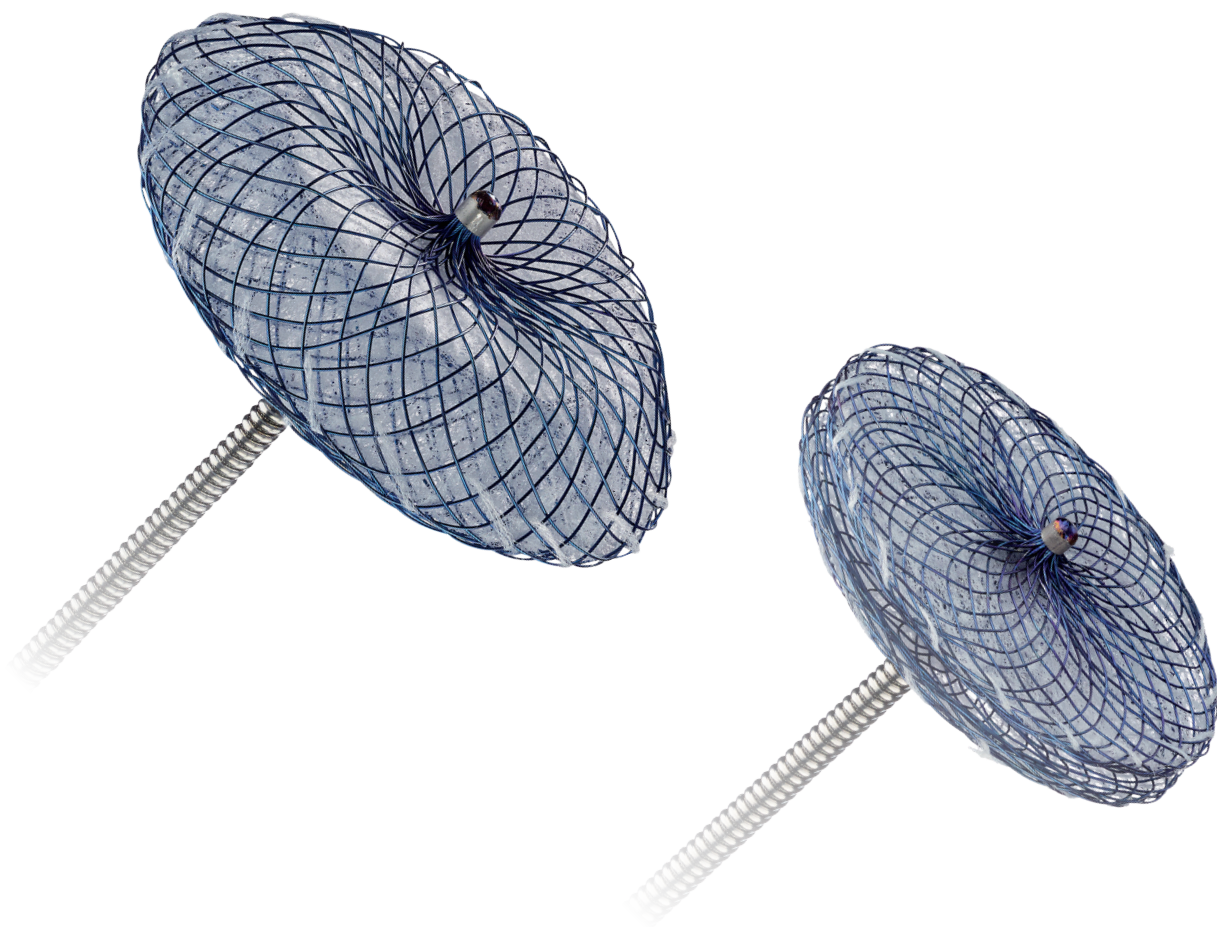


STRUCTURAL HEART THERAPY

AMPLATZER™ SEPTAL OCCLUDERS



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



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.

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

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-up¹

Low Major and Minor Complication Rates:

Postprocedure and long-term based on 5-year follow-up¹

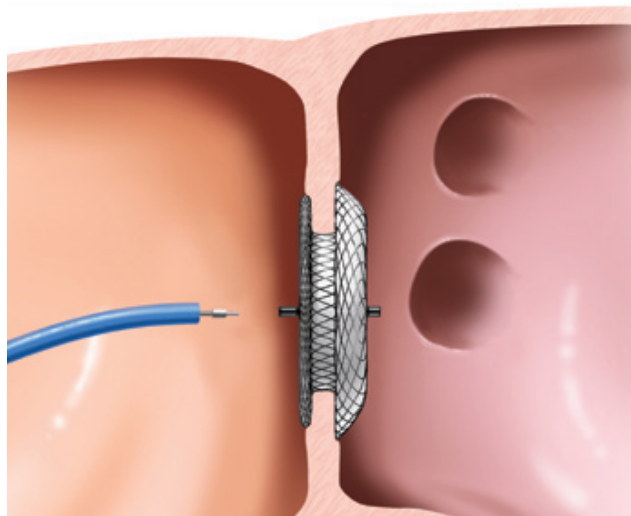
SPECIFICALLY DESIGNED FOR ASD CLOSURE

Wide Waist: Centers device and fills the ASD³

Shape-memory Nitinol Mesh: Designed to securely appose both sides of the septal wall³

Polyester Material: Promotes occlusion and tissue in-growth³

Precise Placement: Device can be easily recaptured and redeployed³



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

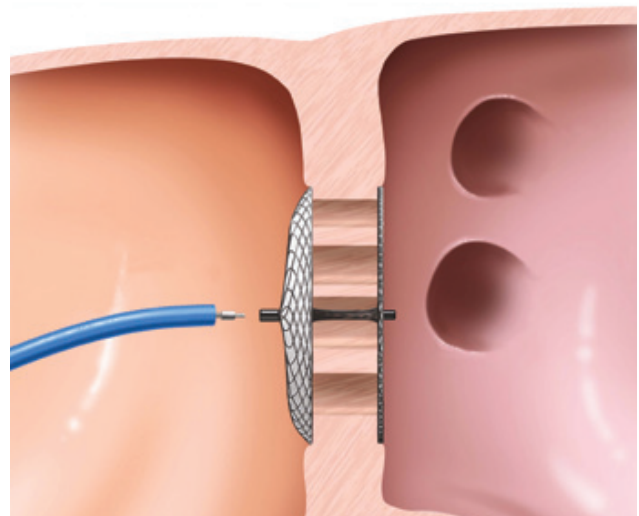
SPECIFICALLY DESIGNED FOR MULTI-FENESTRATED ASD CLOSURE

Narrow Waist: Allows for placement through a central defect³

Matched Disc Diameters: Maximizes coverage of multiple fenestrations³

Polyester Material: Promotes occlusion and tissue in-growth³

Precise Placement: Device can be easily recaptured and redeployed³



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

Signature:

Lisa Becker
Senior Director, Regulatory Affairs

Issue Date



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
Expiration Date: 23 February 2023

Annex II, Clause 3 Certificate No and Expiration Date: Certificate No: CE 590631
Expiration Date: 23 February 2023

Applicable Quality System Standards: ISO 13485

Notified Body: BSI
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP
UK

Notified Body Number: 0086

AMPLATZER Septal Occluder Manufacturing Facilities: AGA Medical Corporation
5050 Nathan Lane North
Plymouth, Minnesota
55442
USA


St. Jude Medical, Costa Rica Ltda.
Edificio #44,
Calle 0, Avenida 2
Zona Franca Coyol,
El Coyol, Alajuela,
Costa Rica

AMPLATZER Multi-Fenestrated Septal Occluder - "Cribiform" Manufacturing Facility: AGA Medical Corporation
5050 Nathan Lane North
Plymouth, Minnesota
55442
USA

AMPLATZER PFO Occluder Manufacturing Facility: AGA Medical Corporation
5050 Nathan Lane North
Plymouth, Minnesota
55442
USA

Signature:


Lisa Becker
Senior Director, Regulatory Affairs



Issue Date

EC Design-Examination Certificate

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

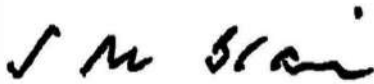
No. **CE 594291**
Issued To: **AGA Medical Corporation**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

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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Page 1 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 594291

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

Amplatz 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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EC Design-Examination Certificate

Supplementary Information to CE 594291

Issued To:

**AGA Medical Corporation
5050 Nathan Lane North
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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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Page 3 of 5

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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

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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Page 5 of 5

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 This certificate was issued electronically and is bound by the conditions of the contract.