- Pain and tenderness
- Laryngospasm or bronchospasm
- Atelectasis
- Pulmonary edema
- Airway obstruction due to edema and hypoxia.

9. DISPOSAL

After use, the sheath, airway balloon catheter, guide-wire and inflation device airway should be disposed of in a manner consistent with standards and protocols for biohazard waste disposal.

10. PACKAGING

- **Sterile**

The supplied content has been sterilized using an Ethylene Oxide process. Do not use if sterile barrier is damaged.

- **Storage**

Use before the expiry date clearly indicated on the label. The product is stored between 5°C and 25°C, away from light and moisture, outside the cleanroom. Long term exposure to high temperatures may reduce the shelf life. The product must not be exposed to extreme temperatures below 5°C or above 40°C.

- **Single use**

For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the integrity of this device and or may lead to device failure, which, in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination.

11. COMPLIANCE

The compliance chart (Table 2) is based on data from in vitro testing at 37°C, rounded to reflect the nominal diameter at nominal pressure. Nominal pressure is 6 atm. Rated burst pressure (RBP) is 12 atm. Do not inflate beyond RBP (rated burst pressure).

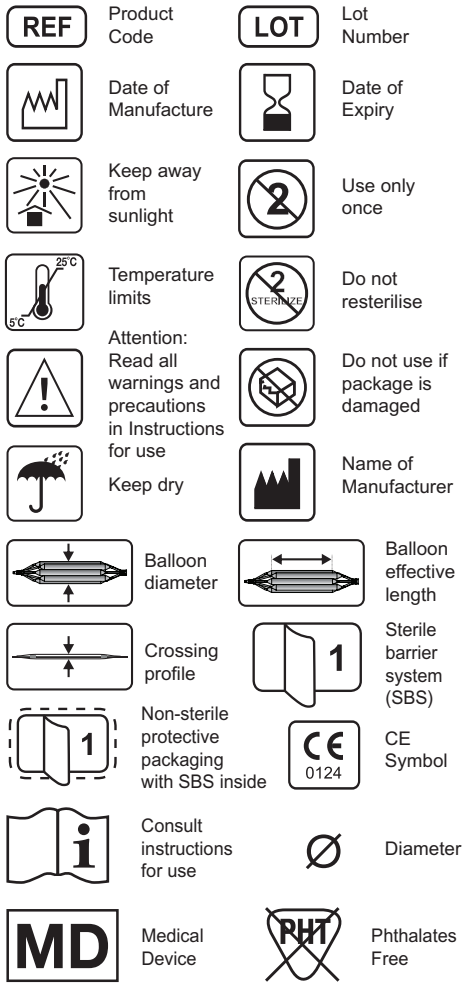
12. WARRANTY AND LIMITATION OF LIABILITY

DISA Medinotec (Pty) Ltd. guarantees that each of its products is treated with utmost care in development, selection of materials and components, manufacture, sterilisation and final testing before it is released for packaging and distribution. Through inexpert storing, handling and other manipulation, the catheter system can be damaged and its operability can be restricted. DISA Medinotec (Pty) Ltd. accepts no liability or warranty for malfunction, breakdown and potential medical complications for patient and hospital staff, or for resulting damages arising from inexpert handling, operation, storing, from acts of God or from other external influences or manipulation.

DISA Medinotec (Pty) Ltd. will replace any device, which, in its opinion, was defective at the time of shipment and if defects that were caused during manufacturing or packaging are immediately brought to the attention of DISA Medinotec (Pty) Ltd. or its distributors. This warranty is exclusive and in lieu of all other warranties, whether expressed or implied, written or oral, including, but not limited to, any implied warranties of merchantability of fitness.

As a result of biological differences in individuals, no product is 100% effective under all circumstances. DISA Medinotec (Pty) Ltd. has no control over the operation, inspection, maintenance, or use of its products after sale, and has no control over the selection of patients. Therefore, DISA Medinotec (Pty) Ltd. and its distributors do not guarantee either a good effect or against a poor result following the use of any DISA Medinotec (Pty) Ltd. product. DISA Medinotec (Pty) Ltd. and its distributors shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of the device or from re-sterilisation or re-use of the product. In the case of product complaint, an appropriate complaint protocol is to be obtained from DISA Medinotec (Pty) Ltd. and the form returned, together with the product, to DISA Medinotec (Pty) Ltd.

13. GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELLING



Rx only **Caution**: Federal law restricts this device to sale by or on the order of a physician

STERILE EO Sterilised with ethylene oxide

EC REP Authorised representative in the European Community

14. BALLOON SPECIFICATIONS

Table 1: Balloon specifications

Product Reference Number	Balloon Length (mm)	Balloon Diameter (mm)	Nominal Pressure (atm)	Maximum Pressure (atm)
TRD1-06030	30	6.0	6	12
TRD1-07030	30	7.0	6	12
TRD1-08030	30	8.0	6	12
TRD1-09030	30	9.0	6	12
TRD1-10030	30	10.0	6	12
TRD1-12040	40	12.0	6	12
TRD1-14540	40	14.5	6	12
TRD1-16040	40	16.0	6	12
TRD1-18040	40	18.0	6	12

15. BALLOON COMPLIANCE DATA

Table 2: Balloon compliance chart

	Diameter (mm)								
Pressure (atm / MPa)	6.0	7.0	8.0	9.0	10.0	12.0	14.5	16.0	18.0
4 / 0.4	5.9	6.7	7.6	8.8	9.7	11.7	13.7	15.9	17.1
6 / 0.6	6.0	6.9	7.8	9.0	9.9	11.9	14.5	16.3	18.1
8 / 0.8	6.2	7.1	8.0	9.2	10.1	12.1	14.7	16.5	18.4
10 / 1.0	6.3	7.2	8.1	9.3	10.2	12.3	15.0	16.9	18.8
12 / 1.2	6.5	7.4	8.3	9.5	10.4	12.5	15.2	17.2	19.1

Nominal Pressure (NP)

Rated Burst Pressure (RBP)

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CE 0124

EC REP **Emergo Europe**
Prinsessegracht 20
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The Netherlands

DISA MEDINOTEC

Trachealator

Rx Non-occlusive Airway Dilation Balloon

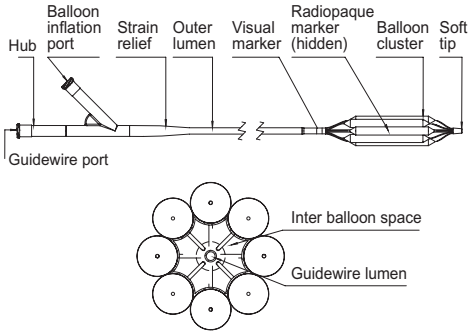
INSTRUCTIONS FOR USE (ENGLISH)

STERILE. Sterilised with Ethylene Oxide gas. Does not contain phthalates. For one procedure only. Do not use opened or damaged packages. Destroy product after use. Do not resterilise.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

1. DESCRIPTION

The Trachealator Non-occlusive Airway Dilation Balloon is comprised of a single lumen, over-the wire, catheter with a clustered balloon system near the distal tip. The balloon cluster, when inflated, features a inter balloon space to avoid airway occlusion during deployment. The inflated balloon cluster generates a strong outward force for dilation of airway strictures. A guidewire is provided to facilitate the advancement of the Trachealator Non-occlusive Airway Dilation Balloon to the desired location. The sizes of the balloons as well as the nominal and maximum inflation pressures for each are summarized in Table 1.



2. INDICATIONS

The Trachealator Non-occlusive Airway Dilation Balloon is intended to dilate strictures or stenoses of the airway.

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3. CONTRA-INDICATIONS

Balloon dilation is contraindicated in any patient whose general medical condition and degree of respiratory failure would not allow the patient to tolerate bronchoscopy (rigid or flexible) and/or the manipulation required to accomplish balloon dilation. Balloon dilation is contraindicated when any of the following are present:

- Significant active bleeding from the site of the proposed dilation.
- Stenoses resistant to high pressure inflation (>12 atm).
- Known perforation at the site of the proposed dilation.
- Known fistula between the tracheobronchial tree and the oesophagus mediastinum or pleural space unless the dilation was being performed in preparation for the placement of a stent to treat the perforation or fistula.

4. WARNINGS

- Check for proper positioning of the balloon catheter using endoscopic visualization. The line on the proximal end of the balloon may facilitate the placement of the balloon. Improper inflation of the balloon at the incorrect location may harm the patient.
- Any use for procedures other than those indicated in these instructions is not recommended.
- Do not attempt to repair this device.

5. PRECAUTIONS

- Federal law restricts this device to sale by or on the order of a physician.
- Use the catheter prior to the “use-by” date specified Intended for single patient use only. DO NOT REUSE.
- Do not use if package is opened or damaged. Do not use if labelling is incomplete or illegible.
- Careful monitoring of patient oximetry is necessary during the procedure.
- Do not soak the airway balloon catheter in water / saline / or contrast medium.
- During dilation caution should be used to avoid any interference and possible obstruction of other devices such as tracheostomy tubes and endotracheal tubes.
- The balloon must be inflated with sterile water or saline.
- Do not use air or any other gas to inflate the balloon.
- Use of a balloon that is too large for the target anatomy may cause damage to the surrounding anatomy.
- Use of a balloon that is too small may result in failure to properly dilate the target area.
- The length of the balloon must be noted to ensure no damage to the carina during placement of the balloon.
- Do not try to force movement of the balloon catheter when inflated.
- If the balloon catheter migrates during inflation of the balloon do not attempt to advance or retract the balloon without completely deflating the balloon first.
- Do not advance, retract or hold the balloon catheter or the balloon catheter with guidewire against excessive resistance as this may damage the device. Reasonable resistance is expected when the balloon is inflated.
- If at any point in the procedure the balloon does not deflate rupture the balloon with a sharp instrument prior to removal.

6. COMPATIBILITY

The Trachealator Non-occlusive Airway Dilation Balloon hub is compatible with appropriate catheter inflation devices

with a pressure monitoring gauge, 20ml, 0 – 30 atm (± 4.0% full scale typical), with a conical 6% male Luer lock (such as the Demax Mastro Inflation Device). Compatible devices are required to be capable of supplying and maintaining the required pressure, and should be equipped with a standard male luer lock fitting. Trachealator Non-occlusive Airway Dilation Balloon is designed to pass over a 0.018” (0.46 mm) guidewire for 6.0 to 12 mm diameters and 0.035” (0.89 mm) guidewire for 14.5 to 18 mm diameters, and through a minimum 4.5 mm working channel.

7. INSTRUCTION FOR USE

Caution: This device should be used only by or under supervision of a physician trained in airway balloon dilation. A thorough understanding of the technical principles, clinical application and risks associated with balloon dilation of the airway is necessary before using this device.

A. General

1. Prior to use, visually examine the package and all equipment to ensure no defects, the seal remains intact, the sterility has not been compromised, and that there is no sign of damage during shipping, storage or handling. Do not use any defective equipment.
2. Visualization of the airway using an endoscope or bronchoscope (flexible or rigid) is preferred to determine the location of the stricture/stenosis and to guide the placement of the balloon along with the guidewire supplied with the product.
3. Trachealator Non-occlusive Airway Dilation Balloon Selection: When choosing the diameter and length of the balloon catheter, the balloon should initially accommodate the narrowed stricture or stenosed airway segments. The maximum diameter should not exceed the diameter of the healthy lumen. Endoscopic visualization or imaging can assist in determining a healthy lumen diameter. The cartilage skeleton i.e. tracheal rings should be considered when selecting the balloon diameter. The length of the balloon should be considered to ensure no damage to the carina.

Note: Whenever possible, a sharp instrument which can reach the site of dilation should be made available during the deflation of the balloon to deflate the device (balloon) if difficulties arise.

B. Preparation

1. Open the sterile packaging and remove the Trachealator Non-occlusive Airway Dilation Balloon.
2. Prepare the appropriate inflation system with a pressure monitoring gauge (such as the Demax Mastro Inflation Device) and a bowl of sterile water / saline/ or diluted contrast medium.

Notes: Refer to the manufacturer’s directions accompanying the inflation system for instructions on preparation and use. The instructions below provide a recommended method to purge air from the catheter.

3. Fill the inflation device with 20ml of sterile water/saline /or diluted contrast medium. Hold the Inflation Device with the tip pointed upwards and force all of the air from the Inflation device and tubing, leaving 15ml of sterile water, saline or diluted contrast medium in the inflation

device. Ensure the inflation device is not completely filled with liquid – allow space to pull the plunger back.
4. Connect the male luer adaptor of the prepared inflation device to the balloon inflation port on the hub (i.e. the side port) of the balloon dilation catheter.

Note: Do not remove the protective sheath from the distal end during preparation of the balloon dilation catheter.

5. With the inflation device connected to the balloon dilation catheter, tilt the inflation device tip downwards, to ensure that the air collects at the back of the inflation device, and withdraw the plunger of the inflation device to remove any excess air from the balloon dilation catheter.
6. Holding the inflation device above the level of the balloon, release the plunger to allow the liquid to enter the catheter.
7. If excessive air remains in the catheter, repeat steps 5 & 6.
8. Ensure that at least 15ml of sterile water/saline remains in the inflation device prior to using the balloon. If not, disconnect the inflation device and refill with water to the 15ml mark, purge the air and reconnect. Avoid allowing air to enter the catheter tubing.
9. Once the excess air has been satisfactorily removed from the balloon catheter tubing, then the protective sheath may be removed from the balloon catheter.

C. Placement

1. Locate the stricture using endoscopy or bronchoscopy (flexible or rigid).
2. Slowly and gently advance the Trachealator Non-occlusive Airway Dilation Balloon to the site of the stricture, preferably through a rigid bronchoscope, endotracheal (ET) tube or Laryngeal Mask Airway (LMA) device. Use a guidewire if necessary.

Note: There is a radiopaque marker in the centre of the balloon for positioning under fluoroscopy.

Caution: If resistance is met during the procedure do not advance the catheter without first determining the cause of resistance and taking necessary action.

3. Centre the balloon portion across the area to be dilated. Confirm that the balloon is correctly positioned with the centre of the balloon at the midpoint of the stricture.

Note: There is a line on the proximal side of the balloon to facilitate correct placement of the balloon.

D. Inflation

1. Hold the shaft of the Trachealator Non-occlusive Airway Dilation Balloon prior to inflation and ensure that the balloon remains in the desired position.
2. Using the inflation device, inflate the balloon with the sterile water/saline or diluted contrast medium to the nominal pressure. Monitor the pressure using the gauge on the inflation device. Preferably, during inflation, endoscopically visualize the diameter, shape, and position of the balloon. If able to visualise, ensure the proximal end of the balloon remains visibly proximal to the stricture throughout inflation.

3. The inter balloon space should not be used to pass any instruments.

Note: Once the nominal pressure has been reached, the pressure is expected to reduce slightly due to compliance in the tubing. Adjust the pressure as necessary to maintain the desired pressure. The pressure should stabilize within a few seconds.

Warning: If the balloon moves distally or proximally at any time during the procedure, especially during inflation, do not hold the balloon against excessive resistance. If this occurs deflate the balloon, re-centre it across the area to dilate, and re-inflate the balloon.

4. If greater pressures are required, refer to the compliance chart (Table 2) and increase to the required pressure, while ensuring that the maximum pressure is never exceeded.

Warning: Do not exceed the maximum pressure of the chosen balloon catheter, which is listed in Table 1.

5. If at any time during the inflation process it is noted that the airway balloon has ruptured (either a rapid or slow and steady decrease in pressure or visually noted under endoscopic visualization), deflate the balloon and carefully remove it.
6. Monitor blood oxygen saturation and returned carbon dioxide among other patient vital signs.

E. Withdrawal

1. Once the desired pressure result is achieved and maintained for the required time, deflate the Trachealator entirely. Preferably, maintain an endoscopic view of the proximal end of the tracheal balloon while a negative pressure is applied using the inflation device and the balloon deflates.
2. Using endoscopic visualization, ensure that the balloon has deflated. Once the Trachealator Non-occlusive Airway Dilation Balloon is fully deflated, retract the balloon.

Warning: Do not advance or retract the balloon if it is partially or fully dilated. The balloon must be thoroughly deflated and all fluid removed before withdrawal (approximately 2-15 seconds depending on the balloon size and inflation medium).

3. Confirm the stricture or stenosis has been sufficiently dilated under endoscopic visualization.
4. If additional inflations are required, repeat the steps for placement and inflation of the balloon.

8. POSSIBLE COMPLICATIONS

Possible complications include, but not limited to, the following:

- Bleeding
- Perforation
- Injury to vocal cords
- Rupture (partial or complete) resulting in pneumomediastinum
- Pneumothorax
- Mediastinitis secondary to tracheal dilation
- Chest pain