FINESSE BTK MULTICATH®

INJECTION PORTS • CROSSING • ANGIOPLASTY

Instructions for Use

℞ ONLY

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

DEVICE DESCRIPTION

The Finesse BTK Multicath® is a high-performance injection/infusion and angioplasty balloon catheter for peripheral indications. The device features a semi-compliant balloon combined with a low-profile tip. The catheter is compatible with 0.014" (0.36 mm) guidewires. The catheter includes a hydrophilic coating over its distal coaxial segment and balloon.

The Finesse BTK Multicath is an Over-The-Wire (OTW) catheter with a semi-compliant balloon fixed at the distal tip. The balloon catheter has a coaxial distal shaft and a dual lumen proximal shaft design. The outer lumen of the distal shaft is in communication with the inflation lumen of the proximal shaft and is used for inflation/deflation of the balloon. The inner lumen of the distal shaft is in communication with the wire lumen of the proximal shaft, which permits the use of 0.014" (0.36mm) guidewires to facilitate advancement of the catheter to and through the stenosis to be dilated. The guidewire lumen of the proximal shaft, comprising three exit holes located at its distal end and proximal to the exit hole's radiopaque marker, serves as the injection lumen when performing fluid or contrast injection such as for visualizing the vessel anatomy.

The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The catheter includes a tapered tip to facilitate advancement to and through the stenosis. The working length of the balloon catheter is available in 65, 100, and 150cm lengths as noted on the product label. There are two radiopaque marker bands located within the balloon working length (one proximal and one distal). These radiopaque marker bands, in conjunction with fluoroscopy, aid in the placement of the catheter's balloon segment. There is one radiopaque marker located distal of the exit holes to aid in locating their position relative to the guiding sheath distal tip. The proximal portion of the catheter includes a sidearm extension with a female Luer-lock port for balloon inflation/deflation, and a Tuohy-borst hub adapter with a Luer-activated valve injection port for fluid/contrast injection that is in communication with the guidewire lumen and three distal exit holes.

CONTENTS

Quantity	Material
1	Finesse BTK Multicath

INTENDED USE / INDICATIONS FOR USE

The Finesse BTK Multicath is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

CONTRAINDICATIONS

Do not use in vessels smaller than the labeled balloon diameter.
Do not use in immature dialysis grafts or fistulae (i.e., have not been in place for at least 28 days and used for at least one hemodialysis treatment).
Do not use in the presence of hemodialysis access site/graft infection.

WARNINGS

Contents supplied STERILE using an electron beam (e-beam) process. Do not use if sterile barrier is damaged. If damage is found, call your Summa Therapeutics representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to a device failure, which in turn, may result in patient injury, illness, or death. Reuse, reprocessing or resterilization 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. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

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

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

To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length 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 felt during manipulation, determine the cause of the resistance before proceeding.

Do not exceed the rated balloon burst pressure. To prevent over pressurization, use of a pressure monitoring device is recommended.

This balloon is not intended for the expansion or delivery of a stent.

Use only the recommended balloon inflation medium (25% Contrast / 75% Sterile Saline). Never use air or any gaseous medium to inflate the balloon.

The safety and effectiveness of the device has not been established, or is unknown, in vascular regions other than those specifically indicated.

PRECAUTIONS

Care should be taken to control the position of the guide catheter or guiding sheath tip during the manipulation of the balloon catheter.

Any use for procedures other than those indicated in these instructions is not recommended.

Carefully inspect the catheter prior to use to verify that the catheter has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used.

The Finesse BTK Multicath shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty.

The Finesse BTK Multicath should be used with caution for procedures involving calcified lesions or synthetic vascular grafts due to the abrasive nature of these lesions.

The Finesse BTK Multicath is not intended for injection of contrast medium, or other fluids, using power injector systems.

In the event that resistance is met during device retraction determine the source of resistance and exercise caution when removing the device. If resistance persists, it is recommended to remove the catheter and guidewire/introducer sheath as a single unit. Exchange the device for a new one to complete the procedure.

Some 0.014" guidewires may be incompatible, especially those with hydrophilic coatings. If resistance is encountered when frontloading a guidewire remove it and replace with a stainless steel shaft guidewire with a spring coil tip.

Precautions to prevent or reduce or clotting should be taken when any catheter is used:

Consider systemic anticoagulation.

Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution prior to use.

During use, flush injection lumen regularly or connect injection lumen to a continuous infusion of flush solution.

Due to variations in individual patient anatomy and individual physician techniques, the procedure may vary.

The size of inflated balloon (diameter and length) should be selected not to exceed the length of the stenosis, as well as the diameter of the artery immediately distal and proximal to the stenosis.

Inflation in excess of the rated burst pressure may cause the balloon to rupture. *In vivo* balloon pressures must never exceed the rated burst pressure (refer to the balloon compliance table -TABLE 1 for rated burst pressures).

To minimize the possible introduction of air into the system, careful attention should be paid before proceeding to the maintenance of tight catheter connections and thorough aspiration and flushing of the system.

Balloon dilatation procedures should be performed only under fluoroscopic observation with radiographic equipment that provides high-resolution images.

Do not advance any portion of the dilatation catheter system against significant resistance. The cause of the resistance should be determined via fluoroscopy before proceeding.

Never advance the angioplasty catheter without the guidewire extending beyond the tip.

Do not pull the Balloon Protector cover proximally onto the catheter shaft.

Avoid wiping the device with dry gauze as this may damage the device coating.

Avoid excessive wiping of the coated device.

Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.

Avoid pre-soaking devices for longer than instructed, as this may impact the coating performance.

POTENTIAL ADVERSE EVENTS

The complications that may result from a balloon dilatation procedure include, but are not limited to:

- Abrupt closure
- Allergic reaction (device, contrast medium and medications)
- Amputation
- Aneurysm
- Arteriovenous fistula
- Death
- Deep vein thrombosis
- Embolization (air, thrombus, plaque, device)
- Hematoma
- Hemorrhage, including bleeding at the puncture site
- Hypotension
- Infection, local or systemic
- Ischemia, including tissue ischemia, and/or necrosis
- Need for additional intervention or surgery
- Neuropathies or nerve injury
- Organ failure (single, multiple)
- Pulmonary embolus
- Pain
- Pseudoaneurysm
- Renal failure
- Restenosis
- Shock
- Vessel injury, e.g., dissection, rupture, perforation
- Vessel occlusion
- Vessel spasm
- Vessel thrombosis

HOW SUPPLIED

Finesse BTK Multicath is supplied STERILE using an electron beam (e-beam) process.
Do not use if the package is opened or damaged.
Do not use if the labeling is incomplete or illegible.

HANDLING AND STORAGE

Store in a cool, dry, dark place.

Do not store catheters where they are directly exposed to organic solvents, ultraviolet light sources, or ionizing radiation. Rotate inventory so that the catheters and other dated products are used prior to the "USE BY" date. Do not use if packaging is damaged or opened

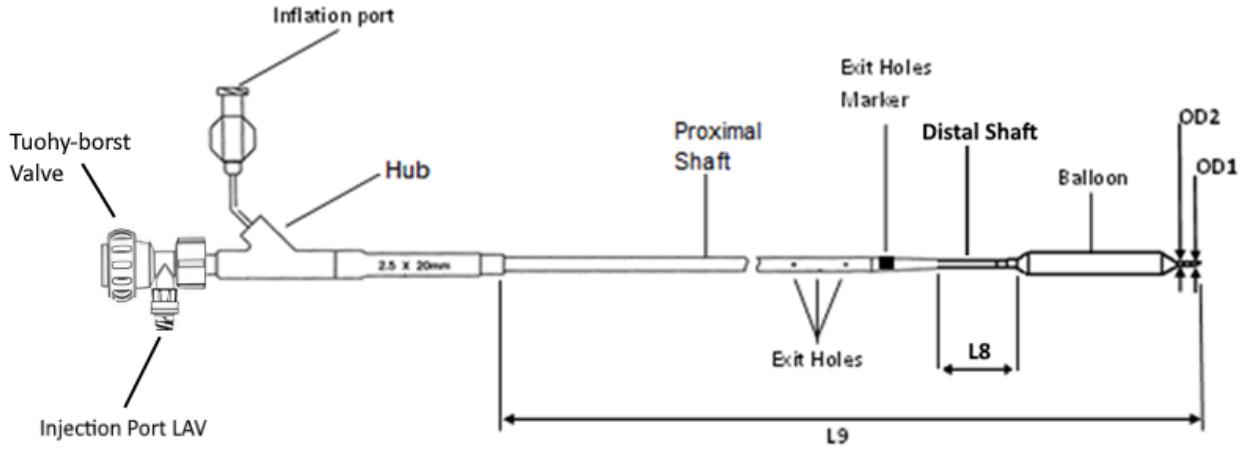
CLINICAL STUDIES

No human clinical studies have been completed at this time.

MATERIALS REQUIRED

Quantity	Material
1 or 2	Guidewire(s) 0.035 in (0.89 mm) x 180-300 cm length for advancement of introducer sheath or guiding catheter
1	Appropriate arterial introducer sheath and dilator set (for femoral approach only) per the Finesse BTK Multicath labeling
1 or 2	Guiding catheters or guiding sheaths in the appropriate size and configuration to select the targeted artery per the Finesse BTK Multicath labeling, if needed
1	Vial of contrast medium
1	Vial of sterile saline solution
1	Inflation device with manometer
1 or 2	Finesse BTK Multicath
1 or 2	Guidewire(s) 0.014 in (0.36 mm) diameter x 180-300 cm long for advancement of Finesse BTK Multicath
1	5cc Luer-lock syringe
1	10cc or 20cc Luer-lock syringe
1	Hemostatic Adapter
1	Three-way stopcock

FIGURE 1: FINESSE BTK MULTICATH



DIRECTIONS FOR USE

INFLATION DEVICE PREPARATION:
Prepare the Inflation device according to the manufacturer's instructions. Purge the system of air.

CATHETER PREPARATION:
1. Remove the pouch from the shelf box.
2. Using sterile technique, open the pouch and remove the insert card containing the catheter.
3. Remove the catheter from the packaging coil mounted on the insert card.
4. Remove the balloon protector and stylet by sliding distally off the balloon. If unusual resistance is felt during removal of the balloon protector or stylet, do not use the catheter and replace with another.
5. Prepare the catheter for purging. First, purge the angioplasty balloon and balloon lumen. Fill a 10cc or 20cc Luer-lock syringe with 3cc of contrast medium. Use only the appropriate balloon inflation medium (the equivalent of a 25% contrast medium/75% sterile saline solution.) Do not use air or any gaseous medium to inflate the balloon.
6. Connect a three-way stopcock to the Inflation Port of the catheter then attach the syringe to the three-way stopcock. Use care when connecting the catheter to avoid damage.
7. Hold the syringe with the nozzle pointing downward and aspirate for 10-20 seconds and then slowly release the plunger.
8. Remove the syringe and evacuate all air from the barrel.
9. Repeat step 7 of the CATHETER PREPARATION section. Close the three-way stopcock.
10. Next, flush the guidewire/injection lumen. Tighten the knob to close the Tuohy-Borst valve of the catheter.
11. Attach a syringe to the Injection Port of the catheter and slowly flush the lumen with ~5cc of sterile saline solution until it is ensured that fluid is discharged from both the exit holes and the distal tip of the catheter. Manually obstruct exit holes to flush end hole if needed.
12. Close the Injection Port stopcock.

INFLATION DEVICE CONNECTION TO CATHETER:
1. Disconnect the 10cc or 20cc Luer-lock syringe from the three-way stopcock on the Inflation Port of the catheter.
2. Ensure that no air is trapped in the Inflation device and then connect the Inflation device to the three-way stopcock on the Inflation Port of the catheter.
3. Open the three-way stopcock to the balloon.

DEVICE INSERTION:
1. Ensure that access has been achieved with an appropriately sized guiding catheter or guiding sheath and that a 0.014" (0.36 mm) guidewire is placed across the area to be treated.
2. Backload the distal tip of the catheter onto the guidewire, fully opening the Tuohy-Borst valve to accommodate the guidewire, and then track the catheter over the guidewire up to the hemostasis valve of the guiding catheter or guiding sheath.
3. Pull vacuum on the Inflation device and lock the Inflation device plunger.

4. Advance the catheter through the hemostasis valve of the guiding catheter or guiding sheath. (If pre-soaking is done, do not pre-soak more than 15-30 seconds.)
5. Under fluoroscopic guidance, advance the catheter to the target location. Confirm that the radiopaque exit hole marker of the catheter is distal to the tip of the guiding catheter or guiding sheath. If not, retract the guiding catheter or guiding sheath as required.
6. Confirm that the catheter's radiopaque balloon markers are positioned relative to the target location and then gently tighten the hemostasis valve of the guiding catheter or guiding sheath. Care should be taken not to over-tighten the hemostasis valve around the catheter shaft as lumen constriction may occur affecting inflation/deflation of the balloon and/or the ability to infuse/inject fluids.

FLUID INJECTION VIA THE CATHETER INJECTION PORT:

1. Connect a 5cc or 10cc Luer-lock syringe filled with 50% Contrast solution/50% sterile saline solution or other physician specified fluid to the Injection Port of the catheter, which will open the Luer-activated valve. Ensure that the syringe is free of air prior to connection
2. Tighten the Tuohy-Borst valve of the catheter over the wire.
3. Inject/infuse the desired volume of fluid manually using the attached syringe.
   CAUTION: THE FINESSE BTK MULTICATH IS NOT INTENDED FOR USE WITH POWER INJECTOR SYSTEMS.
4. Disconnect the Luer-lock syringe once the desired fluid injection is completed. This will close the Luer-activated valve.
5. Flush injection lumen regularly or connect injection lumen to a continuous infusion of flush solution during use.

BALLOON INFLATION AND DEVICE REMOVAL:

1. Ensure that the balloon diameter is appropriately sized for the vessel in which it is placed. Inflate the balloon to the appropriate pressure (Reference the balloon compliance table - TABLE 1).
2. If needed, repeat inflation of balloon (not to exceed 10 total inflations) until the desired result is achieved.
3. Apply negative pressure to fully deflate the balloon. Confirm that the balloon is fully deflated under fluoroscopy.
4. Withdraw the catheter until the balloon is clear of the lesion while maintaining the position of the guidewire across the stenosis, loosening the Tuohy-Borst valve as needed.
5. Following the procedure for fluid Injection via the catheter Injection Port, perform angiography to confirm dilatation.
6. While maintaining negative pressure, withdraw the deflated dilatation catheter and guidewire from the guiding catheter or guiding sheath through the hemostasis valve. Tighten the hemostasis valve.

TABLE 1: BALLOON COMPLIANCE

Pressure Atm	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm
4	1.73	2.23	2.57	2.98	3.46
5	1.79	2.30	2.66	3.12	3.63
6	1.83	2.37	2.74	3.26	3.81
7	1.87	2.45	2.84	3.39	3.96
8	1.91	2.52*	2.93	3.50*	4.09*
9	1.95	2.58	3.01*	3.61	4.21
10	1.98*	2.65	3.08	3.71	4.32
11	2.02	2.70	3.15	3.78	4.43
12	2.06**	2.76**	3.22**	3.87**	4.53**

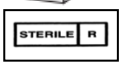
* Nominal Diameter ** Rated Burst Pressure

WARRANTY

Summa Therapeutics has exercised reasonable care in the manufacture of the Finesse BTK Multicath. Summa Therapeutics 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 Summa Therapeutics' control, directly affect the Finesse BTK Multicath and the results obtained from its use. Summa Therapeutics shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of the Finesse BTK Multicath. Summa Therapeutics neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the Finesse BTK Multicath.

Use only under the direction of a physician

Contents (1)



Sterilized using irradiation

Do not re-sterilize


For single use only.
Do not re-use


Consult instructions for use


Do not use if package is damaged


Hydrophilic coating, see instructions for use


Non-pyrogenic


Keep away from sunlight


Keep dry

Manufactured for:
SummaTherapeutics, LLC, 119 Braintree Rd., Ste. 508, Boston, MA 02134