

**AGA MEDICAL CORPORATION**

**AMPLATZER<sup>®</sup> Muscular VSD Occluder**

**Physician's Manual**

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## 1. OVERVIEW OF MANUAL

This manual provides information on the AMPLATZER® Muscular VSD Occluder, AMPLATZER® TorqVue® Delivery System and AMPLATZER TorqVue® Exchange System. This manual also includes items to discuss with your patient (and/or their parents) and explains how to register the patient's device. You will also find instructions for handling, storing, implanting and retrieving the device, as well as instructions for exchanging the delivery system if necessary during a procedure.

## 2. BRIEF DEVICE DESCRIPTION

The AMPLATZER Muscular VSD Occluder is a self-expandable, double disc device made from a Nitinol wire mesh. The two discs are linked together by a short cylindrical waist corresponding to the size of the Ventricular Septal Defect (VSD). In order to increase its closing ability, the discs and waist are filled with polyester fabric. The polyester fabric is securely sewn to the device by polyester thread.

The AMPLATZER TorqVue Delivery System is intended to facilitate the attachment, loading, delivery and deployment of the AMPLATZER Muscular VSD Occluder. The AMPLATZER TorqVue Exchange System is intended for removal of an AMPLATZER TorqVue Delivery Sheath and subsequent exchange for an AMPLATZER Delivery Sheath of equal or larger diameter. Reference AMPLATZER TorqVue Delivery and Exchange Systems Instructions For Use for complete information on these systems.

For a complete list of model numbers, refer to the Detailed Device Description section of this manual.

## 3. INDICATIONS AND USAGE

The AMPLATZER Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left to right shunt, pulmonary hypertension and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

High risk anatomical factors for transatrial or transarterial surgical closure include patients:

- Requiring left ventriculotomy or an extensive right ventriculotomy;
- With a failed previous VSD closure
- With multiple apical and/or anterior muscular VSDs ("Swiss Cheese Septum"); or
- With posterior apical VSDs covered by trabeculae

## 4. CONTRAINDICATIONS

- Patients with defects less than 4 mm distance from the semilunar (aortic and pulmonary) and atrioventricular valves (mitral and tricuspid)
- Patients with severely increased pulmonary vascular resistance above 7 woods units and a right-to-left shunt and documented irreversible pulmonary vascular disease.
- Patients with perimembranous (close to the aortic valve) VSD.
- Patients with post-infarction VSD
- Patients who weigh less than 5.2 kg. (Patients smaller than 5.2kg were studied in the clinical trial, but due to poor outcome these patients have been contraindicated for device placement. Data from these patients has not been included in the overall analysis.)
- Patients with sepsis (local/generalized)
- Patients with active bacterial infections.
- Patients with contraindications to anti-platelet therapy or agents.

## 5. WARNINGS

- Patients allergic to nickel may suffer an allergic reaction to this device.
- The AMPLATZER Muscular VSD Occluder and Delivery System should only be used by those physicians trained in transcatheter defect closure techniques.
- Physicians must be prepared to deal with urgent situations which require removal of embolized devices that result in critical hemodynamic compromise. This includes the availability of a congenital cardiovascular surgical team.
- Embolized devices must be removed. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within a sheath.
- Do not use if the sterile barrier has been compromised in any way.
- Do not release the AMPLATZER Muscular VSD Occluder from the delivery cable if the device does not conform to its original configuration or if the device position is unstable. Recapture the device and redeploy. If still unsatisfactory, recapture the device and replace with a new device.
- Device closure in patients who have suffered a previous thromboembolic stroke should be discussed with the patient or family. In addition, consultation with a neurologist and hematologist is suggested to determine if the benefit of device closure outweighs the risk

## 6. PRECAUTIONS

### 6.1 Handling

- The AMPLATZER Muscular VSD Occluder is for single use only. Do not reuse or resterilize.

### 6.2 Sizing

- Accurate defect sizing is crucial and mandatory for AMPLATZER Muscular VSD Occluder device selection. The VSD should be assessed and sized at end diastole by TEE or angiography to determine the appropriate device size. Device selection should be 2 mm larger than the defect size.

### 6.3 Procedural

- Aspirin (3-5 mg/kg/day) is to be started at least 24 hours prior to the procedure. Cephalosporin therapy is optional.
- Patients should be fully heparinized throughout the procedure with a minimum active clotting time (ACT) of 200 seconds prior to device insertion.
- Transesophageal echocardiography (TEE) or similar imaging equipment (i.e. intracardiac echocardiography) is recommended as an aid in placing the AMPLATZER Muscular VSD Occluder. If TEE is used, the patient's esophageal anatomy must be adequate for placement and manipulation of the TEE probe.
- Patients requiring multiple devices and/or concomitant catheterization procedures might require prolonged fluoroscopy times and multiple cineangiograms. The risks of radiation exposure (e.g., increased cancer risk) should be discussed in detail with the family and alternatives which do not involve radiation exposure should be reviewed.

### 6.4 Post-Implant

- Patients should be treated with antiplatelet/anticoagulation therapy (such as aspirin) for six-months post implant. The decision to continue antiplatelet/anticoagulation therapy beyond six-months is at the discretion of the physician.
- Endocarditis prophylaxis should be followed according to the American Heart Association recommendations.
- Any patient who has a residual shunt should undergo an echocardiographic evaluation of the residual shunt every 6 months until complete closure of the defect has been confirmed.

### **6.5 MR Conditional<sup>1</sup>**

- 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

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 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.

- Patients should be instructed to avoid strenuous activity for one month. Strenuous activities such as contact sports prior to one month after implant may cause the device to dislodge and embolize.

### **6.6 Use in Specific Populations**

- *Pregnancy* – Care should be taken to minimize the radiation exposure to the fetus and the mother.
- *Nursing Mothers* – There has been no quantitative assessment of the presence of leachables from the device/procedure in breast milk and the risk to nursing mothers is unknown.

## **7. ADVERSE EVENTS**

### **7.1 Clinical Summary**

The AMPLATZER Muscular VSD Occluder was evaluated in a prospective, multi-center, non-randomized, controlled investigation to evaluate Muscular VSD closure. The original study included patients receiving primary treatment of VSD without establishment of a prospective statistical plan (i.e. sample size, hypotheses) to establish safety and effectiveness. Of these consecutively enrolled patients, the clinical data presented below comprises a subset of patients retrospectively established by an independent review board to be “high risk”. Safety and effectiveness hypotheses were also retrospectively established.

### **7.2 Deaths**

There were two reported deaths during the clinical trial in the High Risk patient population. Both deaths were adjudicated by the Data Safety Monitoring Board (DSMB) as major adverse events.

A 3-year-old female with multiple muscular ventricular septal defects underwent three cardiac catheterizations. Five coils and five AMPLATZER Muscular VSD Occluders were implanted during the first and third procedures. During the second procedure an attempt was made to implant an AMPLATZER Muscular VSD Occluder which was unsuccessful. Seven months after the third procedure she died suddenly. An independent DSMB adjudicated this death as a major adverse event but was unable to determine if the death was related to the procedure or the device.

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<sup>1</sup> MR Conditional as defined in ASTM F 2503-05

A 7-month-old male with a large muscular ventricular septal defect and pulmonary hypertension underwent cardiac catheterization for device closure of the defect. During the procedure a device was attempted which was too small. The physician encountered difficulties in removing the device and ultimately inadvertently pulled the 10 Fr delivery sheath out of the right internal jugular vein resulting in bleeding, hypotension and cardiac arrest requiring resuscitation. The next day it was noted that the patient had suffered cerebral injury as a result of the procedural complications. The patient died three weeks post procedure. An independent DSMB adjudicated this death as a procedure related major adverse event.

### **7.3 Observed Adverse Events**

Table 1 presents the major and minor adverse events, per patient and per procedure, observed in the "high risk" patient population. As the sample size was limited, the unadjusted 95% confidence interval upper bound for any major adverse event was 60.25% per patient and 55.83% per procedure.

**Table 1: Major and Minor Adverse Events**

<b>Adverse Event Type</b>	<b>Adverse Event Per Patient (%)</b>	<b>95% Upper Confidence Bound<sup>1</sup></b>	<b>Adverse Event Per Procedure (%)</b>	<b>95% Upper Confidence Bound<sup>1</sup></b>
<b>Major Adverse Events</b>				
Hematoma <sup>2</sup>	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Hypotension <sup>2</sup>	5/41 (12.2%)	26.20%	5/51 (9.8%)	21.41%
Bradycardia <sup>2</sup>	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Arterial pulse loss	2/41 (4.9%)	16.53%	2/51 (3.9%)	13.46%
Blood Transfusion	2/41 (4.9%)	16.53%	2/51 (3.9%)	13.46%
Subaortic stenosis	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Cardiomyopathy	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Delivery System Failure	2/41 (4.9%)	16.53%	2/51 (3.9%)	13.46%
Death	2/41 (4.9%)	16.53%	2/51 (3.9%)	13.46%
Stroke	2/41 (4.9%)	16.53%	2/51 (3.9%)	13.46%
Blood loss	4/41 (9.8%)	23.13%	4/51 (7.8%)	18.88%
Device Embolization	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Paroxysmal Ventricular Tachycardia <sup>2</sup>	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Third Degree Heart Block	2/41 (4.9%)	16.53%	2/51 (3.9%)	13.46%
Cardiac perforation	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Hemostasis and coagulation disorders	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Anemias Caused By Blood Loss	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Device Collapse	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Cardiac Arrest	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
<b>Minor Adverse Event Type</b>				
Hematoma <sup>2</sup>	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Hypotension <sup>2</sup>	2/41 (4.9%)	16.53%	2/51 (3.9%)	13.46%
Bradycardia <sup>2</sup>	2/41 (4.9%)	16.53%	2/51 (3.9%)	13.46%
Atelectasis	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Venous Thrombosis	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Atrial Flutter	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Stridor	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Paroxysmal Ventricular Tachycardia <sup>2</sup>	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Cyanosis	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Edema	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Premature Ventricular Contraction	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Fever	1/41 (2.4%)	12.86%	3/51 (5.9%)	16.24%
Second Degree Heart Block Mobitz Type 2	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
Vomiting	1/41 (2.4%)	12.86%	1/51 (2.0%)	10.45%
<b>Any Major Adverse Event</b>	<b>18/41 (43.9%)</b>	<b>60.25%</b>	<b>21/51 (41.2%)</b>	<b>55.83%</b>
<b>Any Minor Adverse Event</b>	<b>10/41 (24.4%)</b>	<b>40.30%</b>	<b>13/51 (25.5%)</b>	<b>39.63%</b>
<b>Any Major or Minor Event</b>	<b>22/41 (53.7%)</b>	<b>69.34%</b>	<b>28/51 (54.9%)</b>	<b>68.87%</b>

<sup>1</sup> Confidence intervals are unadjusted for multiple comparisons

<sup>2</sup> An independent data safety monitoring board reviewed and adjudicated all adverse events and depending on the severity and/or time of occurrence the same type of event could be classified as either a major or a minor adverse event.

#### **7.4 Potential Adverse Events**

Placement of the AMPLATZER Muscular VSD Occluder involves using standard interventional cardiac catheterization techniques. In addition to the above observed adverse events, the following are potential adverse events listed in alphabetical order. The following events might occur from either the catheterization procedure or from the device:

**Table 2: Potential Adverse Events**

- Air embolus
- Allergic dye reaction
- Allergic drug reaction
- Anemia
- Anesthesia reactions
- Apnea
- Arrhythmia
- Arterial pulse loss
- Atelectasis
  
- Bacterial endocarditis
- Blood loss requiring transfusion
- Brachial plexus injury
- Cardiac arrest
- Cardiomyopathy
- Chest pain
- Cyanosis
  
- Death
- Device embolization
- Device fracture
- Fever
- Headache/Migraine
- Heart block
- Hypotension
- Myocardial infarction
- Perforation of the vessel or myocardium
- Peripheral embolism
- Stridor
- Stroke
- Subaortic stenosis
- Thrombus formation on device
- Vascular access site injury
- Venous thrombosis
- Vomiting

## **8. CLINICAL STUDIES**

The original study included patients receiving primary treatment of VSD without establishment of a prospective statistical plan (i.e. sample size, hypotheses) to establish safety and effectiveness. Of these consecutively enrolled patients, the clinical data presented below comprises a subset of patients retrospectively established by an independent review board to be “high risk”. Safety and effectiveness hypotheses were also retrospectively established.

### **8.1 Study Purpose**

The primary purpose of this evaluation was to retrospectively determine if the AMPLATZER Muscular VSD Occluder is reasonably safe and effective for the treatment of congenital muscular ventricular septal defects in patients with complex ventricular septal defect of significant size to warrant closure who are considered to be at high risk for standard transcatheter closure based on anatomical conditions and/or based on overall medical condition.

Primary effectiveness was evaluated at 12-months post-implant. Successful closure of the defect was defined as less than or equal to 2 mm residual shunt. Effectiveness was also evaluated at 24 hours (acutely), 1, 6, and 24-months post-implant.

In addition, patients were classified according to the Clinical Status Scale pre-procedure, 6 and 12-months post-procedure.

Safety was assessed following device placement attempt through the follow-up period by collecting all adverse events that occurred among all consented patients.

### **8.2 Study Design**

This study was a prospective, non-randomized, multi-center clinical investigation. A total of 11 investigational centers received IRB approval and enrolled patients in the High Risk subset.

### **8.3 Patient Demographics**

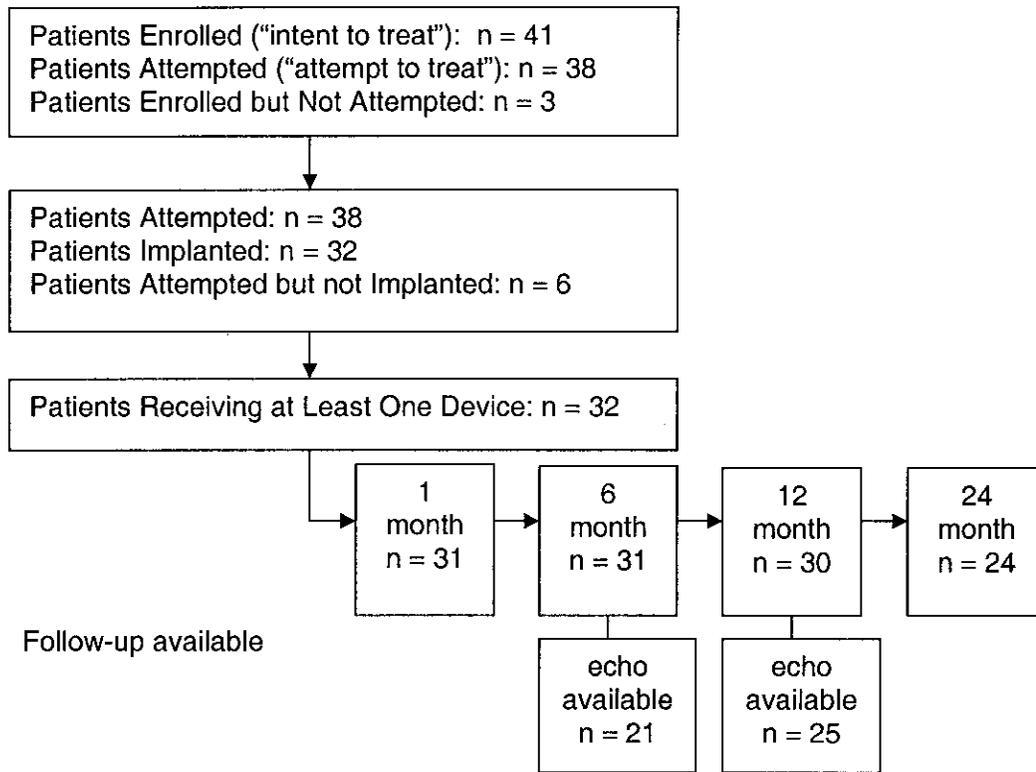
A total of 41 high risk patients were consented to participate in the clinical study and undergo transcatheter VSD closure with the AMPLATZER Muscular VSD Occluder. Of these 41 patients, 3 patients were classified as “intent to treat” patients in which the patient signed the informed consent but the patient was not exposed to the investigational device. The remaining 38 patients underwent a cardiac catheterization procedure and an attempt to place the AMPLATZER Muscular VSD Occluder. Six (6) of the 38 patients were “attempt to treat” patients in that a device was not successfully implanted during any procedure. The mean age of the 41 patients was 3.2 years (range 0.1 to 49.0 years) and 21 (55.2%) of the patients were male.

### **8.4 Study Protocol**

Physical examinations and Doppler transthoracic echocardiograms (TTE) were performed pre-implant procedure and at follow-up. Clinical follow-up testing was required at hospital discharge, and at 1-month, 6-months, 12-months and 24-months post-procedure. All reported adverse events were reviewed and adjudicated by an independent data safety monitoring board (DSMB). Adverse events were adjudicated according to severity (major, minor, observation), using definitions determined by the DSMB. Adverse event relationship to device and procedure, and whether the event was anticipated or not, was also determined by the DSMB. The ventricular septal defect(s) shunt status was evaluated at 1, 6, 12, and 24 month(s) follow-up intervals using TTE and was classified according to degree: none, trivial (<1mm), small (1-2 mm), moderate (>2-4 mm) and large (>4 mm). Of the 31 patients seen for the 6-month follow-up, an independent echo board reviewed tapes for 21 (67.7%) patients. Of the 30 patients who were seen at the 1-year follow-up visit, 25 (83.3%) patients had echo tapes reviewed by the board.

### **8.5 Principal Safety and Effectiveness Results**

The following tables describe the principal safety and effectiveness results of the AMPLATZER Muscular VSD device in high risk patients. Of the 41 high risk patients enrolled in the study, there were 3 “intent to treat” patients who signed the consent but were not exposed to the device. The remaining 38 patients underwent a cardiac catheterization during which device placement was attempted. Of these 38 patients, 6 patients were “attempt-to-treat” patients meaning device placement was not successful at any time during the clinical trial. Two (2) additional patients had an “attempt to treat” procedure but at some point during the clinical trial also had a procedure with successful device placement. The following flow diagram depicts patients enrolled, patients who received at least one device and the number of patients who were seen at each follow-up interval.



The Acute Effectiveness table is broken down by patient, procedure, and finally by device. The data is also provided by patients attempted and also all consented patients.

Technical success by patient is defined as the number of patients who experienced only successful procedures, meaning that the patient did not have any procedures in which they left the catheterization lab without device placement. Acute procedure success by patient is defined as the number of patients who had a shunt less than or equal to 2 mm immediately post-procedure.

The second portion of the following table describes the results by procedure. Technical success by procedure was defined as the number of successful procedures. The acute procedure success was defined as procedures in which there was less than or equal to 2 mm residual shunt immediately post-procedure.

The last analysis was by device. Acute results by device were the number of devices successfully implanted. The acute procedure success closure results by device is the number of devices with a less than or equal to 2 mm residual shunt immediately post-procedure.

**Table 3: Acute Effectiveness**

<b>Acute Results - Effectiveness</b>	<b>All Attempted Patients<sup>1</sup></b>	<b>All Consented Patients<sup>2</sup></b>
<b>Acute Results by Patient</b>		
Technical Success <sup>3</sup>	30/38 (79.0%)	30/41 (73.2%)
Acute Procedure Success <sup>4</sup>	29/38 (76.3%)	29/41 (70.7%)
<b>Acute Results by Procedure</b>		
Technical Success <sup>5</sup>	39/47 (83.0%)	39/51 (76.5%)
Acute Procedure Success <sup>6</sup>	38/47 (80.9%)	38/51 (74.5%)
<b>Acute Results by Device</b>		
Technical Success <sup>7</sup>	65/82 (79.3%)	--
Acute Procedure Success closure results <sup>8</sup>	64/82 (78.1%)	--

Closure by follow-up period is reported both by Echo Board adjudication and by investigator. An independent Echo Board reviewed the 6-month and 12-month echocardiograms for a majority of the patients seen for each follow-up interval. They determined if there was residual shunting and if so, to what degree.

Closure is also reported as assessed by investigator for patients seen at the specific follow-up interval, for all attempted patients, and lastly for all patients. Closure success is defined as patients who had a shunt of less than or equal to 2 mm at the specific follow-up interval.

<sup>1</sup> Acute results for all attempted patients

<sup>2</sup> Acute results for all consented patients

<sup>3</sup> Number of patients who experienced only successful procedure(s), two of the eight technical-failure patients had both successful and unsuccessful procedure(s). Patients who did not receive the device are included in the denominator.

<sup>4</sup> Number of patients who had a shunt of less than or equal to 2 mm immediately post-procedure

<sup>5</sup> Number of successful procedures

<sup>6</sup> Number of procedures in which there was less than or equal to 2mm shunt immediately post-procedure

<sup>7</sup> Number of devices successfully implanted

<sup>8</sup> Number of devices for which the shunt was less than or equal to 2mm shunt immediately post-procedure

**Table 4: Closure by Follow-up Period – Effectiveness**

<b>Closure Success Defined as <math>\leq</math> 2 mm shunt at Follow-Up Interval</b>		
	<b>Results</b>	<b>95% Confidence Intervals<sup>1</sup></b>
<b>Success by ECHO Board adjudication<sup>2</sup></b>		
Six-Month Success	20/21 (95.2%)	(76.2%; 99.9%)
Twelve-Month Success	25/25 (100.0%)	(86.3%; 100.0%)
<b>Success by Investigator Assessment-Patients Seen<sup>3</sup></b>		
One-Month Success	30/31 (96.8%)	(83.3%; 99.9%)
Six-Month Success	29/31 (93.6%)	(78.6%; 99.2%)
Twelve-Month Success	28/30 (93.3%)	(77.9%; 99.2%)
24-Month Success	24/24 (100.0%)	(85.8%; 100.0%)
<b>Success By Investigator Assessment-All Attempted Patients<sup>4, 5</sup></b>		
Acute Procedure Success	29/38 (76.3%)	(59.8%; 88.7%)
One-Month Success	30/38 (79.0%)	(62.7%; 90.5%)
Six-Month Success	29/38 (76.3%)	(59.8%; 88.6%)
Twelve-Month Success	28/38 (73.7%)	(56.9%; 86.6%)
24-Month Success	24/38 (63.2%)	(46.0%; 78.2%)
<b>Success By Investigator Assessment -All Consented Patients<sup>6, 7</sup></b>		
Acute Procedure Success	29/41 (70.7%)	(54.5%; 83.9%)
One-Month Success	30/41 (73.2%)	(57.1%; 85.8%)
Six-Month Success	29/41 (70.7%)	(54.5%; 83.9%)
Twelve-Month Success	28/41 (68.3%)	(51.9%; 81.9%)
24-Month Success	24/41 (58.5%)	(42.1%; 73.7%)

In addition to Closure by Follow-up Period, a Composite Success parameter was calculated to comprehensively evaluate both the safety and effective performance of the device at the 1-month and 12-month follow-up intervals.

Composite Success was defined as patients in which device placement was attempted who did not experience technical failure, a major adverse event, or major shunt at the respective follow-up visit. Patients who were technical successes and did not have a major adverse event at the specific follow-up interval and did not have the shunt evaluated at the follow-up interval, but were classified as a failure at the shunt evaluation at their last follow-up interval,

<sup>1</sup> Confidence intervals are unadjusted for multiple comparisons

<sup>2</sup> Number of patients who had their follow-up ECHO reviewed by the ECHO Board and had a shunt of less than or equal to 2 mm at follow-up interval

<sup>3</sup> Number of patients who were seen at follow-up interval, whether or not they had shunt evaluated, and had a shunt of less than or equal to 2 mm at follow-up interval. Patients who were not seen but had a shunt greater than 2 mm at last follow-up interval are included in the denominator

<sup>4</sup> Number of patients who had an attempted procedure and had a shunt of less than or equal to 2 mm at follow-up interval

<sup>5</sup> The six patients who did not have a device implanted are included in the denominator

<sup>6</sup> Number of patients who had a shunt of less than or equal to 2 mm at follow-up interval

<sup>7</sup> The six patients who did not have a device implanted and the three patients who were never exposed to a device are included in the denominator (i.e., intent to treat)

were classified as composite failures. Technical success patients with no major adverse event at the specific follow-up interval who did not have the shunt evaluated at the follow-up interval, but were classified as a successful closure at the shunt evaluation at their last follow-up interval, were classified as missing.

**Table 5: Composite Results**

<b>Composite Results</b>	<b>Results</b>	<b>95% Confidence Intervals<sup>1</sup></b>
One-Month Composite Success	20/36 (55.6%)	(38.1%; 72.1%)
12-Month Composite Success	14/32 (43.8%)	(26.4%; 62.3%)

**Table 6: Major Adverse Events by Follow-up Period**

<b>Major Adverse Events - Safety</b>		
<b>Major Adverse Event by Patient</b>	<b>Results<sup>2, 3</sup></b>	<b>95% confidence Interval<sup>1</sup></b>
Major AEs at 24-Hour	16/39 (41.0%)	(25.6%; 57.9%)
Major AEs at 1-Month	16/39 (41.0%)	(25.6%; 57.9%)
Major AEs at 6-Months	17/39 (43.6%)	(27.8%; 60.4%)
Major AEs at 12-Months	18/39 (46.2%)	(30.1%; 62.8%)
Major AEs at 24-Months	18/39 (46.2%)	(30.1%; 62.8%)

Mortality results are reported in multiple ways and a range of assumptions are made regarding the outcome of patients due to unavailable follow-up data. For example: death is reported with the assumption that for all consented patients, whether or not they were exposed to the device, who were not seen at a specific follow-up interval and never returned at a later date have died. This includes all “intent to treat” and “attempt to treat” patients who were discontinued immediately post procedure.

<sup>1</sup> Confidence intervals are unadjusted for multiple comparisons

<sup>2</sup> The numerator depicts the number of consented patients who experienced a major adverse event at the specific follow-up interval

<sup>3</sup> The denominator includes the 38 attempted patients plus one “intent to treat” patient who experienced two major adverse events. The other two “intent to treat” patients did not experience a major adverse event and are not included in the denominator.

**Table 7: Mortality Results - Safety**

<b>Mortality-Safety</b>		
	<b>Results</b>	<b>95% confidence Interval<sup>1</sup></b>
<b>Mortality of all attempted patients<sup>2</sup></b>		
Mortality at 24-Hours	0/38 (0.0%)	
Mortality at 1-Month	1/38 (2.6%)	(0.1%; 13.8%)
Mortality at 6-Months	1/38 (2.6%)	(0.1%; 13.8%)
Mortality at 12-Months	2/38 (5.3%)	(0.6%; 50.8%)
Mortality at 24-Months	2/38 (5.3%)	(0.6%; 50.8%)
<b>Mortality of patients seen for follow-up<sup>3</sup></b>		
Mortality at 24-Hours	0/33 (0.0%)	
Mortality at 1-Month	1/33 (3.0%)	(0.1%; 15.8%)
Mortality at 6-Months	1/32 (3.2%)	(0.1%; 16.2%)
Mortality at 12-Months	2/32 (6.3%)	(0.8%; 20.8%)
Mortality at 24-Months	2/28 (7.1%)	(0.9%; 23.5%)
<b>Assumed Mortality of patients implanted with a device<sup>4, 5</sup></b>		
Mortality at 24-Hours	0/32 (0.0%)	
Mortality at 1-Month	1/33 (3.0%)	(0.1%; 15.8%)
Mortality at 6-Months	1/33 (3.0%)	(0.1%; 15.8%)
Mortality at 12-Months	4/33 (12.1%)	(3.4%; 28.2%)
Mortality at 24-Months	6/33 (18.2%)	(7.0%; 35.5%)
<b>Assumed Mortality of all consented patients<sup>6, 7</sup></b>		
Mortality at 24-Hours	7/41 (17.1%)	(7.2%; 32.1%)
Mortality at 1-Month	7/41 (17.1%)	(7.2%; 32.1%)
Mortality at 6-Months	7/41 (17.1%)	(7.2%; 32.1%)
Mortality at 12-Months	10/41 (24.4%)	(12.4%; 40.3%)
Mortality at 24-Months	14/41 (34.2%)	(20.1%; 50.6%)

<sup>1</sup> Confidence intervals are unadjusted for multiple comparisons

<sup>2</sup> Number of attempted patients with a known death at follow-up interval

<sup>3</sup> Number of patients seen for follow-up at follow-up interval with a known death

<sup>4</sup> Number of patients with at least one successful procedure who were discontinued for any reason at follow-up interval and patients with no successful procedures who have died

<sup>5</sup> 12-month and 24-month intervals include the 2 patients who were discontinued due to death and additional patients who were discontinued for other reasons but are assumed to have died

<sup>6</sup> Number of all consented patients who were not seen at the follow-up interval and never came back at a later date were assumed dead (i.e., intent to treat)

<sup>7</sup> One patient who died 3-weeks post-procedure was not evaluated at 24-hours post-procedure and is therefore assumed dead at the 24-hour follow-up interval

**Table 8: Total Fluoroscopy Time Per-Patient**

Procedure variable		Results
Fluoro time (min)	Mean +/- s.d. (N) [range]	95.5 +/- 93.7 (41) [8.7, 573.0]

**Table 9: Total Fluoroscopy Time Per-Procedure**

Procedure variable		Results
Fluoro time (min)	Mean +/- s.d. (N) [range]	76.8 +/- 59.7 (51) [8.7, 356.0]

**9. DIRECTIONS FOR USE**

**9.1 Storage Conditions**

Store in a dry place.

**9.2.1 AMPLATZER® Muscular VSD Occluder**

The AMPLATZER Muscular VSD Occluder is a self-expandable, double disc device made from a Nitinol wire mesh. The two discs are linked together by a short cylindrical waist corresponding to the size of the Ventricular Septal Defect (VSD). In order to increase its closing ability, the discs and waist are filled with polyester fabric. The polyester fabric is securely sewn to the device by polyester thread. The device is available in multiple sizes (Table 10).

**Table 10: Device Specifications**

Device Order Number	Device Size (at waist)	Left and Right Ventricle Disc Diameter	Length of Connecting Waist	TorqVue Delivery System	
				45°	180°
9-VSD-MUSC-004	4 mm	9 mm	7 mm	6 Fr	5 Fr
9-VSD-MUSC-006*	6 mm	14 mm	7 mm	6 Fr	6 Fr
9-VSD-MUSC-008*	8 mm	16 mm	7 mm	6 Fr	6 Fr
9-VSD-MUSC-010*	10 mm	18 mm	7 mm	6 Fr	6 Fr
9-VSD-MUSC-012*	12 mm	20 mm	7 mm	7 Fr	7 Fr
9-VSD-MUSC-014*	14 mm	22 mm	7 mm	8 Fr	8 Fr
9-VSD-MUSC-016	16 mm	24 mm	7 mm	8 Fr	8 Fr
9-VSD-MUSC-018	18 mm	26 mm	7 mm	9 Fr	9 Fr

\* NOTE: The device specifications for the 006 – 014 devices were modified after the clinical trial was completed. The devices used during the clinical trial utilized a right ventricular disc that was 2mm smaller than the left ventricular disc. The marketed devices have equal disc diameters.

### 9.2.2 AMPLATZER® TorqVue® Delivery System

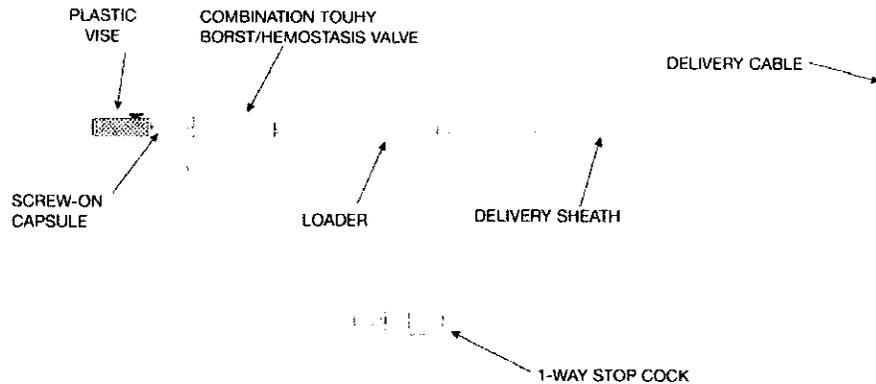
The AMPLATZER Muscular VSD Occluder is implanted with either a 45° or a 180° AMPLATZER TorqVue Delivery System. The delivery system selected is based on physician preference for sheath placement.

**Table 11: Delivery System Selection**

<b><i>If preferred sheath placement is</i></b>	<b><i>Select a</i></b>
Middle of LV	45° delivery system
Ascending aorta	180° delivery system

Delivery System components include:

- Delivery Sheath – used to deliver the device.
- Dilator – used to ease penetration of tissue
- Loader – used to introduce the Occluder device into the delivery sheath.
- Touhy-Borst adapter with extension tube and stopcock – used to minimize bleeding and for flushing of the system.
- Plastic Vise – facilitates direction control and serves as the “handle” for disconnecting (unscrewing) the delivery cable from the device.
- Delivery Cable – allows placement and recapture of the device.



**Figure 1 - AMPLATZER TorqVue Delivery System**

### 9.2.3 AMPLATZER® TorqVue® Exchange System

The AMPLATZER TorqVue Exchange System is intended for removal of an AMPLATZER TorqVue Delivery Sheath and subsequent exchange for an AMPLATZER Delivery Sheath of equal or larger diameter. The system components are identical to the AMPLATZER TorqVue Delivery System, with the exception of the dilator, which incorporates an enlarged inner lumen for passage over a delivery cable.

**Table 12: TorqVue Delivery and Exchange System Descriptions**

<b>Product</b>	
<b>Re-order Number</b>	<b>Product Description</b>
<b>45° APLATZER TorqVue Delivery System</b>	
9-ITV06F45/60	6 French Sheath; 60 cm Length
9-ITV07F45/60	7 French Sheath; 60 cm Length
9-ITV07F45/80	7 French Sheath; 80 cm Length
9-ITV08F45/60	8 French Sheath; 60 cm Length
9-ITV08F45/80	8 French Sheath; 80 cm Length
9-ITV09F45/80	9 French Sheath; 80 cm Length
9-ITV10F45/80	10 French Sheath; 80 cm Length
9-ITV12F45/80	12 French Sheath; 80 cm Length
<b>45° AMPLATZER TorqVue Exchange System</b>	
9-EITV09F45/80	9 French Sheath; 80 cm Length
9-EITV12F45/80	12 French Sheath; 80 cm Length
<b>180° AMPLATZER TorqVue Delivery System</b>	
9-ITV05F180/60	5 French Sheath; 60 cm Length
9-ITV06F180/60	6 French Sheath; 60 cm Length
9-ITV06F180/80	6 French Sheath; 80 cm Length
9-ITV07F180/80	7 French Sheath; 80 cm Length
9-ITV08F180/80	8 French Sheath; 80 cm Length
9-ITV09F180/80	9 French Sheath; 80 cm Length
<b>180° TorqVue Exchange System</b>	
9-EITV06F180/80	6 French Sheath; 80 cm Length
9-EITV8F180/80	8 French Sheath; 80 cm Length
9-EITV10F180/80	10 French Sheath; 80 cm Length

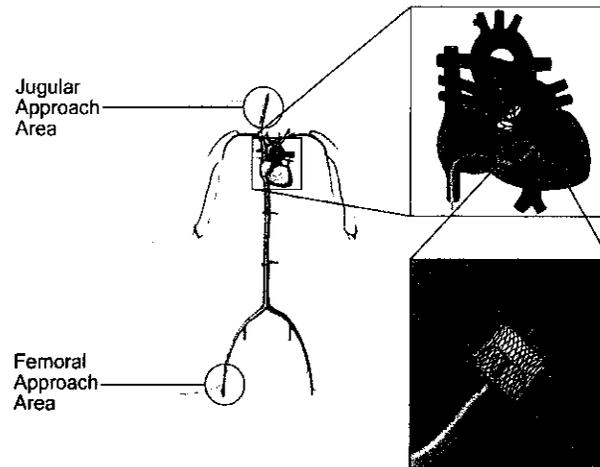
**9.3 Directions for Use**

The AMPLATZER Muscular VSD Occluder is implanted percutaneously by catheter technique (right- or left-sided approach). The approach depends on the location of the muscular ventricular septal defect. Generally, defects in the upper portion of the septum can be approached from the femoral vein, whereas low defects may be easier to close with a transjugular approach.

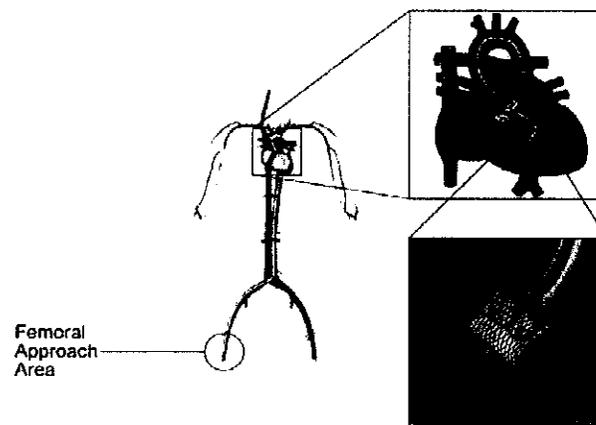
**Catheter Technique**

1. Perform procedure under either general or conscious sedation.
2. Give patient a dose of an appropriate antibiotic during the catheterization procedure.
3. Obtain access in the femoral artery, femoral vein, and/or right internal jugular vein.
4. Administer heparin to achieve an activated clotting time of greater than 200 seconds throughout the procedure.
5. Perform routine right and left heart catheterization. Assess the pulmonary vascular resistance.
6. Perform angiography to define the location, size, and number of VSD(s).
7. Use transesophageal echocardiography (TEE) to provide additional imaging of the VSD(s) and to assist with delivery system and device placement.

8. Select a device up to 2 mm larger than the VSD(s) size as assessed by TEE or angiography at end-diastole (the bigger of the two diameters).
9. Access the VSD(s) with a guidewire using either venous (Figure 2) or arterial approach (Figure 3). The venous approach may be from either the inferior vena cava or the superior vena cava (arteriovenous loop) depending on the location of the VSD.



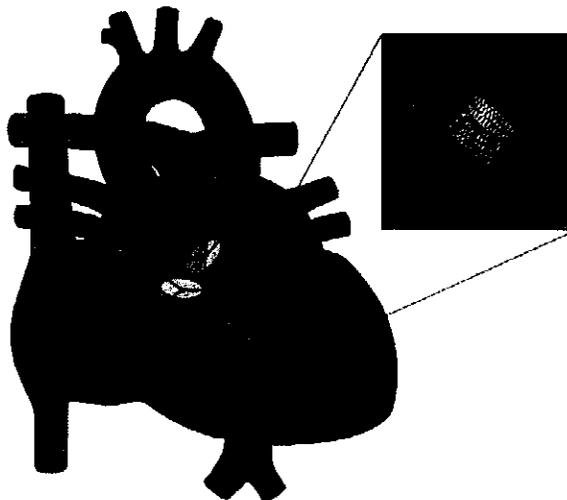
**Figure 2: Right-Sided Approach**



**Figure 3: Left-Sided Approach**

10. Advance the delivery sheath and dilator over the guidewire until the tip of the dilator crosses the VSD.
11. Remove the dilator.
12. Advance the guidewire into the apex of the ventricle and position the tip of the delivery sheath in the body of the ventricle.
13. Pass the delivery cable through the loader and attach the AMPLATZER Muscular VSD Occluder to the tip of the delivery cable by rotating the device clockwise until secure. To ensure proper occluder release, rotate the device counter-clockwise 1/8 of a turn.
14. Immerse the device and loader in saline solution and retract the device into the loader.

15. Slowly remove the guidewire and allow for back-bleeding to purge air from the system.
16. Connect the loader to the delivery sheath.
17. Transfer the device from the loader into the delivery sheath, and without rotation, advance the device to the tip of the delivery sheath.
18. Use TEE and angiography as a guide during each step of device deployment.
19. Retract the delivery sheath slowly until the distal disc is deployed.
20. Pull the entire assembly (delivery cable and delivery sheath) into the VSD.
21. Retract the sheath to deploy the waist of the device in the defect.
22. Once position is confirmed, retract the sheath to deploy the proximal disc.
23. If the position of the device is unsatisfactory:
  - a. Stabilize the delivery cable and re-advance the delivery sheath until the device is completely within the sheath.
  - b. Reposition the device and deploy it again, or remove the device from the patient.
24. If the device position is satisfactory:
  - a. Attach the plastic vise to the delivery cable, then release the device by rotating the delivery wire counter-clockwise until it separates from the device.
  - b. Retract the delivery cable into the delivery sheath
  - c. Remove the delivery cable and delivery sheath from the patient.
25. Complete a TEE evaluation to confirm device placement, assess for residual shunting, obstruction or regurgitation induced by the device.
26. Perform an angiogram to assess for residual flow through the device.
27. Give the patient two doses of an appropriate antibiotic post-catheterization procedure at eight hour intervals.



**Figure 4: Placement of AMPLATZER Muscular VSD Occluder**

## 10. PATIENT COUNSELING INFORMATION

Advise the patient and family of the known risks of the implantation procedure and follow-up (clinical study = 24 hours, 1 and 6 months and 1,2,3,4 and 5 years) as well as the potential benefits. Also advise the patient to read *A Patient's Guide to Transcatheter Closure of a Muscular VSD Using the AMPLATZER® Muscular VSD Occluder System*.

## 11. PATIENT REGISTRATION

An implant registration form is located in each device box. Complete the patient information section and send the form to AGA Medical Corporation. AGA Medical will create an identification card for the patient.

## 12. PHYSICIAN TRAINING

The implantation of the AMPLATZER Muscular VSD Occluder is restricted to physicians who are experts in their field and who have received sufficient training to safely carry on a comprehensive Muscular VSD closure program on their own. The hospital site must have a congenital cardiovascular surgical team as back up to deal with urgent situations and provide TEE to support transcatheter closure of Muscular VSD in the cath lab.

The AMPLATZER Muscular VSD Occluder will be released as follows:

- **Tier I** – Physicians who participated in the AMPLATZER Muscular VSD Clinical Investigation and/or have previously implanted the AMPLATZER Muscular VSD device under emergency or compassionate use. ***Physicians who meet this criteria do not require proctoring.***
- **Tier II** – Interventional Cardiologists who have experience in transcatheter closure of Muscular VSDs with NMT Medical's CardioSeal Occluder and have experience implanting the AMPLATZER Occluder devices. ***Physicians who meet this criteria do not require proctoring.***
- **Tier III** – Interventional Cardiologists who have experience implanting AMPLATZER Occluder devices but have no previous experience closing Muscular VSDs with other devices. ***Physicians who meet this criteria must first observe one case in an approved AGA Medical proctor's cath lab or during a symposium, or reviewing the AMPLATZER Muscular VSD procedure video. Following the case observation, proctoring at the trainee's hospital is required. Final certification will be determined by the proctor.***

AGA Medical Corporation's training policy requires that an AGA Medical approved proctor is present for the initial implant session by Tier III physicians. Upon successful completion of the proctoring session, the physician and the institution will be certified by AGA Medical Corporation to pursue an active AMPLATZER Muscular VSD Occluder program.

If you are interested in being proctored for Muscular VSD closure with the AMPLATZER Muscular VSD Occluder, please contact AGA Medical Corporation's sales and marketing department at [salesmarketing@amplatzer.com](mailto:salesmarketing@amplatzer.com).

## 13. HOW SUPPLIED

The AMPLATZER Muscular VSD Occluder, TorqVue Delivery System and TorqVue Exchange System are all packaged separately.

NOTE: The contents of the inner package are **STERILE**.

#### **14. WARRANTY INFORMATION**

Improper handling or use may damage the AMPLATZER Muscular VSD Occluder, TorqVue Delivery System and TorqVue Exchange System. AGA Medical Corporation disclaims all warranties, expressed and implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. AGA Medical Corporation shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any defect, failure or malfunction of the system, whether a claim for such damage is based upon warranty, contract, tort or otherwise.

**A Patient's Guide to  
Transcatheter Closure of a  
Muscular Ventricular Septal Defect (VSD)  
Using the AMPLATZER® Muscular VSD Occluder System**

**AGA Medical Corporation** 5050 Nathan Lane North • Plymouth MN 55442 USA  
[Tel] 763-513-9227 [toll free] 888-546-4407  
[www.amplatzer.com](http://www.amplatzer.com)

*This brochure is intended to provide you with general information to discuss with your doctor. It is not intended to provide medical care or treatment. You should consult with your doctor regarding the diagnosis or treatment of your medical condition.*

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

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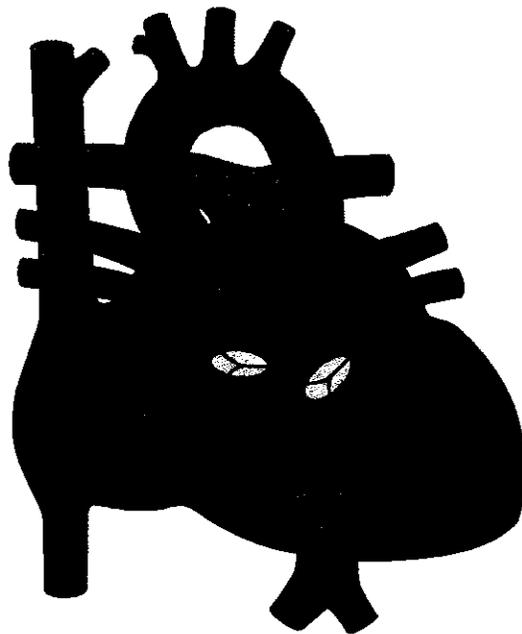
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## INTRODUCTION

You have been diagnosed with a *muscular ventricular septal defect (VSD)* which must be closed. The purpose of this brochure is to provide a better understanding of your medical condition and explain how non-surgical closure can be performed using the AMPLATZER Muscular VSD Occluder.

### *Normal Heart*

Normally, the right side of the heart pumps blood low in oxygen to the lungs. The left side of the heart pumps oxygen-rich blood to the body. Refer to *Figure 1*.



*Figure 1*  
*Diagram of a Normal Heart*

**Blue** = Blood is pumped from the body to the *lungs*

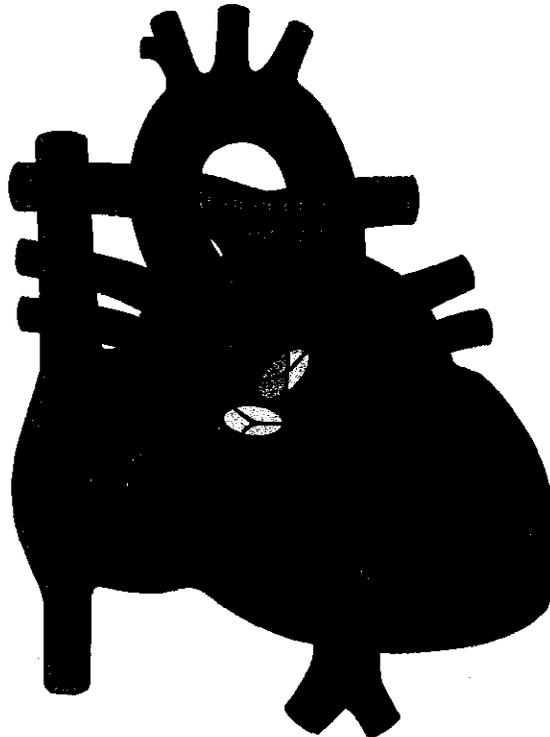
**Red** = Blood is pumped from the *lungs* to the body (oxygenated)

### ***Muscular Ventricular Septal Defect***

A VSD is a ***heart defect*** that occurs when there is an opening (hole) between the heart's two lower chambers (the ***ventricles***). Refer to *Figure 2*. If there is a hole in the wall of the heart between the ventricles, blood from the left side of the heart can pass through the unwanted hole into the right side of the heart. This causes the heart to work less efficiently because blood is going from the left ventricle to the right ventricle instead of going into the aorta as it should.

The position of the VSD in the partition between the ventricles varies from one patient to another. Sometimes there are multiple defects.

This condition can cause symptoms such as ***cyanosis***, an enlarged heart, high blood pressure, leading to possible permanent damage to the blood vessel walls. Children born with these defects may suffer from poor growth, poor exercise tolerance, frequent respiratory infections such as colds and pneumonia, or ***endocarditis***, strokes, fainting spells, heart failure or sudden death.



***Figure 2***  
***Heart with Muscular Ventricular Septal Defects (VSD)***

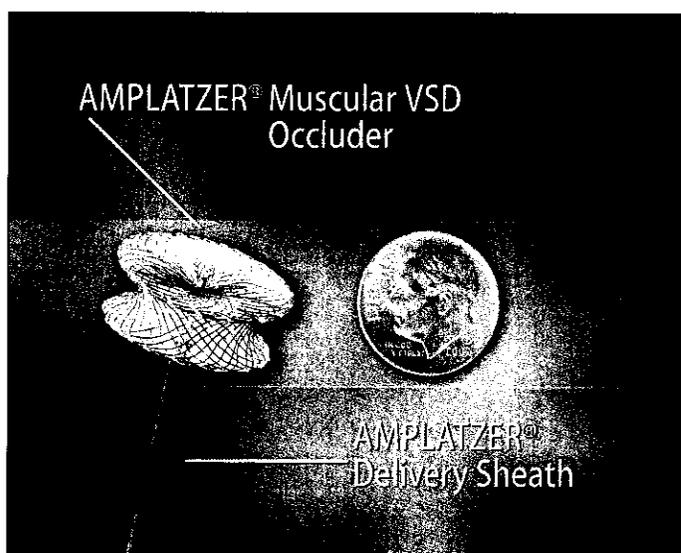
Your doctor has recommended that the VSD be closed using an implantable AMPLATZER Muscular Ventricular Septal Occluder device.

## PURPOSE OF THE DEVICE (INDICATIONS FOR USE)

The AMPLATZER Muscular VSD Occluder is for use in patients who have large muscular ventricular septal defects (VSD) that must be closed and who would experience high risks during a surgical procedure.

## DESCRIPTION OF THE DEVICE

The AMPLATZER Muscular VSD Occluder is wire mesh made out of nickel and titanium (Nitinol). The wire mesh is filled with polyester fabric to help close the defect. The polyester fabric is sewn into the device with polyester thread.



*Figure 3*  
*AMPLATZER Muscular VSD Occluder*

The AMPLATZER Muscular VSD Occluder has a specially designed delivery system that your doctor will use to attach, deliver and release the AMPLATZER Muscular VSD Occluder in your heart.

## WHEN THE DEVICE SHOULD NOT BE USED (CONTRAINDICATIONS)

Your doctor will have more information, but here are some circumstances when the AMPLATZER Muscular VSD Occluder should not be used:

- If you do not have a muscular VSD or if your VSD is from a heart attack.
- If you weigh less than 5.2 kgs.
- If you have an infection anywhere in your body. You may receive the device only after the infection is gone.
- If you are unable to take aspirin (unless you can take other *anti-platelet agents* for 6 months).
- If you, your heart or your veins are very small, or if you cannot undergo the procedure, you may not be able to receive the device.

## POTENTIAL RISKS AND BENEFITS

### *What are the risks?*

There are risks with *cardiac catheterization* procedures as well as additional risks that may be associated with the device.

Potential risks that could occur with the device and procedure include:

- An air bubble or clot that blocks blood flow in a vessel (*Air Embolus*)
- Allergic reaction to dye, drug or anesthesia
- Temporary absence of breathing (*Apnea*)
- Inflammation of the lining of the heart from infection (*Bacterial endocarditis*)
- Injury to the nerves in the arm and lower neck (*Brachial plexus injury*)
- Chest pain
- Headache/migraine
- Incorrect placement of the device (*Device malalignment*)
- Abnormally high blood pressure (*Hypertension*)
- Heart Attack (*Myocardial infarction*)
- Piercing of a vessel or the lining of the heart (*Perforation*)
- *Peripheral Embolism*
- Fluid around the lungs (*Pleural effusion*)
- Increased fluid inside the lung (*Pulmonary edema*)
- *Thrombus*
- Uncontrolled body spasms (*Seizure activity*)
- Invasive procedure (*Surgery*)
- Backwards flow of blood through a valve (*Valvular regurgitation*)
- An abnormal amount of blood in the veins (*Venous congestion*)
- Loss of vocal cord movement (Vocal cord paralysis)

You should also be aware that:

- Patients allergic to nickel may suffer an allergic reaction to this device.
- If you are pregnant, you and your baby are at risk for increased x-ray exposure. Notify your doctor if you are (or believe you might be) pregnant.
- If the device were to be dislodged, you may need surgery for its removal. Your VSD would be repaired at the same time. Surgery following device placement may be more difficult.
- You will be exposed to radiation during the procedure. Patients in the clinical study were exposed to an average of 101 minutes of radiation. If you need to have additional procedures your radiation exposure may be longer. The long-term risks of prolonged radiation exposure are not known at this time.

Because the AMPLATZER Muscular VSD Occluder device is new, the long-term consequences of the implantation of the device are not known. There also may be other risks that are not known at this time.

The safety and effectiveness of the AMPLATZER Muscular VSD Occluder was evaluated in a clinical study of 41 patients. The adverse events in Table 1 were reported in the 38 patients enrolled in the clinical trial who received a device (some patients had more than one adverse event). A total of 43.6% (17/39) of patients experienced a major adverse event by 6 months following the procedure, and 46.2% (18/39) of patients experienced a major adverse event by 12 months following the procedure.

Table 1

Adverse Event	Number of patients experiencing adverse event
Death	2
Damage to the brain due to lack of blood flow ( <i>stroke</i> )	2
The heart stops pumping blood ( <i>cardiac arrest</i> )	1
The heart muscle is perforated ( <i>cardiac perforation</i> )	1
Any disturbance in the electrical activity of the heart i.e. <i>bradycardia, tachycardia, heart block</i> or <i>atrial flutter (arrhythmia)</i>	10
Heart muscle disease that affects the heart's ability to pump blood ( <i>cardiomyopathy</i> )	1
Decreased amount of blood flow through an artery ( <i>arterial pulse loss</i> )	2
Decrease in red blood cells as a result of blood loss or blood cell destruction ( <i>anemia</i> ) which may be treated with a <i>blood transfusion</i> .	7
The device dislodges from the defect it was placed in ( <i>device embolization</i> )	1
A narrowing of the area below the aortic valve ( <i>subaortic stenosis</i> )	1
Device or Delivery System Failure	3
Problems with blood clotting ( <i>coagulation disorder</i> )	1
A bluish tint to the skin, lips, fingernails and other parts of the body due to lack of oxygen to the tissues ( <i>cyanosis</i> )	1
Partial collapse of the lung ( <i>atelectasis</i> )	1
Blood clot in a vein ( <i>venous thrombosis</i> )	1
Abnormally low blood pressure ( <i>hypotension</i> )	7
High pitched breathing sound ( <i>stridor</i> )	1
Swelling or mass of blood ( <i>hematoma</i> )	2

Abnormally high body temperature ( <i>fever</i> )	1
Vomiting or nausea ( <i>emesis</i> )	1
Extremity Swelling ( <i>edema</i> )	1

***What are the benefits of this procedure?***

The primary benefit of having a device is that the defect can be closed without surgery. There was no surgery group in the clinical trial for comparison, but use of the device may result in:

- Shorter hospital stay and recovery time
- No chest scar

In the clinical study, at 6 months after the procedure, 95.2% (20/21) of patients evaluated by their physician had a successfully closed defect (meaning very little or no blood could pass through the defect with the device in place). At 12 months after the procedure, 100% (25/25) patients evaluated by their physician had a successfully closed defect.

## ALTERNATIVES TO THE DEVICE

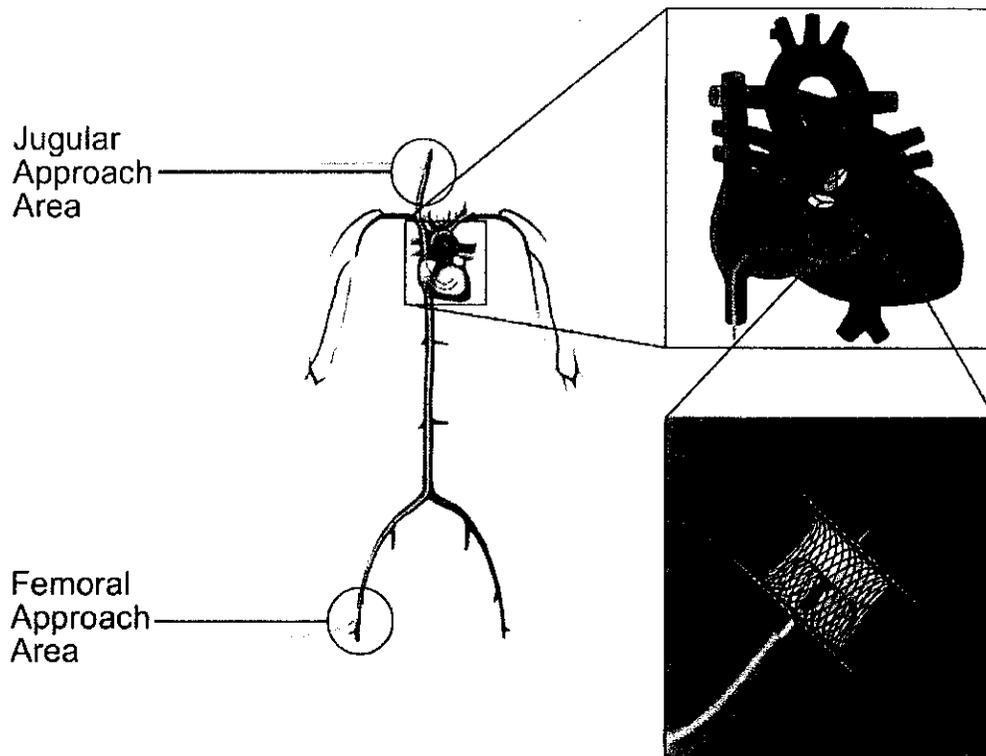
- **Surgical Closure of Muscular VSD**  
A cloth patch is sewn over the VSD to close it completely through an incision in the chest (open heart surgery). Later this patch is covered by the normal heart lining tissue and becomes a permanent part of the heart. Some defects can be sewn closed without a patch. Surgical closure is considered “standard of care” and has been done for many years.
- Treatment with a different FDA Approved Device.
- No Treatment

- **WHAT SHOULD BE EXPECTED DURING AND AFTER THE PROCEDURE?**

*What to expect during and after the procedure will vary. Read this information carefully and discuss any questions or concerns you have with your doctor.*

***What to Expect During the Procedure (Percutaneous Catheter Technique)***

1. Your procedure will be performed in the heart catheterization laboratory, or “cath lab.” You will lie on an x-ray table, and an x-ray camera will move over your chest during the procedure. The staff will monitor your heart using an Electrocardiogram (ECG). During an ECG, electrical sensing devices, called electrodes or leads, are placed on the skin over the heart and at other sites on the chest and limbs. The Electrocardiogram is painless and there is no danger of electrical shock. The ECG helps to evaluate both the heart rates – the number of beats per minute – and the flow of electrical impulses through the heart muscle.
2. Your doctor will give you an anesthetic. It may be general or local. This will depend on the technique the doctor uses to place the device. There should not be significant discomfort.
3. ***Catheter*** introduction into the groin is most common and requires a small incision to be made on the inside of your upper thigh. This incision will allow a guidewire to be inserted into your femoral vein or artery. Your doctor will then insert a ***catheter*** over the guidewire and advance it until it reaches your heart. Another option for ***catheter*** introduction is the neck (or jugular) approach. A small incision is made in your neck. *Refer to Figure 4.* The doctor will perform a procedure (***angiogram***) to visualize your heart and the VSD.



*Figure 4*  
*Access Sites*

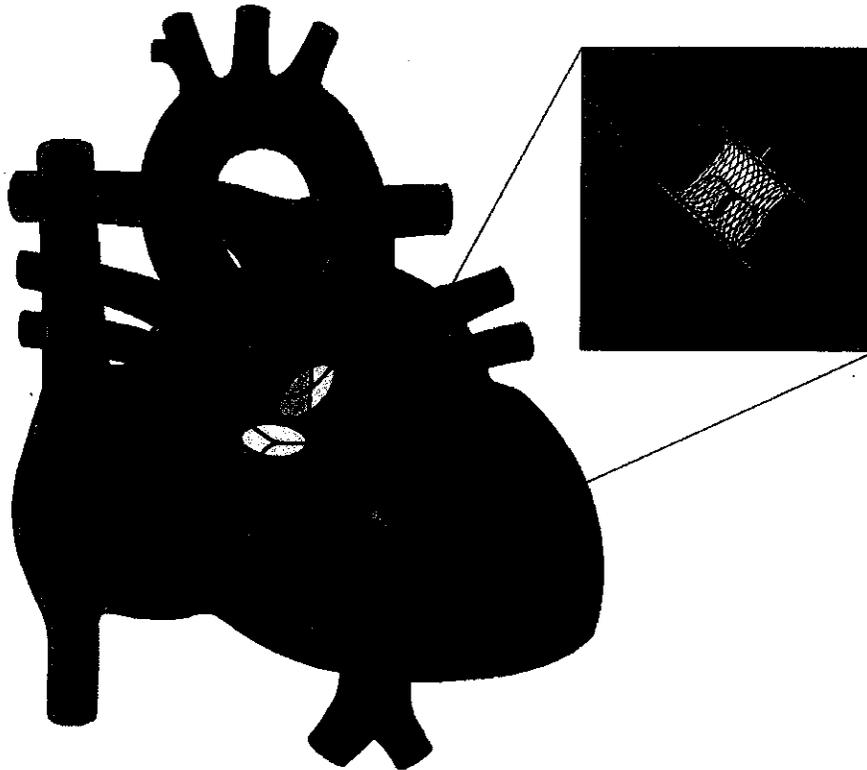
4. Your doctor will then measure the pressure and oxygen content in different chambers of your heart and measure the size of the Muscular VSD.
5. The appropriate size AMPLATZER Muscular VSD Occluder is screwed onto an AMPLATZER Delivery Cable (Figure 5).



*Figure 5*

6. The Muscular VSD Occluder and the cable is put into a special *delivery sheath* and advanced until it reaches the VSD.
7. Your doctor will then push the device out of the *delivery sheath* and implant the AMPLATZER Muscular VSD Occluder in the VSD.

8. Your doctor will carefully study the device's position in your heart. When your doctor is satisfied with the device position, the device is released by unscrewing the cable that was used to slide it through the *delivery sheath*. The AMPLATZER Muscular VSD Occluder is now implanted in your heart (Figure 6).



*Figure 6*  
*Diagram of the heart with the device in place*

9. The *delivery sheath* is removed and the procedure is completed.

***What to Expect after the Procedure)***

After the procedure, you will be observed by the nursing staff. Your blood pressure will be checked frequently, and you may be attached to an ECG monitor so that your heart can be monitored continuously. While you are in bed, a nurse will check the site where the *catheter* was inserted as well as the pulses in your feet and arms.

If the femoral approach (groin area) was used for the procedure, you can expect to stay in bed for several hours. While the introducer sheath is in place, and for several hours after its removal, you will lie flat on your back in bed, keeping your leg with the sheath straight and still.

The procedure should take about 2-4 hours.

After recovery from anesthesia and bed rest, you should be able to sit up and walk about. You will be able to go home that day or stay overnight in the hospital. Before you leave the hospital, a chest x-ray and/or *echocardiogram* will be performed to make sure the device is still positioned properly.

Because the procedure is less invasive than open-heart surgery, your recovery should be easier. You may have an adhesive bandage on the *catheter* insertion site (groin or neck).

Before you leave the hospital, your doctor will give you guidelines for activities and medications.

Antibiotics will be required for *endocarditis prophylaxis* for certain medical procedures. Ask your doctor which procedures require you to take antibiotics.

#### ***Follow-up visits with your Doctor***

It is important to keep all follow-up appointments that are scheduled for you. You will have to return to your doctor for periodic follow-up visits.

#### ***When should you call a Doctor?***

If you experience any of the following symptoms, it is essential that you seek immediate medical attention:

- Pain, numbness, coldness or weakness in your legs or feet
- Any back, chest, abdominal, or groin pain
- Dizziness or fainting, rapid heartbeat, or sudden weakness

#### ***Patient Identification Card***

You will receive a wallet size Patient Identification Card. It is important to keep this card with you and show it to future health care practitioners to inform them that you have an AMPLATZER Muscular VSD Occluder. The Patient Identification Card also contains information to let health care practitioners know that it is safe for you to have an *MRI*.

## FREQUENTLY ASKED QUESTIONS

### ***Will I have pain from the procedure?***

You may experience some discomfort in the area where the *catheter* was inserted. These symptoms should go away within a few days to a week.

### ***Will I be able to feel the device?***

No, you will not be able to feel the device.

### ***What happens with an AMPLATZER Muscular VSD Occlusion device once it gets implanted?***

The device is designed to remain permanently implanted in your body. It will take a matter of time (usually 3-6 months) before the device will be completely covered by the normal heart lining tissue and becomes a permanent part of your heart.

### ***What activities should be avoided after my procedure? When can they resume?***

All strenuous activity should be avoided for one month after the procedure. Even though you may feel ready to resume your normal activity, you should take it easy for at least one month.

### ***What happens if I need an MRI (Magnetic Resonance Imaging)?***

Your AMPLATZER Muscular VSD Occluder device is *MRI* conditional in a 3 Tesla system. If an *MRI* is needed, the *MRI* staff should be informed about the presence of your implant. You will receive a patient identification card that you should always carry with you and show to medical personnel.

### ***If I travel, can I go through metal detectors without setting off an alarm?***

Your AMPLATZER Muscular VSD Occluder device should not set off metal detector alarms. Once again, your patient identification card should be shown to airport security if necessary.

### ***Can I have this procedure if I am pregnant?***

The risk of increased x-ray exposure must be weighed against the potential benefits of this technique. Your doctor will ensure that care will be taken to minimize the radiation exposure to the fetus and the mother.

### ***What if I am a nursing mother?***

It is unknown if the device affects breast milk. You should discuss this issue with your doctor.

## GLOSSARY OF TERMS

**Anemia** – A decrease in red blood cells as a result of blood loss or blood cell destruction.

**Angiogram** – An x-ray image of *blood vessels* or heart chambers filled with contrast media that allows your doctor to see moving pictures of your heart.

**Anti-platelet agents** – Medication that helps prevent blood clots.

**Aortic Valve** – Heart valve between the left ventricle and the aorta. It has three flaps or cusps.

**Apnea** – Temporary absence of breathing.

**Arrhythmia** – Loss of regular heart rhythm.

**Arterial pulse loss** – Decreased amount of blood flow through an artery.

**Arteries** – Blood vessels that carry oxygen-rich blood away from the heart and to other tissues throughout the body.

**Atelectasis** – Partial collapse of the lung.

**Bacterial endocarditis** – Infection Caused by bacteria that enters the bloodstream and settles in the heart lining (endocardium), a heart valve, or a blood vessel.

**Blood transfusion** – the process of transferring blood from one person to another

**Blood vessel** – The pathways through which blood travels in the body.

**Brachial plexus injury** – Injury to the nerves in the arm and lower neck that can result from positioning a patient on an x-ray table.

**Bradycardia** – A slow or unsteady heart beat.

**Cardiac arrest** – When the heart stops pumping blood.

**Cardiac catheterization** – A procedure in which *catheters* are passed through the *arteries* and *veins* of the heart. Pressures are measured and blood samples are taken through a *catheter* from within the heart and its major *blood vessels*.

**Cardiomyopathy** – A disease of the heart muscle that affects the heart's ability to pump blood.

**Catheter** – A sterile, flexible, hollow tube designed for insertion into a vessel to permit injection or withdrawal of fluids or to pass devices through.

**Cyanosis** – A bluish tint to the skin, lips, fingernails and other parts of the body due to lack of oxygen to the tissues.

**Device embolization** – When the device dislodges from the defect that it was placed in.

**Echocardiography/Echocardiogram/Echocardiographic (Echo)** – The use of ultrasound to look at the heart, valves and great vessels.

**Embolus** – A mass, such as an air bubble or blood clot, that travels in the bloodstream and gets stuck in a small *blood vessel* and blocks or decreases blood flow.

**Emesis** – vomiting or nausea

**Endocarditis** – Redness, and swelling of the lining of the heart and its valves due to infection.

**Endocarditis Prophylaxis** – Medicine taken to prevent *endocarditis*.

**Fever** – abnormally high body temperature

**Heart block** – an interruption in the normal rhythm of the heart beat.

**Heart defect** – Imperfection or malformation of the heart.

**Hematoma** – A mass of blood which is a result of a break in a *blood vessel*.

**Hypertension** – High blood pressure.

**Hypotension** – Abnormally low blood pressure.

**Imaging Probe** – A flexible, tube-like medical instrument with a camera that shows a picture on a screen of what is inside the body.

**Lungs** – Pair of breathing organs located within the chest, which remove carbon dioxide from and bring oxygen to the blood. There is a right and left lung.

**Magnetic Resonance Imaging (MRI)** – A type of test used to visualize body tissue that uses a magnetic field.

**Myocardial infarction** – Heart attack. Damage or death of myocardial (heart muscle) tissue caused by an interruption of blood flow to the area.

**Occlusion** – To occlude or block an opening.

**Percutaneous** – Passed through the skin.

**Perimembranous VSD** – Around, about or near the membranous septum

**Peripheral Embolism** – When a small clot or piece of debris passes through the peripheral system creating decreased or blocked blood flow in an artery or vein.

**Pulmonary Artery** – The artery connected to the heart's right ventricle that carries oxygen-depleted blood to the *lungs*.

**Stridor** – high pitched breathing sounds.

**Stroke** – damage to the brain due to lack of blood flow.

**Subaortic stenosis** – A narrowing of the area below the aortic valve.

**Tachycardia** - A fast heart beat.

**Thrombus** – Blood clot.

**TIA (transient ischemic attack)** – A transient (or temporary) lack of oxygen to the brain.

**Transcatheter** – Through a *catheter*.

**Valvular Regurgitation** – An abnormal backward flow of blood through a valve.

**Ventricular septal defect (VSD)** – heart defect developed before birth in which there is a hole between the two lower chambers.

**Veins** – Vessel carrying blood toward the heart.

**Venous Thrombosis** – A blood clot in a vein.

**Ventricles** – The heart's two lower chambers

