Flash™ Ostial System

Dual Balloon Angioplasty Catheter

For Use In Percutaneous Transluminal Coronary Angioplasty

See page 11 for the Peripheral Percutaneous Transluminal Angioplasty Instructions For Use

REF	OCB5014BA

Instructions for Use

Rx Only.

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

Device Name

Flash Ostial System

Device General Description

The Flash Ostial System is a 0.014” (0.36mm) guidewire-compatible, rapid exchange Angioplasty Balloon catheter with a dual balloon design featuring an Anchoring Balloon that enables the operator to precisely position the catheter at aorto-ostial anatomies and prevents distal migration of the balloon during angioplasty.

The dual balloon catheter is comprised of an outer compliant Anchoring (Proximal) Balloon oriented coaxially over an inner semi-compliant Angioplasty (Distal) Balloon. The Anchoring Balloon has a larger diameter spherical shape in the proximal segment. The inflation lumens for the inner and outer balloons are connected to a hub with two female luer connectors. The connector for the Anchoring Balloon has a colored stopcock attached which is matched to the supplied 1cc syringe color, in order to distinguish it from the distal high pressure balloon luer connector.

Accessories included with the Flash Ostial System are a 1.0cc syringe for Anchoring Balloon inflation and a 10cc syringe for Anchoring Balloon deflation.

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

Catalog Number	Size (balloon diameter x balloon length x catheter length)	Guidewire Compatibility	Guide Catheter Compatibility	Crossing Profile
OCB5014BA	5.0mm x 12mm x 135cm	0.014”	6 Fr	0.069”

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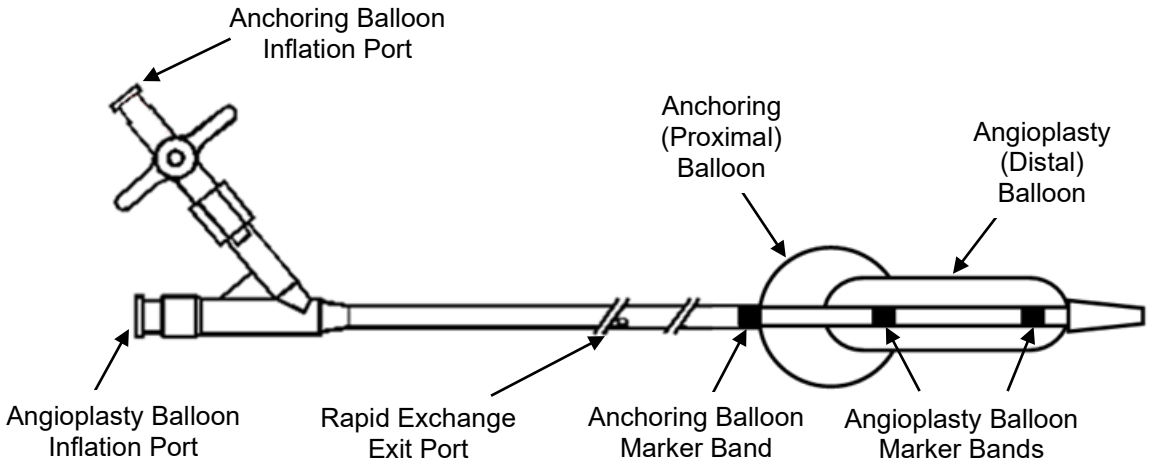

Indications for Use

The Flash Ostial System is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion. The Flash Ostial System is also indicated for the post delivery expansion of balloon expandable stents within the coronary vasculature.

NOTE: The Flash Ostial System was tested on the bench with Boston Scientific VeriFLEX™ balloon expandable stents, which had a nominal length of 20mm. 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 manufacturers' indications and instruction for use.

Contraindications

Unprotected left main coronary artery

Coronary artery spasm in the absence of a significant stenosis

Warnings

Contents are supplied STERILE using radiation (e-beam) 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 under vacuum. 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 Angioplasty Balloon should approximate the diameter of the vessel or graft just proximal and distal to the stenosis.

Do not exceed the rated burst pressure or maximum inflation volume recommended per the compliance table on the product labeling. 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. To prevent over pressurization, use of a pressure monitoring device is recommended for Angioplasty Balloon inflation.

To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium (50% Contrast / 50% Sterile Saline). Never use air or other gaseous medium to inflate the balloon.

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.

The Flash Ostial System is not cleared for expanding balloon expandable stents within the neurovasculature.

Precautions

The catheter 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 Ostial System 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 Ostial System for the treatment of in-stent restenosis has not been established.

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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

The Flash Ostial System is provided sterile (via electron beam) 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.

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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)

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 carefully remove insert card with the Flash Ostial System, supplied 1cc syringe and 10cc syringe.
3. Carefully remove supplied 1cc syringe and 10cc syringe.
4. Gently grasp hub and carefully remove the catheter from the hoop.
5. Remove the protective sheath covering the balloons.
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 1cc syringe with contrast solution (50% saline/50% contrast) to 1.0cc after ejecting all air and excess fluid and set aside.
9. Prepare the inflation device to 10cc (minimum) and attach to the Anchoring Balloon Inflation Port/stopcock. Apply negative pressure to purge the Anchoring Balloon/inflation lumen of air. Return balloon to neutral pressure. Close stopcock and attach supplied 1cc syringe to Anchoring Balloon stopcock.
10. Repeat for the preparation of the Angioplasty Balloon/inflation lumen while attached to the Angioplasty Balloon Inflation Port. Leave the inflation device attached and maintain neutral pressure.

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DEVICE DELIVERY

1. Gain access at the appropriate site utilizing an appropriately sized introducer sheath/guiding catheter as recommended on product package label.

2. Advance a 0.014” guidewire of appropriate length across target lesion.

3. Backload the Flash Ostial System onto the proximal portion of the guidewire while maintaining guidewire position across target lesion.

4. Ensure guidewire and introducer sheath/guiding catheter stability before advancing the Flash Ostial System into the hub of the introducer sheath/guiding catheter.

5. Carefully advance the Flash Ostial System across the target lesion or stent.

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

6. Prior to balloon expansion, retract introducer sheath/guiding catheter to the catheter marker band (the proximal band on the catheter shaft) to ensure that both balloons are completely exposed from the distal end of the introducer sheath/guiding catheter.

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ANGIOPLASTY / POST-DELIVERY STENT DILATATION

1. Under fluoroscopy, position the two angioplasty balloon marker bands (the two most distal markers) across the lesion or stent.

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

2. Pull back guiding catheter to the proximal radiopaque marker to ensure the Anchoring Balloon is completely exposed from the distal end of the guiding catheter.

3. **For balloon angioplasty**: Align the middle marker band with the origin of the vessel ostium. Using the inflation device, inflate the Angioplasty Balloon to a low pressure (~4 ATM) to verify the balloon position across the lesion.

   Open the stopcock and, using the 1cc syringe, inject contrast solution into the Anchoring Balloon to proximally anchor the catheter against the ostium.
   While maintaining engagement of the Anchoring Balloon, inflate the Angioplasty Balloon with the inflation device to the required pressure, per the compliance table on the product label.

   For post-delivery stent dilatation: Align the middle marker band with the origin of the vessel ostium. Confirm that the distal marker band is inside the stent.

   Using the inflation device and the compliance table on the product label, inflate the Angioplasty Balloon to match the inner diameter (ID) of the stent.

   Open the stopcock and using fluoroscopic guidance, inject contrast solution into the Anchoring Balloon in 0.1cc increments using the 1cc syringe to proximally anchor the catheter against the ostium.

   While maintaining engagement of the Anchoring Balloon, inflate the Angioplasty Balloon with the inflation device to the required pressure, per the compliance table on the product label. DO NOT exceed stent manufacturer's recommended maximum stent diameter.

Anchoring Balloon Compliance Table

Contrast Injection Volume (cc)		Anchoring Balloon Diameter (mm)	
1.0	Max	14.0	Max

4. Do not exceed the rated burst pressure shown on the product label.

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DEVICE REMOVAL

1. Deflate the Angioplasty Balloon by pulling vacuum with the Inflation device. Deflate the Anchoring Balloon using a 10cc syringe or an Inflation device.

2. Allow adequate time for both balloons to fully deflate prior to removal.

3. While maintaining negative pressure on the balloon, slowly withdraw the balloons through the guide catheter under fluoroscopic guidance.

   Note: If resistance is encountered upon attempted removal, advance the device out of the distal end of the guiding catheter/introducer sheath and gently try removal again. Do not torque or force removal. Observe removal under fluoroscopy to ensure that the balloon is fully captured inside the guide. If further significant resistance is encountered, remove the guiding catheter and Flash Ostial System as a single unit using standard technique.

4. Withdraw the deflated catheter through the guiding catheter and introducer sheath.

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Warranty

Ostial Corp. has exercised reasonable care in the manufacture of the Flash Ostial System. Ostial Corp. excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device, as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Ostial Corp.'s control, directly affect the Flash Ostial System and the results obtained from its use. Ostial Corp. shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of the Flash Ostial System. Ostial Corp. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the Flash Ostial System.

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Flash™ Ostial System

Dual Balloon Angioplasty Catheter

For Use In Peripheral Percutaneous Transluminal Angioplasty

See page 1 for the Percutaneous Transluminal Coronary Angioplasty Instructions For Use

REF	OCB5014BA	OAB6014BA

Instructions for Use

Rx Only.

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

Device Name

Flash Ostial System

Device General Description

The Flash Ostial System is a .014" (0.36 mm) guidewire-compatible, rapid exchange angioplasty balloon catheter with a dual balloon design featuring an Anchoring Balloon that enables the operator to precisely position the catheter at aorto-ostial anatomies and prevents distal migration of the balloon during angioplasty.

The dual balloon catheter is comprised of an outer compliant Anchoring (Proximal) Balloon oriented coaxially over an inner semi-compliant Angioplasty (Distal) Balloon. The Anchoring Balloon has a larger diameter spherical shape in the proximal segment. The inflation lumens for the inner and outer balloons are connected to a hub with two female luer connectors. The connector for the Anchoring Balloon has a colored stop cock attached which is matched to the supplied 1cc Syringe color, in order to distinguish it from the distal high pressure balloon luer connector.

Accessories included with the Flash Ostial System are a 1.0 cc Syringe for Anchoring Balloon inflation and a 10cc Syringe for Anchoring Balloon deflation.

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

Catalog Number	Size (balloon diameter x balloon length x catheter length)	Guidewire Compatibility	Guide Catheter Compatibility
OCB5014BA	5.0mm x 12mm x 135cm	0.014"	6 Fr
OAB6014BA	6.0mm x 12mm x 135cm	0.014"	6 Fr

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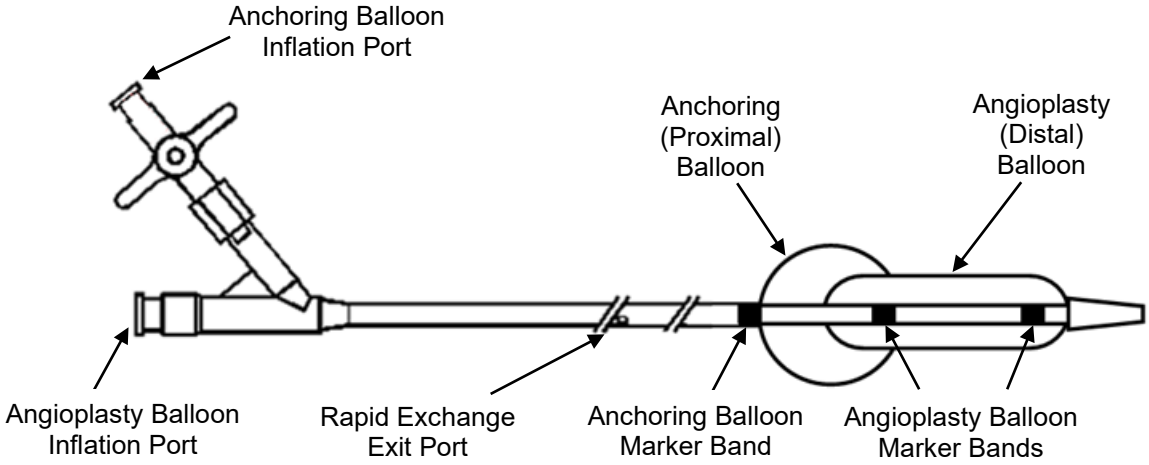

Indication for Use

The Flash Ostial System is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This device is also indicated for post-dilatation of balloon expandable stents in the peripheral vasculature.

NOTE: The Flash Ostial System was tested on the bench with the Boston Scientific Express® SD balloon expandable stent. 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 manufacturers' indications and instruction for use.

Contraindications

None known.

Warnings

Contents are supplied STERILE using radiation (e-beam) and 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 that could lead to serious patient injury.

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

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 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. Do not exceed 2.0 lbs when retracting the device into the guide catheter.

To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length of the vessel or graft just proximal and distal to the stenosis.

Do not exceed the maximum burst pressure or maximum inflation volume recommended per the compliance table on the product labeling. To prevent over pressurization, use of a pressure monitoring device is recommended for angioplasty balloon inflation.

Use the recommended balloon inflation medium (50% Contrast / 50% Sterile Saline). Never use air or other gaseous medium to inflate the balloon.

Precautions

The Flash Ostial System should be used only by physicians trained in percutaneous transluminal angioplasty.

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.

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 or stent to be dilated and the lesion or stent 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 Ostial System 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.

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

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Potential Adverse Effects

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

- Additional intervention
- Allergic reaction to drugs or contrast medium
- Embolization
- Hematoma
- Hemorrhage
- Inflammation
- Ischemia
- Sepsis/ infection
- Thrombosis
- Vascular trauma (vessel dissection, spasm, etc.)

How Supplied

The Flash Ostial System is provided sterile (via electron beam) and is intended for single use only.

Handling and Storage

Do not use if the package is open or damaged.

Do not use if labeling is incomplete or illegible.

Use prior to the Use By date.

Store in a dry location at room temperature.

Flash™ Ostial System

Dual Balloon Angioplasty Catheter

Materials Required

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

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 carefully remove card with the Flash Ostial System, supplied 1cc Syringe and 10cc Syringe.
3. Carefully remove supplied 1cc Syringe and 10cc Syringe.
4. Gently grasp hub and carefully remove the catheter from the hoop.
5. Remove the protective sheath covering the balloons.
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 1cc Syringe with contrast solution (50% saline) to 1.0 cc after ejecting all air and excess fluid and set aside.
9. Prepare the inflation device to 10 cc (minimum) and attach to the Anchoring Balloon Inflation Port/stopcock. Apply negative pressure to purge the Anchoring Balloon/inflation lumen of air. Return balloon to neutral pressure. Close stopcock and attach supplied 1cc Syringe to Anchoring Balloon stopcock.
10. Repeat for the preparation of the Angioplasty Balloon/inflation lumen while attached to the Angioplasty Balloon Inflation Port. Leave the inflation device attached and maintain neutral pressure.

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DEVICE DELIVERY

1. Gain access at the appropriate site utilizing an appropriately sized introducer sheath/guiding catheter as recommended on product package label.

2. Advance a .014" guidewire of appropriate length across target lesion.

3. Backload the Flash Ostial System onto the proximal portion of the guidewire while maintaining guidewire position across target lesion.

4. Ensure guidewire and introducer sheath/guiding catheter stability before advancing the Flash Ostial System into the hub of the introducer sheath/guiding catheter.

5. Carefully advance the Flash Ostial System across the target lesion or stent.

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

6. Prior to balloon expansion, retract introducer sheath/guiding catheter to the catheter marker band (the proximal band on the catheter shaft) to ensure that both balloons are completely exposed from the distal end of the introducer sheath/guiding catheter.

ANGIOPLASTY / POST-DELIVERY STENT DILATATION

1. Under fluoroscopy, position the two angioplasty balloon marker bands (the two most distal markers) across the lesion or stent.

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

2. Pull back guiding catheter to the proximal radiopaque marker to ensure the Anchoring Balloon is completely exposed from the distal end of the guiding catheter.

3. **For balloon angioplasty**: Align the middle marker band with the origin of the vessel ostium. Using the inflation device, inflate the Angioplasty Balloon to a low pressure (~4 ATM) to verify the balloon position across the lesion.

   Open the stopcock and, using the supplied 1cc syringe, inject contrast solution into the Anchoring Balloon to proximally anchor the catheter against the ostium.

   While maintaining engagement of the Anchoring Balloon, inflate the Angioplasty Balloon with the inflation device to the required pressure, per the compliance table on the label.

For post-delivery stent dilatation: Align the middle marker band with the origin of the vessel ostium. Confirm that the distal marker band is inside the stent.

Using the inflation device and the compliance table on the label, inflate the Angioplasty Balloon to match the inner diameter (ID) of the stent.

Open the stopcock and using fluoroscopic guidance, inject contrast solution into the Anchoring Balloon in 0.1cc increments using the supplied 1 cc syringe to proximally anchor the catheter against the ostium.

While maintaining engagement of the Anchoring Balloon, inflate the Angioplasty Balloon with the inflation device to the required pressure, per the compliance table on the label. DO NOT exceed stent manufacturer's recommended maximum stent diameter.

Anchoring Balloon Compliance Table

Contrast Injection Volume (cc)		Anchoring Balloon Diameter (mm)	
1.0	Max	14.0	Max

4. Do not exceed the rated burst pressure shown on the product label.

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Dual Balloon Angioplasty Catheter

DEVICE REMOVAL

1. Deflate the Angioplasty Balloon by pulling vacuum with the Inflation device. Deflate the Anchoring Balloon using the supplied 10cc syringe or an Inflation device.

2. Allow adequate time for both balloons to fully deflate prior to removal.

3. While maintaining negative pressure on the balloon, slowly withdraw the balloons through the guide catheter under fluoroscopic guidance.

   Note: If resistance is encountered upon attempted removal, advance the device out of the distal end of the guiding catheter/introducer sheath and gently try removal again. Do not torque or force removal. Observe removal under fluoroscopy to ensure that the balloon is fully captured inside the guide. If further significant resistance is encountered, remove the guiding catheter and Flash Ostial System as a single unit using standard technique.

4. Withdraw the deflated catheter through the guiding catheter and introducer sheath.

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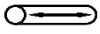
Warranty

Ostial Corp. has exercised reasonable care in the manufacture of the Flash Ostial System. Ostial Corp. excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device, as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Ostial Corp.'s control, directly affect the Flash Ostial System and the results obtained from its use. Ostial Corp. shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of the Flash Ostial System. Ostial Corp. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the Flash Ostial System.

Symbols

	**Use by date - year month**
REF	**Catalog number**
	**Lot number**
	**Consult Instructions for Use**
	**Do not reuse**
	**Do not resterilize**
	**Do not use if the package is damaged**
	**Sterilized using radiation (electron beam)**
	**Contents (numeral indicates quantity of systems in package)**
	**Balloon diameter**
	**Balloon length**
	**Catheter length**
	Compatible Guiding Catheter
	**Manufacturer**

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