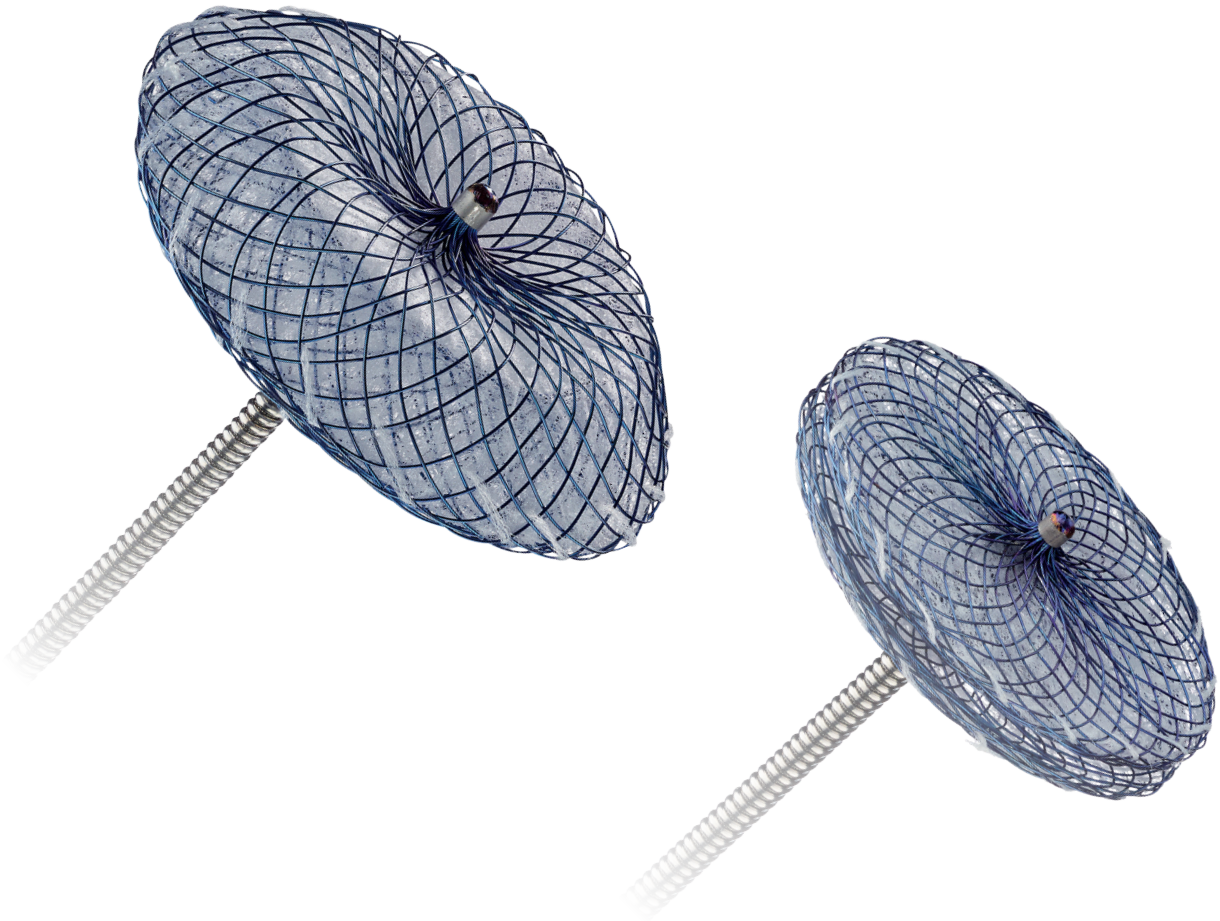
STRUCTURAL HEART THERAPY

# AMPLATZER™ SEPTAL OCCLUDERS







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THE PROVEN STANDARD

# FOR TRANSCATHETER ATRIAL SEPTAL **DEFECT CLOSURE**[1, 2]

Amplatzer™ Septal Occluders are the standard of care for minimally invasive atrial septal defect (ASD) closure. These double-disc occluders are comprised of Nitinol mesh with polyester fabric. They are designed to securely appose the septal wall on each side of the defect and create a platform for tissue in-growth after implantation.

## WHEN SIMPLICITY MATTERS

The primary treatment option for closure of secundum atrial septal defects is with transcatheter devices.[2] This is when trust and simplicity matter. The Amplatzer Septal Occluder is the proven standard of care in transcatheter ASD closure.[1, 2]

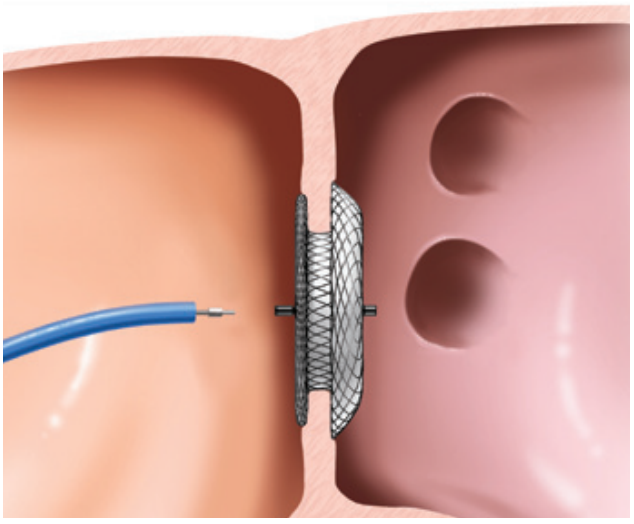
### SAFETY IN NUMBERS

**98.5% Closure Rate:** With no significant residual shunt (less than 2 mm) at 1-year follow-up[1]

**Low Major and Minor Complication Rates:** Postprocedure and long-term based on 5-year follow-up[1]

### SPECIFICALLY DESIGNED FOR ASD CLOSURE

**Wide Waist:** Centers device and fills the ASD[3]
**Shape-memory Nitinol Mesh:** Designed to securely appose both sides of the septal wall[3]
**Polyester Material:** Promotes occlusion and tissue in-growth[3]
**Precise Placement:** Device can be easily recaptured and redeployed[3]



The waist of the Amplatzer™ Septal Occluder fills the defect for optimal occlusion.

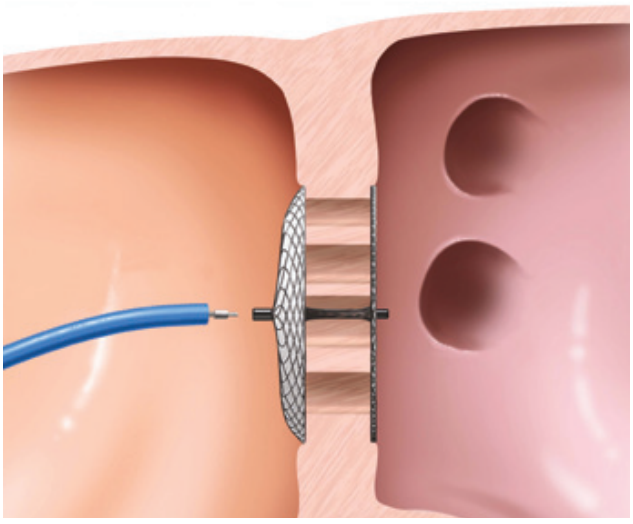
## WHEN FLEXIBILITY MATTERS

Not all septal defects are the same. They come in a variety of shapes, sizes and often there can be multiple communications between the left and right atria. These types of atrial septal defects require a special device designed with the flexibility to meet multiple needs.

The addition of the Amplatzer Mulit-Fenestrated Septal Occluder - “Cribriform” to the Amplatzer family of occluders enables transcatheter closure for the majority of atrial septal defects.

### SPECIFICALLY DESIGNED FOR MULTI-FENESTRATED ASD CLOSURE

**Narrow Waist:** Allows for placement through a central defect[3]
**Matched Disc Diameters:** Maximizes coverage of multiple fenestrations[3]
**Polyester Material:** Promotes occlusion and tissue in-growth[3]
**Precise Placement:** Device can be easily recaptured and redeployed[3]



The Amplatzer™ Cribriform Multi-Fenestrated Septal Occluder enables occlusion of the defect by covering the fenestrations with a single device.

Stocking both **Amplatzer™ Septal and Cribriform Occluders** provides you the ability to choose the appropriate device for a wide size-range of defects.

# ORDERING INFORMATION

## AMPLATZER™ SEPTAL OCCLUDER

| Model / Reorder Number | Waist Diameter (mm) | Waist Width (mm) | Right Atrial Disc Diameter (mm) | Left Atrial Disc Diameter (mm) |
|---|---|---|---|---|
| 9-ASD-004 | 4 | 3 | 12 | 16 |
| 9-ASD-005 | 5 | 3 | 13 | 17 |
| 9-ASD-006 | 6 | 3 | 14 | 18 |
| 9-ASD-007 | 7 | 3 | 15 | 19 |
| 9-ASD-008 | 8 | 3 | 16 | 20 |
| 9-ASD-009 | 9 | 3 | 17 | 21 |
| 9-ASD-010 | 10 | 3 | 18 | 22 |
| 9-ASD-011 | 11 | 4 | 21 | 25 |
| 9-ASD-012 | 12 | 4 | 22 | 26 |
| 9-ASD-013 | 13 | 4 | 23 | 27 |
| 9-ASD-014 | 14 | 4 | 24 | 28 |
| 9-ASD-015 | 15 | 4 | 25 | 29 |
| 9-ASD-016 | 16 | 4 | 26 | 30 |
| 9-ASD-017 | 17 | 4 | 27 | 31 |
| 9-ASD-018 | 18 | 4 | 28 | 32 |
| 9-ASD-019 | 19 | 4 | 29 | 33 |
| 9-ASD-020 | 20 | 4 | 30 | 34 |
| 9-ASD-022 | 22 | 4 | 32 | 36 |
| 9-ASD-024 | 24 | 4 | 34 | 38 |
| 9-ASD-026 | 26 | 4 | 36 | 40 |
| 9-ASD-028 | 28 | 4 | 38 | 42 |
| 9-ASD-030 | 30 | 4 | 40 | 44 |
| 9-ASD-032 | 32 | 4 | 42 | 46 |
| 9-ASD-034 | 34 | 4 | 44 | 50 |
| 9-ASD-036 | 36 | 4 | 46 | 52 |
| 9-ASD-038 | 38 | 4 | 48 | 54 |
| 9-ASD-040 | 40 | 4 | 50 | 56 |

## AMPLATZER™ CRIBRIFORM MULTI-FENESTRATED SEPTAL OCCLUDER

| Model / Reorder Number | Right & Left Atrium Disc Diameter (mm) | Waist Width (mm) |
|---|---|---|
| 9-ASD-MF-018 | 18 | 3 |
| 9-ASD-MF-025 | 25 | 3 |
| 9-ASD-MF-030 | 30 | 3 |
| 9-ASD-MF-035 | 35 | 3 |
| 9-ASD-MF-040 | 40 | 3 |

**REFERENCE:**


1. Amplatzer Septal Occluder Instructions for Use.
2. Kashour TS, Latroche B, Elhoury ME, et al. Successful Percutaneous Closure of a Secundum Atrial Septal Defect through Femoral Approach in a Patient with Interrupted Inferior Vena Cava. Congenital Heart Disease. 2010;5(6):620-623.
3. Test(s) performed by and data on file at Abbott.


**CAUTION:** This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**.
Always check the regulatory status of the device in your region.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.


**Abbott**
3200 Lakeside Dr, Santa Clara, CA 95054, USA
www.cardiovascular.abbott



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ST. JUDE MEDICAL

# SJM Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

**Manufacturer Address:**

AGA Medical Corporation
5050 Nathan Lane North
Plymouth, Minnesota 55442, USA

**European Representative:**

St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium

**Product Type:**

Cardiac Occluder

**Product Name(s):**

AMPLATZER Septal Occluder
AMPLATZER Multi-Fenestrated Septal Occluder - "Cribriform"
AMPLATZER PFO Occluder

**Model Number(s):**

| Product | Model Numbers | Original CE Mark Date |
|---|---|---|
| AMPLATZER Septal Occluder | 9-ASD-004, 9-ASD-005, 9-ASD-006, 9-ASD-007, 9-ASD-008, 9-ASD-009, 9-ASD-010, 9-ASD-011, 9-ASD-012, 9-ASD-013, 9-ASD-014, 9-ASD-015, 9-ASD-016, 9-ASD-017, 9-ASD-018, 9-ASD-019, 9-ASD-020, 9-ASD-022, 9-ASD-024, 9-ASD-026, 9-ASD-028, 9-ASD-030, 9-ASD-032, 9-ASD-034, 9-ASD-036, 9-ASD-038, 9-ASD-040 | 24 February 1998 |
| AMPLATZER Multi-Fenestrated Septal Occluder – "Cribriform" | 9-ASD-MF-018, 9-ASD-MF-025, 9-ASD-MF-030, 9-ASD-MF-035, 9-ASD-MF-040 | 2 September 2002 |
| AMPLATZER PFO Occluder | 9-PFO-018, 9-PFO-025, 9-PFO-030, 9-PFO-035 | 24 February 1998 |

**Signature:**

Lisa Becker
Senior Director, Regulatory Affairs

21Feb18
Issue Date

ST. JUDE MEDICAL

# SJM Declaration of Conformity

| | |
|---|---|
| **Classification:** | Class III per Annex II, Rule 8 |
| **GMDN Code(s):** | 45418 |
| **EC Design Certificate No and Expiration Date:** | Certificate No: CE 594291<br>Expiration Date: 23 February 2023 |
| **Annex II, Clause 3 Certificate No and Expiration Date:** | Certificate No: CE 590631<br>Expiration Date: 23 February 2023 |
| **Applicable Quality System Standards:** | ISO 13485 |
| **Notified Body:** | BSI<br>Kitemark Court<br>Davy Avenue<br>Knowlhill<br>Milton Keynes<br>MK5 8PP<br>UK |
| **Notified Body Number:** | 0086 |
| **AMPLATZER Septal Occluder Manufacturing Facilities:** | AGA Medical Corporation<br>5050 Nathan Lane North<br>Plymouth, Minnesota<br>55442<br>USA<br><br>St. Jude Medical, Costa Rica Ltda.<br>Edificio #44,<br>Calle 0, Avenida 2<br>Zona Franca Coyol,<br>El Coyol, Alajuela,<br>Costa Rica |
| **AMPLATZER Multi-Fenestrated Septal Occluder - "Cribriform" Manufacturing Facility:** | AGA Medical Corporation<br>5050 Nathan Lane North<br>Plymouth, Minnesota<br>55442<br>USA |
| **AMPLATZER PFO Occluder Manufacturing Facility:** | AGA Medical Corporation<br>5050 Nathan Lane North<br>Plymouth, Minnesota<br>55442<br>USA |

**Signature:**

Lisa Becker
Senior Director, Regulatory Affairs

21 Feb 18
Issue Date

By Royal Charter

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** **CE 594291**

Issued To: **AGA Medical Corporation**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

In respect of:

**AMPLATZER Septal Occluder, AMPLATZER Multifenestrated Septal Occluder - "Cribriform" and AMPLATZER PFO Occluder**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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By Royal Charter

# EC Design-Examination Certificate

**Supplementary Information to CE 594291**

Issued To:

**AGA Medical Corporation**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

**Amplatzer Septal Occluder:**

| Device Size (mm) | Model Number | Wire Diameter (mm)/Number of Wires | Distal Disc Diameter (mm) | Proximal Disc Diameter (mm) | Waist Diameter | Waist Length |
|---|---|---|---|---|---|---|
| 4 | 9-ASD-004 | .004/72 | 16 | 12 | 4 | 3 |
| 5 | 9-ASD-005 | .004/72 | 17 | 13 | 5 | 3 |
| 6 | 9-ASD-006 | .004/72 | 18 | 14 | 6 | 3 |
| 7 | 9-ASD-007 | .004/72 | 19 | 15 | 7 | 3 |
| 8 | 9-ASD-008 | .004/72 | 20 | 16 | 8 | 3 |
| 9 | 9-ASD-009 | .004/72 | 21 | 17 | 9 | 3 |
| 10 | 9-ASD-010 | .004/72 | 22 | 18 | 10 | 3 |
| 11 | 9-ASD-011 | .005/72 | 25 | 21 | 11 | 4 |
| 12 | 9-ASD-012 | .005/72 | 26 | 22 | 12 | 4 |
| 13 | 9-ASD-013 | .005/72 | 27 | 23 | 13 | 4 |
| 14 | 9-ASD-014 | .005/72 | 28 | 24 | 14 | 4 |
| 15 | 9-ASD-015 | .005/72 | 29 | 25 | 15 | 4 |
| 16 | 9-ASD-016 | .005/72 | 30 | 26 | 16 | 4 |

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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**Minnesota**
**55442**
**USA**

| Device Size (mm) | Model Number | Wire Diameter (mm)/Number of Wires | Distal Disc Diameter (mm) | Proximal Disc Diameter (mm) | Waist Diameter | Waist Length |
|---|---|---|---|---|---|---|
| 17 | 9-ASD-017 | .005/72 | 31 | 27 | 17 | 4 |
| 18 | 9-ASD-018 | .006/72 | 32 | 28 | 18 | 4 |
| 19 | 9-ASD-019 | .006/72 | 33 | 29 | 19 | 4 |
| 20 | 9-ASD-020 | .006/72 | 34 | 30 | 20 | 4 |
| 22 | 9-ASD-022 | .006/72 | 36 | 32 | 22 | 4 |
| 24 | 9-ASD-024 | .006/72 | 38 | 34 | 24 | 4 |
| 26 | 9-ASD-026 | .007/72 | 40 | 36 | 26 | 4 |
| 28 | 9-ASD-028 | .007/72 | 42 | 38 | 28 | 4 |
| 30 | 9-ASD-030 | .007/72 | 44 | 40 | 30 | 4 |
| 32 | 9-ASD-032 | .007/72 | 46 | 42 | 32 | 4 |
| 34 | 9-ASD-034 | .008/72 | 50 | 44 | 34 | 4 |
| 36 | 9-ASD-036 | .008/72 | 52 | 46 | 36 | 4 |
| 38 | 9-ASD-038 | .008/72 | 54 | 48 | 38 | 4 |
| 40 | 9-ASD-040 | .008/72 | 56 | 50 | 40 | 4 |

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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**Supplementary Information to CE 594291**

Issued To:

**AGA Medical Corporation**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

**Amplatzer Multi-Fenestrated Septal Occluder – "Cribriform":**

| Device Size (mm) | Model Number | Wire Diameter (mm)/Number of Wires | Disc Diameter (mm) | Diameter of Raised Disc (mm) |
|---|---|---|---|---|
| 18 | 9-ASD-MF-018 | .005/72 | 18 | 6 |
| 25 | 9-ASD-MF-025 | .005/72 | 25 | 13 |
| 30 | 9-ASD-MF-030 | .005/72 | 30 | 30 |
| 35 | 9-ASD-MF-035 | .006/72 | 35 | 23 |
| 40 | 9-ASD-MF-040 | .006/72 | 40 | 40 |

**AMPLATZER PFO Occluder:**

| Model Number | Device Size (mm) | Right Atrial Disc Diameter (mm) | Left Atrial Disc Diameter (mm) | Waist Length |
|---|---|---|---|---|
| 9-PFO-018 | 18 | 18 | 18 | 3 |
| 9-PFO-025 | 25 | 25 | 18 | 3 |
| 9-PFO-030 | 30 | 30 | 30 | 3 |
| 9-PFO-035 | 35 | 35 | 25 | 3 |

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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# EC Design-Examination Certificate

**Supplementary Information to CE 594291**

Issued To:

**AGA Medical Corporation**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

## Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 24 February 2013 | 10139223 | First Issue – Transfer from another Notified Body. |
| 28 May 2013 | 10141409 | Change the surface finish of the nitinol wire from black oxide to chemically etched. |
| 03 February 2014 | 10144456 | Update to Amplatzer Septal Occluder IFU. There are no changes to the intended use. |
| 06 February 2015 | 10152724 | Addition of St. Jude Medical Costa Rica Ltda. as an alternate manufacturing site for the Amplatzer Septal Occluder. Addition of Synergy Health AST, SRL as an alternate sterilization site for the Amplatzer Septal Occluder. |
| 25 August 2015 | 10156926 | DuPont Tyvek Medical Transition Project update. |
| 01 February 2016 | 10160623 | Addition of Sterigenics Willowbrook, IL as a sterilizer. |
| Current | 8872315 | Certificate renewal. |

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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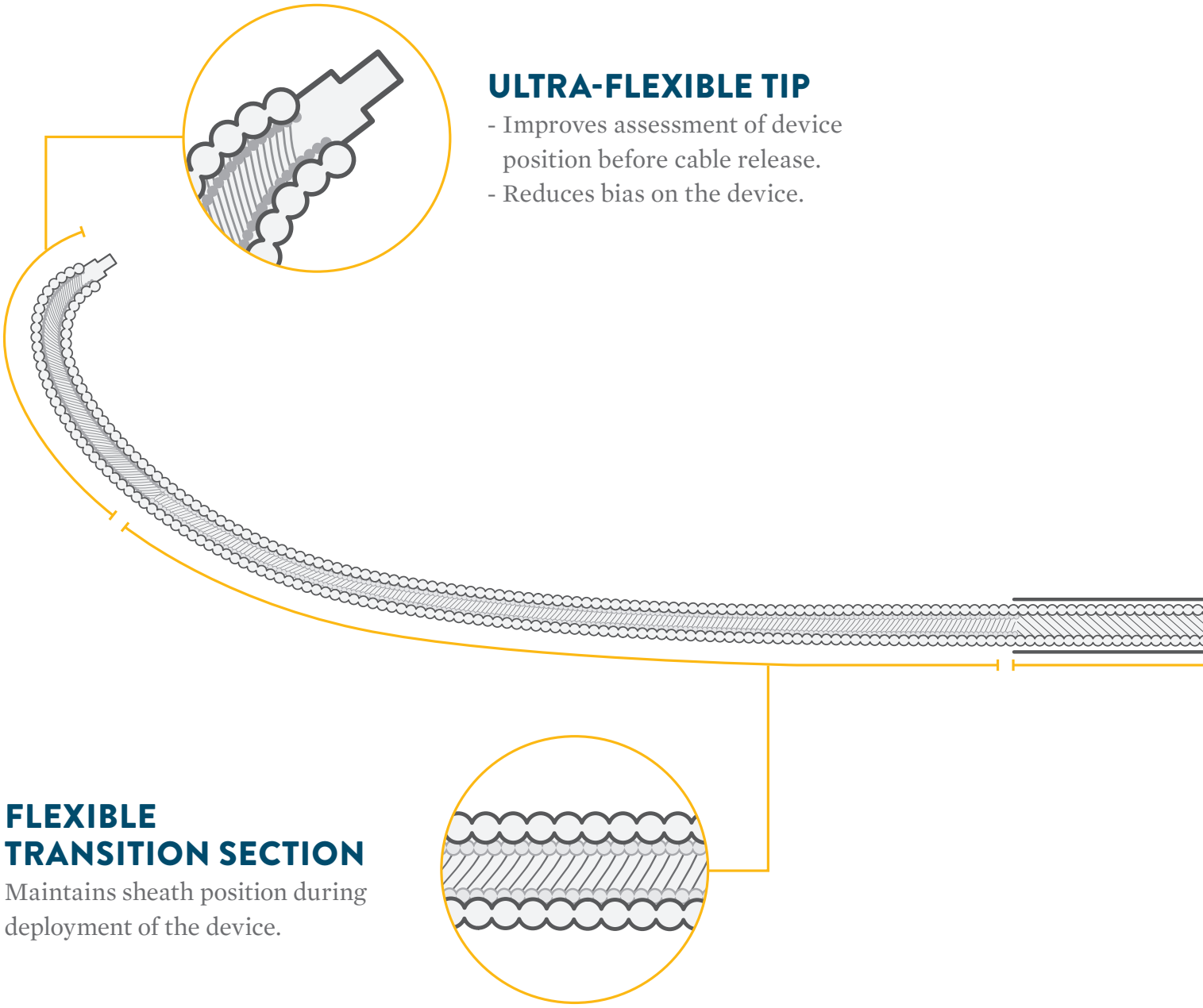
AMPLATZER™ TREVISIO™
INTRAVASCULAR DELIVERY SYSTEM
MORE FLEXIBILITY,
MORE CONTROL
DISCOVER THE UNIQUE
AMPLATZER™ TREVISIO™
Abbott
Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

# RELIABLE PRECISION
# WHEN IT MATTERS MOST

The Amplatzer™ Trevisio™ Intravascular Delivery System is an ultra-flexible delivery system enabling interventional cardiologists to perform their work with complete confidence. It leverages the one-piece cable design utilized by the Amplatzer™ TorqVue™ Delivery System, also know as the Classic Amplatzer™ Delivery System*. Trevisio is designed for no compromises on torque strength, sheath diameter and pushability.



## ULTRA-FLEXIBLE TIP

- Improves assessment of device position before cable release.
- Reduces bias on the device.

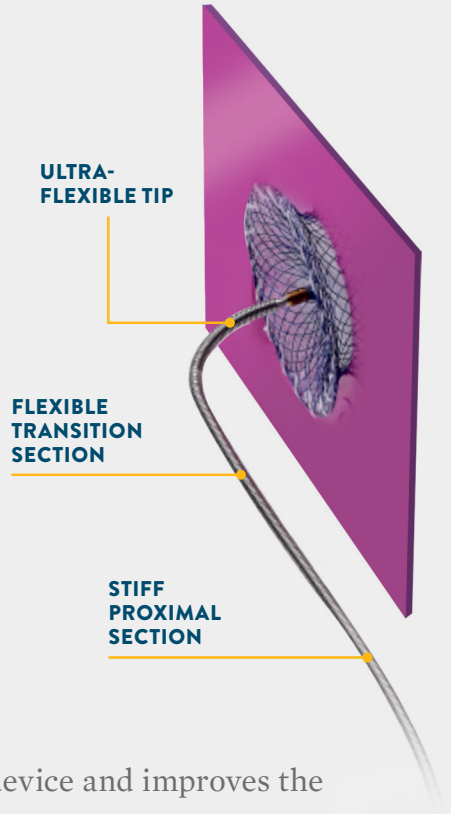
## FLEXIBLE TRANSITION SECTION

Maintains sheath position during deployment of the device.

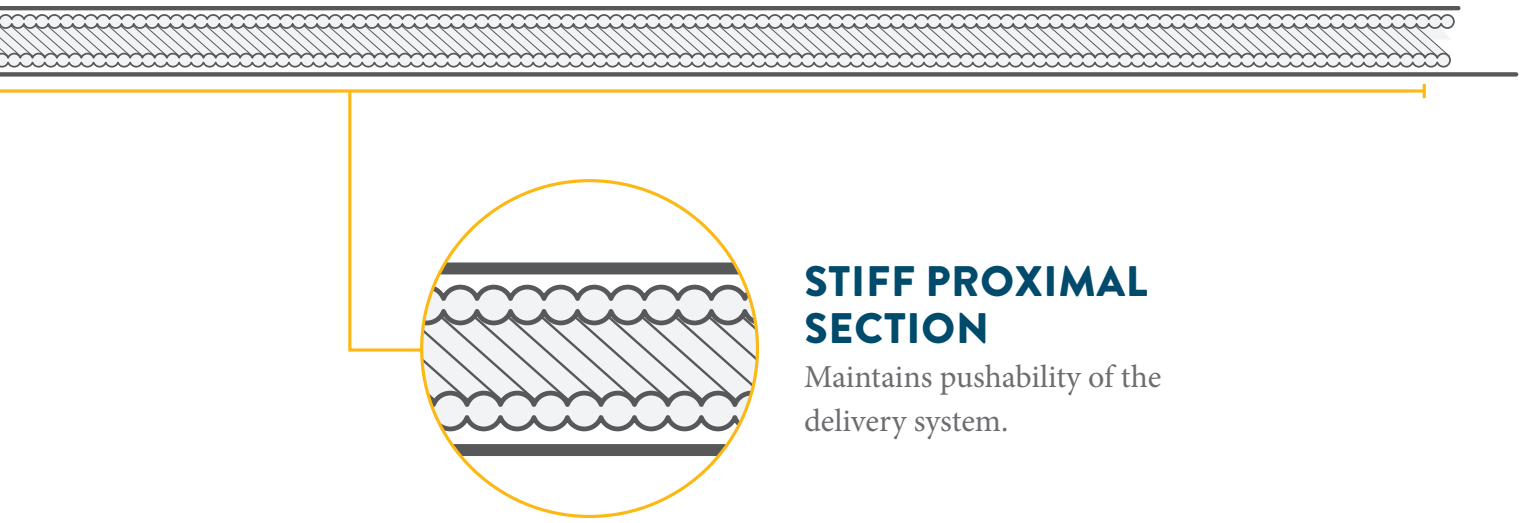
Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Check the regulatory status of the device in areas where CE marking is not the regulation in force

## CLASSIC AMPLATZER™ DELIVERY SYSTEM*

## AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM




Flexible tip reduces the bias on the device and improves the assessment of device position prior to cable release.



### STIFF PROXIMAL SECTION

Maintains pushability of the delivery system.

## DELIVERY SYSTEM DIMENSIONS

| DELIVERY SYSTEM (SHEATH SIZE) | INNER DIAMETER OF SHEATH | OUTER DIAMETER OF SHEATH | MODEL NUMBER/DELIVERY SYSTEM SIZE (MM) |
|---|---|---|---|
| 6 Fr | 2.11 mm (0.08 in) | 2.79 mm (0.11 in) | 9-ATV06F45/60 |
| 7 Fr | 2.44 mm (0.10 in) | 3.18 mm (0.13 in) | 9-ATV07F45/60 |
| 7 Fr | 2.44 mm (0.10 in) | 3.18 mm (0.13 in) | 9-ATV07F45/80 |
| 8 Fr | 2.69 mm (0.11 in) | 3.45 mm (0.14 in) | 9-ATV08F45/60 |
| 8 Fr | 2.69 mm (0.11 in) | 3.45 mm (0.14 in) | 9-ATV08F45/80 |
| 9 Fr | 3.00 mm (0.12 in) | 3.81 mm (0.15 in) | 9-ATV09F45/80 |
| 10 Fr | 3.30 mm (0.13 in) | 4.14 mm (0.16 in) | 9-ATV10F45/80 |
| 12 Fr | 3.99 mm (0.16 in) | 4.80 mm (0.19 in) | 9-ATV12F45/80 |
| 13 Fr | 4.32 mm (0.17 in) | 5.13 mm (0.20 in) | 9-ATV13F45/80 |

*Amplatzer™ TorqVue™ Delivery System


## DOWNLOAD NOW

Download the free Amplatzer™ Portfolio App from your favorite app store.

Download on the App Store

GET IT ON Google Play

**CAUTION:** This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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Park Lake, Culliganlaan 2b, 1831 Diegem, Belgium
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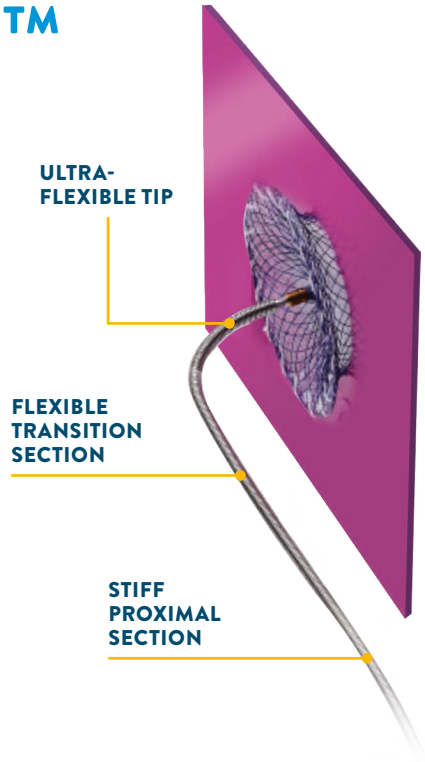
# AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM



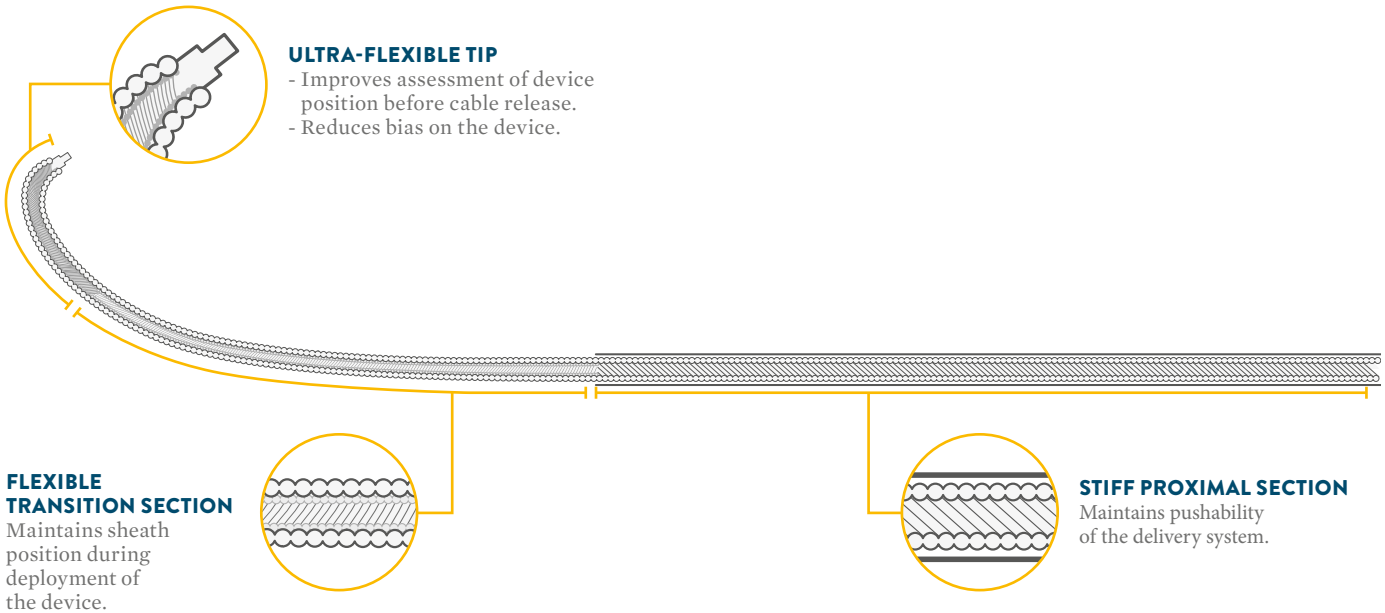

## DEVICE DESCRIPTION

The Amplatzer™ Trevisio™ Intravascular Delivery System is an ultra-flexible delivery system enabling interventional cardiologists to perform their work with complete confidence. It leverages the one-piece cable design utilized by the Amplatzer™ TorqVue™ Delivery System, also known as the Classic Amplatzer™ Delivery System. Trevisio is designed for no compromises on torque strength, sheath diameter and pushability.

The Amplatzer™ Trevisio™ Intravascular Delivery System comes with a 45° sheath curve in 60 or 80 cm lengths from 6Fr to 13Fr.

## INDICATIONS AND USAGE

The Amplatzer™ Trevisio™ Intravascular Delivery System is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Occluder devices. The Amplatzer™ Trevisio™ Intravascular Delivery System is indicated for use by interventional cardiologists to place an Amplatzer™ Occluder device.



**ULTRA-FLEXIBLE TIP**
- Improves assessment of device position before cable release.
- Reduces bias on the device.

**FLEXIBLE TRANSITION SECTION**
Maintains sheath position during deployment of the device.

**STIFF PROXIMAL SECTION**
Maintains pushability of the delivery system.

## DEVICE SPECIFICATIONS

| Model Number/ Delivery System Size<br>mm | Delivery System (Sheath Size)<br>Fr | Inner Diameter of Sheath<br>mm (inch) | Outer Diameter of Sheath<br>mm (inch) | Length<br>cm |
|---|---|---|---|---|
| 9-ATV06F45/60 | 6 | 2.11 (0.08) | 2.79 (0.11) | 60 |
| 9-ATV07F45/60 | 7 | 2.44 (0.10) | 3.18 (0.13) | 60 |
| 9-ATV07F45/80 | 7 | 2.44 (0.10) | 3.18 (0.13) | 80 |
| 9-ATV08F45/60 | 8 | 2.69 (0.11) | 3.45 (0.14) | 60 |
| 9-ATV08F45/80 | 8 | 2.69 (0.11) | 3.45 (0.14) | 80 |
| 9-ATV09F45/80 | 9 | 3.00 (0.12) | 3.81 (0.15) | 80 |
| 9-ATV10F45/80 | 10 | 3.30 (0.13) | 4.14 (0.16) | 80 |
| 9-ATV12F45/80 | 12 | 3.99 (0.16) | 4.80 (0.19) | 80 |
| 9-ATV13F45/80 | 13 | 4.32 (0.17) | 5.13 (0.20) | 80 |

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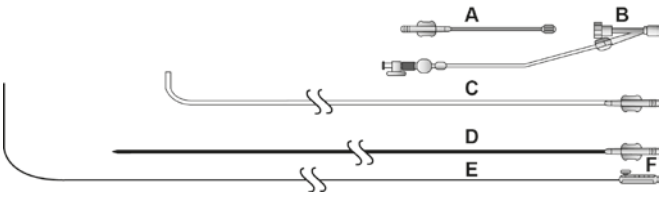
## PACKAGING INFORMATION




A. Loader – Introduces an Amplatzer™ device into the sheath
B. Hemostasis valve with extension tube and stopcock – Allows flushing of the delivery system and controls blood backflow
C. Sheath – Provides a pathway through which an Amplatzer™ device is delivered
D. Dilator – Eases penetration of tissue and minimizes vessel trauma
E. Delivery cable – Attaches to the device to control its movement through the sheath
F. Plastic vise – Attaches to the delivery cable and serves as a handle for disconnecting (unscrewing) the delivery cable from a device

Note that the device and the delivery system are being sold separately.

## ASSOCIATED AMPLATZER™ PRODUCTS

| Amplatzer™ Trevisio™ Intravascular Delivery System Sizes | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 6 Fr | 7 Fr | 8 Fr | 9 Fr | 10 Fr | 12 Fr | 13 Fr |
| Amplatzer™ Septal (ASD) Occluder | 9-ASD-004 | 9-ASD-011 | 9-ASD-018 | 9-ASD-020 | 9-ASD-026 | 9-ASD-032 | 9-ASD-032 |
| | 9-ASD-005 | 9-ASD-012 | 9-ASD-019 | 9-ASD-022 | 9-ASD-028 | 9-ASD-034 | 9-ASD-034 |
| | 9-ASD-006 | 9-ASD-013 | – | 9-ASD-024 | 9-ASD-030 | 9-ASD-036 | 9-ASD-036 |
| | 9-ASD-007 | 9-ASD-014 | – | – | – | 9-ASD-038 | 9-ASD-038 |
| | 9-ASD-008 | 9-ASD-015 | – | – | – | 9-ASD-040 | 9-ASD-040 |
| | 9-ASD-009 | 9-ASD-016 | – | – | – | – | – |
| | 9-ASD-010 | 9-ASD-017 | – | – | – | – | – |
| Amplatzer™ Multi-fenestrated ASD (Cribriform) Occluder | – | – | 9-ASD-MF-018 | 9-ASD-MF-035 | 9-ASD-MF-040 | – | – |
| | – | – | 9-ASD-MF-025 | | | – | – |
| | – | – | 9-ASD-MF-030 | | | – | – |
| Amplatzer™ PFO Occluder | – | – | 9-PFO-018 | 9-PFO-035 | – | – | – |
| | – | – | 9-PFO-025 | | – | – | – |
| | – | – | 9-PFO-030 | | – | – | – |
| Amplatzer™ Muscular VSD Occluder | 9-VSD-MUSC-004 | 9-VSD-MUSC-012 | 9-VSD-MUSC-014 | 9-VSD-MUSC-018 | – | – | – |
| | 9-VSD-MUSC-006 | | 9-VSD-MUSC-016 | | – | – | – |
| | 9-VSD-MUSC-008 | | | | – | – | – |
| | 9-VSD-MUSC-010 | | | | – | – | – |
| Amplatzer™ Muscular PI VSD Occluder | – | – | – | 9-VSDMUSCPI-016 | 9-VSDMUSCPI-020 | – | – |
| | – | – | – | 9-VSDMUSCPI-018 | 9-VSDMUSCPI-022 | – | – |
| | – | – | – | | 9-VSDMUSCPI-024 | – | – |

## LATEX-FREE INFORMATION

These Amplatzer™ products do not contain latex.

**Abbott Vascular International BVBA**
Park Lane, Culliganlaan 2B, B-1831 Diegem, Belgium, Tel: +32 2 714 14 11



Abbott

Abbott

# Abbott Medical Declaration of Conformity

Abbott Medical (Abbott) hereby declares that the following Abbott facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of Abbott. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

| | |
|---|---|
| **Manufacturer Address:** | Abbott Medical<br>5050 Nathan Lane North<br>Plymouth, Minnesota 55442, USA |
| **European Representative:** | Abbott Medical<br>The Corporate Village<br>Da Vincilaan 11 Box F1<br>1935 Zaventem, Belgium |
| **Product Type:** | Cardiac Occluder Delivery Kit |
| **Product Name(s):** | Amplatzer TorqVue Delivery System<br>Amplatzer TorqVue Exchange System<br>Amplatzer TorqVue 2 Delivery Sheath<br>Amplatzer TorqVue LP Delivery System<br>Amplatzer TorqVue LP Catheter<br>Amplatzer TorqVue Delivery System with Pusher Catheter<br>Amplatzer TorqVue 45°x45° Delivery Sheath<br>Amplatzer Amulet Delivery Sheath<br>Amplatzer Trevisio Intravascular Delivery System |

**Signature:**

Michelle Grossman
Director, Regulatory Affairs

April 21, 2020
Issue Date

Abbott

# Abbott Medical Declaration of Conformity

**Model Number(s):**

| Product | Model Numbers | Original CE Mark Date |
|---|---|---|
| **Amplatzer TorqVue Delivery System** | 9-ITV06F45/60<br>9-ITV07F45/60<br>9-ITV07F45/80<br>9-ITV08F45/60<br>9-ITV08F45/80<br>9-ITV09F45/80<br>9-ITV10F45/80<br>9-ITV12F45/80<br>9-ITV13F45/80<br>9-ITV05F180/60<br>9-ITV06F180/60<br>9-ITV06F180/80<br>9-ITV07F180/80<br>9-ITV08F180/80<br>9-ITV09F180/80 | 10 October 2005 |
| **Amplatzer TorqVue Exchange System** | 9-EITV09F45/80<br>9-EITV12F45/80<br>9-EITV06F180/80<br>9-EITV08F180/80<br>9-EITV10F180/80 | 10 October 2005 |
| **Amplatzer TorqVue 2 Delivery Sheath** | 9-TV2-05F120<br>9-TV2-06F120<br>9-TV2-07F120 | 19 February 2010 |
| **Amplatzer TorqVue LP Delivery System** | 9-TVLP4F90/060<br>9-TVLP4F90/080<br>9-TVLP5F90/060<br>9-TVLP5F90/080 | 07 February 2008 |
| **Amplatzer TorqVue LP Catheter** | 9-TVLPC4F90/080 | 28 April 2011 |
| **Amplatzer TorqVue Delivery System with Pusher Catheter** | 9-ITVP07F-180/80<br>9-ITVP08F-180/80<br>9-ITVP09F-180/80 | 21 June 2011 |
| **Amplatzer TorqVue 45°x45° Delivery Sheath** | 9-TV45X45-09F-100<br>9-TV45X45-10F-100<br>9-TV45X45-12F-100<br>9-TV45X45-13F-100<br>9-TV45X45-14F-100 | 03 December 2008 (9-13 Fr)<br>24 February 2012 (14 Fr) |
| **Amplatzer Amulet Delivery Sheath** | DS-TV45X45-12F-080<br>DS-TV45X45-14F-080 | 08 February 2017 |
| **Amplatzer Trevisio Intravascular Delivery System** | 9-ATV06F45/60<br>9-ATV07F45/60<br>9-ATV07F45/80<br>9-ATV08F45/60<br>9-ATV08F45/80<br>9-ATV09F45/80<br>9-ATV10F45/80<br>9-ATV12F45/80<br>9-ATV13F45/80 | 20 April 2020 |

**Signature:**

Michelle Grossman
Director, Regulatory Affairs

April 21 2020
Issue Date

Abbott

# Abbott Medical Declaration of Conformity

| | |
|---|---|
| **Classification:** | Class III (Rule 7) Annex II, Section 4<br>GHTF Class D |
| **GMDN Code(s):** | 45419 |
| **EC Design Certificate No and Expiration Date:** | Certificate No: CE 694956<br>Expiration Date: 23 February 2023 |
| **Annex II, Clause 3 Certificate No and Expiration Date:** | Certificate No: CE 694788<br>Expiration Date: 23 February 2023 |
| **Applicable Quality System Standards:** | ISO 13485 |
| **Notified Body:** | BSI Group The Netherlands B.V.<br>Say Building<br>John M. Keynesplein 9<br>1066 EP Amsterdam<br>The Netherlands |
| **Notified Body Number:** | 2727 |

**Signature:**

Michelle Grossman
Director, Regulatory Affairs

April 21, 2020
Issue Date

By Royal Charter

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** **CE 694956**

Issued To: **Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

In respect of:

**Amplatzer Delivery Systems**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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By Royal Charter

# EC Design-Examination Certificate

**Supplementary Information to CE 694956**

Issued To:

**Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

| **Amplatzer™ TorqVue™ Delivery System** | | | |
|---|---|---|---|
| **Intended purpose per IFU:** The Amplatzer™ TorqVue™ Delivery System is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Occluder devices. | | | |
| **Classification:** Class III | | | |
| **Catalogue Number** | **Model, Type** | | |
| | **Sheath Size (Fr)** | **Tip Angle** | **Usable Length (cm)** |
| 9-ITV06F45/60 | 6 | 45° | 60 |
| 9-ITV07F45/60 | 7 | 45° | 60 |
| 9-ITV07F45/80 | 7 | 45° | 80 |
| 9-ITV08F45/60 | 8 | 45° | 60 |
| 9-ITV08F45/80 | 8 | 45° | 80 |
| 9-ITV09F45/80 | 9 | 45° | 80 |
| 9-ITV10F45/80 | 10 | 45° | 80 |
| 9-ITV12F45/80 | 12 | 45° | 80 |
| 9-ITV13F45/80 | 13 | 45° | 80 |
| 9-ITV05F180/60 | 5 | 180° | 60 |
| 9-ITV06F180/60 | 6 | 180° | 60 |
| 9-ITV06F180/80 | 6 | 180° | 80 |
| 9-ITV07F180/80 | 7 | 180° | 80 |
| 9-ITV08F180/80 | 8 | 180° | 80 |
| 9-ITV09F180/80 | 9 | 180° | 80 |

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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# EC Design-Examination Certificate

**Supplementary Information to CE 694956**

Issued To:

**Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

| **Amplatzer™ TorqVue™ Exchange System** | | | |
|---|---|---|---|
| **Intended purpose per IFU:** The Amplatzer™ TorqVue™ Exchange System is intended for removal of an Amplatzer™ Delivery Sheath and subsequent exchange for an Amplatzer™ Delivery Sheath of equal or larger diameter. | | | |
| **Classification**: Class III | | | |
| **Catalogue Number** | **Model, Type** | | |
| | **Sheath Size (Fr)** | **Tip Angle** | **Usable Length (cm)** |
| 9-EITV09F45/80 | 9 | 45° | 80 |
| 9-EITV12F45/80 | 12 | 45° | 80 |
| 9-EITV06F180/80 | 6 | 180° | 80 |
| 9-EITV08F180/80 | 8 | 180° | 80 |
| 9-EITV10F180/80 | 10 | 180° | 80 |

| **Amplatzer™ TorqVue™ 2 Delivery Sheath** | | | |
|---|---|---|---|
| **Intended purpose per IFU:** The Amplatzer™ TorqVue™ 2 Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature. | | | |
| **Classification**: Class III | | | |
| **Catalogue Number** | **Model, Type** | | |
| | **Sheath Size (Fr)** | **Tip Angle** | **Usable Length (cm)** |
| 9-TV2-05F120 | 5 | none | 120 |
| 9-TV2-06F120 | 6 | none | 120 |
| 9-TV2-07F120 | 7 | none | 120 |

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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# EC Design-Examination Certificate

**Supplementary Information to CE 694956**

Issued To:

**Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

| **Amplatzer™ TorqVue™ Delivery System with Pusher Catheter** | | | |
|---|---|---|---|
| **Intended purpose per IFU:** The Amplatzer™ TorqVue™ Delivery System with Pusher Catheter is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Membranous VSD Occluder device. | | | |
| **Classification:** Class III | | | |
| **Catalogue Number** | **Model, Type** | | |
| | **Sheath Size (Fr)** | **Tip Angle** | **Usable Length (cm)** |
| 9-ITVP07F180/80 | 7 | 180° | 80 |
| 9-ITVP08F180/80 | 8 | 180° | 80 |
| 9-ITVP09F180/80 | 9 | 180° | 80 |

| **Amplatzer™ TorqVue™ LP Delivery System** | | | | |
|---|---|---|---|---|
| **Intended purpose per IFU:** The Amplatzer™ TorqVue™ LP Delivery System is intended to facilitate the attachment, loading, delivery, and deployment of the Amplatzer™ devices. | | | | |
| **Classification:** Class III | | | | |
| **Catalogue Number** | **Model, Type** | | | |
| | **Device Size (Fr)** | **Curve Dimension** | **Length (cm)** | **Delivery Wire Length (cm)** |
| 9-TVLP4F90/060 | 4 | 90° | 60 | 160 |
| 9-TVLP4F90/080 | 4 | 90° | 80 | 195 |
| 9-TVLP5F90/060 | 5 | 90° | 60 | 160 |
| 9-TVLP5F90/080 | 5 | 90° | 80 | 195 |

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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# EC Design-Examination Certificate

**Supplementary Information to CE 694956**

Issued To:

**Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

| **Amplatzer™ Trevisio™ Intravascular Delivery System** | | | |
|---|---|---|---|
| **Intended purpose per IFU:** The Amplatzer™ Trevisio™ Intravascular Delivery System is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Occluder devices. | | | |
| **Classification:** Class III | | | |
| **Catalogue Number** | **Model, Type** | | |
| | **Sheath Size (Fr)** | **Tip Angle** | **Usable Length (cm)** |
| 9-ATV06F45/60 | 6 | 45° | 60 |
| 9-ATV07F45/60 | 7 | 45° | 60 |
| 9-ATV07F45/80 | 7 | 45° | 80 |
| 9-ATV08F45/60 | 8 | 45° | 60 |
| 9-ATV08F45/80 | 8 | 45° | 80 |
| 9-ATV09F45/80 | 9 | 45° | 80 |
| 9-ATV10F45/80 | 10 | 45° | 80 |
| 9-ATV12F45/80 | 12 | 45° | 80 |
| 9-ATV13F45/80 | 13 | 45° | 80 |

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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# EC Design-Examination Certificate

**Supplementary Information to CE 694956**

Issued To:

**Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

| **Amplatzer™ TorqVue™ LP Catheter** | | | | |
|---|---|---|---|---|
| **Intended purpose per IFU:** The TorqVue™ LP Catheter is intended to facilitate the loading, delivery, and deployment of Amplatzer™ devices. | | | | |
| **Classification:** Class III | | | | |
| **Catalogue Number** | **Model, Type** | | | |
| | **Device Size (Fr)** | **Usable Length (cm)** | **Tip Outer Diameter mm (in)** | **Tip Inner Diameter mm (in)** |
| 9-TVLPC4F90/080 | 4 | 80 | 1.40 (.055) | 1.17 (0.046) |

| **Amplatzer™ TorqVue™ 45x45 Delivery Sheath** | | |
|---|---|---|
| **Intended purpose per IFU:** The Amplatzer™ TorqVue™ Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart. | | |
| **Classification**: Class III | | |
| **Catalogue Number** | **Model, Type** | |
| | **Sheath Size (Fr)** | **Length (cm)** |
| 9-TV45X45-09F-100 | 9 | 100 |
| 9-TV45X45-10F-100 | 10 | 100 |
| 9-TV45X45-12F-100 | 12 | 100 |
| 9-TV45X45-13F-100 | 13 | 100 |
| 9-TV45X45-14F-100 | 14 | 100 |

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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# EC Design-Examination Certificate

**Supplementary Information to CE 694956**

Issued To:

**Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

| **Amplatzer™ Amulet™ Delivery Sheath** | | |
|---|---|---|
| **Intended purpose per IFU:** The Amplatzer™ Amulet™ Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart. | | |
| **Classification:** Class III | | |
| **Catalogue Number** | **Model, Type** | |
| | **Sheath Size (Fr)** | **Length (cm)** |
| DS-TV45X45-12F-080 | 12 | 80 |
| DS-TV45X45-14F-080 | 14 | 80 |

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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# EC Design-Examination Certificate

**Supplementary Information to CE 694956**

Issued To:

**Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

# Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 03 September 2018 | 8957249 | First Issue. Mirror certificate to CE 594294. |
| 20 February 2019 | 8243107 | Traceable to NB 0086. |
| 20 March 2019 | 9738457 | Addition of Sterigenics US LLC, Salt Lake City, Utah for ETO Sterilization. |
| 16 December 2019 | 3053900 | Addition of Midwest Sterilization Corporation, Jackson, Missouri USA for ETO Sterilization in chambers 1, 2, 3, 6, and 13. |
| Current | 9784335 | Extension to scope to include the Amplatzer™ Trevisio™ Intravascular Delivery System.<br>Revision to scope statement to remove "TorqVue" brand name.<br>Reformat product tables.<br>Correction of delivery wire length for Amplatzer™ TorqVue™ LP Delivery System.<br>Correction of tip outer diameter for Amplatzer™ TorqVue™ LP Catheter. |

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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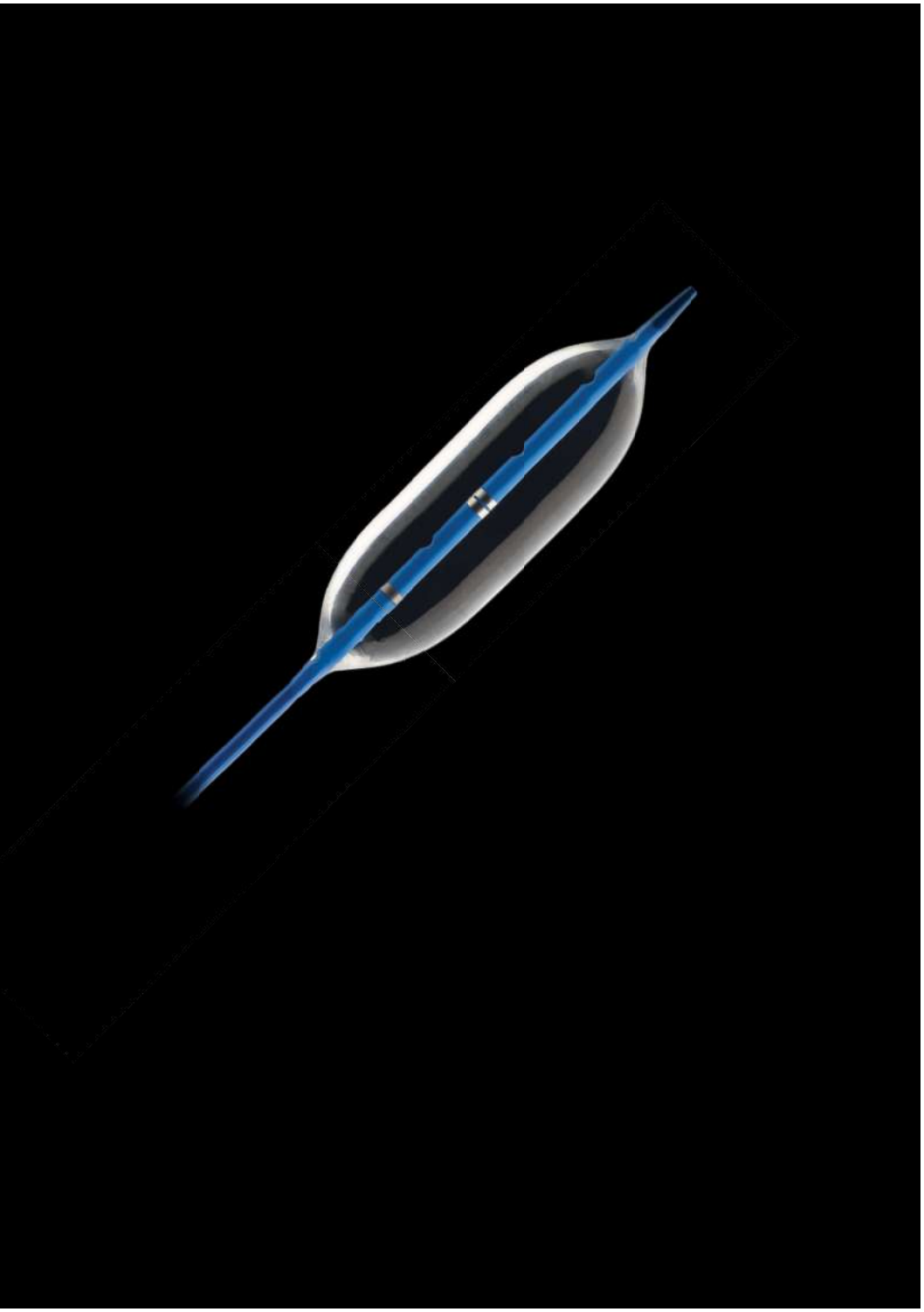

## AMPLATZER™ Sizing Balloon II

**Accessory**

### Product Highlights

- Triple lumen balloon catheter designed to measure cardiovascular structures
- Compliant balloon material supports low pressure inflation and allows precise measurement of a variety of defect shapes when using stop-flow technique
- Three radiopaque marker bands strategically placed to assist with alignment of imaging and support proper sizing calibration radiographically and echocardiographically
- Soft distal tip and flexible shaft offer smooth access for atraumatic balloon positioning
- Ultra thick membrane requires no dilatation of the entry site; balloon can be introduced over the guidewire

### Ordering Information

Contents: 1 sizing balloon

| Model/Reorder Number | Maximum Defect Size | Maximum Inflation Volume | Balloon Length | Shaft Size | Usable Length | Guidewire |
|---|---|---|---|---|---|---|
| 9-SB-018 | 20 mm | 12 cc | 3.5 cm | 6 F | 70 cm | 0.035 inch |
| 9-SB-024 | 27 mm | 25 cc | 4.5 cm | 7 F | 70 cm | 0.035 inch |
| 9-SB-034 | 40 mm | 90 cc | 5.5 cm | 8 F | 70 cm | 0.035 inch |

## AMPLATZER™ Sizing Plate

**Accessory**

### Ordering Information

Contents: 1 sizing plate

| Model/Reorder Number | Description |
|---|---|
| 9-ASD-SZP | Measuring plate with circular openings ranging from 4 to 38 mm |

ST. JUDE MEDICAL

# SJM Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

| | |
|---|---|
| **Manufacturer Address:** | AGA Medical Corpation<br>5050 Nathan Lane North<br>Plymouth, Minnesota 55442, USA |
| **European Representative:** | St. Jude Medical Coordination Center BVBA<br>The Corporate Village<br>Da Vincilaan 11 Box F1<br>1935 Zaventem, Belgium |
| **Product Type:** | Cardiac Catheter, Balloon, Sizing |
| **Product Name(s):** | AMPLATZER Sizing Balloon II |
| **Model Number(s):** | 9-SB-018, 9-SB-024, 9-SB-034 |
| **Classification:** | Class III (Rule 7) Annex II, Section 4,<br>GHTF Class D |
| **GMDN Code(s):** | 42417 |
| **Original CE Mark Date:** | 10 June 2005 (24 mm)<br>02 Sept 2005 (18, 34 mm) |
| **EC Design Certificate No and Expiration Date:** | Certificate No: CE 595439<br>Expiration Date: 23 Feb 2023 |
| **Annex II, Clause 3 Certificate No and Expiration Date:** | Certificate No: CE 590631<br>Expiration Date: 23 Feb 2023 |
| **Applicable Quality System Standards:** | ISO 13485 |
| **Notified Body:** | BSI<br>Kitemark Court<br>Knowlhill<br>Milton Keynes<br>MK5 8PP<br>UK |
| **Notified Body Number:** | 0086 |

**Signature:**

Lisa Becker
Senior Director, Regulatory Affairs

21 Feb 18
Issue Date

bsi.

By Royal Charter

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** **CE 595439**

Issued To: **AGA Medical Corporation**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

In respect of:

**AMPLATZER Sizing Balloon II**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2013-02-24** Date: **2018-01-10** Expiry Date: **2023-02-23**

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By Royal Charter

# EC Design-Examination Certificate

**Supplementary Information to CE 595439**

Issued To:

**AGA Medical Corporation**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

| Finished Product Number | Balloon Diameter (mm) | Volume at Diameter (cc) | Useable Balloon Length (mm) | Catheter Useable Length (cm) | Shaft French Size (F) | Maximum Recommended Inflation Volume (cc) | Minimum Volume at Failure (cc) |
|---|---|---|---|---|---|---|---|
| 9-SB-018 | 18 | 10 | 35 | 70 | 6 | 12 | 25 |
| 9-SB-024 | 24 | 25 | 45 | 70 | 7 | 25 | 60 |
| 9-SB-034 | 34 | 55 | 55 | 70 | 8 | 90 | 120 |

First Issued: **2013-02-24** Date: **2018-01-10** Expiry Date: **2023-02-23**

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By Royal Charter

# EC Design-Examination Certificate

**Supplementary Information to CE 595439**

Issued To:

**AGA Medical Corporation**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

## Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 24 February 2013 | 10139846 | First Issue – Transfer from another Notified Body. |
| 25 August 2015 | 10156926 | DuPont Tyvek Medical Transition Project update. |
| 01 February 2016 | 10160623 | Addition of Sterigenics Willowbrook, IL as a sterilizer. |
| Current | 8864699 | Certificate renewal. |

First Issued: **2013-02-24** Date: **2018-01-10** Expiry Date: **2023-02-23**

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# AMPLATZER™ GUIDEWIRES

## Ordering Information

Contents: 1 guidewire

| Model/ Reorder No | Diam (in) | Body | Floppy Tip Lgth (cms) | Tip Description | Usable Lgth (cm) |
|---|---|---|---|---|---|
| 9-GW-001 | 0.035 | Super Stiff | 6 | 7.5 mm, Modified J-tip | 260 |
| 9-GW-002 | 0.035 | Super Stiff | 5 | 1.5 mm, Modified J-tip | 260 |
| 9-GW-003 | 0.035 | Super Stiff | 20 | 6 mm, J-tip | 300 |
| 9-GW-004* | 0.035 | Soft Tip, Fixed Core | NA | 6 mm, J-tip | 300 |

*9-GW-004, also referred to as "Noodlewire," is a soft tip, flexible guidewire recommended for establishing an arterial-venous loop, facilitating closure of ventricular septal defects.

Abbott

# Amplatzer™ Guidewire

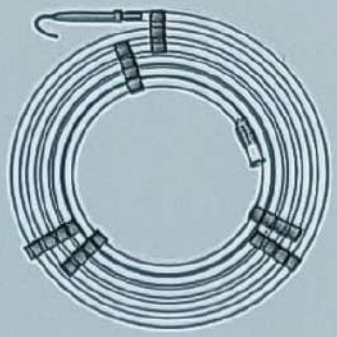
Guidewire

es: Guia
pt: Fio-Guia
tr: Kılavuz Teli

UDI

(01)00811806010724(17)261231(10)9941803

2026-12-31



| | |
|---|---|
| REF | 9-GW-002 |
| LOT | 9941803 |

| | |
|---|---|
| | 0.035/0.889 |
| | 260 cm |
| | 1.5 mm MOD J |
| | PTFE |
| | FIXED |

medicalabbott/manuals

STERILE EO

LATEX

Does not contain natural rubber latex components

2022-01-24

CE 2797

600035212 B


**Abbott Medical**
5050 Nathan Lane North
Plymouth, MN
55442 USA
+1 855 478 5833
+1 651 756 5833

EC REP
**Abbott Medical**
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

Manufactured By
Lake Region Medical Limited,
Butlersland, New Ross, Co.
Wexford, Ireland.


Made in Ireland

AGABF-031V

ST. JUDE MEDICAL

# SJM Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/ECC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

| | |
|---|---|
| **Manufacturer Address:** | AGA Medical Corporation<br>5050 Nathan Lane North<br>Plymouth, Minnesota 55442, USA |
| **European Representative:** | St. Jude Medical Coordination Center BVBA<br>The Corporate Village<br>Da Vincilaan 11 Box F1<br>1935 Zaventem, Belgium |
| **Product Type:** | Catheter Guide Wire |
| **Product Name(s):** | AMPLATZER Guidewires |
| **Model Number(s):** | 9-GW-001, 9-GW-002, 9-GW-003, 9-GW-004 |
| **Classification:** | Class III (Rule 7) Annex II, Section 4<br>GHTF Class D |
| **GMDN Code(s):** | 35094 |
| **Original CE Mark Date:** | 22 March 2001 (1-3), 22 Sept 2003 (4, Noodlewire) |
| **EC Certificate No and expiration date:** | Certificate No: CE 594293<br>Expiration Date: 23 Feb 2023 |
| **Annex II, Clause 3:** | Certificate No: CE 590631<br>Expiration Date: 23 Feb 2023 |
| **Applicable Quality System Standards:** | ISO 13485 |
| **Notified Body:** | BSI<br>Kitemark Court<br>Davy Avenue<br>Knowlhill<br>Milton Keynes<br>MK5 8PP<br>UK |
| **Notified Body Number:** | 0086 |

**Signature:**

Lisa Becker
Senior Director, Regulatory Affairs

21Feb18
Issue Date

By Royal Charter

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** **CE 694955**

Issued To: **Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

In respect of:

**AMPLATZER Guidewires**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2018-09-03** Date: **2019-02-20** Expiry Date: **2023-02-23**

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# EC Design-Examination Certificate

**Supplementary Information to CE 694955**

Issued To:

**Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

| Part Number | Description |
|---|---|
| 9-GW-001 | JFC-SS Modified J, Fixed, PTFE Coated, Super Stiff |
| 9-GW-002 | J1.5FC-SS, Modified J, Fixed, PTFE Coated, Super Stiff |
| 9-GW-003 | J9FC-FS-LLLT Fixed Core, Long (20 cm) PTFE Coated, Finger-Straightenable |
| 9-GW-004 | Noodlewire Guidewire |

First Issued: **2018-09-03** Date: **2019-02-20** Expiry Date: **2023-02-23**

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# EC Design-Examination Certificate

**Supplementary Information to CE 694955**

Issued To:

**Abbott Medical**
**5050 Nathan Lane North**
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**Minnesota**
**55442**
**USA**

# Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 03 September 2018 | 8957249 | First Issue. Mirror certificate to CE 594293. |
| Current | 8243107 | Traceable to NB 0086. |

First Issued: **2018-09-03** Date: **2019-02-20** Expiry Date: **2023-02-23**

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