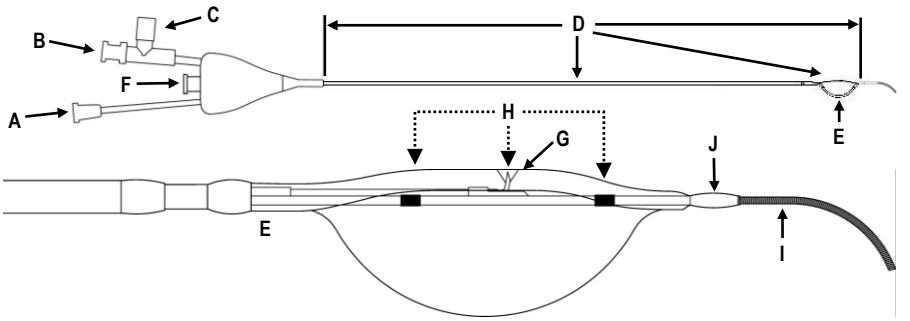
BULLFROG®
MICRO-INFUSION DEVICE

BF102P
INSTRUCTIONS FOR USE

Rx Only | STERILE R | 0344



A	Drug Infusion Port
B	Balloon Inflation Port
C	Pressure Relief Valve
D	See label for dimensions
E	Actuator
F	Guidewire Lumen Port
G	Micro-needle
H	Radio-opaque Markers
I	0.014"
J	Guidewire Lumen (OTW)

In selective areas of peripheral vessels, the BF102P Bullfrog® Micro-Infusion Device is intended for the infusion of diagnostic and therapeutic agents into the vessel wall or perivascular area, including local-acting anti-inflammatory agents to treat local inflammation. The BF102P Bullfrog® Micro-Infusion Device is also intended for the infusion of diagnostic and therapeutic agents intraluminally.

The BF102P Bullfrog® Micro-Infusion Device is indicated for the infusion of anti-inflammatory agents such as dexamethasone sodium phosphate to reduce vascular inflammation associated with endovascular revascularization.

SYMBOLS LEGEND			
REF	Catalog Number		Non-Pyrogenic
LOT	Lot Number	STERILE R	Sterilized using irradiation
	Use-By Date		Caution – Consult Instructions for Use (IFU)
	Do no re-use		Manufacturer
	Do not resterilize	EC REP	Authorized representative in the European Community
	Do not use if package is damaged	Rx Only	This device is for sale or use by the order of a physician
0344	CE mark identification number of Notified Body. The product meets the Essential Requirements of Medical Device Directive (93/42/EEC).		

INSTRUCTIONS FOR USE

CONTENTS

- One (1) BF102P Bullfrog® Micro-Infusion Device
- One (1) distal stylet
- One (1) protective sheath (coil)

Materials Required but Not Provided

- Introducer sheath and/or guide catheter, see label for compatibility
- 0.014 in. guidewire length to accommodate over-the-wire transfer
- Three-way stopcock
- 1-mL, 3-mL, 10-mL, and 20-mL luer lock syringes
- Non-ionic contrast medium
- Sterile saline
- Indeflator

DESCRIPTION

The Mercator MedSystems® Bullfrog® Micro-Infusion Device is a wire-guided, endovascular catheter that consists of a perpendicular microneedle, which is sheathed by and contained within a semi-rigid polymer actuator. The device is designed to be advanced to target vasculature and hydraulically actuated to move the microneedle tip through the external elastic lamina to deliver substances to adventitial and perivascular tissues. A compliant stabilizing balloon inflates with the actuator to provide a force opposite the needle tip for proper seating of the needle. The needle is retracted within the sheathing structure by vacuuming the hydraulic actuator.

The catheter length, needle length, and catheter outer diameter are printed on the package label. The vessel diameters in which the device may be used are also printed on the package label. The compliant stabilizing balloon fills the gap in vessel diameter between the low and high diameter listed on the package label.

The device has two liquid-transport lumens and one guidewire lumen running from the proximal hub to the distal end of the device. One liquid lumen, marked “BALLOON” at the luer, transports pressurized fluid to and from the proximal end to the actuator. The second liquid lumen, marked “DRUG” at the luer, transports therapeutic and diagnostic agents from the proximal end of the catheter to the distal end of the needle. A volume of less than 0.28 mL will prime the infusion line and microneedle.

The guidewire lumen luer is rigidly fixed to the hub, and the guidewire lumen runs from this luer to the distal tip of the device.

PRESSURE RELIEF VALVE: The BALLOON lumen pressure is governed by a pressure-relief valve designed to avoid over-pressurization of the actuator. Upon reaching adequate pressure, the valve will leak inflation fluid. Continued addition of inflation fluid will not cause any additional pressurization and will be

lost through the valve. Occlusion of the pressure relief valve may lead to balloon rupture, as in the bail-out procedure (described below).

A series of radio-opaque markers inside of the balloon are provided to assist in the placement of the distal assembly under fluoroscopy. The location of these radio-opaque markers is illustrated on the package label.

The catheter also has marks on the proximal shaft to indicate, approximately, the exit of the catheter tip from a 100-cm guiding catheter and hemostatic valve assembly.

INDICATIONS

In selective areas of peripheral vessels, the BF102P Bullfrog® Micro-Infusion Device is intended for the infusion of diagnostic and therapeutic agents into the vessel wall or perivascular area, including local-acting anti-inflammatory agents to treat local inflammation. BF102P The Bullfrog® Micro-Infusion Device is also intended for the infusion of diagnostic and therapeutic agents intraluminally.

The BF102P Bullfrog® Micro-Infusion Device is indicated for the infusion of anti-inflammatory agents such as dexamethasone sodium phosphate to reduce vascular inflammation associated with endovascular revascularization.

CONTRAINDICATIONS

- Use in coronary or central circulatory vessels.
- The target inflation site has severe calcification visible by angiography.
- The target inflation site has greater than a 30° bend.
- The target inflation site is distal to extreme vascular tortuosity or is in a vessel segment with diameter less than the minimum target vessel diameter, see label for dimension.
- The target inflation site is within a newly placed stent.
- The patient has a bleeding diathesis or coagulopathy or will refuse blood transfusions.

POTENTIAL ADVERSE EFFECTS

The following complications may be associated with the use of peripheral catheters:

- arrhythmias
- arteriovenous fistula
- bleeding complications
- cerebrovascular accident
- death
- drug reactions, allergic reaction to contrast medium
- embolism
- endocarditis
- headaches
- hemorrhage or hematoma
- hypo/hypertension
- malaise
- pain and tenderness
- pseudoaneurysm
- pyrogenic reaction
- restenosis
- sepsis/infection
- short-term hemodynamic deterioration
- total occlusion of the vessel
- vascular thrombosis
- vessel dissection, perforation, rupture, or injury
- vessel spasm

WARNINGS

- This device is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross-contamination.
- Use the Bullfrog® Micro-Infusion Device only in vessels with diameter in the range printed on the package label. Undersizing or oversizing of balloon may cause vessel trauma or loss of drug with luminal injection.
- 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 actuator balloon is fully deflated under vacuum. If resistance is met during manipulation, determined the cause of resistance before proceeding.
- Do not advance the Bullfrog® Micro-Infusion Device through extreme vascular tortuosity. Advancing the catheter through extremely tortuous vessels may damage catheter or cause vessel trauma.
- Exercise caution when advancing the Bullfrog® Micro-Infusion Device beyond a stent. Advancing or removing the catheter through a stent may dislodge the stent and require additional intervention.
- Except in the case of a bail-out procedure, do not inflate beyond the pressure relief valve pressure (approximately 2 atmospheres [ATM]) or occlude the pressure relief valve. Inflation of the actuator beyond this pressure may lead to actuator damage and vessel trauma.
- Use non-ionic contrast medium in a concentration of at least 16% (1 part contrast to 5 parts drug) in order to visualize the infusion. Ionic contrast media may cause irritation.
- The infusion of fluid materials into the media may lead to damage or dissection of the vasculature.
- The infusion of unapproved or untested agents may lead to high concentrations and tissue or vessel damage. The dosage, infusion technique, rate of administration and duration of infusion should be determined by the operating physician. If blood is seen in the inflation syringe or indeflator, remove the Bullfrog® Micro-Infusion Device and do not use. The procedure may be continued with another Bullfrog® Micro-Infusion Device.
- The device may be used on multiple vessels within the same patient. Inspect the patency of the actuator and re-prime the infusion line prior to insertion into the next vessel. Use of the device for more than 10 inflation/infusion cycles may lead to damage or rupture of the device.
- Use the catheter prior to the “Use By” date specified on the package.

PRECAUTIONS

- Use of the Bullfrog® Micro-Infusion Device requires advanced interventional skills and sterile technique. The instructions will give technical guidance but do not obviate the need for formal training in the use of interventional devices.
- Use a 1-mL (or larger) luer lock syringe for infusion. Use of a smaller syringe may lead to excessive pressure and catheter damage during infusion.
- Infuse slowly into the vessel at a rate of approximately 0.1-0.2 mL per 5 seconds or as otherwise clinically indicated. Too rapid of an infusion or too great a volume of infusate may cause vessel damage.
- The Bullfrog® Micro-Infusion Device may only be used in coronary arteries if it is done at a facility where the patient has immediate access to coronary artery bypass surgery.
- Administration of appropriate anticoagulant/antiplatelet and vasodilator therapy is critical to successful treatment and follow-up.
- Do not aspirate fluids through the needle. Do not aspirate while inside the patient.
- Do not use the device in an area where estimation of the size of the vessel is difficult, such as at vessel bifurcations. The entire length of the actuator between radio-opaque markers must lie within the desired treatment diameter indicated on the packaging.

INSTRUCTIONS FOR USE

Notes:

- Do not use if inner package is open or damaged.
- Single use device, do not resterilize.
- Store in a cool, dark, dry place.
- Use by expiration date noted on the package.

SHEATH, GUIDING CATHETER AND GUIDEWIRE USE AND SELECTION

Prepare the guiding catheter and guidewire according to the manufacturer’s instructions. The Bullfrog® Micro-Infusion Device is compatible with 0.014 in. guidewires. It is recommended that the Bullfrog® Micro-Infusion Device be used with a guiding catheter or introducer sheath with a minimum internal diameter that accommodates the device’s distal profile, as indicated on the label.

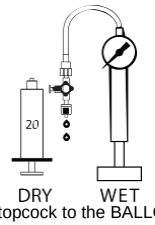
PREPARATION AND INSPECTION OF THE BULLFROG® MICRO-INFUSION DEVICE

1) Remove the Bullfrog® Micro-Infusion Device from the sterile pouch using aseptic technique, leaving the device in the protective coil.

Preparation of the Actuator Balloon

2) Fill an indeflator with attached stopcock approximately halfway with up to approximately 25% solution of contrast medium in sterile saline or water. Purge all air from the indeflator and stopcock.

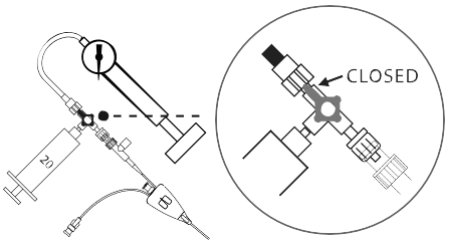
CAUTION: Do not use contrast material that is crystallized or has particles in the solution. Contrast that has crystallized or contains particles may affect inflation or deflation of the balloon.



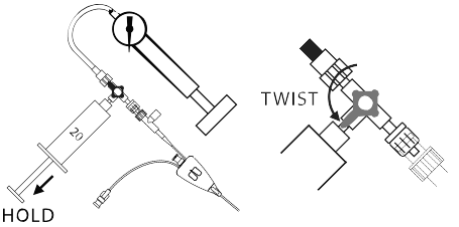
3) Attach the indeflator stopcock to the BALLOON port of the hub.

Note: Hub attachments are standard luer interfaces. Use only compatible luer syringes and stopcocks.

4) Bottom out the plunger of a sterile, dry 20-mL or greater volume syringe. Attach the syringe to the side-arm of the indeflator stopcock.

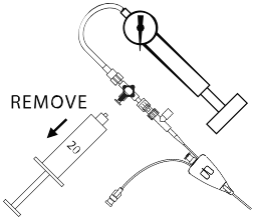


5) Turn the stopcock valve handle to close flow to the indeflator and open flow between the empty dry syringe and the BALLOON port of the hub. Draw a complete air vacuum with the dry syringe and while holding vacuum, turn the stopcock valve handle to close flow to the dry syringe and open flow between the indeflator and the BALLOON port of the hub. Repeat as needed to remove excess air from the balloon.



CAUTION: Upon placing the indeflator into vacuum, an excessive amount of air pulled into the indeflator may indicate damage to the Bullfrog® Micro-Infusion Device. If the device will not inflate or hold pressure, do not use.

6) Remove the vacuum syringe.



7) Using the indeflator, draw and maintain negative pressure on the Bullfrog® Micro-Infusion Device and remove the catheter from the protective coil.

CAUTION: Special care must be taken not to handle the actuation balloon or in any way damage the distal portion of the catheter. This is most important during removal from the protective coil, placement over the guidewire and advancement through the guiding catheter hub.

8) If a balloon leak is suspected, inflate the balloon and inspect for leaks and presence of air in the actuator. If leaks are found, do not use the device. If the actuator does not hold pressure, do not use the device. If, upon visual inspection, air occupies greater than 25% of the inflated actuator, pull vacuum on the indeflator and maintain negative pressure for 30 seconds. Release vacuum with the indeflator upright to allow the inflation lumen to refill with liquid. Repeat this step as necessary, up to 3 times. Once it has been primed, if the balloon does not fully inflate or deflate within 5 seconds, do not use the device. **Note:** During inspection, take care not to touch the microneedle, as the tip may be damaged and become dull. After any inspection, deflate the balloon and leave at ambient pressure.

Preparation and Priming of Drug Line

Note: the following instructions are provided for use of 10 mL (cc) of agent for delivery through the device. Scale volumes and syringes as needed if more or less agent is required.

9) Using aseptic technique, attach a needle to a 10-mL luer lock syringe. Draw up to 8 mL of therapeutic or diagnostic agent into syringe.

Note: Do not use therapeutic or diagnostic agents that contain visible particles, as they may clog the catheter. Concentrated particulate solutions or highly viscous solutions may also lead to catheter clogging and should be avoided.

10) Draw an additional 20-25% of the volume in the 10-mL syringe of non-ionic contrast medium (Isovue 370 or similar). For example, if 8 mL of therapeutic agent was drawn into the syringe, draw an additional 2 mL of contrast medium. If 5 mL of therapeutic agent was drawn into the syringe, draw an additional 1 to 1.25 mL of contrast medium. Agitate to mix.

Note: Non-ionic contrast medium mixes and may precipitate differently with various therapeutic or diagnostic agents. Use only agents that have been tested and approved for use in the vessel wall or perivascular tissue.

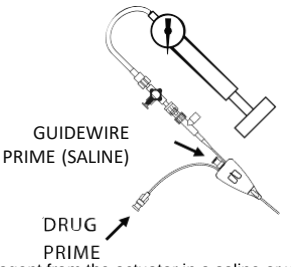
11) Using aseptic technique, connect a 1-mL luer lock syringe to one port of a three-way valve (stopcock) and the drug-filled 10-mL syringe to the side-port of the stopcock. Purge air from the stopcock and draw solution from the 10-mL (reservoir) syringe into the 1-mL (driver) syringe.

Note: The 1-mL driver syringe creates large pressures at the hub interface. Use a luer locking syringe to avoid detachment of the driver syringe and loss of infusion agent.

12) Turn the stopcock to therapeutic agent flow. Infuse just until the air is cleared from the stopcock and the liquid moves to the tip of the stopcock.

13) Attach the stopcock to the DRUG port on the hub of the Bullfrog® Micro-Infusion Device.

14) Prime the infusion lumen of the Bullfrog® Micro-Infusion Device until fluid is seen to exit from the needle at the distal end of the catheter and a noticeable change in fluid resistance is felt, approximately 0.3 mL If the infusate does not come out of the needle, do not use the device. Wash



excess therapeutic agent from the actuator in a saline or water bath.

Priming of Guidewire Lumen

1) Using aseptic technique, fill a 3-mL syringe with sterile heparinized saline. Purge all the air from the syringe.

2) Remove the distal pin from the guidewire lumen at the distal end of the balloon.

3) Attach the 3-mL syringe to the guidewire port on the hub.

4) Prime the guidewire lumen until fluid is seen to exit from the guidewire lumen at the distal end of the catheter. If the saline does not come out of the guidewire lumen, do not use the device. Submerge the device in heparinized saline prior to use and between uses if removed from the body.

INFUSION PROCEDURE

Note: Always maintain vacuum on indeflator during introduction and withdrawal of catheter from the vasculature.

1) Insert the Bullfrog® Micro-Infusion Device over the 0.014 in. guidewire and through a guide catheter or introducer sheath. Insertion into the sheath may be aided by twisting the device, which wraps the backing balloon around the balloon body.
2) Do not allow the device to kink prior to insertion. If it kinks, repeat the actuator and infusion line priming and inspection procedure. If it fails the procedure, do not use the device.
3) Position the device at the selected area, avoiding excessive tortuosity. The diameter of the selected area should be within the range indicated on the device labeling. The selected area should not be within a 30° or greater bend or excessive calcification.

   WARNING: If the indeflator indicates that the actuator is not maintaining pressure or if blood is seen in the indeflator, remove the device and continue the procedure with another device following instructions above.

   WARNING: Do not rotate the device against resistance. If resistance is met, discontinue movement of the device, determine the reason for resistance, and take appropriate action before continuing.
4) Fully actuate the device using an indeflator to inflate until the pressure relief valve opens, which is at approximately 2 ATM. While the balloon may remain inflated for extended time periods, do not continually add fluid during inflation for more than 15 seconds.

   WARNING: Do not rotate the device with the balloon inflated.

   Note: Do not aspirate fluids through the needle. Do not aspirate while inside the patient.
5) Infuse ~50 µL using the infusion syringe while observing the infusion under fluoroscopy to confirm success. If there is evidence of luminal compression, dissection or the success of the infusion cannot be verified, deflate the actuator and discontinue the infusion at that site. Reposition the device to a different area of the vessel and repeat the procedure as needed.
6) When the successful needle placement is confirmed via angiography, infuse the specified volume of the infusion agent through the Bullfrog® Micro-Infusion Device. Infuse at a rate of approximately 0.1-0.2 mL per 5 seconds or as otherwise clinically indicated. Do not occlude arterial or venous blood flow for excessive periods of time. Do not continue infusion if the infusion line loses patency or clogs.
7) Deflate the actuator by pulling a vacuum on the indeflator. Allow adequate time for balloon deflation. Confirm deflation under fluoroscopy before removing the device.
8) If the actuator will not deflate after positioning in the artery, use the following bail-out procedure:

Emergency Bail-out Procedure: First, rule out kinks or stopcock blockage as the cause of the inability to deflate the actuator balloon. If the actuator still does not deflate, occlude the pressure relief valve and inflate the actuator until the actuation balloon no longer holds pressure. Gently torque the device two rotations to remove the needle from the vessel wall. Remove the catheter from the patient. If resistance is met when removing the device, stop the procedure and send the patient to surgery for device removal.

9) Slowly remove device while maintaining negative pressure on the actuator.
10) Flush the guidewire lumen with heparinized saline and submerge the catheter in a heparinized saline bath to prevent blood coagulation on the catheter if additional infusions are desired within the same patient.

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*Isovue is a registered trademark of Bracco Diagnostics, Inc.

The device may be used in multiple vessels within the same patient. Prior to re-use, inspect the actuator for leaks by inflating and checking needle for direction, attachment, and infusion line patency. Discard the device if it fails inspection. Maintain the catheter submerged in a saline bath between uses.

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US Patent Nos. 6,547,803 B2; 6,860,867 B2; 7,070,606 B2; 7,547,294 B2; 7,559,923 B2; 7,666,163 B2; 7,691,080 B2; 7,744,584 B2; 8,016,786 B2; 8,465,752 B2; 8,708,995 B2; 8,721,590 B2; 9,011,879 B2; 9,061,098 B2; 9,149,497 B2; 9,199,065 B2; 10,441,747 B2; 10,561,816 B2; 10,576,063 B2; 10,617,678 B2; 10,849,879 B2; 10,925,863 B2; D902,388 S; D902,389 S; D902,390 S; D903102 S; D903103 S; D903,104 S. Foreign Patent No: EP2073729 (B1).

Other U.S. and Foreign Patents Pending

Mercator MedSystems