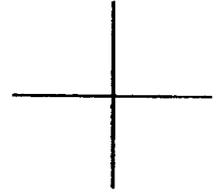
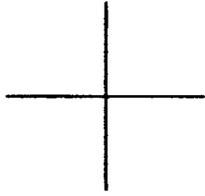


**IMPORTANT INFORMATION:
PLEASE READ PRIOR TO USE**

MBC

**CORONARY BALLOON
DILATATION CATHETER**





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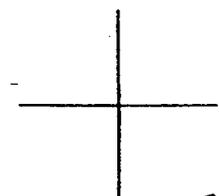
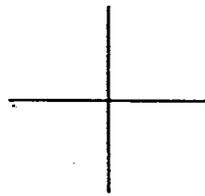
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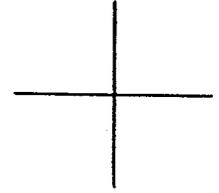
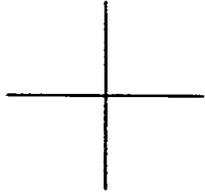
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Table 1. Balloon Compliance (Diameter vs Pressure)

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15 **DEVICE NAME**
COOK® MBC PTCA Balloon Dilatation Catheter

DESCRIPTION

20 The COOK® MBC PTCA balloon dilatation catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter. This device is provided sterile and is intended for one-time use. This device is used in conjunction with conventional PTCA equipment, including, but not limited to, a vascular access set, arterial sheath, guiding catheter, guide wire and inflator device.

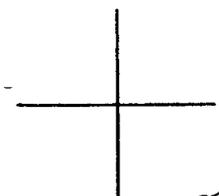
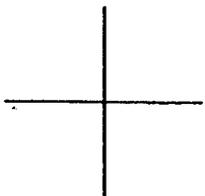
25 The COOK® MBC PTCA balloon catheter is a double lumen catheter with a balloon near the distal tip. The catheter features a minimally compliant balloon constructed from high density polyethylene material. The balloon is designed to expand to a specified diameter and length at a specific pressure as labeled. The balloon catheter is provided in an overall length of 135 cm. The catheter is compatible with 0.014-inch standard PTCA guide wires. Two radiopaque marker bands located at the proximal and distal ends of the balloon segment facilitate fluoroscopic visualization of the balloon during use.

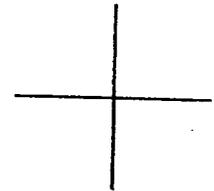
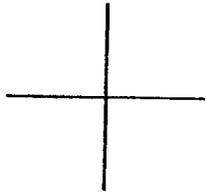
INDICATIONS

35 The COOK® MBC PTCA balloon dilatation catheter is indicated for balloon dilatation of hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

- 40
 - Unprotected left main coronary artery.
 - Coronary artery spasm in the absence of a significant stenosis thought to be of hemodynamic significance.



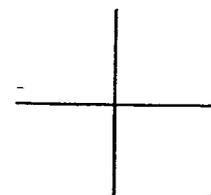
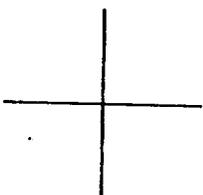


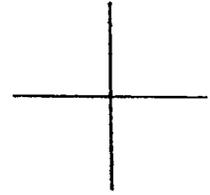
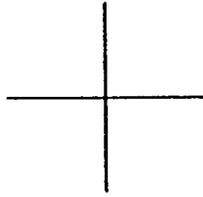
PRECAUTIONS

- 75
- Before insertion of the dilatation catheter, administer appropriate anticoagulant, antiplatelet, and coronary vasodilator therapy.
 - Caution should be taken not to over tighten a Tuohy-Borst type hemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

ADVERSE EFFECTS

- 80
- Possible adverse effects include, but are not limited to, the following:
- coronary artery dissection, perforation, rupture or other injury
 - conduction disturbance
 - acute myocardial infarction
 - unstable angina
- 85
- arteriovenous fistula
 - coronary artery spasm
 - total occlusion of the coronary artery or bypass graft
 - hemorrhage or hematoma
 - embolism
- 90
- infection
 - restenosis of the dilated artery
 - hypo/hypertension
 - death





INSTRUCTIONS FOR USE

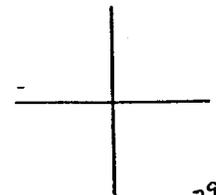
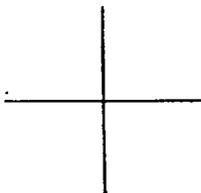
95 Prior to angioplasty, all equipment to be used for the procedure, including the dilatation catheter, should be carefully examined to verify proper performance and freedom from damage.

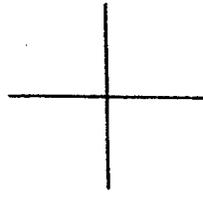
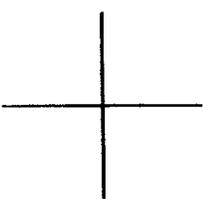
1. Preparation of the Device for Use

- 100 a. Remove the balloon catheter from the package and inspect to ensure the balloon has not been damaged.
- b. Prepare the balloon lumen with standard contrast-saline mixture as follows:
- 105 1) Using a 20 cc syringe containing 5 cc of contrast-saline mixture, apply negative pressure for 20-30 seconds. Do not use air or any gaseous medium to inflate the balloon.
- 2) Release pressure allowing negative pressure to draw mixture into balloon lumen.
- 3) Detach syringe leaving a meniscus of mixture on the hub of the balloon lumen.
- 110 4) Prepare inflation device according to manufacturer's instructions and purge to remove all air from the system.
- 5) Attach inflation device to balloon lumen ensuring no air bubbles remain at connection.
- 6) Pull negative pressure on inflation device.
- 115 c. Flush the catheter lumen marked "DISTAL" in standard fashion to purge air.

2. Testing the Balloon

- 120 a. Inflate the balloon with the contrast-saline mixture to the Nominal Diameter Inflation Pressure (approximately 7 atm). Fully deflate the balloon.
- b. To keep the balloon fully deflated, close the stopcock of the inflation device while maintaining a negative pressure.





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3. Insertion and Advancement of the Catheter

- a. Flush the "DISTAL" lumen of the dilatation catheter with heparinized saline.
- b. Insert a 0.014-inch guide wire into the balloon catheter. Leave the distal end of the guide wire proximal to the distal end of the dilatation catheter to protect the distal tip of the guide wire.
- c. With the balloon fully deflated, insert the COOK® PTCA balloon dilatation catheter, maintaining the position of the guide wire within the dilatation catheter, through the hub assembly of the previously positioned guiding catheter.
- d. Once the dilatation catheter/guide wire assembly is positioned in the lumen of the guiding catheter, advance the guide wire through the dilatation catheter so that the guide wire tip extends beyond the tip of the balloon catheter.
- e. Advance the guide wire beyond the tip of the guiding catheter. Select the target vessel and position the guide wire across the stenosis such that the guide wire tip extends 2-6 cm beyond the stenosis. Advance the dilatation catheter over the guide wire and through the stenosis. The radiopaque balloon markers should be used to confirm that the indentation caused by the stenosis is centrally located within the balloon segment before proceeding with the dilatation.

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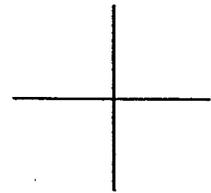
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4. Balloon Inflation

- a. Open the stopcock on the inflation device. Inflate the balloon to dilate the lesion using standard PTCA procedure. Deflate the balloon by pulling negative pressure on the inflation device.
- b. After the first inflation and each subsequent inflation, assess distal coronary blood flow by dye injection through the guiding catheter while the deflated balloon remains in the stenosis. Maintain the guide wire across the stenosis until distal blood flow is adequate. If distal coronary blood flow is reduced and myocardial ischemia develops before an effective dilatation is achieved, the guide wire may be advanced and maintained across the stenosis as the balloon is deflated and/or withdrawn, permitting reperfusion of the distal vessel.

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- c. Should a significant stenosis persist, inflate the balloon to gradually increasing pressures not to exceed the rated burst pressure or until the stenosis fails to improve with each subsequent inflation (see Table 1).

5. Balloon Deflation and Removal

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- a. After angioplasty is completed, deflate the dilatation balloon and withdraw the balloon catheter until it is clear of the lesion. Maintain position of the guide wire across the dilated stenosis.
- b. Perform post dilatation angiography to confirm dilatation.
- c. After angiography has confirmed that the lumen of the dilated artery has been optimally dilated, slowly withdraw the guide wire and the deflated balloon catheter from the guiding catheter.

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Upon completion of the dilatation procedure and removal of guiding catheter and introducer sheath(s), adhere to standard post-PTCA practices for arterial access hemostasis.

REFERENCES

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Physicians should consult current medical practice guidelines regarding PTCA interventional techniques as recommended by the American College of Cardiology and the American Heart Association.

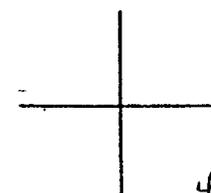
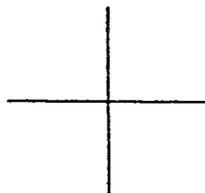


Table 1. Balloon Compliance (Diameter vs Pressure) for All Sizes of COOK® MBC PTCA Catheters

Diameter (mm)	2.5						3.0						3.5						4.0						
	15	20	30	45	15	20	20	30	45	15	20	30	20	30	45	15	20	30	20	30	45	15	20	30	45
Length (mm)	2.31	2.34	2.32	2.31	2.76	2.74	2.74	2.74	2.67	3.22	3.18	3.12	3.15	3.12	3.15	3.61	3.55	3.52	3.46	3.46	3.46	3.68	3.63	3.62	3.64
3	2.35	2.37	2.36	2.34	2.81	2.79	2.79	2.79	2.75	3.27	3.22	3.21	3.21	3.21	3.21	3.68	3.63	3.62	3.64	3.64	3.64	3.75	3.70	3.70	3.70
4	2.39	2.42	2.39	2.38	2.85	2.83	2.83	2.83	2.79	3.33	3.27	3.27	3.27	3.27	3.27	3.82	3.77	3.77	3.78	3.78	3.78	3.91	3.86	3.86	3.86
5	2.43	2.45	2.43	2.43	2.90	2.89	2.89	2.89	2.85	3.39	3.34	3.33	3.32	3.32	3.32	3.99	3.95	3.95	3.95	3.95	3.95	4.07	4.05	4.04	4.04
6	2.46	2.50	2.47	2.48	2.96	2.94	2.94	2.94	2.90	3.46	3.41	3.40	3.39	3.39	3.39	4.22	4.20	4.20	4.21	4.21	4.21	4.29	4.27	4.27	4.27
**7	2.51	2.55	2.52	2.53	3.02	3.01	3.01	3.01	3.00	3.53	3.48	3.47	3.46	3.46	3.46	4.29	4.27	4.27	4.27	4.27	4.27	4.29	4.27	4.27	4.27
8	2.57	2.60	2.58	2.58	3.08	3.08	3.08	3.08	3.07	3.60	3.56	3.55	3.54	3.54	3.54	4.29	4.27	4.27	4.27	4.27	4.27	4.29	4.27	4.27	4.27
9	2.62	2.66	2.63	2.63	3.14	3.14	3.14	3.14	3.13	3.67	3.63	3.62	3.61	3.61	3.61	4.29	4.27	4.27	4.27	4.27	4.27	4.29	4.27	4.27	4.27
10	2.67	2.70	2.67	2.68	3.19	3.19	3.19	3.19	3.19	3.73	3.70	3.69	3.68	3.68	3.68	4.29	4.27	4.27	4.27	4.27	4.27	4.29	4.27	4.27	4.27
**11	2.71	2.74	2.71	2.72	3.24	3.24	3.24	3.24	3.24	3.79	3.76	3.75	3.75	3.75	3.75	4.29	4.27	4.27	4.27	4.27	4.27	4.29	4.27	4.27	4.27

* Nominal Inflation Pressure

** Labeled Rated Burst Pressure