Verge MEDICAL

FLASH Flex™
Aorto-Ostial Angioplasty System

For Use In Percutaneous Transluminal Coronary Angioplasty

REF	FF30A	FF35A	FF40A	FF45A	FF50A

Instructions for Use

Rx Only.

Caution: Federal Law (USA) restricts this device for sale by or on order of a physician.

Device Name

Flash Flex™

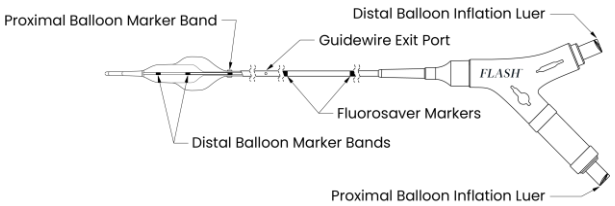
Device General Description

Flash Flex is a 0.014" (0.36mm) guidewire compatible, rapid exchange balloon catheter with a dual balloon design featuring a compliant Proximal Balloon oriented coaxially over an inner semi-compliant Distal Balloon. The Proximal Balloon has a larger diameter spherical shape in the proximal segment. The independent inflation lumens for the Proximal and Distal balloons are connected to a hub with two female luer connectors, one for each balloon. The connector for the Proximal Balloon has a pressure relief bladder with red cuffs to distinguish it from the high-pressure Distal Balloon luer connector. The integrated pressure relief feature helps prevent over pressurization of the Proximal Balloon.

An accessory included with Flash Flex is a locking 20cc syringe for inflation and deflation of the Proximal Balloon.

The following table includes the device configurations available and the associated guide catheter compatibility.

Catalog Number (REF)	Size (balloon diameter x balloon length x catheter length)	Proximal Balloon Diameter Max	Guidewire Compatibility	Guide Catheter Compatibility
FF30A	3.0 mm x 8 mm x 135 cm	11 mm	0.014"	6 Fr
FF35A	3.5 mm x 8 mm x 135 cm	11 mm	0.014"	6 Fr
FF40A	4.0 mm x 8 mm x 135 cm	11 mm	0.014"	6 Fr
FF45A	4.5 mm x 8 mm x 135 cm	11 mm	0.014"	6 Fr
FF50A	5.0 mm x 12 mm x 135 cm	14 mm	0.014"	6 Fr



Indication for Use

Flash Flex is indicated for the post-delivery expansion of balloon expandable stents within the coronary vasculature.

Note: Flash Flex was tested on the bench with Abbott Xience balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to differences in stent design. All stents should be deployed in accordance with the Indications for Use Statement per the Manufacturer's Instructions for Use.

Contraindications - Coronary

Unprotected left main coronary artery

Coronary artery spasm in the absence of a significant stenosis

Warnings

Contents are supplied sterile using ethylene oxide and are non-pyrogenic. Do not use if sterile barrier is opened or damaged.

This device is intended for single use only. Do not reuse, reprocess or re-sterilize. Balloon and/or catheter integrity may be compromised by reprocessing or re-sterilization and could lead to serious patient injury.

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 balloons are fully deflated. If resistance is felt during manipulation, determine the cause of the resistance before proceeding.

Applying excessive pull force to the catheter can result in tip breakage or balloon separation.

To reduce the potential for vessel damage, the inflated diameter of the Distal Balloon should approximate the diameter of the vessel or graft just distal to the stented segment.

Do not exceed the rated burst pressure recommended per the compliance table on the product labeling for the Distal Balloon. To prevent over pressurization, use of an indeflator is recommended for Distal Balloon inflation.

Do not exceed the maximum inflation volume recommended per the compliance table on the product labeling for the Proximal Balloon. The maximum inflation volume is based on the results of in-vitro testing.

Do not exceed stent manufacturer's recommended maximum stent diameter.

If the pressure relief bladder at the hub remains inflated, deflate both the Proximal Balloon and the Distal Balloon and reposition the catheter.

Note: The pressure relief bladder is designed to inflate when the catheter has been incorrectly positioned. When repositioning the catheter, ensure that the marker bands are correctly positioned as indicated in the POST-DELIVERY STENT DILATATION section of this IFU.

Do not pinch or manipulate the pressure relief bladder when it is inflated. This could potentially result in vessel damage if the catheter has not been properly positioned.

To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium (50% Contrast / 50% Sterile Saline).

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery warrants careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

Flash Flex is not cleared for expanding balloon expandable stents within the neurovasculature.

Precautions

Flash Flex system should be used only by physicians trained in percutaneous transluminal coronary angioplasty (PTCA).

Carefully inspect the catheter prior to use to verify that the catheter has not been damaged during shipment. Do not use if damage is evident.

Use the catheter prior to the "Use Before" date specified on the package.

Prior to use, read all instructions and label information. Failure to do so may result in severe patient injury or death.

Prior to use, the operator should ensure balloon size is compatible with the diameter of the vessel and the lesion location in relation to the aorto-ostial junction.

Do not continue to use the catheter if the shaft has been bent or kinked.

Do not rotate the catheter luer hub in excess of 5 turns during use.

If resistance is felt during device withdrawal, remove the guide catheter and Flash Flex as a single unit using standard technique. Do not torque or force removal.

Appropriate anticoagulation of the patient is indicated with the use of this device. Do not use this device on patients who cannot be anticoagulated.

The safety and effectiveness of the Flash Flex for the treatment of in-stent restenosis have not been established.

This device should be used with caution for procedures involving highly calcified lesions.

Potential Adverse Effects

The complications that may result from a balloon dilatation procedure include:

- Death
- Acute myocardial infarction
- Acute vessel closure
- Total occlusion of the coronary artery or bypass graft
- Coronary vessel dissection, perforation, rupture or injury
- Restenosis of the dilated vessel
- Hemorrhage or hematoma
- Unstable angina
- Arrhythmias, including ventricular fibrillation
- Drug reactions, allergic reaction to contrast medium
- Hypotension
- Hypertension
- Infection
- Coronary artery spasm
- Arteriovenous fistula
- Stroke, air embolism and embolization or fragmentation of thrombotic or atherosclerotic material

How Supplied

Flash Flex is provided sterile (via ethylene oxide) and is intended for single use only.

Handling and Storage

Use prior to the "Use By" date.

Do not use if the package is open or damaged.

Do not use if labeling is incomplete or illegible.

Store in a dry location at room temperature

Materials Required

Quantity	Description
As Required	Appropriate sheath introducer(s)/guiding catheters
1	0.014" (180cm long) diameter guidewire
1	Inflation device
1	Contrast solution (50% saline / 50% contrast)

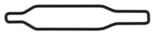
Directions For Use

DEVICE PREPARATION

1. Open the box and remove sterile package. Do not use if the integrity of the sterile package has been compromised.
2. Open the sterile package and remove product within the protective hoop.
3. Remove supplied 20cc syringe.
4. Gently unclip hub and carefully remove the catheter from the hoop.
5. Carefully remove the protective sheath covering the balloons and the support stylet.
6. Check for bends, kinks and other damage. Do not use if any defects are noted.
7. Flush guidewire lumen with heparinized saline.
8. Fill the supplied 20cc syringe with contrast solution (50% saline/50% contrast) to 2cc (3cc for 5.0mm device) after ejecting all air and excess fluid.
9. Attach the 20cc syringe to the Proximal Balloon luer. Apply negative pressure with the tip of the syringe oriented downward and hold for minimum 15 seconds, then release, to purge the Proximal Balloon and inflation lumen of air.

Proximal Balloon pictogram

10. Fill an indeflator device with contrast solution (50% saline/50% contrast) to 5cc. Apply negative pressure with the tip of the indeflator oriented downward and hold for a minimum of 15 seconds, then release, to purge the Distal Balloon and inflation lumen of air.



Distal Balloon pictogram

DEVICE DELIVERY

1. Place an appropriate stent, per manufacturer instructions for use, over a 0.014" guidewire at the target lesion.
2. Backload the Flash Flex onto the proximal portion of the guidewire while maintaining guidewire position across the stent.
3. Carefully advance the Flash Flex to the end of the guide catheter, up to the appropriate fluorosaver markers on the proximal shaft.
4. Using fluoroscopic guidance, continue carefully advancing the Flash Flex into the stent.

Note: If unusual resistance is encountered, the Flash Flex should be removed. See *Precautions* section for specific removal instructions.

POST-DELIVERY STENT DILATATION

1. Using fluoroscopic guidance, position the two most distal radiopaque balloon marker bands within the stent.

   Note: When utilizing the Proximal Balloon, the middle marker band should be aligned with the origin of the vessel ostium prior to inflation of the Proximal Balloon for optimal ostial apposition. Inflation of the Proximal Balloon is not recommended if middle marker is distal to vessel ostium.

2. Pull back the guiding catheter to the proximal radiopaque marker to ensure the Proximal Balloon is completely exposed from the distal end of the guiding catheter.
3. Align the middle marker band with the origin of the vessel ostium. Confirm that the distal marker band is inside the stent.
4. Using the inflation device and the compliance table on the product label, inflate the Distal Balloon to match the inner diameter (ID) of the stent.

   Note: Do not exceed the maximum burst pressure shown on the product label.

5. Using fluoroscopic guidance, use the 20cc syringe to inject remaining contrast solution into the Proximal Balloon to dilatate the stent against the ostium.

   Note: If the Proximal Balloon is not visible under fluoroscopy and the pressure relief bladder at the proximal balloon port inflates, deflate both the Proximal Balloon and the Distal Balloon, and reposition the catheter.

Proximal Balloon Compliance Table

REF	Contrast Injection Volume (cc)		Proximal Balloon Diameter (mm)	
FF30A FF35A FF40A FF45A	0.4	Max	11.0	Max
FF50A	1.0	Max	14.0	Max

DEVICE REMOVAL

1. Deflate the Proximal Balloon by pulling vacuum with the 20cc syringe and locking. Deflate the Distal Balloon by pulling vacuum with the indeflator.
2. Allow adequate time for both balloons to fully deflate prior to removal.
3. While maintaining negative pressure on the balloons, slowly withdraw the device through the guide catheter under fluoroscopic guidance.

   Note: If resistance is encountered upon attempted removal, do not torque or force removal. Observe removal under fluoroscopy to ensure that the balloons are fully captured inside the guide if possible. If further significant resistance is encountered, remove the guiding catheter and Flash Flex as a single unit using standard technique.

Product Pictograms

	Distal Balloon		Proximal Balloon

Manufacturer

Verge Medical Inc.
747 Camden Avenue, Suite A
Campbell, CA 95008 U.S.A
Tel: +1 (844) 352-7411
Fax: +1 (408) 716-2792