

TRANS-ID
Balloon Inflation Device
Instructions for use



Manufacturing Facility



Translumina Therapeutics LLP
Plot No.#12, Pharmacity, Selaqui,
Dehradun, 248011, Uttarakhand India.
Phone:+ 91 135 2699944, 0135 2699795
Fax: + 91 135 2699944, 0135 2699795
Email: info@translumina.in
Web: www.translumina.in

Registered Office

Translumina Therapeutics LLP
Ground floor Metro Tower, LSC
MOR land, New Rajender Nagar.
New Delhi-110060 , India
Phone: +91 11 2874 2874
Fax: +91 11 2874 2873
Email: info@translumina.in
Web: www.translumina.in

1. PRODUCT DESCRIPTION

The Trans-ID balloon Inflation Device is a 14ml disposable device capable of producing a maximum pressure of 55atm/bars; Fitted with a threaded plunger, a flexible high pressure extension tube. The inflation device allows inflation to generate and monitor pressure over a range of vacuum to 55 atm/bars (734 psi) with accuracy of $\pm 1\text{atm}/\text{bar}$ (14.7 psi).

Trans ID – Product Matrix with Product reference No.

Reference No.	Description
TRID 55AT	14CC,55ATM

2. INDICATIONS

An Inflation device is used for the inflation and deflation of a balloon dilatation catheter, to dilate the vessel or implant a stent.

INSTRUCTION FOR USE

3. Preparation:

- Check the package and Inflation Device to ensure they are not damaged.
- Push the piston to the 0 (Zero) Graduation, in order to eliminate the air out of this syringe while pressing the lock lever.
- Submerge the male rotating adapter into prepared contrast medium; then hold down the lock lever and draw back piston. When the contrast medium has reached the amount required. Release the lock lever.
- Connect the device with the stopcock securely. Hold the device upright with Pressure Gauge upward; push the piston forward while pressing the lock lever to remove the inside air. Slightly tap the syringe in order to eliminate residual air, if necessary.
- Switch off the liquid path of stopcock; test the Gauge indicator by increasing or decreasing the pressure.

Connecting Inflation Device to Balloon Dilatation Catheter:

1 Note: Prior to connecting the Inflation Device, Balloon Dilatation Catheter should be prepared and tested according to the manufacturer's instructions.

- Remove the stopcock from the male rotating adapter of the Inflation Device.

Caution: Failure to remove the stopcock could result in allowing the air to enter system and/or contrast solution leak out. Inflation pressure may not be maintained.

- Create a fluid-fluid connection between the male rotating adapter of the In-deflation Device and the balloon dilatation catheter, and tighten the joint securely.

Operating In-Deflation Device

1. Holding the lock lever to release mechanism to allows freely push or pull of piston for inflation or deflation.
2. To remove any residual air in the balloon dilatation catheter, hold the device upright with Pressure Gauge upward, and then pull back the piston to generate vacuum pressure while holding the lock lever held.
3. Balloon Inflation: Rotate the handle clockwise to increase the pressure.
4. Balloon deflation: Rotate the handle counter clockwise two laps until the pressure reduces to below 10 atm. Then pushed the lock lever to release the pressure.
5. If necessary, please repeat steps 3 and 4.
6. Vacuum pressure generating: Press the lock lever and pull back the handle, then release the lock lever to generate vacuum pressure.
7. Pressing the lock lever and allows pressure quick release.



Caution: Fast pressure release may cause risk to patient. Please use according to clinical requirement. Over repeat of fast pressure release may cause decline of meter accuracy.

WARNINGS

- Don't use it if the package is damaged or unsealed.
- Please read the instruction before use.
- The device is designed for single use. Please don't re-sterilize and/or reuse.
- Don't use it after expiry date.

4. PRECAUTIONS

- The Luer connector must be securely connected. Otherwise there could be leakage or air ingress into blood vessel.
- Please don't increase the pressure over 55atm.
- Please don't use gas medium to inflate the balloon.
- Eliminate any air out of the system before use.
- For Qualified physician use only.

Caution: Please dispose the device after use, in accordance with local laws and regulations.






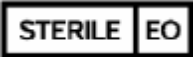



5. PACKAGING








- **Sterile:** This device is sterilized with ETO gas.
- **Contents:** One Trans-ID Balloon Inflation Device.
- **Storage:** Store in a dry, dark, cool place below 40°C

6. CONVERSION CHART

1 cc	1 ml		
1 bar	0.987atm	14.5 PSI	10 ⁵ Pa

7. SYMBOLS

Description	Symbol
Reference No.	
Batch No.	
Pyrogen free	
Manufactured Date	 YYYY MM
Expiry Date	 YYYY MM
Sterile and Method of sterilization	
Single use only & do not re-sterile	
Storage Condition	
Medical Device	

Description	Symbol
Name of Manufacturer	
Content : Trans-ID	
Read the documents/Instruction for use	
Do not use if package open or damaged	
Keep away from direct sun light	
Keep dry	
Caution/Warning	
Single Sterile barrier system	