Brief Device Description
The AMPLATZER Duct Occluder is a self-expandable device made from nitinol wire mesh. A retention skirt on the aortic side provides secure positioning in the ampulla of the ductus. As the occluder is implanted, it expands outward and the wires push against the wall of the ductus. Polyester fabric is sewn into the occluder with polyester thread. The fabric induces thrombosis that closes the communication. Refer to “Complete Device Description” on page 6 for a detailed description of the device.

The AMPLATZER 180° Delivery System is composed of a delivery sheath, dilator, loader, plastic vise, and delivery cable. 180° indicates the curve of the delivery sheath.

Indications and Usage
The AMPLATZER Duct Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA).

Contraindications
• Patients weighing less than 6 kg
• Patients less than 6 months of age
• Presence of thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the defect is gained
• Active endocarditis or other infections producing bacteremia
• Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate sheath size
• Patients with pulmonary hypertension with pulmonary vascular resistance of greater than 8 Wood units or Rp/Rs of greater than 0.4

Warnings
• The device should be removed if greater than 3 mm extends into the pulmonary artery, or if more than half of the left pulmonary artery lumen is occupied by the device.
• The AMPLATZER Duct Occluder consists of a nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from a similar AMPLATZER occluder device, made of the same nitinol material as the AMPLATZER Duct Occluder, for a minimum of 60 days. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted. Some forms of nickel have also been associated with carcinogenicity (ability to cause cancer) in animal models. In humans, carcinogenicity has been demonstrated only through an inhalation route (breathing nickel in) which will not occur with this procedure.
• There is limited clinical data for patients over 40 years of age.
• The AMPLATZER Duct Occluder and 180° 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 an on-site surgeon.
• 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 Duct 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.

Precautions

Handling
The AMPLATZER Duct Occluder and 180° Delivery System are for single use only. Do not reuse or resterilize.

Sizing
Accurate defect sizing is crucial and mandatory for AMPLATZER Duct Occluder device selection. Refer to Table 4 for sizing instructions.

Post-implant
• Endocarditis prophylaxis is carried out for 6 months according to the recommendation of the American Heart Association. The decision to continue endocarditis prophylaxis beyond 6 months is at the discretion of the physician.
• Any patient who has a residual shunt will undergo an echo cardiographic evaluation of the residual shunt until complete closure of the defect has been confirmed.
• Lung perfusion scan should be completed if flow through is greater than 3 m/s, or if the Z-score is -2 for the left pulmonary artery diameter.
• MR Conditional to 3.0 Tesla
  Through nonclinical testing, the AMPLATZER device has been known 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 118µ tesla. The AMPLATZER device 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.
  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 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.
• 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 in breast milk.

Adverse Events

Clinical Summary
The AMPLATZER Duct Occluder was evaluated in a multi-center, non-randomized, pivotal study evaluating the clinical performance for PDA closure. 435 patients received 435 devices with a total device exposure of 371.9 years. Individual patient exposure to the device averaged 10.4 months (ranging from 0.0 to 28.5 months).

Deaths
There was 1 death reported 5 months post-procedure. The Data Safety Monitoring Board members reviewed this adverse event and were unable to determine if the death was device related.
Observed Adverse Events

Table 1. Observed Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event Definition</th>
<th>Number of Patients</th>
<th>95% Upper Confidence Bound</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serious Adverse Event</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>1/393 (0.3%)</td>
<td></td>
</tr>
<tr>
<td><strong>Major Adverse Events</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Embolization with percutaneous removal</td>
<td>1/393 (0.3%)</td>
<td></td>
</tr>
<tr>
<td>Thrombus on Device</td>
<td>1/393 (0.3%)</td>
<td></td>
</tr>
<tr>
<td>Partial Obstruction of Pulmonary Artery</td>
<td>1/393 (0.3%)</td>
<td></td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>1/393 (0.3%)</td>
<td></td>
</tr>
<tr>
<td><strong>Total Serious and Major Adverse Events</strong></td>
<td>5/393 (1.2%)</td>
<td>2.7%</td>
</tr>
<tr>
<td><strong>Minor Adverse Events</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematoma of the groin</td>
<td>7/393 (1.7%)</td>
<td></td>
</tr>
<tr>
<td>Other c</td>
<td>6/393 (1.5%)</td>
<td></td>
</tr>
<tr>
<td>Loss of peripheral pulse</td>
<td>4/393 (1.0%)</td>
<td></td>
</tr>
<tr>
<td>Cardiac arrhythmia requiring cardioversion or medication</td>
<td>2/393 (0.5%)</td>
<td></td>
</tr>
<tr>
<td><strong>Any Adverse Event</strong></td>
<td>23/393 (5.9%)</td>
<td>8.2%</td>
</tr>
</tbody>
</table>

a. One patient had a Major and Minor Adverse event. 23 patients had 24 adverse events.
b. Patients less than 6 months of age and less than 6 kg are not included in this analysis.
c. Air embolism, allergic reaction, blood loss/no transfusion, laryngospasm, respiratory arrest, and thrombus on device.

Definitions
Death – death during or after the procedure due to complications of the procedure.
Device embolization – embolization with transcatheter removal.
Thrombus – thrombus on the device with or without embolization.
Partial Obstruction of Pulmonary Artery – increase in the pressure gradient of greater than 10 mmHg and a lung perfusion scan with less than 30% flow to the left pulmonary artery (LPA).
Loss of peripheral pulse – transient or requiring only heparin therapy.
Cardiac arrhythmia – requiring cardioversion or medication.

Potential Adverse Events
Placement of the AMPLATZER Duct 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 that were not observed in the clinical study.

The following events might occur from either the catheterization procedure or from the device:
- Air embolus
- Allergic drug reaction
- Allergic dye reaction
- Anesthesia reactions
- Apnea
- Arrhythmia
- Bacterial endocarditis
- Bleeding
- Brachial plexus injury
- Chest pain
- Death
- Delivery system failure
- Fever
- Headache/migraine
- Hypertension/hypotension
- Myocardial infarction
- Partial obstruction of aorta
- Partial obstruction of pulmonary artery
- Perforation of vessel or myocardium
- Peripheral embolism
- Stroke/transient ischemic attack
- Thrombus
- Valvular regurgitation
- Vascular access site complications
Clinical Studies

Purpose: The purpose of the trial was to evaluate the safety and effectiveness of the AMPLATZER Duct Occluder for the nonsurgical closure of patent ductus arteriosus (PDA).

Conclusions: In selected patients, use of the AMPLATZER Duct Occluder demonstrated effective defect closure and acceptable rates of adverse events when compared to Objective Performance Criteria (OPC).

Design: The AMPLATZER Duct Occluder was evaluated in a multicenter, non-randomized, pivotal study evaluating the clinical performance for PDA closure. The OPC formulated the following specific outcome measure criteria as guidelines for safety and efficacy of the AMPLATZER Duct Occluder:

- Primary Efficacy Outcome measure (complete closure) greater than 85% at 12 months
- Clinical examination closure (absence of continuous heart murmur) greater than 95% at 12 months
- Serious and major adverse event rate of less than 6%

Attempt to treat was initiated in 441 patients. Enrolled patients had angiographic or echocardiographic evidence of patent ductus arteriosus and body weight greater than or equal to 5 kg. Exclusion criteria included:

- Pulmonary vascular resistance above 8 Wood units or a Rp/Rs greater than 0.4.
- Additional cardiac or noncardiac abnormalities that could reasonably be expected to significantly affect the patient's health adversely in the next 2 years, ie, cancer, Eisenmenger's syndrome, other serious congenital heart disease.
- Pelvic vein or inferior vena cava thrombosis.
- Sepsis (local/generalized) or any type of infection that could not be successfully treated prior to device placement.
- History of repeated pulmonary infection.
- Demonstrated intracardiac thrombi on echocardiography.
- Inability to obtain informed consent.

A total of 441 patients were enrolled in the clinical study. Of the 441 patients, 6 patients were acute procedure failures and did not receive the device, 42 patients were less than 6 kg in weight or were younger than 6 months of age. Thus 393 patients were evaluated for effectiveness and safety in the following tables. Note that significantly higher serious and major adverse event rates and 12-month composite failure rates were observed for patients less than 6 months of age. In addition, acute procedure success and pre-discharge efficacy was significantly lower for patients less than 6 kg in weight. These patients were excluded from the analysis and are contraindicated for device placement.

Demographics: Factors evaluated included age (mean 7.0 ± 12.2 years; range 0.5–70.7) gender (68% female; 32% male) and weight (mean 21.9 ± 22.3 kilograms; range 6.1–164.5) and presence of continuous murmur (94.4%).

Methods: Patients with clinical symptoms of patent ductus arteriosus who were being evaluated for PDA closure underwent physical examination, an electrocardiogram, a chest x-ray, and an echocardiogram to assess the presence of ductus and to assess left pulmonary artery stenosis.

Device placement was attempted in 441 patients. The patients underwent baseline evaluations and pre-closure angiographic measurements. 435 patients received devices. No patient had 2 devices implanted.

The patients were instructed to avoid strenuous activity for a period of 1 month. Endocarditis prophylaxis was carried out for 6 months according to the recommendation of the American Heart Association. Additionally, patients were examined and a transthoracic echocardiogram (TTE) was conducted at 24 hours, 6 months, and 1 year.

Results: A total of 390/393 (99.2%) of patients were successfully implanted with the AMPLATZER Duct Occluder. There were 5/393 (1.3%) patients with serious and major adverse events reported, and 19/393 (4.8%) patients experiencing a minor adverse event. Overall, 23/393 (5.9%) of enrolled patients experienced an adverse event. Complete closure of the ductus was 98.4% at the 6-month interval and 98.6% at the 12-month interval. The composite success rate at 12 months was 96.7%. Refer to Table 2 for all Principal Safety and Efficacy Results.

Table 2. Principal Effectiveness and Safety Results

<table>
<thead>
<tr>
<th>Principal Efficacy</th>
<th>Patient</th>
<th>Percent</th>
<th>95% Lower Confidence Bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Procedure Success</td>
<td>390/393</td>
<td>99.2%</td>
<td>98.0%</td>
</tr>
<tr>
<td>Acute Efficacy</td>
<td>308/393</td>
<td>78.4%</td>
<td>74.7%</td>
</tr>
<tr>
<td>Pre-discharge Efficacy</td>
<td>354/392</td>
<td>90.3%</td>
<td>87.5%</td>
</tr>
<tr>
<td>6-month Efficacy</td>
<td>312/317</td>
<td>98.4%</td>
<td>96.7%</td>
</tr>
<tr>
<td>12-month Efficacy</td>
<td>205/208</td>
<td>98.6%</td>
<td>96.3%</td>
</tr>
<tr>
<td>Heart Murmur Success</td>
<td>201/201</td>
<td>100.0%</td>
<td>98.5%</td>
</tr>
<tr>
<td>Composite Success</td>
<td>205/212</td>
<td>96.7%</td>
<td>93.9%</td>
</tr>
<tr>
<td>Extended Efficacy</td>
<td>265/268</td>
<td>98.9%</td>
<td>97.1%</td>
</tr>
</tbody>
</table>
Table 2. Principal Effectiveness and Safety Results

<table>
<thead>
<tr>
<th></th>
<th>Carry Forward Efficacy</th>
<th>Principal Safety (Adverse Events)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>383/390</td>
<td>383/390</td>
</tr>
<tr>
<td></td>
<td>98.2%</td>
<td>0.3%</td>
</tr>
<tr>
<td></td>
<td>96.7%</td>
<td>1.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.9%</td>
</tr>
</tbody>
</table>

**Principal Safety (Adverse Events)**

- **Serious**
  - 1/393 (0.3%)
  - 1.2%
- **Major**
  - 4/393 (1.0%)
- **Total Serious and Major**
  - 5/393 (1.3%)
- **Minor**
  - 19/393 (4.8%)
- **Any Adverse Event**
  - 23/393 (5.9%)

**Carry Forward Efficacy**

- 383/390 (98.2%)
- 96.7%

**Principal Safety (Adverse Events)**

- **Serious**
  - 1/393 (0.3%)
  - 1.2%
- **Major**
  - 4/393 (1.0%)
- **Total Serious and Major**
  - 5/393 (1.3%)
- **Minor**
  - 19/393 (4.8%)
- **Any Adverse Event**
  - 23/393 (5.9%)

a. One patient had a Major and Minor Adverse event. 23 patients had 24 adverse events.
b. Definitions for Adverse events can be found in Table 1.
c. Patients less than 6 months of age, and less than 6 kg are not included in this analysis.

**Acute Procedure Success** – Of the number of patients where the device was attempted, those who successfully received a device.

**Acute Efficacy** – Of the number of patients where the device was attempted, those who had complete closure of the ductus at procedure.

**Pre-discharge Efficacy** – Complete closure of the ductus at pre-discharge in the attempted patients.

**6-month Efficacy** – Complete closure of the ductus at the 6-month visit in the attempted patients.

**12-month Efficacy** – Complete closure of the ductus as measured by echocardiography at the 12-month visit.

**Heart Murmur Success** – Clinical closure of the PDA as measured by absence of continuous heart murmur at the 12-month visit.

**Composite Success** – Device attempt with successful placement without a serious or major adverse event, surgical reintervention, embolization, or residual shunt at the 12-month visit.

**Extended Efficacy** – Complete closure of the ductus at the 12-month-or-longer visit in the attempted patients.

**Carry Forward Efficacy** – Complete closure of the ductus at the last visit.

**Summary of Post-approval Study Data**

A post-approval study was conducted to evaluate long-term safety and efficacy issues that may not have been adequately addressed during the pivotal study clinical investigation. Of the study population that received the device, a total of 152 patients were followed for a minimum of 5 years from the time of implant. Of these 152 patients seen for a long-term visit, 128 had echocardiographic evaluation of the ductus, which demonstrated complete closure of the ductus arteriosus.

The following adverse events were reported during the long-term follow-up period:

### Table 3. Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic gradient</td>
<td>1</td>
</tr>
<tr>
<td>Aortic stenosis with chest pain</td>
<td>1</td>
</tr>
<tr>
<td>Atrial arrhythmia</td>
<td>1</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>1</td>
</tr>
<tr>
<td>Death due to gastric cancer</td>
<td>1</td>
</tr>
<tr>
<td>Diabetic ketoacidosis</td>
<td>1</td>
</tr>
<tr>
<td>Mitral valve regurgitation/insufficiency</td>
<td>1</td>
</tr>
<tr>
<td>Musculoskeletal chest pain</td>
<td>1</td>
</tr>
<tr>
<td>Stenosis/pulmonary artery gradient</td>
<td>2</td>
</tr>
</tbody>
</table>

**Patient Information**

How Supplied
The AMPLATZER Duct Occluder is packaged separately from the AMPLATZER Delivery System. Refer to Table 4 for recommended delivery sheath sizes.

Directions for Use

Storage Conditions
• Store in a dry place.

Complete Device Description
AMPLATZER Duct Occluder
The AMPLATZER Duct Occluder is a self-expandable device made from nitinol wire mesh. A retention skirt on the aortic side provides secure positioning in the ampulla of the ductus. As the occluder is implanted, it expands outward and the wires push against the wall of the ductus. Polyester fabric is sewn into the occluder with polyester thread. The fabric induces thrombosis that closes the communication.

Table 4. Device Specifications/Recommended Sheath Sizes

<table>
<thead>
<tr>
<th>Device Order Number</th>
<th>A(^a) Device Diameter at Descending Aorta (mm)</th>
<th>B(^a) Device Diameter at Pulmonary Artery (mm)</th>
<th>C(^a) Retention Skirt Diameter (mm)</th>
<th>D(^a) Length (mm)</th>
<th>Recommended Sheath Size (French)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-PDA-003</td>
<td>5</td>
<td>4</td>
<td>9</td>
<td>5</td>
<td>5–6</td>
</tr>
<tr>
<td>9-PDA-004</td>
<td>6</td>
<td>4</td>
<td>10</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>9-PDA-005</td>
<td>8</td>
<td>6</td>
<td>12</td>
<td>7</td>
<td>6–7</td>
</tr>
<tr>
<td>9-PDA-006</td>
<td>10</td>
<td>8</td>
<td>16</td>
<td>8</td>
<td>6–7</td>
</tr>
<tr>
<td>9-PDA-007</td>
<td>12</td>
<td>10</td>
<td>18</td>
<td>8</td>
<td>7</td>
</tr>
</tbody>
</table>

a. See Figure 1a.

AMPLATZER 180° Delivery System (refer to Figure 1b)
The AMPLATZER 180° Delivery System includes:
• Delivery Sheath with Tuohy-Borst Adapter – used to deliver the device. 180° indicates the curve of the delivery sheath
• Dilator – used to ease penetration of the tissue
• Loader – used to introduce the AMPLATZER Duct Occluder into the delivery sheath
• Plastic Vise – facilitates direction control and serves as the “handle” for disconnecting (unscrewing) the delivery cable from the device
• Delivery cable – the device is screwed onto the distal tip of the delivery cable, which allows for placement (and if necessary, retrieval) of the device

Directions for Use
1. Perform a right-heart catheterization in routine fashion. There are 2 options for angiographic demonstration of the patent ductus arteriosus. The first is to introduce an exchange guidewire through the ductus and pass a pigtail catheter with side holes in the communication. Perform a biplane angiogram to opacify the PDA (refer to Figure 2). The second option is to pass a pigtail catheter into the proximal descending aorta via the femoral artery and perform the biplane angiogram to opacify the PDA (refer to Figure 3).

Note: Angiographic appearance of the patent ductus arteriosus are classified according to the categories described by Krichenko et al. Refer to Figure 4.

2. Select an AMPLATZER Duct Occluder based on the smallest diameter measured in the PDA (refer to the “B” measurement in Figure 5). It is recommended to select a device so that the smaller end of the device is at least 2 mm larger than the narrowest portion of the PDA. The device size is a 2-digit number. For example in the 8/6 device, the 8 refers to the diameter inside the retention skirt of the device, and the 6 refers to the opposite smaller end of the device. If the “B” measurement in the ductus is 4 mm, select the AMPLATZER Duct Occluder with the smaller end of at least 6 mm. Therefore, the 8/6 device would be selected.

3. Introduce an exchange J-tipped guidewire. Remove the catheter. Advance the introducing sheath with dilator over the exchange guidewire into the aorta and position the sheath in the descending aorta while removing the dilator (refer to Figure 6). Position can be confirmed by a test injection of contrast medium. Remove the guidewire.

4. Pass the delivery cable through the loader and screw the AMPLATZER Duct Occluder clockwise onto the tip of the delivery cable (refer to Figure 7).

5. Immerse the device and the loader in sterile saline solution and pull the AMPLATZER Duct Occluder into the loader.

6. Introduce the loader into the delivery sheath and without rotation, advance the device into the descending aorta (refer to Figure 8).

7. Deploy the retention skirt only and pull firmly against the orifice of the patent ductus arteriosus. This can be observed by fluoroscopy, or it can be clearly felt as a tugging sensation in synchrony with the aortic pulsation. The position of the device is confirmed with repeated angiograms in the aorta using the pigtail catheter. The device can be adjusted until the retention skirt is well seated in the ampulla. Retract the delivery sheath and deploy the device securely in the patent ductus arteriosus while applying slight tension (refer to Figure 9).

8. Perform an aortogram to verify correct position of the device. Perform and record on cine a power injection through the catheter using 1 cc per kg of contrast at 12 ml per second at 400 psi. To have optimal visualization of the anatomy, angulate the AP camera at 35° LAO and 35° cranial, and the lateral camera straight. These views will allow you to delineate the length of the device protruding into the pulmonary artery lumen.

WARNING: Remove the device if greater than 3 mm extends into the pulmonary artery, or if more than half of the left pulmonary artery lumen is occupied by the device. In questionable cases, perform transthoracic echocardiography before release of the device with Doppler measurement of left pulmonary artery flow velocity. The device should be removed if left pulmonary artery flow is greater than 3.0 m/s (or greater than 75% greater than the LPA velocity before cardiac catheterization).

9. If position is not satisfactory, recapture the device into the sheath by pulling back on the delivery cable while advancing the sheath.

Note: Do not release the device from the delivery cable if the device does not conform to its original configuration or if device position is unstable. Recapture the device and redeploy. If still unsatisfactory, recapture the device and replace with a new device.

10. Screw the plastic vise on the delivery cable and detach the device by rotating the cable counterclockwise as indicated by the arrow on the vise (refer to Figure 10). Repeat the aortogram.

Post-procedure Instructions
- Temporary patient ID card – Go to www.amplatzer.com/tempIDcard to print the temporary patient identification card. Complete this card and give it to the patient.
- Registration form – An implant registration form is located in each device box. Complete the patient information section and send the form to AGA Medical Corporation.

Disposal
- Dispose of all packaging materials as appropriate.
- Dispose of delivery systems and accessories per standard solid biohazard waste procedures.

Warranty
AGA Medical Corporation warrants to buyer that, for a period equal to the validated shelf life of the product, this product shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. AGA Medical Corporation's obligation under this warranty is limited to replacing or repairing at its option, at its factory, this product if returned within the warranty period to AGA Medical Corporation and after confirmed to be defective by the manufacturer.

EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY, AGA MEDICAL CORPORATION DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

See the Terms and Conditions of Sale for further information.

Symbol Definitions
The following symbols may appear on the device packaging.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td>EC REP</td>
<td>EU authorized representative</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>REF</td>
<td>Reference number</td>
</tr>
<tr>
<td>SN</td>
<td>Product serial number</td>
</tr>
<tr>
<td>LOT</td>
<td>Product lot number</td>
</tr>
</tbody>
</table>
| 🥈    | Use-by date
(Use on or before the last day of the expiration month noted on the product packaging.)
| 🚫    | Do not reuse                |
| STERILE EO | Sterilized using ethylene oxide |
| 📖    | Consult operating instructions |
| ⛈     | Keep dry                    |
| 🚫    | Do not use if package is damaged |
| ⚠️    | MR Conditional              |
| 🧾    | Does not contain natural rubber latex components |
| 🔧    | Inner diameter              |
| 🔧    | Outer diameter              |
| ↔     | Length                      |
| ←     | Usable length               |
| 🪓    | Recommended delivery sheath/catheter dimensions |
| 📢    | Indication of conformity with the essential health and safety requirements set out in European Directives |
| 📰 Only | Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner). |