MEDORAH MEDITEK

PANZER™

WIRE GUIDED MULTI-STAGE BALLOON DILATOR

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

PANZER™ Wire Guided Multi-Stage Balloon Dilator

Intended Use / Indications for use

Intended use- PANZER™ Wire Guided Multi-Stage Balloon Dilator is intended to use for endoscopic dilation of esophagus, Trachea, colon, duodenum and pylorus strictures in the GI tract.

PANZER™ Wire Guided Multi-Stage Balloon Dilator is supplied sterile and is intended for single use only.

Device Description

PANZER™ Wire Guided Multi-Stage Balloon Dilator is a catheter shaped tube used for the dilation of the Esophagus, colon, duodenum and pylorus strictures in the GI tract. It consists of a balloon attached at the distal end of the device. It also consists of two ports one for guide wire and another for inflation device along with a wire for guidewire port.

PANZER™ Wire Guided Multi-Stage Balloon Dilator consists of double lumen tube; first lumen is connected with the balloon at the distal end and inflation port at the proximal end; the second lumen is for guide wire insertion. The balloon lumen is designed in such a way that it can easily enable passage of the guidewire without compromising the effectiveness of the balloon. Guidewire guides the balloon and when it reaches the desired location, an inflation device is used to inflate the balloon.

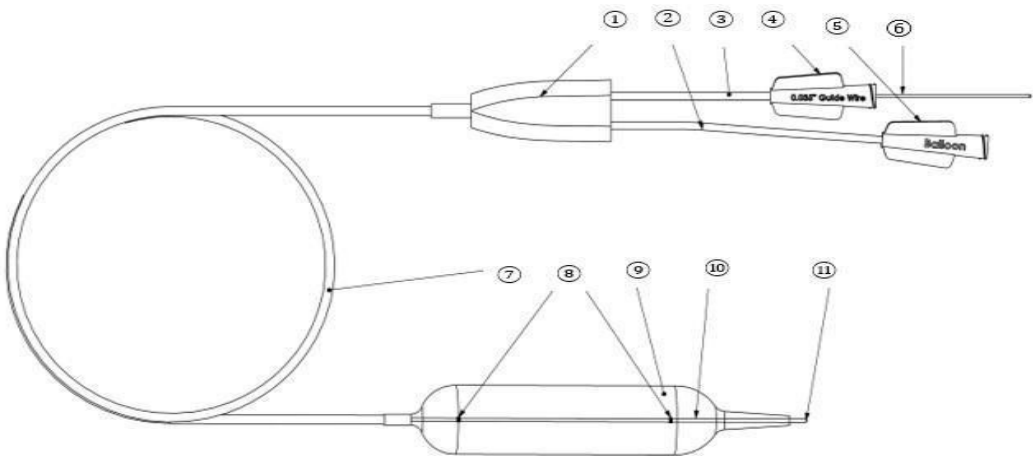
The PANZER Wire Guided Multi-Stage Balloon Dilator is inflatable with water to three distinct and progressively larger size diameters to exert force on the strictures resulting in stricture dilation. PANZER™ Wire Guided Multi-Stage Balloon Dilator is composed of dual ports at the proximal end of the device, one for entry of guidewire and the other port for inflation of balloon, known as balloon port, pipes connecting each port to the hub, Luer-lock Y-connector (hub) which consists of a guide wire lumen and a balloon inflation lumen, Catheter and a balloon at the distal end and a distal soft tip. Catheter is available in different lengths as per the intended use. Maximum guide wire diameter is 0.035". The balloon is designed to reach specific diameters at specific pressures (see compliance table on the labels). Two radiopaque markers are placed under the balloon segment of the catheter to provide visual reference points fluoroscopically for balloon positioning within the stricture. The catheter includes a smooth, soft and tapered atraumatic tip to facilitate advancement of the catheter through the stricture.

PANZER™ Wire Guided Multi-Stage Balloon Dilator Specifications

Balloon Length: 55mm

Balloon Diameter: 6mm to 20mm adjustable

Catheter Length: 230cm



①	Hub
②	Tube Connecting Balloon Port
③	Tube Connecting Guidewire Port
④	Balloon Port
⑤	Guidewire Port
⑥	Guidewire 0.035 inch
⑦	Catheter
Ⓑ	Radiopaque Marker
⑨	Balloon
⑩	Inner tube
⑪	Guidewire 0.035 inch

Contraindications

Those specific to the primary endoscopic procedure to be performed in gaining access to the dilation site.

Those specific to dilation include, but are not limited to:

- Uncooperative patient
- Asymptomatic rings, webs or strictures

- Inability to advance balloon dilator through strictured area
- Coagulopathy Known or suspected perforation
- Severe inflammation and scarring near dilation site

Potential Complications

The following complications may occur when using the PANZER™ Wire Guided Multi-Stage Balloon Dilator:

- Perforation
- Haemorrhage
- Aspiration
- Fever
- Sepsis/Infection
- Hypotension
- Allergic reaction to medication
- Respiratory depression or arrest
- Cardiac arrhythmia or arrest

Warnings

These instructions must be followed, as well as instructions from compatible components and hospital regulations for infection prevention, safe use, cleaning and sterilization. Failure to do so may result in serious injury to the patient and/or the user.
The following applies to the product:

- The device is designed and intended for single use only. DO NOT RESTERILIZE AND/OR REUSE.
- Reuse or resterilisation may create a risk of contamination as well as compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, transmission of infectious diseases and death. The manufacturer will not be responsible for any direct, incidental, or consequential damages resulting from resterilisation or reuse.
- Inspect the device, prior to procedure, to verify functionality and lack of damaged parts. Do not use the device if the outer or the inner package is damaged or opened.
- When the catheter is in the body, it should be manipulated while under sufficient and/or high-quality fluoroscopy. Prior to withdrawing the catheter from the lesion, the balloon must be completely deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium.
- Do not expose the device to organic solvents, e.g. alcohol.
- To prevent balloon burst, do not exceed the inflation pressure given for the largest diameter on the catheter's hub and package label.

- If the balloon does rupture or a significant loss of pressure within the balloon occurs, deflate the balloon completely and carefully remove the balloon and endoscope together as a unit. Do not attempt to withdraw a ruptured balloon through the endoscope.
- Only physicians thoroughly trained and educated in the performance of balloon dilatation should use this device.
- Use prior to "Use Before" date.

Precautions

- Do not pre-inflate balloon.
- Prior to insertion of balloon dilator, negative pressure is mandatory to maintain balloon profile.
- Endoscope should remain as straight as possible when advancing or withdrawing balloon dilator.
- Entire balloon should be extended beyond tip of endoscope, and be completely visualized and positioned before inflation.
- During withdrawal of balloon dilator from endoscope, negative pressure is mandatory to maintain balloon deflation.
- Apply a water-soluble lubricant to balloon to allow easier passage through accessory channel.
- Endoscopy should be used to confirm proper placement of the catheter.
- Verify that the shaft segment of the catheter is within endoscopic view.
- This ensures that the balloon has exited the endoscope completely. Fluoroscopy may be used to confirm balloon placement.

Procedure

Product Preparation:

1. Consult the product label to select the suitable device, considering compatibility with the working channel specified.
2. Before usage, examine the package for any signs of damage. Refrain from using if the package is compromised. Open the package cautiously after confirming the expiration date.
3. Gently extract the device from its packaging and unwind it. Avoid applying excessive force, as this could potentially harm the device and impact its functionality.
4. If there are any indications of damage to this device, refrain from using it. Avoid attempting to repair a malfunctioning or damaged device.
5. Avoid pre-inflating or conducting tests on the balloon prior to insertion.

Instructions for use

- Connect the balloon to an inflation device equipped with a gauge for monitoring balloon pressure.

- To ease passage through the endoscope, apply negative pressure to the catheter before removing the protective sleeve.
- Detach the protective sleeve from the balloon.
- Apply a lubricant to the balloon to aid in its passage through the endoscope accessory channel.
- Sustain a vacuum within the catheter while inserting it through the scope.

Caution: If encountering significant resistance during the procedure, ascertain the cause of the resistance and implement corrective measures before continuing.

- Progress the catheter into the endoscope through deliberate, short movements of 2-3cm. Variations in endoscope construction may result in initial resistance upon entry and again 2-3cm before exiting the distal end of the working channel.
- Once the balloon has exited the distal end of the endoscope and is within the endoscopic view, the guidewire may be advanced beyond the distal end of the catheter. To use the guidewire as a catheter guide:

(i) Advance guidewire into desired position beyond catheter tip (fluoroscopy is recommended).

(ii) Advance catheter over extended portion of the guidewire until balloon segment is in desired position.

- The PANZER™ Wire Guided Multi-Stage Balloon Dilator includes 2 radiopaque markers, located under the balloon to help proper placement across the stricture.
- Match the distal and proximal radiopaque markers of the balloon with the location of the stricture.
- Once the balloon is in position across the stricture, inflate the balloon per the Balloon Inflation instructions.

Caution: Never use Air or Gas to inflate the balloon.

- PANZER™ Wire Guided Multi-Stage Balloon Dilator is capable of the 3 distinct diameters listed on the package and hub labels. Inflate the balloon to the pressure corresponding to the smallest balloon diameter and maintain until desired dilatation is achieved. To achieve larger balloon diameters, increase pressure as indicated up to the maximum inflation pressure listed on the catheter hub and package labels.

Caution: If the balloon bursts during the procedure, stop the procedure immediately and take remedial action.

- Carefully observe the balloon pressure during dilatation. Minor adjustments may need to be made to maintain the appropriate pressure. This is normal.
- To remove the balloon, apply a negative pressure using the inflation device. Under direct endoscopic view, ensure that all liquid is withdrawn from the balloon before slowly removing the catheter from the endoscope.

Note: Ensure all fluid is removed before attempting to remove the balloon. Depending upon the inflation balloon size and chosen medium, this may take between 10-30 seconds.

Change of performance

If the device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

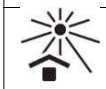
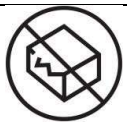
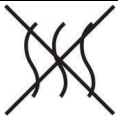
Disposal of a used device

After use, this product may be a potential biohazard. It must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

Storage

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment. Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

Explanation of Symbols

	Date of Manufacture		Use-By Date
	Catalogue Number		Do not re-use
	Consult instructions for use		Caution
	Keep away from sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Non-Pyrogenic		Keep dry
	Do Not resterilize		Sterilized using Ethylene Oxide
	Temperature Limitation		

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

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