (if shorter than 40 mm).

PREPARATION OF THE PERFUSION CATHETER



1 Fill syringe with 10 cc of heparinized saline solution.



2 Connect the three-way valve at the proximal end of Amicath® II.



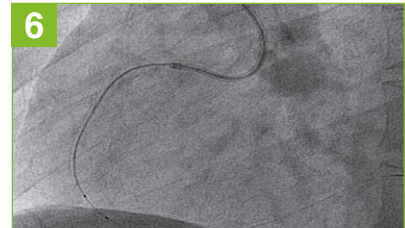
3 Connect the syringe with heparinized saline solution to the three-way valve and purge all the system with the heparinized saline solution until liquid emerges from the distal holes of the catheter.



4 Close the three-way valve located at the proximal end of Amicath® II.



5 Slowly advance the Amicath® II catheter over the angioplasty guidewire through the rotating haemostatic valve and continue advancing it carefully through the guide catheter until reaching the lesion.



6 Cross the lesion carefully until the proximal marker is distal to the lesion.

The injection holes are located between the second and third proximal marks.



7 Prior to injecting any medication or contrast media solution, aspirate until blood reflux is obtained to avoid air entering, and confirm the distal holes are not in the middle of the lesion or thrombus.

In case of an intra-thrombus lysis, as you must be inside the thrombus, it is normal that blood reflux cannot be obtained by aspiration.



8 Connect the syringe containing the contrast media or medication to the other side of the three-way valve.

After an aspiration to avoid any air bubble in the system, inject carefully.



9 After any bolus or any contrast media or medication infusion, flush the system with the saline syringe to avoid crystallization and to remove medication from inside the catheter. Always flush the system after any infusion.

LOCAL DRUG ADMINISTRATION

ADENOSINE SOLUTION* (prevention of no reflow)

- Add 16 cc normal saline solution to 100 cc normal saline solution.
- Add 2 vials (2 cc/vial) of adenosine (6 mg/vial) to the previous 116 cc normal saline.
- Total solution should be: 12 mg adenosine in 120 cc.
- Each 10 cc syringe should contain 1 mg adenosine.
- Each cc contains 0.1 mg adenosine.

Inject boluses of 0.5-1.5 mg gradually as tolerated by patient

MAXIMUM DOSE: LAD 2-4 mg; RCA 1-2 mg

ADRENALINE*

- Dilute 1 cc (1 mg) adrenaline in 9 cc normal saline solution.
- Each cc contains 100 µg.

NTP*

- Dilute the 50 mg NTP with its solvent (5 cc).
- Extract 0.5 cc and dilute in 250 cc of 5% glucose solution.
- Each cc contains 25 µg.

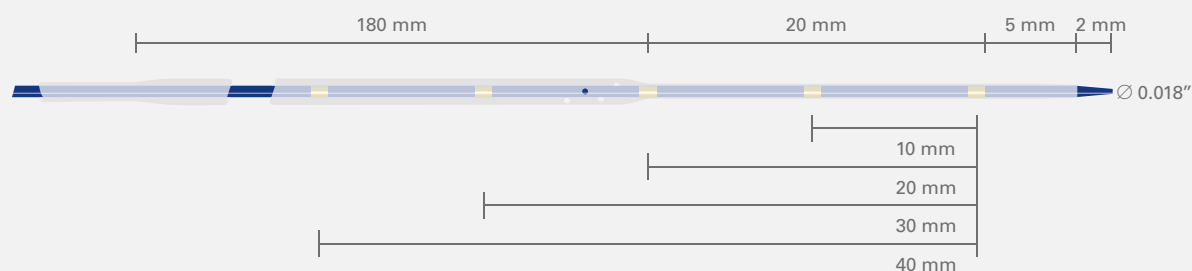
VERAPAMIL*

- Dilute 1 cc (2.5 mg) verapamil in 9 cc normal saline solution in a 10 cc syringe.
- Each cc contains 250 µg.

*Drug administration and doses are under physician criteria and responsibility.

Amicath® II is indicated for local drug and contrast media administration in primary or rescue coronary angioplasty.

Amicath® II



Summary of technical specifications

Total length	145 ± 2 cm
Distal body length	2.5 ± 1 mm
Tip profile	0.019"
Tip length	2.5 ± 1 mm
Cross-tip profile	≤ 0.026 "/ ≤ 0.65 mm
"Dotter" profile	1.28 ± 0.0254 mm
Radiopaque markers	5 gold radiopaque markers spaced 10 mm apart
Side holes	4 placed in a spiral between the proximal markers
Diameter of proximal body	2.3 F - 2.4 F
Diameter of distal body	High
Flexibility	High
Navigability	High

Ordering reference number

0053950

Recommended guiding catheter: 6F
Recommended steerable guide wire: 0.014"

Device restricted for use by a doctor or under the supervision of a doctor.
 Before using this device, carefully read the warnings and possible complications described in the instructions for use.

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