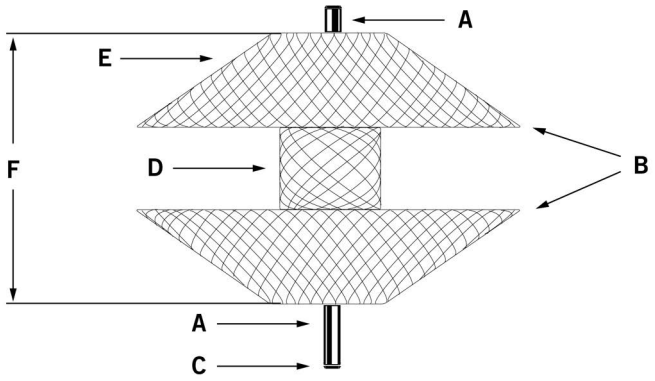
Amplatzer™ Duct Occluder II

Instructions for Use

Device Description

The Amplatzer™ Duct Occluder II is a self-expanding nitinol mesh device for the occlusion of the patent ductus arteriosus. The device configuration is a central waist with two retention discs. The central waist is designed to fill the defect and the two retention discs are designed to be deployed on the arterial and venous sides of the defect. Devices are available in two lengths for the occlusion of various length patent ductus arteriosus; see Table 2 for sizing recommendations. The Amplatzer™ Duct Occluder II has a screw attachment for a delivery wire and radiopaque markers (Figure 1).

The Amplatzer™ Duct Occluder II is available in the sizes referenced in Table 1.



A. Radiopaque Markers
B. Retention Discs
C. Screw Attachments
D. Central Waist
E. Nitinol Mesh
F. Nominal Length (see Table 1)

Figure 1. The Amplatzer™ Duct Occluder II

STERILE EO

℞ ONLY

LATEX Does not contain natural rubber latex components

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Abbott

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Table 1. Amplatzer™ Duct Occluder II and delivery system sizes

Order Number	Waist diameter [mm (in)]	Disc diameter [mm (in)]	Nominal length [mm (in)]	TorqVue™ LP (minimum ID)
9-PDA2-03-04	3 (0.12)	9 (0.35)	4.25 (0.17)	4 Fr (0.046 in)
9-PDA2-04-04	4 (0.16)	10 (0.39)	4.25 (0.17)	4 Fr (0.046 in)
9-PDA2-05-04	5 (0.20)	11 (0.43)	4.25 (0.17)	5 Fr (0.059 in)
9-PDA2-06-04	6 (0.24)	12 (0.47)	4.25 (0.17)	5 Fr (0.059 in)
9-PDA2-03-06	3 (0.12)	9 (0.35)	6.25 (0.25)	4 Fr (0.046 in)
9-PDA2-04-06	4 (0.16)	10 (0.39)	6.25 (0.25)	4 Fr (0.046 in)
9-PDA2-05-06	5 (0.20)	11 (0.43)	6.25 (0.25)	5 Fr (0.059 in)
9-PDA2-06-06	6 (0.24)	12 (0.47)	6.25 (0.25)	5 Fr (0.059 in)

Table 2. Amplatzer™ Duct Occluder II sizing chart

		Measured Ductus Length				
		< 5 mm	5-8 mm	8.1-10 mm	10.1-11 mm	11.1-12 mm
Measured Ductus Diameter	< 2.5 mm	9-PDA2-03-04	9-PDA2-03-06	9-PDA2-04-06	9-PDA2-05-06	9-PDA2-06-06
	2.5-3.5 mm	9-PDA2-04-04	9-PDA2-04-06	9-PDA2-05-06	9-PDA2-06-06	9-PDA2-06-06
	3.6-4.5 mm	9-PDA2-05-04	9-PDA2-05-06	9-PDA2-05-06	9-PDA2-06-06	9-PDA2-06-06
	4.6-5.5 mm	9-PDA2-06-04	9-PDA2-06-06	9-PDA2-06-06	9-PDA2-06-06	9-PDA2-06-06

Intended use

The Amplatzer™ Duct Occluder II is a percutaneous transcatheter occlusion device intended for the non-surgical closure of patent ductus arteriosus.

Contraindications

The Amplatzer™ Duct Occluder II is contraindicated for the following:

- Patients weighing less than 6 kg
- Patients less than 6 months of age
- Patients with a window-type patent ductus arteriosus (for example, length less than 3 mm)
- Patients with an active infection
- Patients with thrombus at the intended site of implant
- Patients with pulmonary hypertension with pulmonary vascular resistance of greater than 8 Wood units or Rp/Rs of greater than 0.4
- Patients with patent ductus arteriosus greater than 12 mm in length by angiography
- Patients with patent ductus arteriosus greater than 5.5 mm in diameter by angiography

Warnings

- Patients at greater risk of complications can include:
  - Patients with a descending aorta < 10 mm in diameter
  - Patients with cardiac anomalies requiring surgical or interventional correction
  - Patients with have had more than 2 lower respiratory infections within the last year
- Do not release the occluder from the delivery wire if the occluder does not conform to its original configuration or if the occluder position is unstable. Recapture the occluder and redeploy. If still unsatisfactory, recapture the occluder and replace with a new occluder.
- The Amplatzer™ Duct Occluder II should only be used by physicians trained in transcatheter defect closure techniques.
- Physicians must have an on-site surgeon available in the event that surgical removal of an occluder is required.
- Embolized occluders must be removed. Embolized occluders should not be withdrawn through intracardiac structures unless they have been adequately collapsed within a catheter.
- This device has not been studied in patients older than 18 years of age.

Precautions

- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or re-sterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Use before the expiration date noted on the product packaging.
- Patients should have an activated clotting time (ACT) of greater than 200 sec prior to device replacement.
- The Amplatzer™ Duct Occluder II contains nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device 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 seek medical assistance immediately if they suspect they are experiencing an allergic reaction. Symptoms may include difficulty in breathing or swelling of the face or throat. While data are currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.
- 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.
- Store in a dry place.
- Do not use if the packaging sterile barrier is opened or damaged.
- Do not use contrast power injection with delivery catheter.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this device.

MRI Safety Information

	A patient with the Amplatzer™ Duct Occluder II may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Device Name	Amplatzer™ Duct Occluder II
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Maximum Field Spatial Gradient	19T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	2.0W/kg (Normal Operating Mode)
Maximum Head SAR	N/A
Scan Duration	2.0W/kg whole-body-averaged SAR for 15 minutes of continuous scanning
MR Image Artifact	The presence of this implant may produce an image artifact.

Potential adverse events

Potential adverse events that may occur during or after a procedure using this device may include, but are not limited to:

- Air embolus
- Allergic dye reaction
- Allergic drug reaction
- Anesthesia reactions
- Apnea
- Arrhythmia
- Bacterial endocarditis
- Bleeding
- Cardiac perforation
- Cardiac tamponade
- Chest pain
- Device embolization
- Device erosion
- Death
- Fever
- Headache/migraine
- Hypertension
- Hypotension
- Myocardial infarction
- Palpitations
- Pericardial effusion
- Pericarditis
- Peripheral embolism
- Pleural effusion
- Pulmonary embolism
- Reintervention for device removal
- Stroke
- Transient ischemic attack
- Thrombus
- Valvular regurgitation
- Vascular access site injury
- Vessel perforation

Clinical Study

Clinical Summary

The Amplatzer™ Duct Occluder II study was a single-arm, open-label, multicenter study that was conducted to evaluate the safety and efficacy of the Amplatzer™ Duct Occluder II device. A total of 192 subjects from 6 months to less than 18 years of age were enrolled in the Amplatzer™ Duct Occluder II study from August 28, 2008 through April 5, 2011 at 25 US investigational sites. A total of 178 subjects received the investigational device with a technical success rate of 92.7%.

Methods

The Amplatzer™ Duct Occluder II study was a single-arm study. It was intended that all subjects receive the study device. The comparator was a pair of performance goals based on a similar subject population from the original Amplatzer™ Duct Occluder clinical study. The performance goals established for the Amplatzer™ Duct Occluder II study were based on results of a subgroup of the Amplatzer™ Duct Occluder subjects that would have met enrollment criteria for the Amplatzer™ Duct Occluder II study. The primary safety endpoint was the rate of device- and/or procedure-related SAEs reported within 180 days of the implant compared to a performance goal of 5.34%. The primary efficacy endpoint was the rate of complete closure of the PDA (as assessed by a composite endpoint of an absence of residual flow and continuous murmur at 6-month follow-up) compared to a performance goal of 94.60%. Follow-up assessment of implanted subjects was conducted post procedure, 30 days, 6 months, 12 months, and annually through 5 years post procedure. Subjects who were enrolled but did not have a successful device placement were followed for safety only through the 6-month visit. Follow-up testing for these subjects was not required unless it was medically necessary to evaluate an adverse event.

Patients Studied

Patients considered for inclusion in this study were screened to ensure they had a PDA that was 5.5 mm or smaller in diameter and 3 to 12 mm in length. Patients were excluded if they were younger than 6 months, 18 years or older, or had a descending aorta less than 10 mm in diameter. Patients were also excluded if comorbidities or anatomical considerations made them a poor candidate for the Amplatzer™ Duct Occluder II device or would interfere with the evaluation of the primary endpoints of the study.

Subjects were eligible to participate in the Amplatzer™ Duct Occluder II clinical study if all eligibility criteria were met. Exclusion criteria, also listed in the contraindication, warning, or precaution section, included:

- Subject must not be <6 kg for the procedure
- Subject must not be < 6 months or ≥18 years of age
- Subject must not have a descending aorta <10 mm in diameter
- Subject must not have a right to left shunt through the PDA
- Subject must not have PVR above 8 Woods units or a Rp/Rs >0.4
- Subject must not have intracardiac thrombus
- Subject must not have additional cardiac anomalies requiring surgical or interventional correction
- Subject must not have history of more than 2 lower respiratory infections within the last year (such as pneumonia)
- Subject must not have active infection requiring treatment at the time of implant
- Subject must not have contraindication to anticoagulation treatment
- Female subjects of childbearing age must not be pregnant or desire to become pregnant within 6 months post implant. (If a subject desires to become pregnant after 6 months post implant, further restriction is at the discretion of their physician.)

Table 3. Demographics and baseline characteristics

Demographic	Results N=192
Age, years[1,2]	4.4 (4.2) [0.5, 18.0]
Sex, female	120 (62.5%)
Height (cm)	99.73 (28.92) [60, 182]
Weight (kg)	19.35 (15.88) [6.35, 112]

Continuous variables are reported as mean (SD), [min, max] and categorical variables as n (%).

[1] Subject did not meet the eligibility criteria for age. A protocol deviation is on file.

[2] Subject was 17.95 years old at the time of implant but shows up as 18.0 due to rounding.

Table 4. Primary endpoint results – Primary analysis populations

Endpoint	Performance goal	% (n/N) [95% CI]	*P* value
Primary safety[1]	5.34%	1.60% (3/188) [0.33 - 4.59]	0.0113
Primary efficacy[2]	94.60%	98.19% (163/166) [94.81 - 99.63]	0.0201

[1]The primary safety endpoint is the rate of device- and/or procedure-related SAEs reported through 180 days post procedure in subjects in whom device placement was attempted.

[2]The primary efficacy endpoint is the rate of complete closure of the PDA as evidenced by the absence of residual flow by TTE and absence of continuous murmur by physical examination at the 6-month follow-up.

Table 5. Device- or procedure-related SAEs Through 180 days

SAE event[3]	Device-related	Procedure-related	Days to event
Residual shunt requiring closure	Probably/likely related	Possibly related	30
Device embolization	Probably/likely related	Unlikely/not related	0
Sinus tachycardia	Unlikely/not related	Probably/likely related	0

[3]SAEs that contributed to the Primary Safety Endpoint in Table 4.

Table 6. Distribution of PDAs Types in the Amplatzer™ Duct Occluder II Study Population

PDA Type	Distribution N=192
A-1	93 (48.4%)
A-2	31 (16.1%)
A-3	14 (7.3%)
B-1	1 (0.5%)
B-2	1 (0.5%)
B-3	0 (0.0%)
C	4 (2.1%)
D	10 (5.2%)
E	38 (19.8%)

Technical Success

Acute technical success is defined as the proportion of subjects that left the catheterization lab with an Amplatzer™ Duct Occluder II device implanted. Of the 192 subjects enrolled, 178 (92.7%) experienced successful device placement.

Post-Approval Study

Summary of the Post-Approval Study Methods

Study Objective

A post-approval study was conducted to evaluate the long-term safety and effectiveness of the Amplatzer™ Duct Occluder II device to close the ductus arteriosus in subjects with a patent ductus arteriosus (PDA).

Study Design

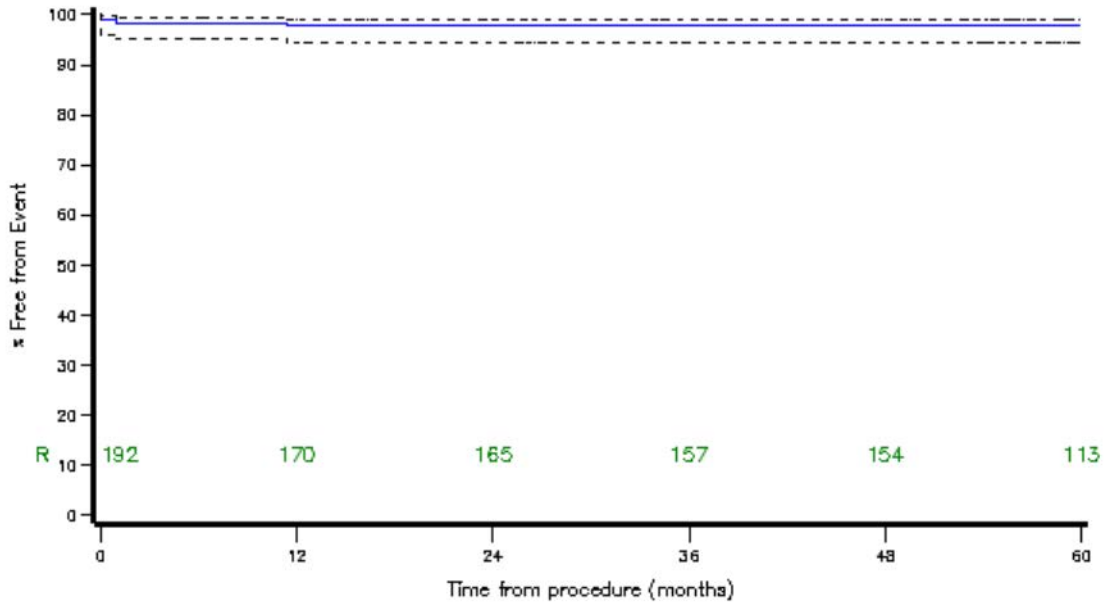
Prospective, single-arm, multi-center, non-randomized study.

Study Population

The post-approval study included continued follow-up on subjects from the ADO II IDE study in whom an ADO II device implant was attempted.

Data Source

Sponsor clinical study



Key Study Endpoints

Primary Safety Endpoint

The primary ADO II PAS safety endpoint was the rate of device- and procedure-related serious adverse events (SAE) reported from the procedure through 5 years post-procedure.

Primary Effectiveness Endpoints

The primary ADO II PAS effectiveness endpoints were the 48- and 60-month post-procedure rates of complete closure of the patent ductus arteriosus.

Study Visits and Length of Follow-up

The required length of follow-up for enrolled subjects was five years. Follow-up visits occurred at post-procedure, one month, six months, 12 months, 2 years, 3 years, 4 years, and 5 years.

Total Number of Enrolled Subjects

A total of 178 subjects implanted with a device in the IDE study were followed through 5 years. A total of 14 subjects without a successful implant were followed through 6 months.

Follow-up Rate

The follow-up visit rate was calculated by using the number of actual visits occurring at each visit interval as numerator and the number of expected visits at each visit interval as denominator. The follow-up rate was 100% (192/192) at the post-procedure visit, 98.4% (189/192) at the 1-month visit, 97.4% (187/192) at the 6-month visit, 96.1% (171/178) at the 12-month visit, 92.1% (163/177) at the 2-year visit, 85.9% (152/177) at the 3-year visit, 78.5% (139/177) at the 4-year visit, and 83.6% (148/177) at the 5-year visit.

Summary of the Post-Approval Study Results

Final Safety Findings

Figure 2 presents the freedom from device- or procedure-related serious adverse events through 5 years of follow-up. The figure shows that freedom from device- or procedure-related serious adverse events through 5 years is 97.9%.

Figure 2. Freedom from Device- or Procedure-related SAEs (Kaplan-Meier) Through 5 years

Table 7. Kaplan-Meier Estimates for Device- or Procedure-related Events Through Five Years

Start of interval (months)	0-1 Year	1-2 Year	2-3 Year	3-4 Year	4-5 Year	>5-Year
Number at risk at start of interval	192	170	165	157	154	113

Table 7. Kaplan-Meier Estimates for Device- or Procedure-related Events Through Five Years

Number of events in interval	4	0	0	0	0	0
Cumulative number of events	4	4	4	4	4	4
Number censored in interval	18	5	8	3	41	113
Cumulative number censored	18	23	31	34	75	188
% Freedom from event	100.0	97.9	97.9	97.9	97.9	97.9
Lower 95% confidence limit	100.0	94.4	94.4	94.4	94.4	94.4
Upper 95% confidence limit	100.0	99.2	99.2	99.2	99.2	99.2

As shown in Table 8, there were four (4) SAEs that were device- or procedure-related, reported through 5 years as adjudicated by an independent Clinical Events Committee.

Table 8. Details of the Device- or Procedure-related Events Through Five Years

Event	n/N (%) of Subjects	Device-related	Procedure-Related	Days to Event
Residual shunt requiring closure	2/192 (1.0%)	Probably/likely related	Possibly related	Patient 1: 30 Patient 2: 349
Device embolization	1/192 (0.5%)	Probably/likely related	Unlikely/not related	0
Sinus tachycardia	1/192 (0.5%)	Unlikely/not related	Probably/likely related	0

Final Effectiveness Findings

Subjects who had an echocardiogram with residual shunt assessed at 48- or 60-month follow-up visits are included in Table 9. The overall site-reported closure rate was 100% at the 48- or 60-month follow-up visits.

Table 9. Shunt Status over Time: Implanted Subjects

	Visit Interval	
Shunt Status	**48 Months (4 Years)**	**60 Months (5 Years)**
Closed	133/133 (100%)	145/145 (100%)
Smoke	0/133 (0%)	0/145 (0%)
Small	0/133 (0%)	0/145 (0%)
Large	0/133 (0%)	0/145 (0%)

Study Strength and Weaknesses

- Strengths—The post-approval study included long-term follow-up through 5 years.
- Weaknesses—The study did not have an active control group.

Directions for Use

Materials recommended for use with the device

- Amplatzer™ TorqVue™ LP Delivery System
- 0.035-inch guidewire

1. Perform a right heart catheterization and hemodynamic measurements. Size the diameter and length of the patent ductus arteriosus using angiography. See Figure 3 for sizing locations.

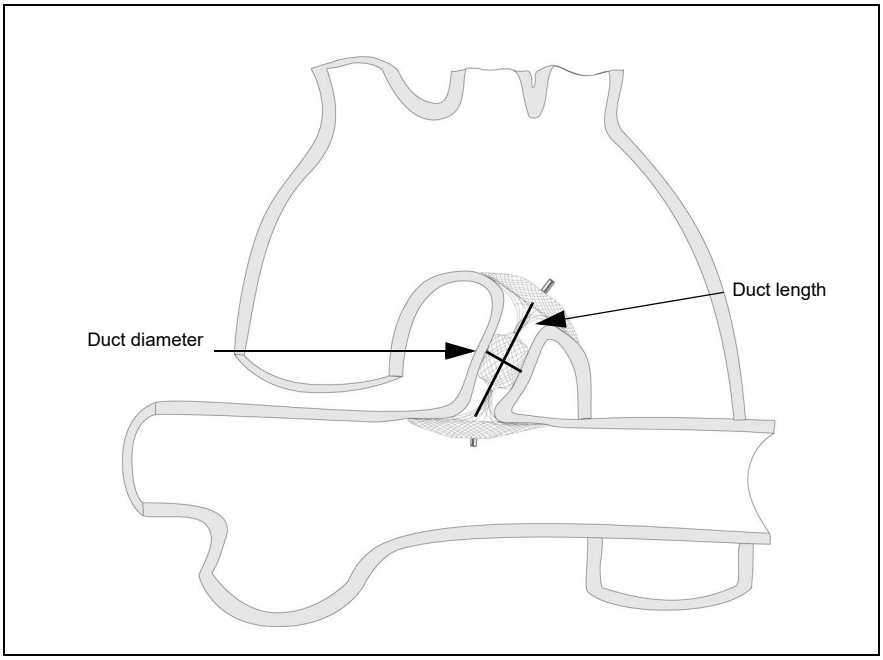


Figure 3. Amplatzer™ Occluder II Sizing Locations

2. Select appropriate occluder and delivery system according to Tables 1 and 2.
3. Attach hemostasis valve to the delivery catheter. Flush the delivery catheter. Introduce guidewire using either arterial or venous approach and cross the patent ductus arteriosus. Advance the delivery catheter over the guidewire and cross the patent ductus arteriosus.
4. Confirm delivery catheter position by a test injection of contrast medium.
5. Pass the delivery wire through the loader and attach the occluder by rotating clockwise until secure on the tip of the delivery wire. To ensure proper occluder release, rotate occluder counter-clockwise 1/8 of a turn.
6. Immerse the occluder and the loader in saline solution and pull the occluder into the loader.
7. Slowly remove the guidewire from the delivery catheter. Allow back bleeding to purge all air from the system.
8. Introduce the loader through the hemostasis valve, into the delivery catheter until the loader no longer advances. Hold the loader in place while transferring the occluder into the delivery catheter.
9. Push the occluder to the distal tip of the delivery catheter. Do not rotate the delivery wire. Remove the loader.
10. Deploy the distal disc and slowly retract the system until distal disc conforms to vessel wall. Confirm distal disc placement with fluoroscopy.
11. While maintaining tension on the delivery wire, deploy the waist and proximal disc by carefully retracting the delivery catheter.
12. Perform test injection to verify position of the occluder.
13. If occluder position and disc conformance to vessel walls is unsatisfactory:
    - Stabilize the delivery wire and re-advance the delivery catheter until the occluder is completely within the catheter.
    - Reposition and deploy, or remove the occluder from the patient.
14. If the occluder position and disc conformance to vessel walls is satisfactory:
    - Attach the wire vise to the delivery wire, and release the occluder by rotating the delivery wire counter-clockwise until it separates from the occluder.
    - Retract delivery wire into delivery catheter.
    - Remove the delivery wire and delivery catheter from the patient.
15. Repeat angiogram with hemodynamic measurements including direct “pull back” from left pulmonary artery to main pulmonary artery and ascending aorta to descending aorta to evaluate for obstruction.
16. Perform an aortogram to evaluate occlusion of the ductus arteriosis and verify correct position of the occluder.

Post-procedure Instructions

- Instruct the patient when to seek medical attention.
- Temporary patient ID card – A temporary patient ID card is included in the product packaging. 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 Abbott Medical.

Disposal

- The carton and IFU are recyclable. Dispose of all packaging materials as appropriate.
- Devices may be returned to Abbott Medical for disposal. Contact your Abbott Medical representative or returns@amplatzer.com for instructions.
- Devices may be disposed of following standard solid biohazard waste procedures.

Warranty

Abbott Medical 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. Abbott Medical'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 Abbott Medical and after confirmed to be defective by the manufacturer.

EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY, ABBOTT MEDICAL 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.

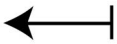
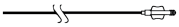
State of California (USA) Only:

⚠ **WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.**

Symbol Definitions

The following symbols may appear on the device packaging:

Symbol	Definition
	Caution, consult accompanying documents
	Manufacturer
	Manufacture date
	Reference number
	Product serial number
	Batch code
	Unique Device Identification
	Use-by date
	Do not re-use
	Sterilized using ethylene oxide
	Consult instructions for use
	Keep dry; keep away from rain
	Do not use if package is damaged
	Does not contain natural rubber latex components
	MR Conditional
	Inner diameter
	Outer diameter
	Length

Symbol	Definition
	Usable length
	Recommended delivery sheath/catheter dimensions
	Federal law restricts this device to sale by or on the order of a physician.
	Quantity
	Follow instructions for use on this website
Duct Occluder	Duct Occluder