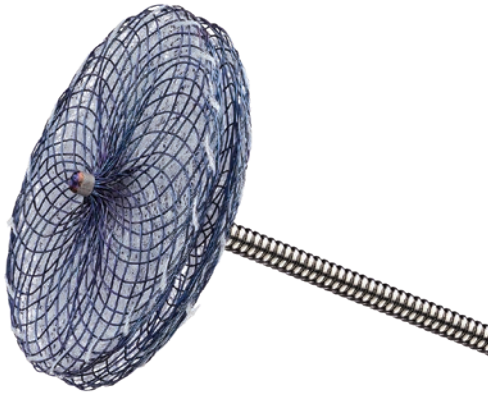
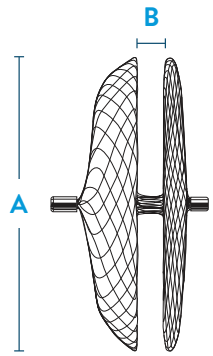
# AMPLATZER™ MULTI-FENESTRATED SEPTAL OCCLUDER — "CRIBRIFORM"



## INDICATION

The Amplatzer™ Cribriform Occluder is a percutaneous, transcatheter atrial septal defect (ASD) closure device intended for the closure of multi-fenestrated (Cribriform) ASDs.

Patients indicated for ASD closure have echocardiographic evidence of a fenestrated ostium secundum ASD with clinical evidence of right ventricular (RV) volume overload (i.e., 1.5:1 degree of left to right shunt or RV enlargement).




## DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

### Amplatzer™ Cribriform Occluder

| Model/Reorder Number | Device Size/Disc Diameter (mm) A | Waist Length (mm) B |
|---|---|---|
| 9-ASD-MF-018 | 18 | 3 |
| 9-ASD-MF-025 | 25 | 3 |
| 9-ASD-MF-030 | 30 | 3 |
| 9-ASD-MF-035 | 35 | 3 |
| 9-ASD-MF-040[a] | 40 | 3 |

a. Device not available for sale in the United States. Device not available for sale in all countries.

### Amplatzer™ Trevisio™ 45° Delivery System

| Model/Reorder Number | Minimum Recommended Sheath Size | Sheath Inner Diameter (mm [inch]) | Sheath Outer Diameter (mm [inch]) |
|---|---|---|---|
| 9-ATV08F45/60 or 9-ATV08F45/80 | 8 F, 45° Curve | 2.69 [0.106] | 3.45 [0.136] |
| 9-ATV09F45/80 | 9 F, 45° Curve | 3.00 [0.118] | 3.81 [0.150] |
| 9-ATV10F45/80 | 10 F, 45° Curve | 3.30 [0.130] | 4.14 [0.163] |

Information contained herein for **DISTRIBUTION in Australia and New Zealand ONLY**.

## DEVICE SPECIFICATIONS AND DELIVERY SYSTEM COMPATIBILITY

### Amplatzer™ TorqVue™ 45° Delivery System

| Model/Reorder Number | Minimum Recommended Sheath Size | Sheath Inner Diameter (mm [inch]) | Sheath Outer Diameter (mm [inch]) |
|---|---|---|---|
| 9-ITV08F45/60 or 9-ITV08F45/80 | 8 F, 45° Curve | 2.69 [0.106] | 3.45 [0.136] |
| 9-ITV09F45/80 | 9 F, 45° Curve | 3.00 [0.118] | 3.81 [0.150] |
| 9-ITV10F45/80 | 10 F, 45° Curve | 3.30 [0.130] | 4.14 [0.163] |

## ANCILLARY PRODUCT SPECIFICATIONS

### Amplatzer™ Guidewire

| Model/Reorder Number | Diameter (inches) | Body | Tip Description | Usable Length (cm) |
|---|---|---|---|---|
| 9-GW-002 | 0.035 | Super Stiff | 1.5 mm, Modified J-tip | 260 |

## MRI SAFETY INFORMATION

Through nonclinical testing, Amplatzer™ devices have been shown to be MR Conditional. A patient with an implanted Amplatzer device can be scanned under the following conditions:

- Static magnetic field of 3 Tesla or less
- - Maximum magnetic resonance (MR) system reported, whole body averaged specific absorption rate of 3.83 W/Kg at 1.5 Tesla and 5.57 W/kg at 5.0 Tesla for a 20 minute exposure

MR image quality may be compromised if the area of interest is in the same area as or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

## LATEX-FREE INFORMATION

These Amplatzer™ products do not contain latex.

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.

Information contained herein for DISTRIBUTION in Australia and New Zealand ONLY.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

Photo(s) on file at Abbott.

Abbott Medical Australia Pty Ltd, 299 Lane Cove Road, Macquarie Park, NSW 2113, Ph: 1800 839 259.
Abbott Medical New Zealand Ltd, 4 Pacific Rise, Mount Wellington, Auckland 1060, Tel: 0800 756 269.



Abbott