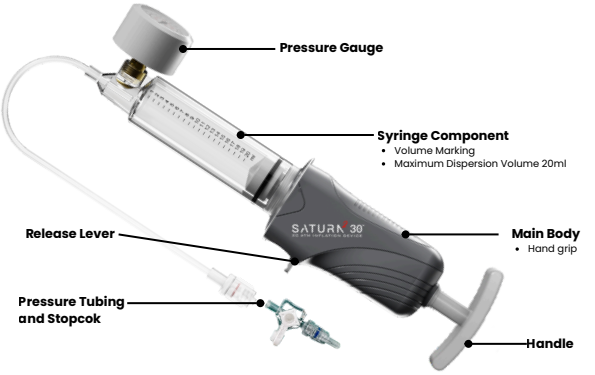
**(INSTRUCTION FOR USE)**

# SATURN 2™ INFLATION DEVICE

SATURN 2 20ML, 30ATM INFLATION DEVICE (ST)
**SYN2030ST**




## PRODUCT DESCRIPTION

The Inflation Device is used in PCI operations to pressurize the balloon dilation catheter, causing the balloon to expand. This facilitates the expansion of blood vessels or the placement of a stent within the vessel. The Inflation Device is mainly consisted of a syringe, a plunger, a trigger, shell, a piston seat, a pressure gauge, a tubing, a male rotating adapter and stopcock.

## APPLICABLE SCOPE

It is used to pressurize and deflate blood vessel molding balloons or other interventional medical apparatus and instruments, allowing for the measurement of the pressure within the balloon.

## INTENDED USE

Inflation Device for Single Use are used in PCI procedures to pressurize balloon dilation catheters, enabling the balloon to expand for the purpose of widening blood vessels or securing a stent. It is also employed to inflate and deflate vascular balloons or other interventional tools, allowing for precise pressure measurement within the balloon.

## INDICATIONS

- **Coronary Heart Disease (CHD), including coronary artery disease**
- **Angina Pectoris**
- **Acute Myocardial Infarction (AMI)**
- **Ischemic Heart Disease**

## STORAGE CONDITIONS

It should be stored in the environment with the relative humidity lower than 80% and the temperature lower than 40°C without any corrosive gas; and stored in a shady and cool, dry, well-ventilated and clean place.

SYNDEO MEDICAL
EMPOWERING OUTCOMES™

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## INSTRUCTIONS

1. Before use, check the package and Saturn2 to ensure they are not damaged.
2. Pull the trigger backward while simultaneously pulling the plunger. Release the trigger once the dilution contrast medium (or other liquid) reaches the designated amount.
3. Hold the Saturn2 upright and pull the trigger backward while simultaneously pushing the plunger forward to expel any residual air from the syringe. If necessary, release the trigger and rotate the plunger to ensure all residual air is released from the syringe.
4. Connect the male rotating adapter of the Saturn2 and the balloon catheter; ensure that the pressure gauge dial plate faces directly towards the operator.
5. Pull the trigger backward and pull the plunger backward simultaneously to release the residual air inside the balloon catheter.
6. Release the trigger, and rotate the plunger clockwise to pressurize the balloon; rotate the plunger counterclockwise to release the balloon's pressure. When the pressure drops below 10atm, pull the trigger backward to discharge the pressure from the balloon.
7. Pull back the trigger, and pull back the plunger simultaneously. Release the trigger to create a negative pressure inside the balloon.
8. When the Saturn2 is kept at a certain pressure, the pressure can be released quickly by pulling the trigger backward.

**Note:** Releasing the pressure too quickly might result in risks, please operate according to clinical conditions.

## WARNINGS, PRECAUTIONS, & CONTRAINDICATIONS

- The device is intended for use only by trained healthcare professionals. Always read and understand the Instructions for Use (IFU) before operating the device.
- Single-use only — do not re-sterilize or reuse the device, as this may compromise safety and performance.
- The device is sterilized using ethylene oxide (EO) and is supplied sterile and non-pyrogenic. Do not use if the packaging is damaged or opened prior to use.
- The product has a shelf life of 3 years. Always check the expiry date on the packaging before use. Do not use expired devices.
- Before use, refer to the maximum rated inflation pressure specified by the balloon dilation catheter or other interventional device manufacturer. A drop in pressure during the procedure may indicate a leakage in the system.
- Ensure compatibility when connecting with other devices — the product is designed to interface with a female rotating adapter with a 6% (Luer) taper.
- After use, the device may be considered a potential biohazard. Handle, contain, and dispose of in accordance with accepted medical practices and applicable hospital, local, and national regulations.

**NOTE:** *Any serious incident involving this device such as malfunction, unintended operation, or any event that may have caused or could cause harm to a patient or user must be reported immediately to the manufacturer.*

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## SIGNS AND LEGENDS:

| | | |
|---|---|---|
| Sterlized Using Ethlene Oxide | Use By | Keep Dry |
| Do Not Reuse | Manufacturer | Caution |
| Date of Manufacture | Catalogue Number | Humidity Limitation |
| Do Not Use If Package Is Damaged | Do Not Re-sterilize | Fragile, Handle With Care |
| Batch Code | Medical Device | Keep Away From Sunlight |
| CE Marking of Conformity | Consult Instruction For Use | Unique Device Identification |
| Temperature Limit | Quantity | |

## TRANSPORTATION CONDITION:

Keep away from heavy and sunshine, keep dry
Temperature limit: 0°C - 40°C
Humidity limitation: 0% - 80%

**MANUFACTURED BY**
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A BELGIAN BRAND

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