AMPLATZER™

Sizing Balloon II

Instructions for Use

Device Description

The AMPLATZER™ Sizing Balloon II is a triple lumen balloon catheter with three (3) radiopaque marker bands located inside the balloon to allow for radiographic measurement. The center of the balloon contains a pair of marker bands 0.4 mm apart (inside to inside), and one (1) marker band 15 mm proximal of that pair (15 mm from the proximal edge of the pair of marker bands) (figure 1).

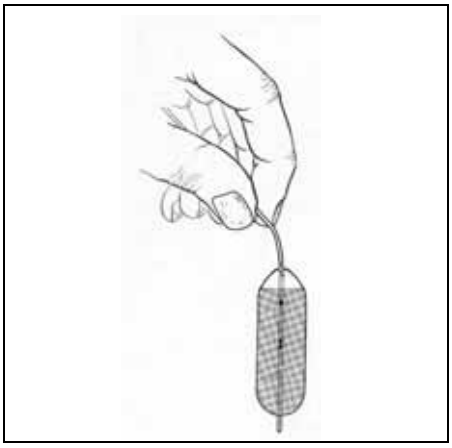

Figure 1. AMPLATZER™ Sizing Balloon II

Intended Use

The AMPLATZER™ Sizing Balloon II is designed to measure cardiovascular structures. Sizing can be accomplished in two ways: radiographically or echocardiographically.

Indications for Use

The AMPLATZER™ Sizing Balloon II is indicated for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important in selecting the appropriately sized occluder device.

Precautions and Warnings

- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Do not use this device if the sterile package is open or damaged.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- Do not insert the balloon catheter through an introducer sheath.

STERILE EO

℞Only

LATEX
Does not contain natural rubber latex components

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- This device should be used only by physicians who are trained in standard transcatheter techniques. The physician should determine which patients are candidates for procedures that use this device.
- Store in a dry place.

Adverse Events

Potential adverse events that may occur during or after a procedure using this delivery system may include, but are not limited to:

- Arrhythmia
- Cardiac obstruction
- Death
- Embolization
- Endocarditis
- Hematoma
- Oversizing of the defect
- Pain and tenderness
- Sepsis/Infection
- Short-term hemodynamic compromise
- Stroke
- Thromboembolic event
- Valve impingement
- Vascular thrombosis
- Vessel dissection
- Vessel perforation
- Vessel spasm

Potential complications specific to balloon sizing include:

- Movement of the balloon toward the mitral valve or right atrium
- Enlargement of the ASD
- Obstruction of venous return from the inferior vena cava
- Difficulty in deflating the balloon

Defect sizing information is provided in table 1, and device dimensions are provided in table 2.

Table 1. Defect sizing parameters

Reference Number	Maximum Defect Size mm	Maximum Inflation Volume cc	Balloon Length cm/mm
9-SB-018	20	15	3.5/35
9-SB-024	27	30	4.5/45
9-SB-034	40	90	5.5/55

Table 2. Device dimensions

Reference Number	Shaft Size Fr	Usable Length cm/mm	Guidewire in
9-SB-018	6.0	70/700	0.035
9-SB-024	7.0	70/700	0.035
9-SB-034	8.0	70/700	0.035

Directions for Use

Recommendations on Guidewire and Balloon Use

The guidewire must remain in place during the procedure. The removal of the guidewire during the procedure can cause kinking and/or migration of the sizing catheter. The maximum inflation volume of the balloon should not be exceeded to prevent over-inflation, bursting or detachment of the balloon.

Procedure

Carefully inspect the sterile pouch and verify that it is unopened and undamaged. Gently open the sterile pouch and inspect the balloon catheter prior to use to verify that it is undamaged. Slowly slide the protective cover off the balloon segment. Avoid acute bends or kinking of the AMPLATZER™ Sizing Balloon II during removal from the packaging.

The procedure will vary according to the type of occlusion or measurement to be performed. Because of the ultra thin plastic membrane, dilatation of the entry site is not necessary.For the measurement of secundum atrial septal defects, the following steps are recommended:

1. Inflate the balloon with saline solution and purge the air in a position as shown in figure 1 or inflate with CO2 and aspirate. Flush the other lumen with heparinized saline.
2. Manipulate a 0.035 inch stiff exchange wire into the left upper lobe pulmonary vein. Introduce the balloon catheter over the guidewire.
3. Introduce the balloon catheter over the exchange wire transcutaneously.
4. Advance the collapsed balloon through the defect. Position the sizing catheter to center the balloon in the communication.
5. Partially inflate the balloon with contrast medium (diluted 3:1 or 4:1).
6. Observe the patient in a shallow left anterior-oblique position without cranial angulation.
7. Gradually move the imaging source to visualize the 0.4mm space between the pair of marker bands in the center of the balloon (figure 2). This aligns the imaging source with the balloon to achieve the best angle for size measurement.

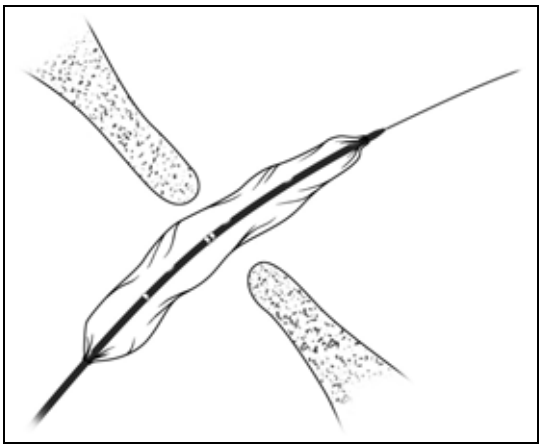

Figure 2. Balloon alignment

8. Inflate the balloon until the right-to-left shunt ceases and a stop-flow condition is observed by Doppler observation. Slightly deflate the balloon, and gradually re-inflate to the minimum balloon diameter that achieves a stop-flow condition. A minimal balloon “waist” may or may not be present.

   WARNING: Do not inflate the balloon beyond the stop-flow point or beyond the balloon’s maximum inflation volume. Inflation beyond the stop-flow point may cause distention of the defect resulting in inaccurate sizing of the defect and/or balloon damage.
9. Using echocardiography, adjust the image for best visualization, and measure the minimum diameter between the septal wall contact points with the balloon (figure 3). If a balloon waist is detected, radiographic measurement may also be used to confirm defect diameter.

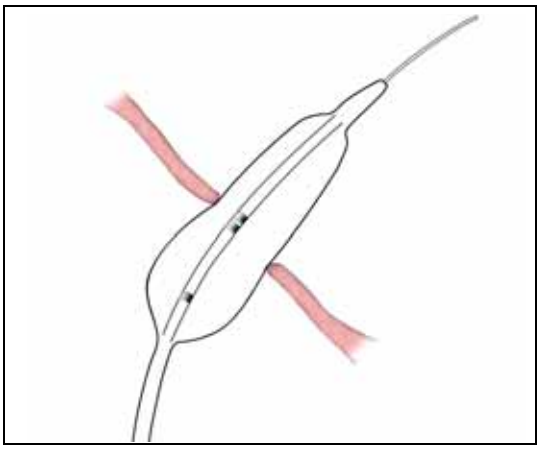

Figure 3. Minimum diameter measurement

10. Forcefully aspirate all of the contrast medium and then remove the balloon catheter.

Proceed with recommended implantation protocol for the device.

Disposal

- The instructions for use are recyclable. Dispose of all packaging materials appropriately.
- Dispose of delivery systems and accessories following standard solid biohazard waste procedures.

Warranty

AGA Medical Corporation warrants to buyer that, for a period equal to the validated shelf life of the product, this product shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. AGA Medical Corporation's obligation under this warranty is limited to replacing or repairing at its option, at its factory, this product if returned within the warranty period to AGA Medical Corporation and after confirmed to be defective by the manufacturer.

EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY, AGA MEDICAL CORPORATION DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

See the Terms and Conditions of Sale for further information.

State of California (USA) Only:

WARNING: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Symbol Definitions

The following symbols may appear on the device packaging:

Symbol	Definition
	Manufacturer
	EU authorized representative
	Reference number
	Product serial number
	Product lot number
	Use by date (Use on or before the last day of the expiration month noted on the product packaging.)
	Do not reuse
	Sterilized using ethylene oxide
	Consult instructions for use
	Keep dry
	Do not use if package is damaged
	Does not contain natural rubber latex components
	Inner diameter
	Outer diameter
	Length
	Usable length
	Hydrophilic coating
	Recommended delivery sheath/catheter dimensions
	Indication of conformity with the essential health and safety requirements set out in European Directives

℞Only	Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
	Quantity
	Date of manufacture