Lineage™ NC

Rx PTCA Balloon Dilatation Catheter

IFU11301/18122020

Instructions for use - English

1. Device Name:

The device brand name is Lineage™ NC. The generic name of the device is Rapid Exchange PTCA Balloon Dilatation Catheter.

2. Device Description:

Lineage™ NC - Rx PTCA Balloon Dilatation catheter is a sterile, single use rapid exchange catheter consisting of a non-compliant balloon, a soft tip, a dual lumen distal shaft and a single lumen proximal shaft. The balloon is folded to achieve a low profile.

Radiopaque platinum/iridium marker(s) facilitate fluoroscopic visualization of the proximal and distal ends of the Lineage™ NC balloon's working length.

The outer lumen of the distal shaft is used for inflation and deflation of the balloon and the inner lumen provides guide wire (≤ 0.014") access for advancement of the catheter through the artery and across the lesion. The Rx port, located 25 cm proximal to the soft tip, provides an exit port for the guide wire. A hydrophilic coating covers the balloon and extends proximally from the balloon to the Rx port.

The proximal shaft has a luer locking hub for balloon inflation/deflation. Two markers on the proximal shaft indicate the catheter position relative to the tip of a brachial (90 cm) or femoral (100 cm) guiding catheter.

A protective sheath is placed over the balloon to prevent any inadvertent damage to the balloon before use and also to retain the balloon profile. A stylet is inserted in the inner lumen to prevent kinking or damage to the inner lumen. The protective sheath and the stylet are to be removed prior to use.

Lineage™ NC is compatible with ≤0.014" (0.36mm) Guide wires and ≥5F (0.056"/1.42mm) Guiding catheters. The usable length of the Lineage™ NC is 142cm. The Lineage™ NC product range includes balloon diameters ranging from 2.00 mm to 5.00 mm and balloon lengths ranging from 8 mm to 38 mm.

3. Indications:

The Lineage™ NC - Rx PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Lineage™ NC - Rx PTCA Balloon Dilatation Catheter is also indicated for post-delivery expansion of balloon expandable stents.

4. Contraindications:

- Unprotected left main coronary artery lesions.
- Coronary artery spasm in the absence of a significant stenosis.
- Patients with hypersensitivity or allergies to aspirin, heparin, clopidogrel, ticlopidine or materials such as pebax, nylon, stainless steel, poly tetra fluoro ethylene, sodium hyaluronate or any contrast media.

5. Warnings:

- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/ or cause patient infection or cross-infection, including, but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including potential haemodynamic support during the procedure, as treatment of this patient population carries special risk.
- Guiding catheters used must have lumen sizes that are suitable to accommodate the introduction of Lineage™ NC - Rx PTCA Balloon Dilatation Catheter.
- Do not use if the inner package is open or damaged. Carefully remove the PTCA catheter from the pouch to prevent damage and premature removal of the balloon cover.
- To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract catheter unless the balloon is fully deflated under vacuum. If resistance is felt during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. 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.
- Should any unusual resistance be felt at any time during either lesion access or removal, the entire system must be removed as single unit.

6. Precautions:

- Prior to angioplasty, examine the PTCA catheter to verify functionality. Ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Only the physicians trained in the performance of PTCA should use the catheter system.
- Appropriate anticoagulant/antiplatelet therapy should be used during the procedure.
- Prior to reinsertion or withdrawal of the PTCA catheter, wipe the guide wire with saline-soaked gauze to remove blood or other residues.
- After the procedure, anticoagulant therapy should be continued as recommended by the physician.
- Use the catheter before the “Use by” date specified on the package.

7. Adverse Effects:

Potential adverse events, which may be associated with the use of the PTCA Balloon Dilatation Catheter, include but are not limited to:

- Acute myocardial infarction.
- Acute vessel closure
- Allergic reactions to anti-coagulant and /or antithrombotic therapy/ contrast medium.
- Arrhythmia, including ventricular fibrillation (VF).
- Arteriovenous fistula.
- Coronary embolism.
- Coronary artery spasm.
- Coronary aneurysm.
- Coronary vessel dissection/injury/perforation/rupture.
- Death.
- Emergency or non-emergent Coronary Artery Bypass Graft Surgery.
- Hematoma or Hemorrhage.
- Hypotension / Hypertension.
- Infection and / or pain at the access site.
- Restenosis of treated segment.
- Total occlusion of coronary artery/bypass graft.
- Unstable angina pectoris.
- Stroke, air embolism and embolization or fragmentation of thrombotic or atherosclerotic material.

8. How Supplied:

Sterile: This device is sterilized with Ethylene oxide, Non pyrogenic.

Do not use if the package is open or damaged.

Contents: One (1) Lineage™ NC - Rx PTCA Balloon Dilatation Catheter housed in a protective circular hoop dispenser,

One (1) Instructions for use, One (1) Re - grooming sheath for refolding balloon, if needed,

One (1) Flushing needle, One (1) Looper clip to hold the catheter in a coil configuration, One (1) Compliance chart.

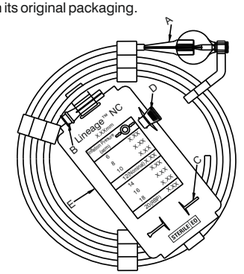
See sections 9.5 and 9.7 for the Re-grooming sheath and the Looper Clip instructions for use.

See the figure below for the placement of the contents in Lineage™ NC package.

Storage: Store in a cool, dry and dark place in its original packaging.

Note:

A - Lineage™ NC - in Hoop Dispenser
B - Flushing Needle
C - Re-grooming Sheath
D - Looper Clip
E - Compliance chart



9. Operator's Manual:

The following instructions provide guidance but do not obviate the necessity of training in the use of the device.

- The PTCA procedure should be carried out according to standard PTCA guidelines.
- Read Instructions for Use.

9.1 Preparation:

a. Remove the Aluminium pouch from the product shelf box. Open the Aluminium pouch and remove the inner pouch containing the Lineage™ NC - Rx PTCA Balloon Dilatation Catheter within the hoop dispenser.

Note: Do not use if the package is open or damaged. Remove carefully to avoid damage.

b. Remove protective sheath and stylet from the tip.

c. Prior to using Lineage™ NC - Rx PTCA Balloon Dilatation Catheter, carefully inspect for bends, kinks, and other damages.

d. Insert the flushing needle into the distal tip of the PTCA Catheter. Flush the guide wire lumen of the Catheter with sterile heparinised solution by gently applying pressure with the syringe for at least 10 seconds. The saline should exit from the guide wire port. Remove the syringe while flushing the needle.

e. Attach a stopcock to the Catheter's inflation hub.

f. Attach an appropriate size of syringe filled with a minimum of 3cc of 50% solution of contrast medium in sterile heparinised saline to the stopcock.

g. Open the stopcock and induce negative pressure, pulling the syringe plunger as far back as possible without dislodging it from the syringe barrel. Aspirate till the air is fully evacuated.

h. Gently release the negative pressure to fill the Catheter lumen with the solution.

i. Close the stopcock, remove the syringe and purge the air.

j. Repeat steps (g) through (i) if, necessary till there are no air bubbles left.

k. Fill an Angioplasty Inflation Device with a minimum of 3cc of a 50% solution of contrast medium in sterile heparinised saline and attach it to the purged Catheter.

Note: Purge the Angioplasty Inflation Device with air prior to connecting to the stopcock.

l. Induce negative pressure and close the stopcock. Purge any air from the Angioplasty Inflation Device through the stopcock. Leave the Catheter under negative pressure until it is ready to be used.

9.2 Assembly and Insertion Procedure for PTCA:

a. Attach a haemostatic valve connector to the proximal luer of the guide catheter already positioned within the vasculature.

b. Insert the guide wire carefully through the haemostatic valve connector. While observing under fluoroscopy;, advance the guide wire past the lesion according to accepted PTCA techniques.

c. Gradually tighten the haemostatic valve to avoid back flow of blood.

d. Backload the distal end of the guide wire into the tip of the Balloon Catheter. The guide wire will exit through the guide wire exit port.

Note: When back loading the Catheter, provide adequate support to all shaft segments. Do not try to straighten a kinked Catheter.

e. Open the valve to facilitate easy movement of the Balloon Catheter over the guide wire.

f. Advance the PTCA Catheter until appropriate shaft markers correspond to the haemostatic valve hub. This indicates that the tip of the balloon catheter has reached the distal end of the guiding Catheter.

Warning: If a Tuohy-Borst type adjustable haemostatic valve is used, avoid over tightening since this may restrict the flow of contrast medium in and out of the inflation lumen, thereby slowing inflation/deflation.

Caution: To avoid shaft movement restrictions, adjust haemostatic valve when advancing/withdrawing Catheter, allowing for changes in the shaft diameter.

Caution: During the advance, ensure that negative pressure is maintained in the Inflation Device to keep the balloon fully deflated.

Caution: Do not advance or withdraw the PTCA Catheter within the coronary vasculature unless it is preceded by a guide wire.

Caution: Care should be taken when inserting the PTCA Catheter into the haemostatic valve in order to avoid kinking.

g. Determine the correct position of the Balloon Catheter under fluoroscopy using radiopaque markers as a guide.

h. If resistance is encountered during advancement, do not force passage. Determine the cause of resistance and take corrective actions.

9.3 Inflation:

a. Dilate the stenotic lesion following standard PTCA techniques.

Caution: Use of oversized balloon may cause dissection. Do not exceed the Rated Burst Pressure mentioned on the product labels.

b. If needed, carry out repeat inflations. Maintain negative pressure between inflations.

c. After each subsequent inflation, determine the distal blood flow.

d. If significant stenosis persists, the lesion may require additional balloon inflations or further treatment.

e. Determine the procedural results under fluoroscopy.

9.4 Catheter Exchange/Withdrawal and Disassembly Procedure:

a. Apply negative pressure to the inflation device to achieve complete deflation of the Balloon. Confirm the balloon is completely deflated under fluoroscopy.

b. Loosen the haemostatic valve to facilitate removal.

c. While holding the guide wire and the haemostatic valve with one hand, gradually remove the balloon catheter from the guide catheter.

d. In case of exchange procedure, follow steps (e) through (l). For withdrawal or disassembly, follow steps (j) and (k).

e. Maintain the guide wire position if reinsertion/further procedure is planned.

f. Withdraw the PTCA Catheter till the guide wire exit port is exposed.

g. Slide the reminder of the PTCA catheter along the guide wire until the tip of the PTCA catheter exits the haemostatic valve. Retighten the haemostatic valve onto the guide wire to hold it securely in place.

h. Completely remove the PTCA Catheter from the guide wire. Clean with gauze soaked in sterile normal saline to wipe residues of blood and other substances.

i. Prepare and insert the next catheter according to manufacturer's instructions. If reinserting the same Lineage™ NC - Rx PTCA Balloon Dilatation Catheter, flush the guide wire lumen of the Lineage™ NC - Rx PTCA Balloon Dilatation Catheter using the flushing needle (as described in step (d) under 9.1 Preparation). Prior to reinsertion, the balloon may be refolded as described in Section 9.5: Re-grooming sheath. Before use, examine the PTCA Catheter carefully for any damage. If damaged, do not reuse.

j. Withdraw the deflated PTCA Catheter and guide wire from the guiding catheter.

k. Remove the guiding catheter from the vasculature following an accepted technique for removal.

9.5 Re-grooming Sheath

The Re-grooming sheath is an accessory component that allows the balloon to be re-folded if needed during the procedure.

Instruction for use:

a. Deflate the balloon by applying negative pressure to the inflation device and maintain under vacuum.

b. Visually inspect the balloon to confirm that it is fully deflated.

c. Carefully load the stylet back through the distal tip of the catheter then load the flared end of the re-grooming sheath over the stylet.

d. Hold the catheter just proximal to the balloon and push the re-grooming sheath over the balloon in a gentle twisting motion until the entire balloon is covered.

e. Gently remove the re-grooming sheath and the stylet form the balloon catheter.

f. Visually inspect the balloon for any potential damage. Discard the balloon catheter if there is any visible damage on the balloon.

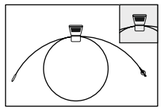
9.5.2 Flushing needle

This needle is used to flush the guide wire lumen.

9.5.3 Looper clip

The Looper clip is an accessory component that allows the catheter to be fastened in a coiled configuration for ease of handling during use (See the figure below).

Instruction for use:



a. Form the catheter into a single or double loop as needed.

b. Press down the arms of the Looper clip to open the clipping section for retention of the hypotube.

c. Release the arms of the Looper clip with the hypotube inside to secure the catheter in a coiled configuration. Discard the catheter if any bend or kink is observed upon placement or removal of the Looper clip.

9.5.4 Compliance Chart

To provide balloon compliance information.

9.6 Disposal:

After usage, dispose of the balloon catheter and accessories in accordance with accepted regulations for medical waste management.

Note: The literature should be consulted for updates to the current PTCA procedural guidelines.

10. Balloon Compliance Data:

Table 10.1: Balloon compliance chart

Pressure (atm)	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	4.00 mm	4.50 mm	5.00 mm
6	1.84	2.18	2.24	2.50	2.76	3.03	3.38	3.65	4.03	4.48
8	1.91	2.20	2.35	2.60	2.82	3.11	3.42	3.82	4.22	4.68
10	1.96	2.23	2.42	2.68	2.91	3.18	3.46	3.94	4.39	4.86
12	2.00	2.25	2.50	2.75	3.00	3.25	3.50	4.00	4.50	5.00
14	2.03	2.28	2.54	2.77	3.03	3.29	3.54	4.08	4.58	5.10
16	2.06	2.30	2.56	2.79	3.06	3.33	3.58	4.14	4.66	5.18
18	2.09	2.32	2.58	2.83	3.10	3.37	3.62	4.18	4.74	5.24
20	2.11	2.35	2.61	2.86	3.13	3.40	3.66	4.23	4.80	5.29

Grey background: Nominal pressure, **Black background:** RBP (Rated Burst Pressure)

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Symbols used in labeling

Balloon outer diameter

Balloon length

Contains one unit

Keep dry

Do not use if package is damaged

Non-Pyrogenic

REF
Reference number

LOT
Lot number

Max. guide wire diameter

MGCID
Min guide catheter I.D.

Consult instructions for use

Use-by date

STERILE EO
Sterilized using ethylene oxide

Manufacturer

Do not re-use

Date of manufacture

EC REP
Authorized representative in the European community

Do not resterilize

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Meril

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