

AMPLATZER™

SIZING BALLOON II

PRECISE MEASUREMENT FOR ACCURATE DEVICE SELECTION

Featuring a radiopaque marker system for better visualization and positioning, the Amplatzer™ Sizing Balloon II provides a simple, precise method for sizing cardiovascular structures. It features compliant balloon material to accurately measure cardiovascular defects of various shapes and tissue properties.

DESIGNED FOR ACCURATE DEFECT MEASUREMENT

Radiopaque Marker Bands

- Are strategically placed to assist with alignment of imaging and support proper sizing calibration (Figure 1)

Soft Distal Tip and Flexible Shaft

- Offer smooth access for atraumatic balloon positioning

Compliant Balloon Material

- Allows precise measurement of a variety of defect shapes and tissue properties when using a stop-flow technique
- Supports low-pressure inflation

The balloon shall be available in 3 sizes, 18mm, 24mm and 34mm.

- A minimum of 18mm when inflated with 10cc of saline
- A minimum of 24mm when inflated with 25cc of saline
- A minimum of 34mm when inflated with 55cc of saline

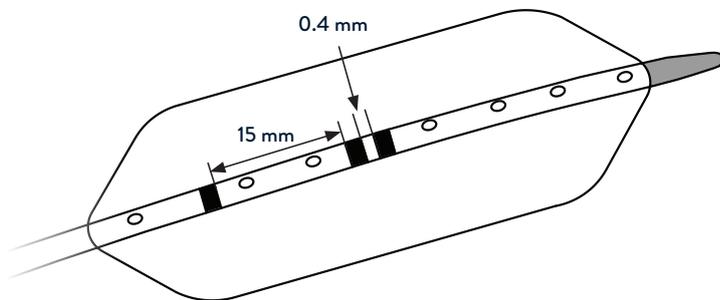


Figure 1: The most proximal marker band is for sizing calibration. The two central marker bands provide visual alignment for catheter placement in the cardiovascular defect.

ORDERING INFORMATION

Amplatzer™ Sizing Balloon II Specifications

Model/Reorder Number	Max Defect Size ^a (mm)	Balloon Length (mm)	Shaft Size (F)	Useable Length (cm)	Guidewire (inch)	Max Balloon Inflation Volume (cc)
9-SB-018	20	35	6	70	0.035	15
9-SB-024	27	45	7	70	0.035	30
9-SB-034	40	55	8	70	0.035	90

a. Maximum defect size refers to diameter of native defect as measured by echocardiography.
Note: Do not insert balloon catheter through an introducer sheath.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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Always check the regulatory status of the device in your region.

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