

NC Gallant™

PTCA Dilatation Catheter

INSTRUCTIONS FOR USE



Rx ONLY

CAUTION: Federal law restricts this device to sale by or on the order of a physician

STERILE. Sterilized with ethylene oxide gas

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INSTRUCTIONS FOR USE

NC Gallant™ PTCA Dilatation Catheter

1 DEVICE DESCRIPTION

CAUTION

Carefully read all instructions, warnings and precautions prior to use. Failure to do so may result in complications.

The NC Gallant™ PTCA Dilatation Catheter is a double lumen catheter comprising an expandable balloon on a rapid exchange (RX) catheter. It is a rapid-exchange design, and is therefore assembled from a combination of single lumen and dual lumen tubing. One lumen, which starts at the Catheter's proximal side and ends at the balloon, is used for inflation of the balloon with contrast medium. The second lumen, from the RX-port section to the distal tip, permits the use of a guide wire to facilitate advancement of the NC Gallant™ to and through the stenosis to be dilated. The distal shaft of the NC Gallant™ including the folded balloon is coated with a hydrophilic coating.

The catheter's distal tip is composed of two components: a metal spring and a soft jacket, partially covering the spring.

The device has two platinum-iridium radiopaque marker bands defining the balloon's working length, and aiding in positioning the balloon in the stenosis. Additionally, the proximal shaft has proximal (exit) markers which aid in gauging NC Gallant™ position relative to the guiding catheter tip (one marker is for femoral guiding catheters and the other marker is for brachial guiding catheters).

The usable length of the NC Gallant™ is 137.5-147.5cm with proximal shaft profile of 2.1F (0.70mm). For catheters with balloon diameters of 2.00-3.75mm the distal shaft profile is 2.7F (0.90mm). For catheters with balloon diameters of 4.00-5.00mm distal shaft profile is 2.95F (0.98mm). The catheter RX port (the guide wire access) 260±60 mm proximal to the distal tip.

TABLE 1: NC Gallant™ SPECIFICATIONS

BALLOON LABELED DIAMETER (MM)	MINIMUM GUIDING CATHETER COMPATIBILITY (ID)	NOMINAL PRESSURE (ATM)	RATED BURST PRESSURE RBP (ATM)	CROSSING PROFILE
2.00	5F (0.056")	12	18	0.90 mm
2.25	5F (0.056")	12	18	0.90 mm
2.50	5F (0.056")	12	18	0.90 mm
2.75	5F (0.056")	12	18	0.95 mm
3.00	5F (0.056")	12	18	0.95 mm
3.25	5F (0.056")	12	18	0.95 mm
3.50	5F (0.056")	12	18	0.95 mm
3.75	5F (0.056")	12	18	1.05 mm
4.00	5F (0.056")	12	18	1.05 mm
4.50	6F (0.070")	12	18	1.10 mm
5.00	6F (0.070")	12	18	1.15 mm

2 INDICATIONS FOR USE

The NC Gallant™ is indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion;
- Post-deployment stent expansion.

3 CONTRAINDICATIONS

The NC Gallant™ is not intended to be used:

- In an unprotected left main coronary artery;
- To treat coronary artery spasm in the absence of a significant stenosis.

4 HOW THE DEVICE IS SUPPLIED

STERILE: This device is Ethylene Oxide (ETO) sterilized and is non-pyrogenic.

FOR SINGLE USE ONLY: Do not reuse, do not re-sterilize.

USE PRIOR TO: The expiration date ("Use By" date).

CONTENTS: One (1) NC Gallant™ ; one (1) flushing tool.

STORAGE: Store in a cool, dark, dry place.

5 WARNINGS

- The device is for a single use only. Do not re-sterilize and/or reuse the device; as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.
- Do not use the NC Gallant™ if catheter shaft is bent, kinked or distorted in any way. Use a new NC Gallant™ instead.
- Do not expose the NC Gallant™ to organic solvents such as alcohol or detergents.
- Percutaneous transluminal coronary angioplasty (PTCA) should only be performed by trained, professional medical doctors, at hospitals where emergency facilities are available, and emergency coronary artery bypass graft surgery can be readily performed in the event of potentially injurious or life-threatening complication.
- Only the recommended balloon inflation medium is to be used when performing PTCA procedures. Gaseous media should never be used to inflate the balloon.
- Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of in vitro testing; and at least 99.9% of the balloons (with 95% confidence) will not burst at a pressure below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation.
- Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance under fluoroscopy before proceeding.
- Recovery of damaged/separated catheters should be performed at the discretion of the physician and based on determination of individual patient condition and appropriate retrieval protocol.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- Careful consideration is required in patients for whom anticoagulation is not indicated.
- Use extreme caution and careful judgement in patients who have severe reaction to contrast agents that cannot be adequately premedicated.
- Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60 – 85%, and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment, and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and / or damage / separation of the catheter.
- Do not torque the catheter more than one (1) full turn.

6 PRECAUTIONS

- Use the catheter prior to the: "Use By" date specified on the package.
- Before angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Inspect all products prior to use. Do not use if the package is opened or damaged, or if there is any indication that the product has been damaged.
- The NC Gallant™ should be used only by physicians trained in percutaneous transluminal coronary angioplasty.
- Appropriate anticoagulant and coronary vasodilator therapy must be administered to the patient throughout the procedure as needed. Medicine regimen should continue for a period of time deemed fit by the physicians.
- When back-loading the catheter on the guidewire, provide adequate support to shaft segment.
- The safety and effectiveness of the NC Gallant™ for the treatment of in-stent restenosis (ISR) have not been established.

7 POTENTIAL ADVERSE EVENTS / COMPLICATIONS

Known adverse events (alphabetical order) that may be associated with the use of non-compliant dilatation catheters include, but are not limited to:

- Acute myocardial infraction
- Acute vessel closure/Abrupt closure of main artery or side branch
- Arrhythmias, including ventricular fibrillation
- Arteriovenous fistula
- Cardiac tamponade/pericardial effusion
- Cardiogenic shock
- Cerebrovascular accident/stroke/TIA
- Coronary aneurysm
- Coronary artery bypass graft surgery
- Coronary artery spasm
- Coronary vessel dissection, perforation, rupture or injury
- Death
- Drug reactions, allergic reaction to contrast medium
- Embolism
- Stroke, air embolism and embolization or fragmentation of thrombotic or atherosclerotic material
- Hemodynamic compromise
- Hemorrhage or hematoma
- Hypotension / Hypertension
- Infection and pain at the insertion site
- Minor vessel trauma
- Myocardial ischemia
- Pain
- Percutaneous re-intervention
- Pseudoaneurysm (at site of catheter insertion)
- Pyrogenic reaction / Infection
- Renal failure
- Respiratory insufficiency
- Restenosis of the dilated vessel
- Slow flow/no reflow
- Thrombosis
- Total occlusion of the coronary artery or bypass graft
- Unstable angina or Chronic Angina
- Vasovagal reactions
- Ventricular arrhythmia
- Volume overload

8 OPERATOR'S MANUAL

8.1 INSPECTION PRIOR TO USE

Before opening, carefully inspect the NC Gallant™ package for damage to the sterile barrier.

CAUTION

Do not use if the device packaging is damaged.

Prior to using the device, carefully remove the NC Gallant™ from the package and inspect for bends, kinks and other damage.

CAUTION

Do not use if there is any indication that the product has been damaged.

8.2 EQUIPMENT AND MATERIALS REQUIRED

The following table lists the equipment and materials required for the procedure.

TABLE 2: REQUIRED EQUIPMENT AND MATERIALS

EQUIPMENT	QUANTITY
NC Gallant™	1
Flushing tool (provided with the NC Gallant) or a similar device	1
Sterile Heparinized Normal Saline (HepNS)	500cc
Appropriate guiding catheter (see Table 1)	1
Hemostatic valve / Rotating hemostatic valve with an appropriate internal diameter	1
50% contrast medium diluted 1:1 with normal saline	NA
20cc syringes	1-3
Inflation device	1-3
Three-way stopcock	2-3
0.014" [0.36mm] diameter guidewire	1
Guidewire introducer	1
Guidewire torque device	1
Appropriate medicinal supply (anticoagulant and coronary vasodilator therapy)	NA

8.3 NC Gallant™ PREPARATION

- Carefully extract the catheter from the hoop.
- Carefully remove the balloon cover tube and mandrel.

CAUTION

If unusual resistance is felt during removal of the balloon cover tube and mandrel, do not use this product.

- Using the flushing tool supplied by Medinol or a similar device - flush the catheter with sterile heparinized normal saline solution.
- Evacuate air from the balloon segment using the following procedure:
 - Fill a 20cc syringe or the inflation device with approximately 4cc of 50% contrast medium diluted 1:1 with normal saline.
 - Attach the 20cc syringe or the inflation device to the balloon inflation port.
 - Orient the NC Gallant™ with the distal tip and the balloon pointing in a downward vertical position.
 - Apply negative pressure and aspirate for 15 seconds. Gradually and continually release the pressure to neutral, enabling contrast medium to fill the shaft of the NC Gallant™.
 - Disconnect the syringe or the inflation device from the balloon inflation port.
 - Drain all air from the syringe or the inflation device barrel. Reconnect the syringe or the inflation device to the inflation port of the NC Gallant™. Reapply negative pressure and aspirate until bubbles no longer appear during aspiration, and air no longer returns to the device.
 - Gradually and continually release the device pressure to neutral.
- Disconnect the syringe (if used) and connect the inflation device to the inflation port of the NC Gallant™. Make sure no air is introduced into the catheter.

CAUTION

if air is seen in the shaft, repeat NC Gallant™ preparation to prevent uneven balloon inflation.

8.4 PROCEDURE

- Prepare vascular access site according to standard practice.
- Insert a compatible guidewire through the hemostatic valve. Carefully advance the guidewire into and through the guiding catheter. Once insertion of the guidewire is complete, withdraw the guidewire introducer, if used.

NOTE

A dual hemostatic valve should be used when using dual wire technique. Special care should be taken when introducing, torquing, and removing one or both wires. Guidewires should not be rotated more than 180 degrees in either direction during the dual wire procedure, to avoid entanglement. It is advised to firstly completely withdraw one wire from the patient, before removing any additional equipment.

- At the physician discretion, attach a torque device to the guidewire. Under fluoroscopy, advance the guidewire to the desired vessel, then carefully across the stenosis.
- Backload the distal tip of the NC Gallant™ onto the proximal portion of guidewire. Make sure that the guidewire emerges from the notch located approximately 22cm proximal to the balloon.

NOTE

Support the NC Gallant™ when backloading it onto the guidewire.

- Advance the NC Gallant™ over the guidewire until it approaches the hemostatic valve. Open the hemostatic valve. Insert the NC Gallant™, while maintaining guidewire position, until the catheter reaches the lesion.

NOTES

- Support the NC Gallant™ and firmly grasp the proximal shaft while advancing the NC Gallant™ into the guiding catheter.
- Catheter diameter differences should be taken into consideration when opening and tightening the hemostatic valve and upon withdrawal of the NC Gallant™.
 - a. Tighten the hemostatic valve to create a seal around the NC Gallant™ without inhibiting intentional movement of the NC Gallant™, allowing continuous recording of proximal coronary artery pressure.

NOTE

Do not over tighten the hemostatic valve, to avoid restricting the flow of contrast medium into and out of the balloon or restricting guidewire movement.

- b. Advance the NC Gallant™ until the appropriate proximal exit marker (located on the proximal shaft) aligns with the hemostatic valve hub.
- Advance the NC Gallant™ over the guidewire and into the stenosis or stent. Utilize radiopaque markers to position the balloon. Use very low pressure to inflate the balloon (1 atm, 1 bar or 15 psi) to confirm correct positioning of the balloon.
 - Carefully inflate the balloon (without exceeding 10 total inflations in a stent or 20 total inflations without a stent) to the appropriate pressure, to perform PTCA or post-implant dilatation of a stent per standard procedure. Make sure to continue maintaining negative pressure on the balloon between inflations.

CAUTION

Do not exceed rated burst pressure (see Table 1).

- After completion of PTCA or post-implant dilatation of a stent, carefully deflate the balloon by applying negative pressure on the syringe or the inflation device, until the balloon is fully deflated.
- Withdraw the deflated NC Gallant™ and guidewire from the guiding catheter through the hemostatic valve. Tighten the hemostatic valve.

8.5 CATHETER EXCHANGE TECHNIQUE

- Make sure the balloon is fully deflated.
- Loosen the hemostatic valve.
- In one hand hold the guidewire and hemostatic valve, while holding the balloon shaft in the opposite hand.
- Hold the guidewire steadily and slowly begin pulling the NC Gallant™ out of the guiding catheter. Continuously monitoring the guidewire position under fluoroscopy.
- Withdraw the deflated NC Gallant™ slowly and gradually until the flexible, distal portion of the NC Gallant™ exits the hemostatic valve, while maintaining the guidewire's position across the lesion.
- Completely remove the NC Gallant™ from the guidewire.
- Prepare next NC Gallant™ to be used, as previously described in the NC Gallant™ preparation section.
- Backload another NC Gallant™ onto the guidewire, as previously described in the procedure section and continue the procedure accordingly.

9 DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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