

# STRUCTURAL INTERVENTIONS AMPLATZER™ CARDIAC OCCLUDERS

Magnetic Resonance Imaging (MRI) Safety Information



# TECHNICAL INSIGHTS

A PUBLICATION DELIVERING CONCISE TECHNICAL DATA

## TECHNICAL MRI INFORMATION FOR AMPLATZER™ CARDIAC OCCLUDERS

### INTRODUCTION

This document provides a comprehensive overview of safety information for Amplatzer Cardiac Occluders, specifically related to Magnetic Resonance Imaging (MRI). The provided information is obtained from the various Instructions For Use (IFU) documents for these devices. The following Amplatzer™ Cardiac Occluders are covered:

- **Atrial Septal Defect Closure:**
  - Amplatzer™ Septal Occluder
  - Amplatzer™ Multifenestrated Septal Occluder (“Cribriform”)
- **Patent Foramen Ovale Closure:**
  - Amplatzer™ Patent Foramen Ovale Occluder
- **Patent Ductus Arteriosus Closure:**
  - Amplatzer™ Duct Occluder
  - Amplatzer™ Duct Occluder II
  - Amplatzer Piccolo™ Occluder
- **Ventricular Septal Defect Closure:**
  - Amplatzer™ Membranous VSD Occluder
- **Left Atrial Appendage Occlusion:**
  - Amplatzer™ Amulet Left Atrial Appendage Occluder
- **Paravalvular Leak Closure:**
  - Amplatzer™ Valvular Plug III

## ATRIAL SEPTAL DEFECT OCCLUDERS

Amplatzer™ Septal Occluder

### MODELS

#### 9-ASD-0xx

(xx denotes different available sizes, e.g., 9-ASD-010)

Through non-clinical testing, Amplatzer™ devices have been shown to be MR Conditional. A patient with an implanted Amplatzer™ device can be scanned safely immediately after placement of the device under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient magnetic field of 720 G/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

### RADIO FREQUENCY (RF) HEATING

During testing, the device produced a clinically non-significant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning in a 3-Tesla MR system using a transmit/receive body coil.

### MR ARTIFACTS

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 device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

## PATENT FORAMEN OVALE CLOSURE

Amplatzer™ Patent Foramen Ovale Occluder

### MODELS

#### 9-PFO-0xx

(xx denotes different available sizes, e.g., 9-PFO-030)

Through non-clinical testing, the Amplatzer™ PFO Occluder has been shown to be MR Conditional at field strengths of 3.0 Tesla or less with a maximum whole body averaged specific absorption rate (SAR) of 3.83 W/kg at 1.5 Tesla and 5.57 W/kg at 5.0 Tesla for a 20 minute exposure to a B1 of 118 μT. The Amplatzer™ PFO Occluder should not migrate in this MR environment. Nonclinical testing has not been performed to rule out the possibility of migration at field strengths higher than 3.0 Tesla.

### RF HEATING

In this testing, the device produced a temperature rise of 1.1° C at 1.5 Tesla and 1.6° C at 5.0 Tesla.

### MR ARTIFACTS

MR image may be compromised if the area of interest is in the exact same area or relatively close to the position of the device.

## ATRIAL SEPTAL DEFECT OCCLUDERS

Amplatzer™ Multifenestrated Septal Occluder – “Cribriform”

### MODELS

#### 9-ASD-MF-0xx

(xx denotes different available sizes, e.g., 9-ASD-MF-025)

Through non-clinical testing, the Amplatzer™ Cribriform Occluder has been shown to be MR Conditional at field strengths of 3.0 Tesla or less with a maximum whole body averaged specific absorption rate (SAR) of 3.83 W/Kg at 1.5 Tesla and 5.57 W/kg at 5.0 Tesla for a 20 minute exposure to a B1 of 118 μT. The Amplatzer™ Cribriform Occluder should not migrate in this MR environment. The non-clinical testing has not been performed to rule out the possibility of migration at field strengths higher than 3.0 Tesla.

### RF HEATING

In this testing, the device produced a temperature rise of 1.1 °C at 1.5 Tesla and 1.6 °C at 3.0 Tesla.

### MR ARTIFACTS

MR image may be compromised if the area of interest is in the exact same area or relatively close to the position of the device.

## PATENT DUCTUS ARTERIOSUS CLOSURE

Amplatzer™ Duct Occluder

### MODELS

#### 9-PDA-0xx

(xx denotes different available sizes, e.g., 9-PDA-010)

Through non-clinical testing, the Amplatzer™ device has been shown to be MR Conditional at field strengths of 3.0 Tesla or less with a maximum whole body averaged specific absorption rate (SAR) of 3.83 W/kg at 1.5 Tesla and 5.57 W/kg at 5.0 Tesla for a 20 minute exposure to a B1 of 118 μT. The Amplatzer™ device should not migrate in this MR environment. Non-clinical testing has not been performed to rule out the possibility of migration at field strengths higher than 3.0 Tesla.

### RF HEATING

In this testing, the device produced a temperature rise of 1.1°C at 1.5 Tesla and 1.6°C at 5.0 Tesla.

### MR ARTIFACTS

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 device.

## PATENT DUCTUS ARTERIOSUS CLOSURE

Amplatzer™ Duct Occluder II

### MODELS

#### 9-PDA2-0x-0y

(*x and y denote different available sizes, e.g., 9-PDA2-04-06*)

Through non-clinical testing, Amplatzer™ devices have been shown to be MR Conditional. A patient with an implanted Amplatzer™ device can be scanned safely immediately after placement of the device under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient magnetic field of 720 G/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

### RF HEATING

During testing, the device produced a clinically non-significant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning in a 3-Tesla MR system using a transmit/receive body coil.

### MR ARTIFACTS

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 device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

## VENTRICULAR SEPTAL DEFECT CLOSURE

Amplatzer™ Membranous VSD Occluder

### MODELS

#### 9-VSD-MEMB-0xx

(*xx denotes different available sizes, e.g., 9-VSD-MEMB-010*)

Through non-clinical testing, Amplatzer™ devices have been shown to be MR Conditional. A patient with an implanted Amplatzer™ device can be scanned safely immediately after placement of the device under the following conditions:

- Static magnetic field of 3 T or less
- Spatial gradient magnetic field of 720 G/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

### RF HEATING

During testing, the device produced a clinically non-significant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning in a 3-Tesla MR system using a transmit/receive body coil.

### MR ARTIFACTS

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 device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

## PATENT DUCTUS ARTERIOSUS CLOSURE

Amplatzer Piccolo™ Occluder

### MODELS

#### 9-PDAP-0x-0y-L

(*x and y denote different available sizes, e.g., 9-PDAP-03-06-L*)

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

- Static magnetic field of 3 Tesla or less
- Spatial gradient magnetic field of 720 G/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

### RF HEATING

During testing, the device produced a clinically nonsignificant temperature rise at a maximum MR system-reported, whole-body-averaged SAR of 3 W/kg for 15 minutes of scanning in a 3-Tesla MR system using a transmit/receive body coil.

### MR ARTIFACTS

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 device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

## LEFT ATRIAL APPENDAGE OCCLUSION

Amplatzer™ Amulet™ Left Atrial Appendage Occluder

### MODELS

#### 9-ACP2-0xx-0yy

(*xx and yy denote different available sizes, e.g., 9-ACP2-007-018*)

Through non-clinical testing, Amplatzer™ devices have been shown to be MR Conditional. A patient with an implanted Amplatzer™ device can be scanned safely immediately after placement of the device under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient magnetic field of 720 G/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

### RF HEATING

During testing, the device produced a clinically non-significant temperature rise at a maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning in a 3-Tesla MR system using a transmit/receive body coil.

### MR ARTIFACTS

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 device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

## PARAVALVULAR LEAK CLOSURE

Amplatz™ Valvular Plug III

### MODELS

#### 9-APVL3-xxx

(xxx denotes different available sizes, e.g., 9-APVL3-103)

Non-clinical testing has demonstrated that the AVPIII devices implanted in conjunction with the Masters Series valves are MR Conditional. A patient with AVPIII device(s) implanted to address paravalvular leakage, in combination with the referenced valves, can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T)
- Maximum spatial gradient field of 19 T/m (1900 G/cm)
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

### RF HEATING

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 3°C after 15 minutes of continuous scanning.

### MR ARTIFACTS

In non-clinical testing, the image artifact caused by the device extends radially up to 1.8 cm and 3.6 cm (respectively) from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a spin echo pulse sequence in a 3.0T MR system.

**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](http://eifu.abbottvascular.com) or at [medical.abbott/manuals](http://medical.abbott/manuals) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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#### Abbott

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