



BALLOON EXPANDABLE



COVERED STENT

.035

:: *Instructions For Use*



ATRIUM

Instructions For Use

DESCRIPTION

The iCAST Covered Stent is a balloon expandable endoluminal device consisting of a laser cut 316L stainless steel stent with an encapsulated cover made of expanded PTFE. The device is crimped and premounted to a multi lumen delivery catheter. The catheter main or wire (W) lumen is used for flushing and guidewire introduction. The secondary or inflation (I) lumens are used for inflation/deflation of the attached balloon to deploy the endoprosthesis. To facilitate accurate device placement, two radiopaque bands are attached to the catheter shaft marking the ends of the crimped device.

The iCAST Covered Stent is supplied STERILE.

INTENDED USE/INDICATIONS

The iCAST Covered Stent is indicated for the treatment of tracheobronchial strictures produced by malignant neoplasms.

CONTRAINDICATIONS

Non-Compliant Obstructions where full expansion of a balloon dilatation catheter can not be achieved during pre-dilation, or where obstructions can not be dilated sufficiently to allow passage of the delivery catheter.

WARNINGS

- The safety and effectiveness of this device for use in the vascular system have not been established and can result in serious harm and/or death.
- The use of metallic tracheal stents may preclude the success of subsequent surgical procedures and should be considered only for patients after all alternative thera-

pies have been exhausted. Please consider the use of tracheal surgical procedures or placement of silicone stents before using metallic tracheal stents.

- Do not use the iCAST Covered Stent in a non-compliant lesion where full expansion of the balloon dilatation catheter, appropriately sized for the lumen, can not be obtained.
- Special care should be taken to ensure that the appropriate size device, guidewire (if used), compatible bronchoscope (if used) and endotracheal tube (if used) are selected prior to introduction. Native lumen dimensions must be accurately measured, not estimated.
- Do not cut the device. The device should only be placed and deployed using the supplied balloon catheter.
- Do not use a kinked bronchoscope or endotracheal tube as this may increase the force necessary to deploy the device and may cause a deployment failure or catheter breakage on removal.
- Do not withdraw the iCAST Covered Stent back into the bronchoscope or endotracheal tube once the device is fully introduced.
- Inadvertent, partial, or failed deployment or migration of the device may require surgical intervention.
- Do not remove the iCAST Covered Stent from the balloon delivery catheter; the iCAST Covered Stent cannot be removed and placed on another balloon catheter for deployment.
- Special care must be taken not to handle or in any way disrupt the placement of the iCAST Covered Stent on the balloon. This is most important during catheter removal from packaging, placement over the wire guide and advancement through the bronchoscope or endotracheal tube.
- Use only the appropriate balloon inflation

media. Do not use air or any gaseous medium to inflate the balloon.

- Balloon pressures should be monitored during inflation. Do not exceed maximum recommended inflation pressures as indicated on the product label. Exceeding this pressure increases the potential for balloon rupture and possible damage.
- Expansion of the iCAST Covered Stent should not be undertaken if the iCAST Covered Stent is not appropriately positioned in the tracheal. If the position of the stent is not optimal, it should not be expanded.
- Prior to stent expansion, utilize high-resolution fluoroscopy to verify that stent has not been damaged or dislodged during positioning.
- Incomplete deployment of the stent (i.e., stent not fully expanded) may cause procedural complications resulting in patient injury.
- Use caution when using the iCAST Covered Stent in patients with prolonged bleeding times, coagulopathies, prior pneumonectomy, or concurrent infection and/or inflammation (as this may lead to granuloma formation), or in cases where the obstruction is in very close proximity to a major blood vessel (as this may lead to fistula formation).

PRECAUTIONS

- Federal law restricts this device to sale by or on the order of a physician.
- Use of the system requires advanced technical skills. The following instructions will give technical guidance but do not obviate formal training in the use of the device.
- Significant amounts of air in the balloon may cause uneven expansion of the stent and difficulty in deployment of the stent.

Do not pre-inflate the balloon prior to stent deployment. Use balloon-prepping technique described within this instructional material.

- Do not attempt to pull an unexpanded stent back through the bronchoscope or endotracheal tube since dislodgement of the stent may result (refer to REMOVAL OF AN UNEXPANDED STENT).
- Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the deployed stent. If the target stricture is not covered fully, use additional stents as necessary to adequately treat the stricture.
- A magnetic resonance imaging (MRI) scan should not be performed until the implant has been completely epithelialized, in order to minimize the risk of migration of the stent under a strong magnetic field. The 316L stainless steel stent may cause susceptibility artifacts in MRI scans due to distortion of the magnetic field.
- The device is provided sterile, for one procedure only. Do not re-sterilize. Use prior to the expiration date noted on the package.
- Do not use the iCAST Covered Stent if the sterile package is compromised or the iCAST Covered Stent is damaged.
- Follow the Directions for Use supplied by the manufacturer of any ancillary device used in conjunction with the iCAST Covered Stent.
- Once deployment is initiated, repositioning and removal is not recommended.
- Do not attempt to withdraw or reposition a balloon catheter within the lumen of the deployed device unless the balloon is completely deflated.

HAZARDS AND ADVERSE EVENTS

As with all procedures that utilize techniques for introducing a catheter, bronchoscope, endotracheal tube, or introducer sheath into the tracheobronchial system lumen, complications may be expected. Similarly, complications and adverse events can occur when using any endoluminal device in the tracheobronchial application. These include, but are not limited to: endoprosthesis misplacement, endoprosthesis migration, aphonia, recurrent dyspnea, infection, septic shock, endoprosthesis occlusion due to tumor or granulomatous tissue overgrowth at the device ends, mucous accumulation within the endoprosthesis, tracheobronchial wall ulceration, perforation or hemorrhage, and death.

Atrium Medical iCAST Covered Stent has not been tested for safety in the MRI environment; therefore, MRI scans should not be performed on patients post-implantation until the stent has completely epithelialized to minimize the potential for migration.

DIRECTIONS FOR USE

Sizing and Selection of the iCAST Covered Stent:

To achieve accurate measurement and ensure precise sizing and placement of the device, use image-centered, magnified-view fluoroscopy, including a marker guidewire or catheter.

Check that the diameter and length of the device as well as the balloon catheter length are correct before removing from the packaging.

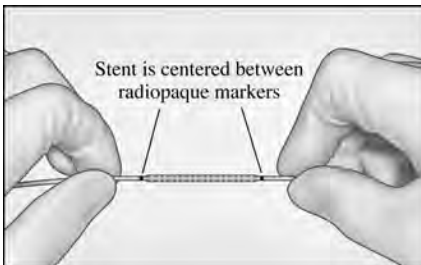
- In selecting the appropriate size device, a careful assessment of the lumen is necessary. In general, to assure adequate anchoring, the diameter of the device should be approximately 5-20% larger than the healthy lumen diameter immediately proximal and distal to the target lesion (See STENT SIZING TABLE on label).
- Verify that there is sufficient catheter length to access the target lesion.
- When overlapping (telescoping) multiple devices, the following are suggested:
 - Balloon touch-up (post-dilatation) should be performed on the first device prior to placing the second device.
 - To ensure proper seating, at least 1 cm of overlap between devices is suggested.
 - Overlapping devices should not differ by more than 1 mm in diameter.

PREPARATION OF THE iCAST COVERED STENT AND DELIVERY CATHETER

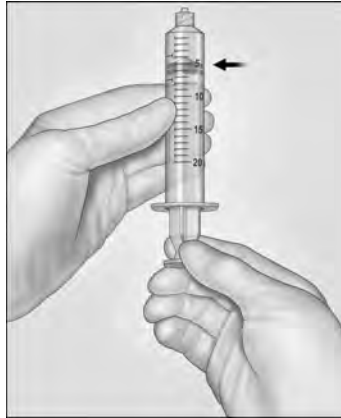
1. Carefully remove the device from the package, so as to not allow the crimped stent or catheter shaft to come in contact with any non-sterile surfaces or instruments.



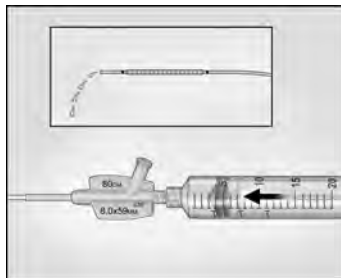
2. Visually inspect the stent to ensure it is centered within the radiopaque markers which are viewable through the folded balloon.



3. Fill a 20cc or smaller syringe with a minimum of 5cc's sterile saline mixture, or the hospital's preferred balloon catheter priming fluid mixture.



4. Begin by attaching the pre-filled priming syringe to the catheter hub as shown. Prime the catheter and balloon by flushing the guidewire lumen (labeled W on the catheter hub) of the iCAST catheter so as to remove all apparent air from this catheter lumen.



5. Next, attach the prefilled syringe to the inflation lumen (labeled I on the catheter hub) and draw back on the syringe applying negative pressure to the catheter for 20-30 seconds (making sure you hold the syringe in an upright position so the air rises to the top of the syringe), then release the pressure by gently letting go of the syringe plunger (keeping syringe in an upright position).

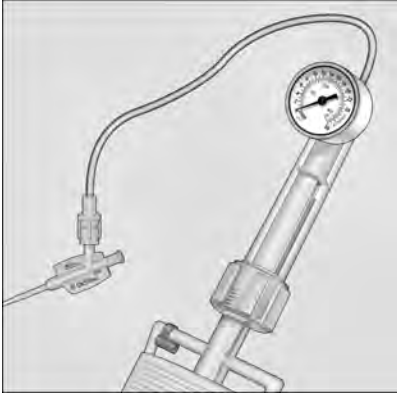


6. Release of the pressure by the syringe will allow fluid from the syringe to fill the inflation lumen. **IMPORTANT: Do not apply positive pressure to the balloon.** This important step removes the air from the inflation lumen and balloon, allowing the contrast/saline mixture to fill into the folded balloon. This procedure helps provide for a more uniform inflation of the balloon during stent deployment.

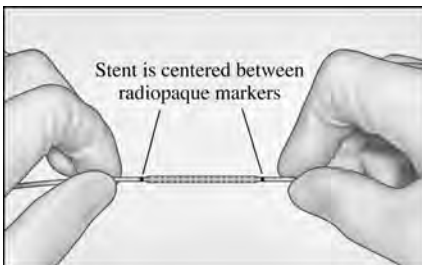


7. Repeat steps 5 and 6 until all air in the delivery catheter is expelled or removed. Repeat these steps at least 3 times. Most institutions using balloon expandable stents repeat the priming process a minimum of 3 times to ensure removal of all residual air prior to patient use.

8. After completion of the priming steps, attach the prefilled inflation device to the inflation lumen of the catheter hub (labeled I), ensuring no air bubbles remain at the catheter connection. A 20cc inflation device is recommended for use with this device.



9. After inflation device connection, re-inspect the covered stent on the distal balloon end to verify that the covered stent is located between the RO markers. This visual inspection step verifies that through all preparation steps that no positive pressure has been applied (which could cause inadequate stent deployment) and that the stent still remains securely positioned within the RO markers prior to patient use.



10. Any movement of the iCAST Covered Stent should result in the return of the unused device to Atrium Medical Corporation.

11. Moisten the iCAST Covered Stent with saline.

12. Carefully advance the iCAST Covered Stent balloon catheter over the wire guide and into the hub of the sheath.

CAUTION: If resistance is encountered, do not force passage, Refer to REMOVAL OF AN UNEXPANDED iCAST Covered Stent.

13. The iCAST Covered Stent balloon catheter can now be advanced through the sheath.

Introduction and Positioning of the iCAST Covered Stent

1. If a bronchoscope or endotracheal tube is used, ensure the size is compatible (See STENT SIZING TABLE on label) with the selected iCAST Covered Stent.
2. Ensure the guidewire (if used) is 0.035" and has a length at least twice that of the balloon catheter.
3. Care should be taken to maintain the position of the guidewire (if used) beyond the obstructing lesion while removing the balloon catheter. If the guidewire is displaced, proper guidewire position should be regained prior to introduction of the iCAST Covered Stent.

Note: If a bronchoscope or endotracheal tube is used and excessive resistance is felt as the iCAST Covered Stent is introduced through the bronchoscope or endotracheal tube carefully remove and inspect the delivery system for damage. Do not reuse the iCAST Covered Stent if damaged. Confirm that a correctly sized broncho-

scope (if used) or endotracheal tube (if used), have been selected (See STENT SIZING TABLE on label), and are free of kinks and obstructions.

- Using fluoroscopic guidance, advance the remainder of the delivery catheter over the guidewire (if used). Advance cautiously, especially if resistance is felt.
- Position the iCAST Covered Stent across the target lesion using the radiopaque markers on the catheter. These markers identify the proximal and distal ends of the device, respectively.

Note: If balloon dilatation of the obstruction is performed, the iCAST Covered Stent length should cover the entire lumen segment treated with balloon dilatation. For treatment of stenotic or obstructive lesions, the iCAST Covered Stent should extend a minimum of 1 cm proximal and distal to the margins of the lesion.

- Once the optimal position is verified fluoroscopically, the device is ready to be deployed.

Deployment of the iCAST Covered Stent

- Determine the reference diameter prior to iCAST Covered Stent deployment.
- Position the iCAST Covered Stent across the lesion, using the proximal and distal radiopaque markers on the balloon as a reference point. Optimal placement requires the proximal end of the iCAST Covered Stent to be deployed approximately 1 cm proximal to the beginning of the segment to be stented.

CAUTION: Expansion of the iCAST Covered Stent should not be undertaken if the iCAST Covered Stent is not properly posi-

tioned in the lesion. If the position of the iCAST Covered Stent is not optimal, it should be repositioned.

- Inflate the balloon to the appropriate pressure to expand the iCAST Covered Stent. Refer to product labeling for the proper inflation pressure.
- A 15-30 second inflation time is recommended for full expansion. Refer to product labeling for the proper inflation pressure.

CAUTION: Under expansion of the iCAST Covered Stent may result in stent movement. Care must be taken to properly size the iCAST Covered Stent to ensure that the iCAST Covered Stent is in full contact with the wall upon deflation of the delivery balloon.

CAUTION: Over sizing of the iCAST Covered Stent and use of higher than recommended inflation pressures may cause dissection.

- Using an inflation device, deflate the balloon. Allow adequate time for full balloon deflation.
- Very slowly withdraw the balloon from the iCAST Covered Stent, maintaining negative pressure.
- While maintaining the position of the guidewire (if used) across the treated lesion, carefully withdraw the balloon catheter through the lumen of the device and remove it under fluoroscopic visualization. Moderate resistance may be felt when the distal tip exits through the bronchoscope or endotracheal tube.

REMOVAL OF AN UNEXPANDED STENT

Should it become necessary to remove the iCAST Covered Stent from the lumen prior to deployment and a bronchoscope or endotracheal tube is being used, do not withdraw the iCAST Covered Stent back into the bronchoscope or endotracheal tube after the device is fully introduced. To remove the iCAST Covered Stent prior to deployment, the iCAST Covered Stent /balloon catheter should be withdrawn until the proximal end of the iCAST Covered Stent is aligned with the distal tip of the bronchoscope or endotracheal tube. The iCAST Covered Stent/balloon catheter, guidewire and bronchoscope or endotracheal tube, should then all be removed as one unit. After removal, the iCAST Covered Stent should not be reused.

CAUTION: Do not attempt to pull an unexpanded iCAST Covered Stent back through

the bronchoscope or endotracheal tube; dislodgement of the iCAST Covered Stent may occur.

EMERGENCY WITHDRAWAL PROCEDURE OF AN EXPANDED STENT

In order to withdraw an expanded stent either in an emergency or due to misplacement, the following withdrawal procedure should be followed:

Place a rigid bronchoscope. Pass biopsy forceps through the rigid bronchoscope. Using forceps capture and compress the proximal edges of the stent, until it is flattened and can fit into the opening of the bronchoscope. Grasp the flattened edge of the stent and pull back into the bronchoscope to remove the stent. If needed, a twisting or rotating motion will aid in withdrawal. Following removal, examine area of stent placement for any damaged tissue.

SYMBOLS USED ON PRODUCT LABELS

 CODE NUMBER  LOT NUMBER

  STERILE. STERILIZED BY ETHYLENE OXIDE.

 SEE PACKAGE INSERT  SINGLE USE ONLY  EXPIRATION DATE

 DIMENSIONS  **Rx Only** PRESCRIPTION ONLY



BALLOON EXPANDABLE



COVERED STENT

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ATRIUM MEDICAL CORPORATION
5 Wentworth Drive
Hudson, New Hampshire 03051 U.S.A.
 603-880-1433  603-880-6718

ATRIUM EUROPE B.V.
Rendementsweg 20 B
3641 SL Mijdrecht, The Netherlands
 +31-297-230-420  +31-297-282-653

ATRIUM AUSTRALIA-PACIFIC RIM PTY. LTD.
Level 6, 579 Harris Street
Ultimo NSW 2007 Australia
 +61 2 8272 3100  +61 2 8272 3199



ATRIUM MEDICAL CORPORATION

5 Wentworth Drive
Hudson, New Hampshire 03051 U.S.A.

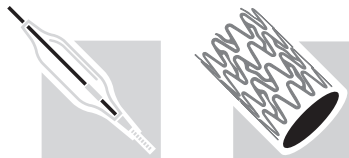
☎ 603-880-1433 📠 603-880-6718



ATRIUM EUROPE B.V.

Rendementsweg 20 B
3641 SL Mijdrecht, The Netherlands

☎ +31-297-230-420 📠 +31-297-282-653



ATRIUM AUSTRALIA-PACIFIC RIM PTY. LTD.

Level 6, 579 Harris Street
Ultimo NSW 2007 Australia

☎ +61 2 8272 3100 📠 +61 2 8272 3199

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