

Sizing Balloon II

*Internal Marker Bands to
Assist with Sizing of
Heart Defects*

*Highly Compliant Soft
Balloon Material with
Low Pressure Inflation*

*Softer Tip and Flexible
Shaft for Improved
Positioning*



*A Rapid, Precise Method of
Measuring Heart Defects*

*Helping Hearts Heal
Themselves*

AMPLATZER® Sizing Balloon II

Intended Use

The AMPLATZER® Sizing Balloon II is designed to measure cardiovascular structures. Sizing can be accomplished in two ways: radiographic or ultrasonographic.

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 15mm proximal of that pair (15mm from the proximal edge of the pair of marker bands). See Figure 1.

Indications For Use

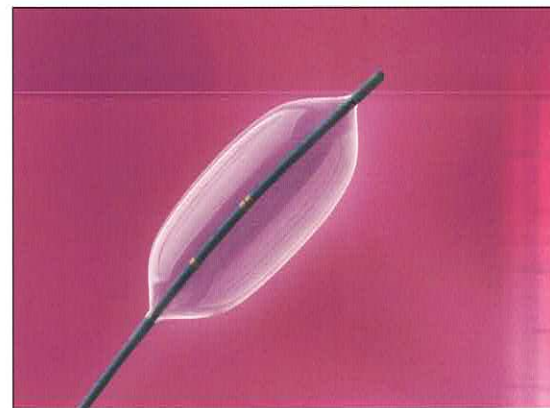
The AMPLATZER Sizing Balloon II is indicated for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important in selecting the appropriately sized occluder device.

Recommendation On Guidewire and Balloon Use

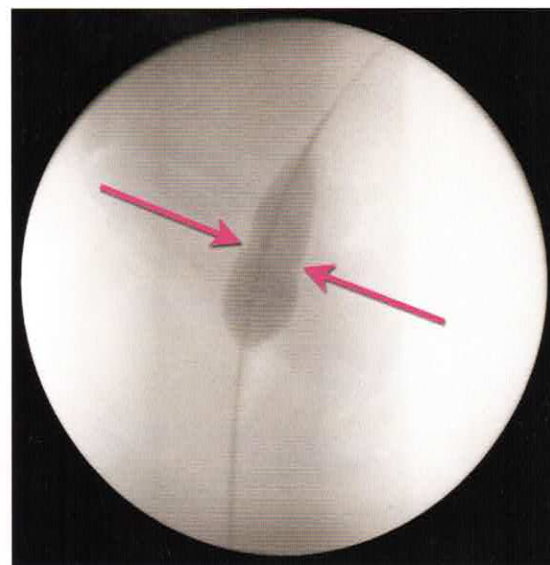
The recommended 0.035 inch stiff guidewire must remain in place during the procedure. The removal of the guidewire during the procedure can cause kinking and/or migration of the catheter. The maximum amount of recommended contrast medium should not be exceeded to avoid over inflation, bursting or detachment of the balloon.

NOTE: Refer to Instructions for Use for a complete listing of Indications and Usage, Contraindications, Warnings and Precautions. Contact AGA Medical Corporation for further information.

AMPLATZER Sizing Balloon II - Ordering Information							
Order No.	Max Defect Size (mm)	Max Inflated Balloon Diameter (mm)	Balloon Length (cm)	Shaft Size (Fr)	Usable Length (cm)	Guidewire (Inch)	Maximum Balloon Inflation Volume (cc)
9-SB-018	16	18	3.5	6.0	70	0.035	15
9-SB-024	22	24	4.5	7.0	70	0.035	30
9-SB-034	32	34	5.5	8.0	70	0.035	90



AMPLATZER® Sizing Balloon II



Stop Flow Measurement with Minimal Waist

The Sizing Balloon is inflated until left to right shunt ceases as determined by Doppler with the appearance of a slight waist in the balloon.

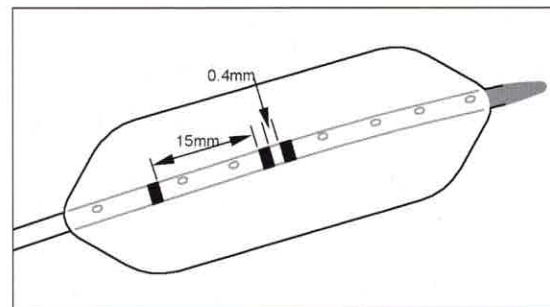


Figure 1



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