

PremierPro™ Reusable Pressure Infuser Bag

REF 8820, 8821

EN PremierPro™ Reusable Pressure Infuser Bag

DEVICE DESCRIPTION: The device is non-sterile and reusable. A device with an inflatable bladder, a pressure gauge, and an inflation bulb.

INTENDED PURPOSE: A pressure infuser has an inflatable sleeve which is placed around an I.V. bag. When the device is inflated, it assists in the infusion of fluid.

INDICATIONS FOR USE: To assist in the infusion of fluid, for use with rapid infusion of fluid, for use with intraarterial monitoring and for surgical irrigation. For use with crystalloid or colloid solutions, and blood products.

ENVIRONMENT: Hospital, sub-acute, pre-hospital.

PATIENT TARGET GROUP: Newborns, infant, pediatric, adult.

EXPECTED CLINICAL BENEFITS:

1) Rapid Infusion: provides a life-saving clinical benefit by enabling rapid infusion of fluid and blood to replace blood loss in situations such as severe trauma, hemorrhage, PPH, and organ transplants.

2) Intraarterial and Swan-Ganz Monitoring:

- Ensures line patency and prevents retrograde of blood flow for continuous blood pressure and hemodynamic monitoring by providing back pressure greater than systolic blood pressure up to 200 mm Hg.
- Enables clinicians to easily obtain blood samples, therefore reduces needle punctures minimizing patient discomfort and decreases infection risk associated with needle punctures.

3) Low pressure (<10 PSI) surgical irrigation procedures:

- During open procedures, irrigation 1) clears tissue debris before incision closure to decrease the risk of surgical site infections, 2) improves the view of patient's anatomy to help identify bleeding site and adhesions, and 3) delivers antibiotics or antiseptics to tissue in the surgical cavity. These promote faster wound healing and decreases hospital length of stay or hospital admissions.
- During ureteroscopy, irrigation improves physician's visualization and removes blood clots and stones to reduce patient's pain.

CONTRAINDICATIONS: None Known.



WARNINGS:

- Over-pressurization of the bladder may cause the bladder or fluid bag to rupture.
- Rapid infusion therapy has a potential risk of venous air embolism, hypothermia and infection at insertion site.
- Infusion therapy may cause infiltration/extravasation at insertion site.
- Surgical irrigation may cause tissue injury and perioperative hypothermia.

CAUTIONS:

- Maintain proper inflation pressure during use.
- Ensure green band is displayed on pressure gauge.
- During rapid infusion user may experience hand fatigue.
- For best transfer of pressure to the IV Bag, ensure fluid bag is placed within the pressure infuser panel.
- Use protective methods for irrigation splashback.

RESIDUAL RISKS: Refer to Warnings and Cautions.

NECESSARY USER QUALIFICATIONS: This device is restricted to sale by or on the order of a physician. There are no additional requirements for special facilities, special training, or particular qualifications for the use of this device.

INSTRUCTIONS: 1.) SELECT the correct size infuser for the IV fluid bag.
2.) INSERT IV fluid bag between the pressure infuser and sleeve. 3.) HANG IV fluid bag on the infuser's plastic hook. 4.) HANG pressure infuser on IV pole or other location IV fluid bags are normally hung. 5.) **Inflation using Stopcock Model:** a.) TURN the stopcock valve so the arrow points to the right. This is the INFLATE position. b.) SQUEEZE the inflation bulb repeatedly until a pressure of 300 mm Hg (green band) is displayed on pressure gauge. c.) TURN the stopcock valve so the arrow points UP (towards the infuser). This is the HOLD position. The stopcock valve is required to be in this position for as long as pressure is to be held. d.) To Deflate: Turn the stopcock valve so the arrow points down (towards the inflation bulb).

CLEANING INSTRUCTIONS: Follow instructions to avoid risk of infection and contamination. PremierPro™ manual pressure infusers are reusable devices but may be cleaned by using the following method: (Note: Do not soak or immerse the infuser) 1.) APPLY either a 10% bleach solution or hospital-approved detergent for porous surfaces to the infuser. 2.) USE a soft brush or cleaning cloth to remove stains. 3.) RINSE thoroughly with running water. Ensure the vent hole in the pressure gauge is facing down so water doesn't enter the gauge. 4.) ALLOW infuser to air dry before use. Discard and replace immediately if the PremierPro™ bag becomes damaged and fails to maintain pressure, is unable to be cleaned or has been contaminated with blood or other bodily fluids.

SAFE DISPOSAL: Dispose of device in accordance with local, state or national regulations.

INCIDENT REPORTING: Contact your country's Competent Authority and Manufacturer to report any serious incident.

PERFORMANCE CHARACTERISTICS:

- Gauge Accuracy: $\pm 10\%$
- Pop-Off Pressure Range: 360-400 mm Hg
- Average flow rate at 8.65 mL/s of infused fluid between 0-350 mL, rate may vary depending on catheter gauge and fluid viscosity.

The PremierPro™ Pressure Infusers are compatible with fluid bags that fit within the length and width specifications.

PIB Size	Length	Width
500 mL	8in. [20.32 cm]	5.25in. [13.34 cm]
1000 mL	10.5in. [26.67 cm]	6.375in. [16.19 cm]

For use with fluids with a viscosity of 1.07 to 8.9 cP and pH of 4.5 to 7.5.*

Fluid	Viscosity*	pH (Polarity)*
Saline Solution	1.07 - 1.12 cP	4.5 - 7.0
Platelets Solution	3.4 - 8.9 cP	6.0 - 7.5
Human Blood	3.5 - 5.5 cP	7.35 - 7.45

**Values are representative only*



Non-clinical testing demonstrated that these devices are MR Conditional. These devices can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 7-Tesla or less.
- Maximum spatial gradient magnetic field of 1,900-Gauss/cm (19-T/m).

These devices should be positioned away from the area being scanned to reduce the possibility of artifacts on the image.

Manufactured for S2S Global
13034 Ballantyne Corporate Pl.
Charlotte, NC 28277 USA
Made in China
www.s2s-global.com

