English

basixSky™

Inflation Device

INSTRUCTIONS FOR USE

DESCRIPTION
The basixSky™ Inflation Device by Merit Medical is a 20mL disposable device with a threaded plunger assembly and a flexible high-pressure extension tube. The basixSky™ is designed to create positive and negative pressures over a range of zero to +30ATM/BAR (zero to +441 PSI). The accuracy of this inflation device has been determined to be within ±0.9 ATM (± 3% of full scale).

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

INTENDED USE
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 in the body.

CLINICAL BENEFITS
The Merit basixSky Inflation Device provides an indirect clinical benefit to patients by facilitating inflation, deflation, and pressure measurement for angioplasty balloons or other interventional devices during procedures utilizing these devices.

INTENDED USER(S)
General Surgeons, Thoracic Surgeons, Otorhinolaryngologists (ENT), Gastroenterologists, Interventional Cardiologists, Interventional Radiologists, Vascular Surgeons, Nurses, Lab Technicians

PATIENT POPULATION
Patient undergoing procedures involving the inflation of a balloon or other interventional device.

CONTRAINDICATIONS AND WARNINGS
There are no contraindications or warnings specified for Merit's inflation devices.

INSTRUCTIONS FOR USE
Before use, inspect the device and packaging to verify that no damage has occurred as a result of shipping.

If the pressure gauge needle is not resting within the "0" box, do not use.

DEVICE PREPARATION
1. To prepare 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.
2. Push handle against table or other solid surface to remove air in syringe

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

ATTACHING THE INFLATION DEVICE TO THE BALLOON
NOTE: Refer to the manufacturer's directions accompanying the balloon dilation catheter or other interventional device for specific information on use, maximum inflation pressure, precautions, 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 device extension tube, connect the luer connectors securely.
3. Squeeze the trigger and pull back on the plunger handle to apply a vacuum to the balloon.

BALLOON INFLATION AND DEFLATION
1. To inflate the balloon, squeeze the trigger to allow the plunger to return to a resting position (0 ATM/BAR or PSI). Release grip on the trigger, which will lock the plunger into position. To increase pressure, rotate handle clockwise until the desired pressure is achieved.

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

   CAUTION: If applied pressure does not indicate on gauge display, discontinue use immediately and replace it with a new unit.
2. To deflate balloon, squeeze the trigger and pull back to generate a negative pressure. Release grip to lock the plunger in a negative pressure position.

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

POTENTIAL COMPLICATIONS
The potential exists for complications which may include, but are not limited to the following:

- Infection
- Inflammation
- Dissection/Perforation
- Thrombosis

REUSE PRECAUTION STATEMENT
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to 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 crossinfection, 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.

Users should follow local guidelines and practices regulating the disposal of infected waste products.

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

	Caution
	Do not use if package is damaged and consult instruction for use
REF	Catalog number
LOT	Batch code
MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
	Consult Instructions for Use For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within seven calendar days, call U.S.A. or EU Customer Service.
STERILE EO	Sterilized using ethylene oxide
℞ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single sterile barrier system

	Use by date: YYYY-MM-DD
	Date of manufacture: YYYY-MM-DD
	Manufacturer
EC REP	Authorized Representative in European Community
	Keep away from sunlight
	Keep dry
	Non-pyrogenic
	Temperature limitation

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CE 2797

MERIT MEDICAL®

www.merit.com

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