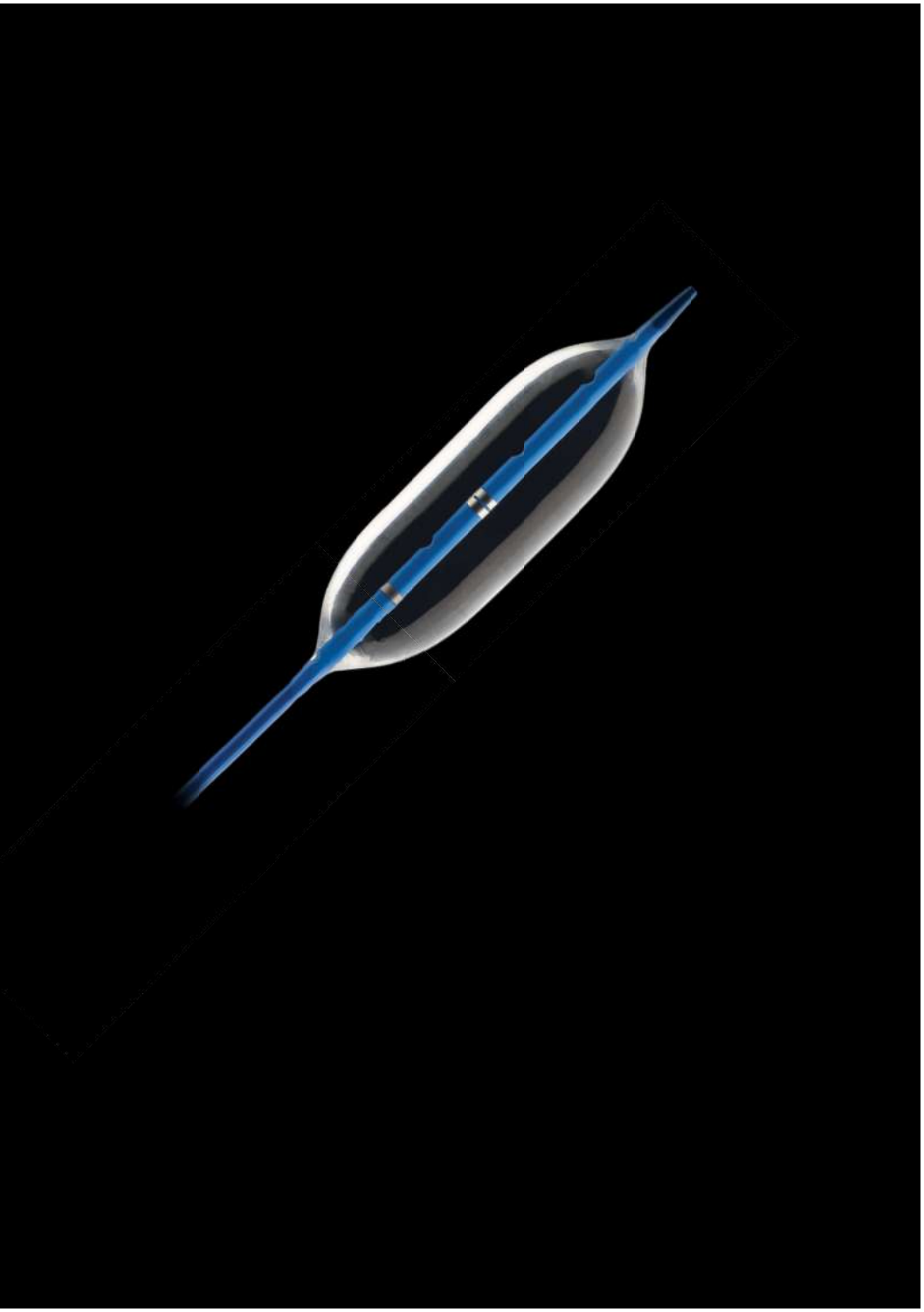

AMPLATZER™ Sizing Balloon II

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 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:	Class III (Rule 7) Annex II, Section 4, GHTF Class D
GMDN Code(s):	42417
Original CE Mark Date:	10 June 2005 (24 mm) 02 Sept 2005 (18, 34 mm)
EC Design Certificate No and Expiration Date:	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

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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Supplementary Information to CE 595439

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Minnesota
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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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Supplementary Information to CE 595439

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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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