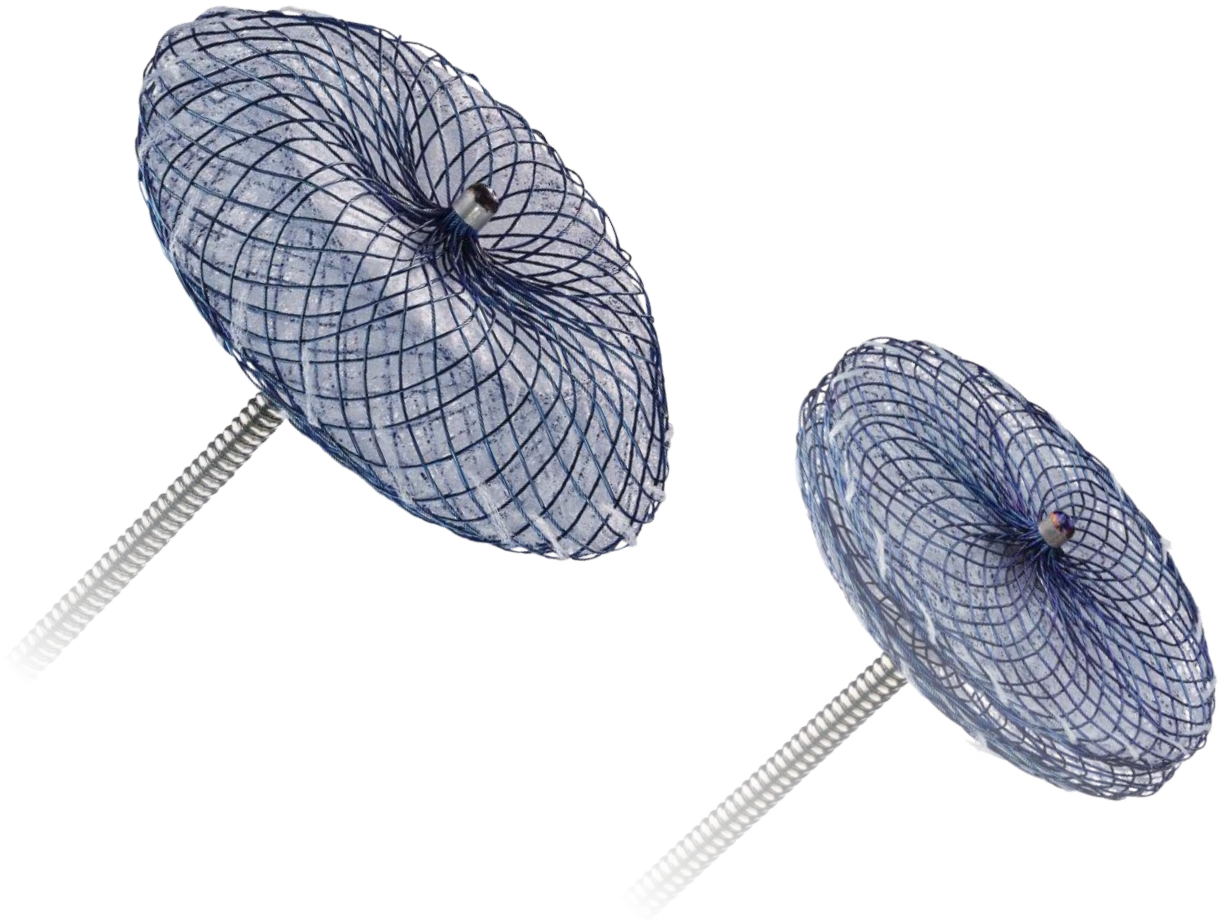
STRUCTURAL HEART THERAPY

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.

Abbott

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]

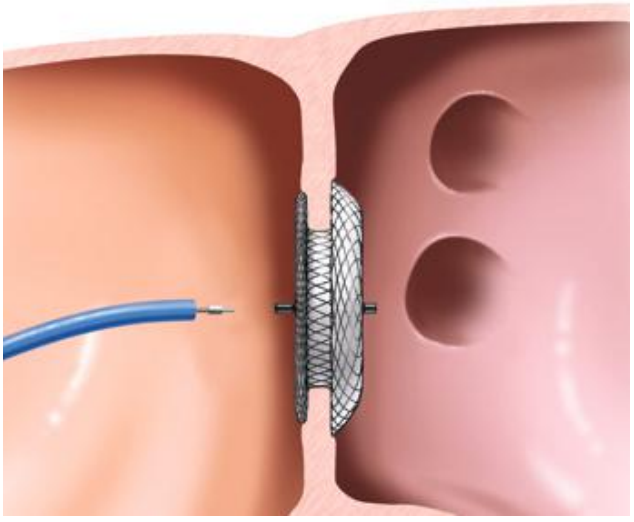
WHEN FLEXIBILITY MATTERS

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.

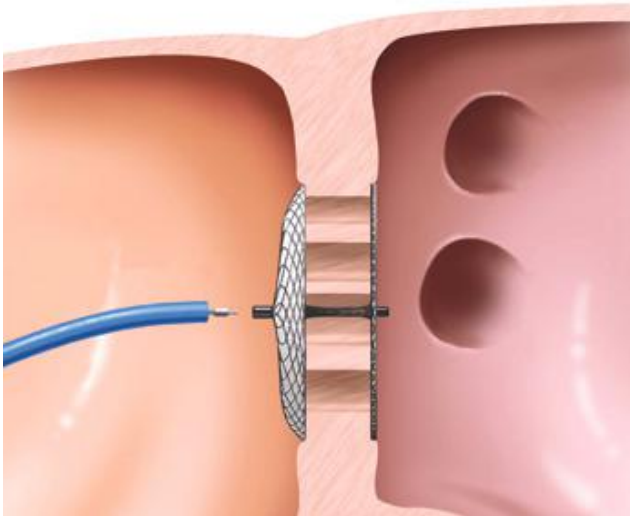
The addition of the Amplatzer Mulit-Fenestrated Septal Occluder - “Cribriform” to the Amplatzer family of occluders enables transcatheter closure for the majority of atrial septal defects.

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



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.

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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 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 - "Cribriform" 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

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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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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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

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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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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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