

Inflation Device

INSTRUCTIONS FOR USE

DESCRIPTION:

The Merit basixTAU™ Inflation Device is a 20mL disposable device fitted with a threaded plunger assembly with lock/ release bar, a flexible high-pressure extension tube, and a three-way medium pressure stopcock. The basixTAU is designed to generate positive and negative pressure, and monitor positive pressures over a range of zero to +30ATM/BAR (zero to +441 PSI). The basixTAU has an added “fold-out” handle feature designed to provide a secondary mechanism for turning the handle during inflation and deflation of angioplasty balloons or other interventional devices.

Rx ONLY: **CAUTION:** Federal (U.S.A.) law restricts this device to use by or on the order of a physician.

INDICATIONS AND USAGE:

This inflation device is used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the pressure within the balloon.

NOTE: This device has not been cleared for dispensing fluids into the body.

INSTRUCTIONS FOR USE:

Before use, inspect the device and packaging to verify that no damage has occurred as a result of shipping. Prior to use, free the plunger tip by twisting the syringe plunger/handle 360 degrees clockwise.

DEVICE PREPARATION:

1. To prepare the syringe, turn the device with gauge facing down and aspirate up to 20mL of contrast solution or other fluid into the syringe by squeezing the trigger and pulling back on the handle.

CAUTION: Inspect the barrel, tubing, and stopcock (if used) to ensure there is no air in the system.

2. Remove any excess air by orienting the syringe upwards, squeezing the trigger located in the syringe handle and pushing the handle forward.

REUSE PRECAUTION STATEMENT:

For single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the 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.

ATTACHING THE INFLATION DEVICE TO THE BALLOON:

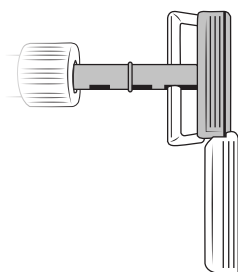
NOTE: Refer to the manufacturer’s directions accompanying the balloon dilatation catheter or other interventional device for specific information on use and warnings for that device.

1. Prepare and test the balloon catheter according to the catheter manufacturer’s directions for use.
2. Create a fluid-fluid connection between the balloon and the inflation syringe extension tube and connect the luer connectors securely.
3. Squeeze the trigger and pull back on the handle to apply a vacuum to the balloon.

BALLOON INFLATION AND DEFLATION:

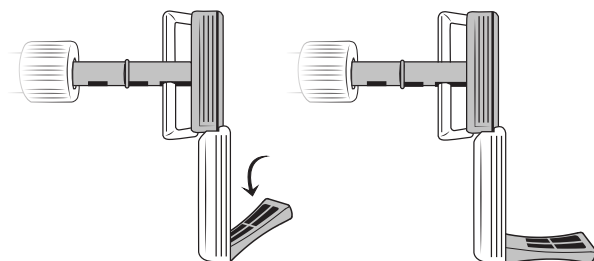
1. To inflate the balloon, squeeze the trigger allowing the plunger to return to the resting position (0 ATM/BAR). Release grip on the trigger, locking the plunger into position. To increase pressure, rotate the handle clockwise until the desired inflation pressure is reached. The lock mechanism maintains the pressure.
2. If desired, use the “fold-out” handle feature:
 - a. Open the handle by pulling down on the white handle portion. Fold the white portion out completely.

Figure 1



- b. Reach into the white handle portion and fold out the purple swivel handle completely.

Figure 2.









CAUTION: Rotating resistance will be lower due to the mechanical advantage provided by the “fold out” handle. Until the user is familiar with the hand feel of the device, caution should be used during inflation.

NOTE: Significant loss of pressure may indicate a leak in the system.

CAUTION: To protect the threads of the lock release handle, the device must be displaying 25 ATM or lower before quick release mechanism is used to deflate the angioplasty balloon.

3. To deflate the balloon, squeeze the trigger and pull back to generate a negative pressure. Release grip on the trigger to lock the plunger in the negative pressure position.

Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.		Caution: Consult accompanying documents. Read instructions prior to use.
	Single use.		Do not re-sterilize
	Do not use if package is damaged.	STERILE EO	Sterilized using ethylene oxide.
	For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U Customer Service.		Non-pyrogenic



CE₂₇₉₇
www.merit.com



Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748



Authorized Representative:
Merit Medical Ireland Ltd,
Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22