

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 |

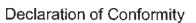
AMPLATZER™ Sizing Plate

Accessory

Ordering Information

Contents: 1 sizing plate

| Description |
|--|
| Measuring plate with circular openings ranging from 4 to 38 mm |
| |





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

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 Catheter, Balloon, Sizing

Product Name(s):

AMPLATZER Sizing Balloon II

Model Number(s):

9-SB-018, 9-SB-024, 9-SB-034

Classification:

GMDN Code(s):

Class III (Rule 7) Annex II, Section 4,

GHTF Class D

42417

Original CE Mark Date:

10 June 2005 (24 mm) 02 Sept 2005 (18, 34 mm)

EC Design Certificate No and Expiration

Certificate No: CE 595439 Expiration Date: 23 Feb 2023

Annex II, Clause 3 Certificate No and

Expiration Date:

Certificate No: CE 590631 Expiration Date: 23 Feb 2023

Applicable Quality System Standards:

ISO 13485

Notified Body:

BSI

Kitemark Court Knowlhill Milton Keynes MK5 8PP

UK.

Notified Body Number:

0086

Director, Regulatory Affairs







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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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 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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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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