

bsi.

Certificate

Design Examination

No. CE 576208



Issued to:

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

In respect of:

Peel-Away Introducers

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4.
For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **18 Feb 2013**

Date: **18 Feb 2013**

Expiration Date: **17 Feb 2018**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

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Supplementary Information to CE 576208

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Peel-Away Introducer Set Components

Component	Size	Length (cm)	Curl Size
Peel-Away Introducer	5-16 F	14 or 23 cm	Straight
Dilator	5-16 F	-	-
Guidewire	0.038"	50 or 80 cm	3 mm "J" Tip
Needle	18 Ga	-	-
Syringe	12 cc	-	-

Reorder Number

405XXX

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History of Certificate

Date	Reference Number	Action
18 February 2013	10124740	First Issue

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