
FLUENCY[®] Plus

Tracheobronchial Stent Graft

**with PUZZLE[®] Tantalum Markers
and BARD S.A.F.E.[®] Delivery System**

Information for Use

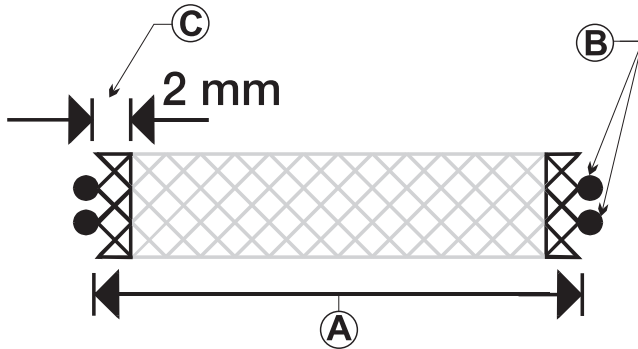
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BARD | PERIPHERAL
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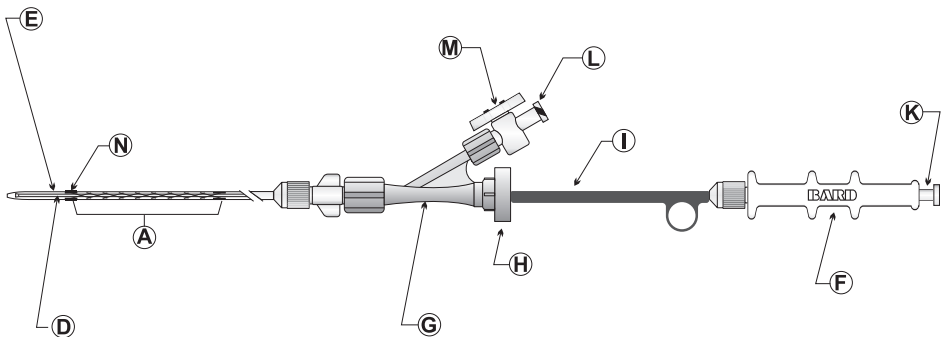
FLUENCY[®] Plus

Tracheobronchial Stent Graft Diagrams

Implant with PUZZLE[®] Tantalum Markers



BARD S.A.F.E.[®] Delivery System



(1) S.A.F.E. = Secure Adhesive Free Tip Design

FLUENCY[®] Plus

Tracheobronchial Stent Graft

INFORMATION FOR USE

Device Description (see diagram and illustrations on the first page of this booklet)

The **FLUENCY[®] Plus Tracheobronchial Stent Graft** (implant) is a self-expanding Nitinol Stent encapsulated with ePTFE (expanded Polytetrafluoroethylene) **(A)**. There are four radiopaque **Puzzle[®] Tantalum Markers (B)** on each end of the Nitinol stent, facilitating stent graft placement by enhancing visibility under fluoroscopy. The Nitinol stent is encapsulated with ePTFE along the entire length, except the flared stent graft ends with the radiopaque tantalum markers. The length of the uncovered portion of the stent graft is approximately 2 mm at each end **(C)**, **NOT** including the radiopaque tantalum markers.

The **FLUENCY[®] Plus Tracheobronchial Stent Graft** is available in various diameters and lengths.

The stent graft **(A)** is supplied premounted between the inner catheter **(D)** and the outer sheath **(E)** on the distal section of the delivery system. In this compressed configuration, the Nitinol stent struts lie close together and the radiopaque tantalum markers appear as a contiguous band at each end of the stent graft.

The flexible delivery system is a coaxial catheter system consisting of an inner catheter **(D)**, which connects to the handgrip **(F)** via a metal tube and a coaxial outer sheath **(E)**, which connects to

a Y-injection-adaptor **(G)** with a Tuohy-Borst valve **(H)**.

Using the **BARD S.A.F.E.[®] Delivery System** technology, the soft and flexible catheter tip is formed from the outer catheter sheath. The catheter tip is tapered to accommodate an 0.035 in. guide wire.

Tightening the Tuohy-Borst valve (by turning it clockwise) prevents movement of the outer sheath relative to the inner catheter. There is also a removable safety clip **(I)** that prevents premature outer sheath retraction. The safety clip can be removed by pressing down on the top of the clip. In order to deploy the stent graft, the Tuohy-Borst valve must be open and the safety clip must be removed.

The delivery system has two female luer ports: one **(K)** at the proximal end of the handgrip, and the second **(L)** on top of the Y-injection-adaptor, with a 2-way stopcock **(M)**.

There is a radiopaque marker band **(N)** on the outer sheath of the delivery system. Before stent graft deployment, this marker band overlaps the highly radiopaque tantalum markers. During stent graft deployment the marker band will retract (towards the handgrip). When the moving marker band is past the proximal stent graft end by approximal 10 mm the stent graft is fully

released. Furthermore, the radiopaque tantalum markers on the proximal end of the stent graft will have visually separated when the stent graft is fully released.

How Supplied:

The **FLUENCY® Plus Tracheobronchial Stent Graft** is supplied sterile (by ethylene oxide gas) unless the package has been opened or damaged. For single patient use only. Do not reuse. Do not resterilize. Store in a cool (room temperature), dry place. Protect the packaged product from direct sunlight.

Indications for Use:

The **FLUENCY® Plus Tracheobronchial Stent Graft** is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Warning

The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

Contraindications:

The **FLUENCY® Plus Tracheobronchial Stent Graft** is contraindicated for:

- Small bronchi which could impede catheter removal.
- Tracheobronchial obstruction with a luminal diameter which cannot be dilated to and maintained at a minimum of 4 mm.
- Patients for whom bronchoscopic procedures are not recommended.

Warnings:

- This product has been designed for single patient use only. Do not reuse. Do not resterilize.

- **DO NOT** expose the stent graft to temperatures higher than 500 °F (260 °C). ePTFE decomposes at elevated temperatures, producing highly toxic decomposition products.
- Use of a laser on or around the surface of the stent graft may result in damage to the stent graft and could create toxic fumes, which may harm the patient or operator.
- The sterile packaging and devices should be inspected prior to use. Verify that the packaging and the device are undamaged and that the sterile barrier is intact. If damaged, do not use.
- The delivery catheter is not intended for any use except stent graft deployment.
- Placing a stent graft across a major bifurcation may prevent or hinder future access or other procedures
- Placing the encapsulated portions of the device across bifurcations or side branches could impede airflow to the affected portion of the lung.
- The stent graft (implant) cannot be repositioned after total or partial deployment.
- Once partially or fully deployed, the **FLUENCY® Plus Tracheobronchial Stent Graft** cannot be retracted or remounted onto the delivery system.
- Do not place a stent graft in a tumor stricture that is adjacent to a major vessel, as this may create a potential for fistula formation.
- An appropriate guide wire is required before introduction of the stent graft delivery system into the body. The guide wire must remain in place during the introduction, manipulation and eventual removal of the deployment system.
- After use, the **FLUENCY® Plus Tracheobronchial Stent Graft** deployment system is a potential biohazard. Handle and dispose of

in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

Precautions:

- This device should be used only by physicians who are familiar with the complications, side effects, and hazards commonly associated with tracheobronchial stent graft procedures.
- Faulty placement techniques may lead to failure in stent graft deployment.
- Do not kink the delivery catheter. Ensure that the Tuohy-Borst valve on the Y-injection adapter is closed during insertion and overall manipulation of the delivery system. The Tuohy-Borst valve must remain closed until the stent graft is positioned at the final intended location and about to be released.
- The delivery system can function only after the safety clip is removed and the Tuohy-Borst valve is loosened. This should not be done until the stent graft is about to be released.
- Higher deployment force may be encountered on longer length stent grafts.
- Careful attention of the operator is warranted to mitigate the potential for distal migration of the endoprosthesis during deployment.
- Do not attempt to resheath the deployment system after stent graft release.
- The **FLUENCY® Plus Tracheobronchial Stent Graft** cannot be balloon expanded beyond its stated diameter.
- The effects of drugs, mucolytic agents, and alternative therapies including, but not limited to, cryotherapy and radiofrequency ablation, have not yet been tested with this device.

Note:

- Read all instructions for use thoroughly.
- Predilatation of the stenosis may be performed

prior to stent graft deployment at the discretion of the physician.

- The use of a superstiff guide wire is recommended for stent graft placement. Consult the guide wire IFU prior to use.
- The stent graft lumen must be flushed before introduction of the delivery system.
- Stent graft expansion begins, after the Y-injection-adapter moves approximately 20 mm towards the handgrip.
- Post dilatation of the implanted stent graft is required with a balloon equal in diameter to that of the selected stent graft diameter.
- Prophylactic antibiotic therapy should be prescribed at the physician's discretion.

Potential Complications:

Complications associated with the use of the **FLUENCY® Plus Tracheobronchial Stent Graft** may include the usual complications associated with Tracheobronchial stent graft placement such as stent graft misplacement, stent graft migration, bleeding, tracheobronchial perforation and pneumothorax, pain, aspiration, infection, stent graft obstruction secondary to tumor or granuloma ingrowth through the bare sections of the device, tumor or granuloma overgrowth at the stent graft ends, or mucous occlusion, stent graft fracture, stent graft kinking, insufficient stent graft expansion, stent graft expectoration, gastrobronchial fistula, increased bronchial secretion, sputum retention, pneumonia, pneumonitis, hemoptysis, atelectasis, dysphagia, halitosis, hoarseness, death.

Emergency Removal

The **FLUENCY® Plus Tracheobronchial Stent Graft** is a permanent implant. The safety of and hazards associated with the retrieval of the **FLUENCY® Plus Tracheobronchial Stent Graft**

after deployment have not been established in a clinical study.

Once full epithelialization of the **FLUENCY® Plus Tracheobronchial Stent Graft** has occurred, the stent graft should only be removed by surgical means.

If emergency removal becomes necessary immediately following stent graft deployment, minimally invasive removal under bronchoscopic or fluoroscopic guidance may be possible with standard grasping forceps, by grasping the proximal stent graft end and carefully pulling the stent graft and bronchoscope together through the tracheobronchial tract and vocal cords. It is up to the physician's discretion to determine the most appropriate and safest method of removal based upon the clinical situation and physician preference.

Stent Graft Sizing and Selection:

Special care must be taken to ensure that the appropriate size **FLUENCY® Plus Tracheobronchial Stent Graft** is selected prior to introduction.

- The stent graft diameter should be about 1 mm larger than the normal lumen diameter. Oversizing of the stent graft of more than 2 mm relative to the lumen diameter should be avoided.
- If a stent graft diameter 1 mm greater than the lumen to be stented is chosen (1 mm oversizing) there is minimal foreshortening of the stent graft during deployment; therefore, the length of the compressed stent graft is virtually equivalent to the expanded stent graft length. Depending on the stent graft size, the length of the stent graft can vary from the labeled length up to 5 mm. In order to ensure safe stent graft placement and lesion coverage, we recommend the use of a stent graft that is long enough to extend a

minimum of 10 mm beyond the lesion/stenosis at both ends. When selecting the stent graft length, keep in mind that 2 mm of the stent graft are uncovered at each end.

Directions for Use:

Preparation:

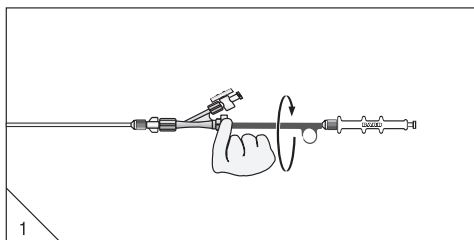
1. Carefully remove the delivery system from its packaging and inspect for any damage or defects. Do not use if a compromise to the sterile barrier is suspected.

2. A superstiff guide wire (0.035 in.) is advanced across the stricture.

Note: Consult the guide wire IFU prior to use.

Note: Predilatation of the stenosis may be performed prior to stent graft deployment at the discretion of the physician.

3. Tighten the Tuohy-Borst valve on the Y-injection-adaptor (by turning it clockwise). (*see figure 1*)

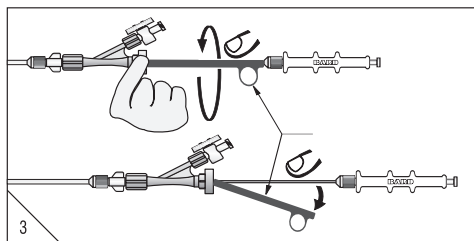


4. Flush the stent graft lumen with sterile saline. Attach a 10-cc syringe to the luer port of the Y-injection-adaptor on top of the delivery system and apply positive pressure. Ensure that the 2-way stopcock is open.

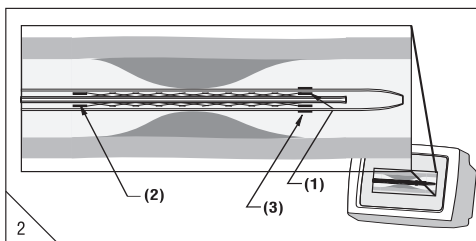
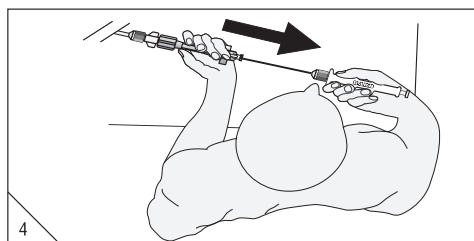
- After flushing with sterile saline, use the full volume of a 10-cc syringe to flush the port with air in order to remove saline from the stent graft lumen.

Introduction of the delivery system:

- Under radiographic guidance, advance the stent graft across the lesion. Use the radiopaque stent graft ends to center the stent graft across the stricture.
- It is recommended to advance the delivery system past the lesion and then pull back slightly on the entire system to attain correct positioning of the radiopaque markers and to ensure the delivery catheter is straight.
- Confirm the exact position of the radiopaque tantalum markers on the stent graft ends. (see figure 2) It is recommended that the position of the stent graft ends (1, 3) and (2) be marked on the monitor or that radiopaque skin markers be placed as reference points for stent graft ends.



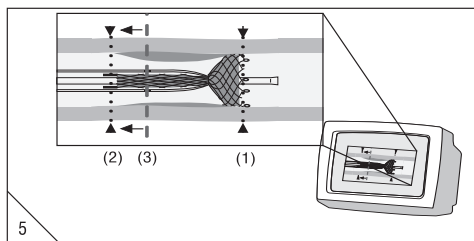
- Confirm that the positions of both radiopaque stent graft ends still correspond to the lesion location, then slowly pull back the Y-injection-adaptor. Pulling the Y-injection-adaptor back towards the handgrip directly retracts the outer sheath and exposes a corresponding portion of the stent graft. (see figure 4) Higher deployment force may be encountered with longer length stent grafts.



Note: The radiopaque tantalum markers on the stent graft ends (1) and (2) should not move laterally during stent graft deployment. The radiopaque marker band on the outer catheter (3) moves backwards during stent graft release. (see figure 5)

Stent Graft Deployment:

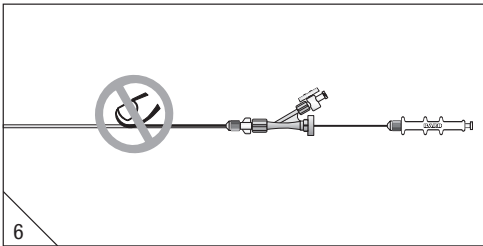
- When the stent graft is about to be released, open the Tuohy-Borst valve, then remove the safety clip by pressing down on the top of the grip surface with the thumb, then pulling downward. (see figure 3)



Note: Stent graft expansion begins, after the Y-injection-adapter moves approximately 20 mm towards the handgrip.

11. During release of the stent graft, the entire length of the flexible deployment system should be kept as straight as possible. A slight back tension on the handgrip is recommended to ensure that the deployment system is stationary and straight.

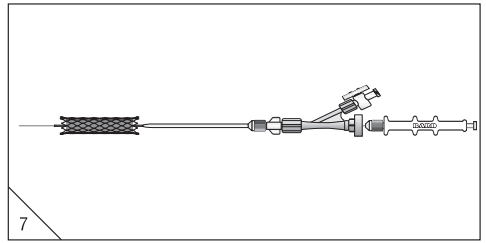
Note: Do not hold or kink the outer sheath of the delivery catheter since it must be free to move during deployment. (see figure 6)



12. Ensure that only the Y-injection-adapter and outer sheath move during stent graft deployment, and the handgrip is kept stationary.

13. Pull back on the Y-injection-adapter slowly until the stent graft has expanded by approximately 15 mm, then wait a few seconds in order to ensure secure "anchoring" of the distal stent graft end. Once anchored, the remainder of the stent graft can be released slowly.

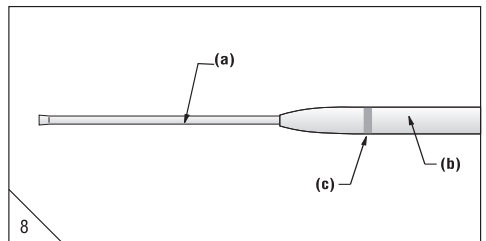
14. Full release of the stent graft is achieved when the Tuohy-Borst valve touches the handgrip (see figure 7). Furthermore, the radiopaque tantalum markers on the proximal end of the stent graft will have visually separated when the stent graft is fully released.



15. Remove the flexible deployment system over the guide wire. Do not attempt to resheath the deployment system after stent graft release.

After withdrawing the deployment system, visually confirm that the complete system has been removed. (see figure 8)

- (a) inner catheter with flared distal end
(b) outer sheath with radiopaque marker band (c)



16. Careful post dilatation of the implanted stent graft is required with a balloon equal in diameter to the diameter of the stent graft.

17. Final evaluation of the implanted stent graft should be performed.

Post-Procedure Patient Care:

- Exercise caution during suctioning or evaluation of the tracheobronchial tract; the suction catheter or bronchoscope may dislodge the device.
- Recurrence of dyspnea may indicate that the stent graft has become occluded, been dislodged or migrated out of the stricture.

Bronchoscopic or fluoroscopic assessment may be required.

- Tracheobronchial stent graft placement has been shown to decrease the patient's ability to clear mucous secretions from the respiratory tract. The physician may prescribe mucolytic agents at his or her discretion.

Detailed information about MR test of the **FLUENCY® Plus Tracheobronchial Stent Graft** (implant) is available upon request.

Magnetic Resonance Imaging (MRI) Information:

Non-clinical testing has demonstrated that the **FLUENCY® Plus Tracheobronchial Stent Graft** (implant) is “**MR-Conditional**”. A patient with this stent graft can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla or less
- Magnetic spatial gradient field of 720 gauss/cm or less
- Maximum MR system reported Whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg and spatial peak SAR of 5.9 W/kg for 15-minutes of MR imaging

In non-clinical testing, the **FLUENCY® Plus Tracheobronchial Stent Graft** produced a temperature rise of less than or equal to 0.7°C at an MR system reported maximum Whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15-minutes of MR scanning in a 3-Tesla MR system (Excite, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the **FLUENCY® Plus Tracheobronchial Stent Graft** (implant). Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

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U.S. Patent Nos.: US 5,827,327; US 6,124,523; US 6,383,214;
 US 5,707,386; US 5,716,393; US 5,860,999
 US 6,053,941; US 6,572,647.

Other patents pending.

Labeling issue date: 03/10

In the event that 3 years have elapsed between this date and product use, the user should contact Bard to see if additional product information is available.

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Caution: Federal law (U.S.) restricts the use of this device to sale by or on the order of a physician.

Symbols used on labeling



Keep away from sunlight



Keep dry



The Green Dot



Recyclable



Single use



Caution, consult accompanying documents



Units



Use by



Manufacturer



Date of manufacture



Catalogue number



Lot number



Sterile

FLUENCY[®] Plus

Tracheobronchial Stent Graft

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