BRK™ Transseptal Needles, XS Series

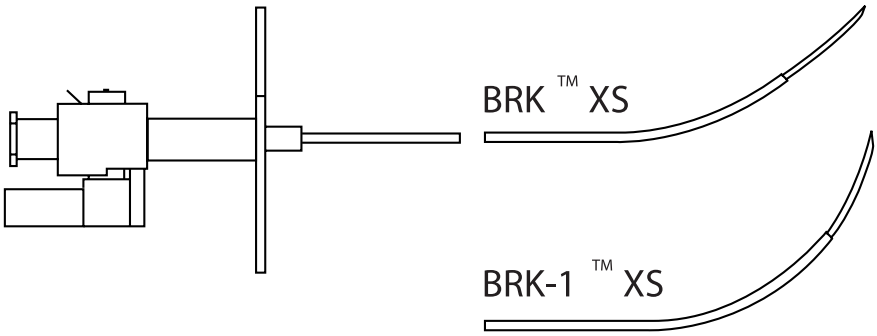
Product Highlights

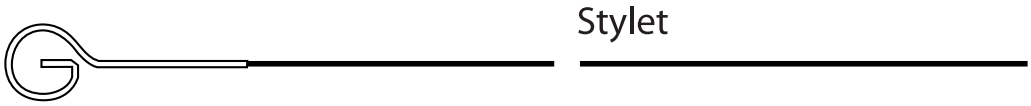
- Bevel angle 30 degrees
- Steeper primary bevel angle and two back bevels that combine to form a distinct point at the tip of the needle
- Pointer on the needle shield shows the direction of the needle curve

Ordering Information

Contents: Stainless Steel Transseptal Needle and Stylet (1 unit per box)

Reorder Number	Curve Type	Size	Needle Usable Length (cm)
G407208	BRK™ XS	Adult, 18 ga	71
G407209	BRK-1™ XS	Adult, 18 ga	71
G407210	BRK™ XS	Adult, 18 ga	89
G407216	BRK-1™ XS	Adult, 18 ga	89
G407211	BRK™ XS	Adult, 18 ga	98
G407212	BRK-1™ XS	Adult, 18 ga	98





EC Design-Examination Certificate

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

No. **CE 553178**

Issued To: **St. Jude Medical**
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA

In respect of:

BRK™ Transseptal Needle

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: **2009-10-01** Date: **2019-09-23** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 553178

Issued To:

St. Jude Medical
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA

Product: BRK Transseptal Needle

Model Number	Device Name	Device Description	Intended Purpose per IFU	Classification
407200	Standard BRK Transseptal Needle	BRK™ (71 cm)	The BRK TSN is used in conjunction with a transseptal catheter and/or introducer to create the puncture in the patient's interatrial septum during a transseptal catheterization procedure in order to gain access to a patient's left heart.	Class III
407201		BRK-1™ (71 cm)		
407205		BRK™ (89 cm)		
G407215		BRK-1™ (89 cm)		
407206		BRK™ (98 cm)		
407207		BRK-1™ (98 cm)		
G407208	XS BRK Transseptal Needle	BRK XS (71 cm)		
G407209		BRK-1™ XS (71 cm)		
G407210		BRK XS (89 cm)		
G407216		BRK-1™ XS (89 cm)		
G407211		BRK XS (98 cm)		
G407212		BRK-1™ XS (98 cm)		

First Issued: **2009-10-01** Date: **2019-09-23** Expiry Date: **2024-05-26**

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Supplementary Information to CE 553178

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14901 DeVeau Place
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Certificate History

Date	Reference Number	Action
01 October 2009	10109234	First Issue - Transfer from another Notified Body
07 January 2014	10144867	Addition of alternate adhesive used for bonds on the needle to the shaft and shaft to valve assembly.
30 September 2014	10150702	Certificate renewal.
30 October 2014	10151695	Addition of St. Jude Medical Costa Rica facility as an additional manufacturing site and Synergy Health in Costa Rica as an additional sterilization facility.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
01 February 2016	10160623	Addition of Sterigenics Willowbrook, IL as a sterilizer.
19 June 2016	10163123	Changes to product family catalogue numbers.
05 March 2019	7780627	Traceable to NB 0086.
15 April 2019	9718016	Addition of Sterigenics US, LLC, Salt Lake City, Utah for ETO Sterilization.
10 June 2019	9767661	Addition of higher capacity sterilization chambers 3 and 4 at Synergy Health Costa Rica and new sterilization process challenge device.
Current	9787848	Certificate Renewal.

First Issued: **2009-10-01** Date: **2019-09-23** Expiry Date: **2024-05-26**

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SJM Declaration of Conformity BRK™ Transseptal Needle

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 as amended by 2007/47/EC. 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:	St. Jude Medical 14901 DeVeau Place Minnetonka, Minnesota 55345-2126, USA
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Needle, Transseptal
Product Name(s):	BRK™ Transseptal Needle
Model Number(s):	407200, 407201, 407205, 407206, 407207, G407208-G407212, G407215-G407216
Classification:	Class III, Rule 6 according to Annex IX of MDD 93/42/ECC
GMDN Code(s):	47248, Transseptal Needle
Original CE Mark Date:	24-September-2007
Certificate No and expiration date:	Certificate No: CE 553178 Expiration Date: 26-May-2024
Applicable Quality System Standards:	ISO 13485:2016
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Kaynesplein 9 1066 EP Amsterdam The Netherlands
Notified Body Number:	2797 (Traceable to NB number 0086, BSI reference #7780627)

Signature:

Blair Schwartz
Regulatory Affairs Manager

06 JAN 2020
Issue Date

SJM Declaration of Conformity BRK™ Transseptal Needle

Manufacturing Facilities:

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

Signature:

Blair Schwartz
Regulatory Affairs Manager

06 JAN 2020
Issue Date

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Medical Costa Rica Ltda.
Edificio #44
Calle 0, Ave. 2
Zona Franca Coyol
El Coyol, Alajuela
Costa Rica

Holds Certificate No: **FM 728657**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacture and distribution of radio-frequency (RF) ablation catheters, electrophysiology (EP) catheters, intracardiac echocardiography catheters, cardiac mapping system accessories, transseptal access system, introducer catheters, vascular closure systems; and the design of cardiac mapping system accessories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-06
Effective Date: 2021-12-14
Latest Revision Date: 2022-03-22
Expiry Date: 2024-12-13

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