

BALLOON INFLATION DEVICE (MEGA TYPE)

1. PRODUCT DESCRIPTION:

Seguro Mega Balloon Inflation Device is consisting of a 20 cc syringe body with a plunger which may be engaged by a control button, a rotator handle, a manometer and a high pressure connector with a rotating male luer locks. The manometer is graduated between vacuum and 30 ATM with an equivalent in PSI. There are two gripping choices by changing the manometers position.

2. INTENDED USE:

The Seguro Mega balloon inflation device is precisely designed for use during PTCA and any other intravascular therapeutic procedures that utilize a balloon catheter and pressure monitoring.

3. CONTRAINDICATIONS:

There are NO known contraindications for this device.

4. WARNING:

- Do NOT re-use or re-sterilized.
- Use Seguro Mega Balloon Inflation Device prior to the expiration date specified on the package,
- Do not autoclave
- Do not use if the package is damaged
- Keep Away from Sunlight

5. PRECAUTIONS:

- Mega Balloon Inflation device is supplied sterile.
- Do not use if the product package or a part of the product is damaged during handling.
- The product is for single Use only.
- It must be used by doctors.
- Before each inflates confirm that the needle of the manometer is set to the zero position +/- 1 ATM.
- Refer to the balloon catheter leaflet (precautions for use, maximum pressure etc.)
- When releasing the deflation, it is recommended to go with the handle.
- If the control knob can't return in unlocked position, turn the handle counter clockwise to deflate the balloon catheter.

6. SIDE EFFECT & CONTRAINDICATIONS:

- There is no side effect for this product.
- There are NO known contraindications for this device.

7. PRODUCT INSTRUCTION:

The Plunger is in free position when the button is in the press position. In this position you may pull the plunger to aspirate or push it to inject. Turn the button un-press position to lock the plunger. Turn the handle clockwise to inject the mixture of contrast medium. The pressure in the balloon is displayed on the manometer.

OPERATION PROCEDURES:

Operation

- The plunger is free to move when the control button is pressed.
- To lock the plunger, Un- press control button.
- Turn the handle clock wise to deliver the mixture of contrast media. The estimated pressure is indicated on the manometer.

Preparation & Use

- Prepare the mixture of contrast media for balloon catheter following the manufacturer's recommendations for the contrast media.
- Check the plunger is unlocked.
- Hold the Seguro Mega Balloon Inflation Device with its manometer downwards and insert the end of connector into the contrast solution to fill the syringe.
- Hold the device with the manometer upwards to purge the air contained in the syringe and in the connector.
- Connect the Seguro Mega Balloon Inflation Device to the balloon catheter.
- To inflate the balloon catheter, point the manometer downwards and turn slowly the handle clockwise up to posting of desired pressure.
- This pressure is kept due to the locking system.
- To deflate the balloon catheter, unlock the plunger and pull completely the handle.

Use in Special Patient Population: The Seguro Mega Balloon Inflation Device is used for all ages of group.

8. MAIN PERFORMANCE INDICES:

Appearance: Transparent and smooth. Airproof: There should be no air leakage.

Sterility: The product is sterilized by EO.

9. INDICATIONS:

The Seguro Mega Balloon Inflation Device is used during angioplasty procedures to inflate the balloon catheter, control pressure and deflate the balloon catheter.

10. STORAGE:

- Storage temperature 0 - 30 °C
- Avoid Exposure to direct Sunlight or Heater.
- Keep the Product in a clean, organized cool and dry place.

11. DISPOSAL:

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted hospital medical practice, and applicable local European and international disposal regulation.

Explanation of symbols as per MDD 93/42/EEC, ISO 15223-1:2021:

Sr. No.	Symbol	Meaning
1.		Symbol for "Reference number"
2.		Symbol for "Batch code"
3.		Symbol for "Date of manufacture"
4.		Symbol for "Use Before"
5.		Symbol for "Do not reuse"
6.		Symbol for "Manufacturer"
7.		Symbol for "Caution"
8.		Symbol for "Do Not use if package is damaged"
9.		Symbol for "Keep away from sunlight"
10.		Symbol for "Keep Dry"
11.		Symbol for Consult Instruction for Use
12.		Symbol for Do not Re-sterilize
13.		Symbol for Quantity
14.		Store at 0-30 °C
15.		Non Pyrogenic

Warranty / Liability:

Although this product has been manufactured under carefully controlled quality conditions, Seguro Life Science has no control over the conditions under which this product is used. Seguro Life Science therefore disclaims all warranties both express and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Seguro Life Science shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Seguro Life Science to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular term held to be invalid.



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