



## REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratia de conformitate CE
I.3. Certificatul CE	Certificat_CE_DE
I.3. Certificatul CE	Certificat_CE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		Vista Britel								
DM000200123	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-074-00	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	
DM000200165	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-166-00	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	
DM000200132	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-064-00	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	
DM000200111	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-054-90	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	
DM000200103	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-082-90	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	
DM000200176	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-191-00	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	
DM000200145	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-040-0L	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	
DM000200108	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-098-00	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	
DM000200130	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-062-00	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	
DM000200115	CATETERE GHID PENTRU ABORD RADIAL	CORDIS®VISTA BRITE TIP®	6F	670-056-00	SUA	CORDIS CORPORATION	CLASDAC S.R.L.	A07.PS-01.Rg04-43	18-02-2019	

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[Содержит\(\[NameMake\], 'Vista Brite'\)](#)

[Очистить](#)



DoC Number/Revision: 10523855 rev. 6  
GMDN Code: 17846  
Product Family: Vista Brite Tip  
Product Group: Catheter, intravascular, guiding

CFF 10255063 rev 6  
Only native file to be used

## Declaration of Conformity (DoC)

**Manufacturer: Name:** Cordis Corporation  
**Address:** 14201 North West 60th Avenue  
Miami Lakes  
Florida, FL 33014  
USA

**Full Quality Assurance Certificate Number CE 00340.**

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### Authorized Representative:

**Name:** Cordis Cashel  
**Address:** Cahir Road,  
Cashel,  
Co. Tipperary. Ireland

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### Products/Model No:

The **Cordis 6F 0.070" Vista Brite Tip Guiding Catheter and Cordis 6F 0.070" Envoy Guiding Catheter** are classified as Class III, per Rule Number 6 of Annex IX of the Medical Device Council Directive 93/42/EEC. This declaration applies to the following product codes bearing the CE marking. **Design Examination Certificate CE 69002.**

CFF 10255063 rev 6  
 Only native file to be used

## Declaration of Conformity (DoC)

<b>Catalogue Numbers: 670-XXX-XX(B)</b>										
General Designation:     XXX – XXX – XXX										
X	X	X	-	X	X	X	-	X	X	X
1	2	3		4	5	6		7	8	9
<b>Number / Designation</b>								<b>Limitation</b>		
1     Outer Diameter (last Digit of French Size)								Will always be 6 French		
2,3   Lumen Size (last two digits in thousandths of an inch)								0.065 – 0.075 inches		
4,5,6   Configuration 000-299 Standard (subassembly) design 300-599 Design Variation 1 600-899 Design Variation 2 900-999 Design variation 3 / Overflow								Odd numbers contain a side hole  Even numbers do not contain a side hole		
7, 8    Length (last two digits in cm)								50 – 125 cm		
In addition, digits 8 or 9 may contain a single letter code: For example, E – Econopack L – Long Brite Tip N – Guiding Catheter with an introducer										
In addition, digit 9 (i.e. “B”) is sometimes used and indicates extra backup devise										
Modified Standards: SMXXXX and SMXXXXX										
<b>Lot number(s)</b>										
This Declaration of Conformity applies to all lot numbers										

CFF 10255063 rev 6  
Only native file to be used

## Declaration of Conformity (DoC)

### Manufacturing site:

The Cordis 6F 0.070" Vista Brite Tip Guiding Catheter and Cordis 6F 0.070" Envoy Guiding Catheter are manufactured at the following site:

Cordis de México S.A.de C.V.  
Calle Circuito Interior Norte #1820  
Parque Industrial Salvarcar  
Ciudad Juarez, Chihuahua  
CP 32574  
México

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**Declaration:** We, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of Directive 93/42/EEC as last amended.  
In order to affix CE marking, Cordis Corporation has followed the procedure relating to the EC declaration of conformity set out in Annex II, Clause 4 of the Directive 93/42/EEC as last amended. The full quality system has been certified by British Standards Institution (BSI) a Notified Body authorized to carry out such assessments and having the designation 0086.

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### Approved by:

Mayra Cisneros  
Manager, Regulatory Affairs  
Cordis Corporation

  
(Signature)

06/07/13  
(Date)



DoC Number/Revision: 10723643 Rev. 10  
 GMDN Code: 17846  
 Product Family: Vista Brite Tip  
 Product Group: Guiding Catheters

10255063 rev 6  
 Only native file to be used

## Declaration of Conformity (DoC)

**Manufacturer: Name:** Cordis Corporation  
**Address:** 14201 North West 60th Avenue  
 Miami Lakes  
 Florida 33014  
 USA

**Full Quality Assurance Certificate Number CE 00340.**

**Authorized Representative:**

**Name:** Cordis Cashel  
**Address:** Cahir Road,  
 Cashel,  
 Co. Tipperary, Ireland

**Products/Model No:**

The Vista Brite Tip Guiding Catheters are classified as Class III, Rule Number 6, per the Medical Device Directive. This declaration applies to the following product codes bearing the CE marking. Design Examination Certificate CE 01110.

Vista Brite Tip – 5F			Vista Brite Tip – 7F					
5560020L	5561700L	778-00000	778-01500	778-04500	778-06500	778-00490	778-18200	778-22455
5560040L	5561720L	778-00100	778-01600	778-04800	778-08000	778-03690	778-18300	778-25090
5560080L	5561740L	778-00200	778-01800	778-04900	778-08100	778-08290	778-18800	778-27090
SM7331	5561900L	778-0020E	778-02200	778-11400	778-08200	778-08390	778-19000	778-27855
5560400L	55625000	778-00300		778-05200	778-0820E	778-11090	778-19100	778-27890
5560540L	55625090	778-00400	778-03400	778-05300	778-08300	778-18090	778-27000	778-27990
5560560L	55625400	778-0040E	778-03600	778-05400	778-0830E	778-19090	778-27100	778-28055
5560600L	55625490	778-00500	778-0360E	778-05500	778-08400	778-19190	778-27200	778-28090
5560620L	55625600	778-0050E	778-03700	778-05600	778-08500	778-27090	778-27300	
5560800L	55625690	778-00600	778-03800	778-05700	778-08800	778-27890	778-27055	
5560820L	55625800	778-00700	778-03900	778-05800	778-08900	778-27990	778-27800	
5561100L	55625890	778-00800	778-04000	778-05900	778-09000	778-11000	778-27900	
5561120L	55626000	778-00900	778-04090	778-06000	778-09100	778-11100	778-21055	
5561620L	55626090	778-01000	778-04100	778-06100	778-09200	778-11200	778-21255	
5561640L	55627000	778-01200	778-04200	778-06200	778-11600	778-11300	778-21455	
5561660L	5562700L	778-01300	778-04300	778-06300	778-11800	778-18000	778-21690	
5561680L	5562780L	778-01400	778-04400	778-06400	778-00290	778-18100	778-22255	



DoC Number/Revision: 10723643 Rev. 10  
 GMDN Code: 17846  
 Product Family: Vista Brite Tip  
 Product Group: Guiding Catheters

10255063 rev 6  
 Only native file to be used

### Declaration of Conformity (DoC)

Vista Brite Tip 8F						
588-800	588-854	588-8116	588-8102	588-839	588-858	588-883
588-809	588-828	588-815	588-8103	588-840	588-859	588-884
588-810	588-830	588-818	588-8104	588-842	588-860	588-885
588-812	588-830E	588-816	588-8105	588-840P	588-861	588-886
588-813	588-831	588-819	588-803	588-841	588-862	588-887
588-821	588-831E	588-801	588-804	588-841P	588-863	588-889
588-822	588-833	588-802	588-805	588-850	588-864	588-890
588-823	588-835	588-815T	588-806	588-857P	588-865	588-891
588-823E	588-855	588-816T	588-817	588-858P	588-866	588-892
588-824	588-856	588-823T	588-820	588-842P	588-867	588-892T
588-825	588-857	588-830T	588-836	588-843P	588-870	588-893
588-825E	588-811	588-831T	588-837	588-844P	588-871	588-894
588-826	588-8106	588-841T	588-845	588-845P	588-872	588-895
588-827	588-8107	588-842P	588-846	588-846P	588-873	588-896
588-832	588-8108	588-843T	588-843	588-847P	588-874	588-898
588-834	588-8109	588-844T	588-843E	588-848P	588-875	588-899
588-834E	588-8110	588-845T	588-844	588-849P	588-876	
588-851	588-8111	588-850T	588-844E	588-8200	588-877	
588-851E	588-8112	588-851T	588-847	588-8201	588-878	
588-852	588-8113	588-829	588-848	588-8202	588-879	
588-853	588-8114	588-8100	588-849	588-8206	588-880	
588-853E	588-8115	588-8101	588-838	588-8207	588-882	

Vista Brite Tip 9F				Vista Brite Tip 10F	
598-900	598-915	598-949	598-941P	511-040P	
598-909	598-918	598-978	598-942P		
598-910	598-916	598-991	598-943P		
598-923	598-919	598-994	598-944P	556-002-00	556-080-00
598-932	598-917	598-996	598-945P	556-004-00	556-082-00
598-934	598-920	598-997	598-946P	556-008-00	556-112-00
598-951	598-941	598-942	598-949P	556-040-00	556-162-00
598-952	598-950	598-986		556-054-00	556-168-00
598-953	598-937	598-987		556-056-00	556-172-00
598-928	598-945	598-992		556-060-00	556-174-00
598-930	598-936	598-9200			
598-931	598-943	598-9201			
598-933	598-944	598-9202			
598-955	598-947	598-9206			
598-966	598-948	598-9207			

Modified Standard for Vista Brite Tip Guidig Catheters  
 SMXXXX series, SMXXXXX series – Modified Standards



DoC Number/Revision: 10723643 Rev. 10  
GMDN Code: 17846  
Product Family: Vista Brite Tip  
Product Group: Guiding Catheters

10255063 rev 6  
Only native file to be used

## Declaration of Conformity (DoC)

### Manufacturing site:

The Vista Brite Tip Guiding Catheter is manufactured at the following site:

Cordis de México S.A.de C.V.  
Calle Circuito Interior Norte #1820  
Parque Industrial Salvarcar  
Ciudad Juarez, Chihuahua  
CP 32574  
México

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**Declaration:** We, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of Directive 93/42/EEC as last amended.  
In order to affix CE marking, Cordis Corporation has followed the procedure relating to the EC declaration of conformity set out in Annex II, Clause 4 of the Directive 93/42/EEC as last amended. The full quality system has been certified by British Standards Institution (BSI) a Notified Body authorized to carry out such assessments and having the designation 0086.

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### Approved by:

Babu Periasamy  
Manager, Regulatory Affairs

(Signature)

11- APR - 2014

(Date)



# EC Design-Examination Certificate

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

**No.** **CE 01110**  
**Issued To:** **Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

In respect of:

**Cordis Guiding Catheters**

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **03 January 1996**

Date: **13 December 2015**

Expiry Date: **02 January 2021**

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Page 1 of 6

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 01110

Issued To:

**Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

<b>Guiding Catheter Cat. Nos</b>	<b>Family Name</b>	<b>French Size</b>
511-XXX, 511-XXXX, SMXXXX, SMXXXXX series	Vista brite tip	10
588-8XX, 588-8XXX, 8XXE, 8XXP, 8XXT, SMXXXX, SMXXXXX series	Long Brite tip	8F
598-9XX, 9XXE, 9XXP, 9XXT, SMXXXX, SMXXXXX series	Vista brite tip	9
778-XXX-XX, XXX, XE, SMXXXX, SMXXXXX series	Vista Brite tip	7F
<b>Guiding Catheter Cat. Nos</b>	<b>Family Name</b>	<b>Type/Family</b>
556-0(x)(x)-xx, SMXXXX, SMXXXXX	Vista Brite tip / Envoy	JL Family, AL Family, XB Left Family, JR Family
556-1(x)(x)-xx, SMXXXX, SMXXXXX	"	Right Superior Take Off, AR Family, Other Right Family, XBR Family, Left/Right Coronary Bypass
556-2(x)(x)—xx, SMXXXX, SMXXXXX	"	Endovascular / Radiology / Peripherals
	<b>Multivessel Shapes</b>	
556-27(x)-xx, SMXXXX, SMXXXXX		Multipurpose Family
556-27(x)-xx, SMXXXX, SMXXXXX		Hockey Stick Family
556-28(x)-xx, SMXXXX, SMXXXXX		Straight Family

First Issued: **03 January 1996**

Date: **13 December 2015**

Expiry Date: **02 January 2021**

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# EC Design-Examination Certificate

## Supplementary Information to CE 01110

Issued To:

**Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

## Certificate History

Date	Reference Number	Action
3 January 1996	MD 000065	First Issue
3 September 1996	MD 000143	All products present in the scope except for the Envoy have had a line extension to provide catheters with longer lengths
26 June 1997	MD 000242	Change of Body material and lengths of the 5F and 6F ENVOY and 6F, 7F, and 8F Vista Brite Tip Catheters. Inclusion of the ECO package (5 single pouched catheters in a box)
30 June 1997	MD 000242	Amendment to 10F Vista Brite tip catalogue number to read 511-XXXOXXT
19 December 1997	MD 000272	4.7F and 6F Eco-packs; 6F and 8F Long Brite Tip products added to the product listing

First Issued: **03 January 1996**

Date: **13 December 2015**

Expiry Date: **02 January 2021**

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# EC Design-Examination Certificate

## Supplementary Information to CE 01110

Issued To:

**Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

## Certificate History

Date	Reference Number	Action
1 May 1998	MD 000395	620-5F SMXXXX, SMXXXXX Envoy 620-6F SMXXXX, SMXXXXX Envoy 562-6F SMXXXX, SMXXXXX Petit Brite Tip TM Vista 564-6F SMXXXX, SMXXXXX Vista Brite Tip 572-7F SMXXXX, SMXXXXX Brite Tip 574-7F SMXXXX, SMXXXXX Vista Brite Tip TM Vista 578-8F SMXXXX, SMXXXXX Brite Tip 584-8F SMXXXX, SMXXXXX XL Brite Tip 586-8F SMXXXX, SMXXXXX Vista Brite Tip 598-9F SMXXXX, SMXXXXX Vista Brite Tip 511-10F SMXXXX, SMXXXXX Vista Brite Tip 523-4.7F SMXXXX, SMXXXXX ECO packs 564-4.7F and 6F SMXXXX, SMXXXXX ECO packs 564-6F SMXXXX, SMXXXXX Long Brite Tip 588-8F SMXXXX, SMXXXXX Vista Brite Tip Added to the product range

First Issued: **03 January 1996**

Date: **13 December 2015**

Expiry Date: **02 January 2021**

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# EC Design-Examination Certificate

## Supplementary Information to CE 01110

Issued To:

**Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

## Certificate History

Date	Reference Number	Action
3 June 1998	MD 000403	562-6F SMXXXX, SMXXXXX Petit Brite Tip TM 564-6F 6MBLC, 6MBRC, 6MA, 6MB, 6MC, 6MD, 6ME, 6LAD3, 6LAD3.5, 6LAD 4 Vista Brite Tip TM Vista 788-7F XXX-XX, XXX-XE, SMXXXX, SMXXXXX Vista Brite Tip Added to the product listing.  564-6F 6XXX, Vista Brite Tip and Envoy deleted from the product listing
16 September 1998	MD 000464	667-6F XXX_XX, XXX-XE Vista Brite Tip 620-6F XXX-XX, XXX-XE SMXXXX, SMXXXXX Vista Brite Tip Added to the product listing
23 March 1999	MD 000558	Scope changed to read: "Cordis Guiding catheters and Introducing Catheters"  523-050-5F SMXXXX, SMXXXXX Eco Pack 677-5F and 6F XXX-XN, SMXXXX, XMXXXXX Eco pack Added to the product listing
23 June 1999	MD 000558	667-XXX-XL – 6F Long Brite Tip 588-8XX-8F long Brite Tip Added to the product range

First Issued: **03 January 1996**

Date: **13 December 2015**

Expiry Date: **02 January 2021**

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# EC Design-Examination Certificate

## Supplementary Information to CE 01110

Issued To:

**Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

## Certificate History

Date	Reference Number	Action
11 May 2000	10011849	Guiding Catheter 5F range added to the product listing 556-37 (X) – XX Multipurpose Family 556-27 (X) – XX Hockey Stick Family 556-28 (X) – XX Straight Family Added to the product listing
3 January 2001	10020673	5 year Renewal
29 November 2001	10032354	SMXXXX, SMXXXXX sizes added to the 5F Guiding Catheter and Multivessel shape product range
10 October 2002	10042512	Change catalogue numbers from 511-OXX to 511-XXXX
31 March 2006	10078108	5 Year Renewal, change scope, remove eco packs and introducing catheters
08 June 2007	10088941	Change in pouch heat seal coating from CR 27 (ex. Perfecseal) and 703 HSC (ex. Mangar) to PTH 025 (ex. Mangar)
01 August 2007	10089895	Add pouch with RLE004 PET/PE film PTH 034 heat seal coating, and Tyvek 1073B
07 December 2010	10119347	Certificate Renewal
13 December 2015	10159051	Certificate renewal and Envoy Interventional Neuro-Radiology product codes removed from scope – transferred to Codman & Shurtleff Inc. certificate CE 555760.

First Issued: **03 January 1996**

Date: **13 December 2015**

Expiry Date: **02 January 2021**

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# EC Design-Examination Certificate

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

**No.** CE 69002  
**Issued To:** **Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

In respect of:

**Cordis 6F 0.070" Vista Brite Tip<sup>®</sup> Guiding Catheters**

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: **2002-08-19**

Date: **2017-07-31**

Expiry Date: **2022-08-18**

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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 69002

Issued To:

**Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

### Product:

<b>General Designation: 670-XXX-XX</b>	
<b>XXX – XXX – XXX</b>	
123 456 789	
Number / Designation	Limitation
1 Outer Diameter (last digit of French Size)	Will always be 6 French
2,3 Lumen Size (last 2 digits in thousandths of an inch)	0.065-0.075 inches
4,5,6 Configuration 000-299 Standard (subassembly) design 300-599 Design variation 1 600-899 Design variation 2 900-999 Design variation 3 / Overflow	Odd numbers contain a side hole Even numbers do not contain a side hole
7,8 Length (last 2 digits in cm)	50-125 cm
In addition digits 8 or 9 may contain a single letter code. For example, E – Econopack L – Long Bright Tip N – Guiding catheter with an introducer	

Modified Standards: SMXXXX and SMXXXXX

First Issued: **2002-08-19**

Date: **2017-07-31**

Expiry Date: **2022-08-18**

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# EC Design-Examination Certificate

## Supplementary Information to CE 69002

Issued To:

**Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

## Certificate History

Date	Reference Number	Action
19 August 2002	EQ 10040583	First issue. Change of format of the Certificate product listing.
09 December 2003	EQ 10052521	The addition of Roden, The Netherlands to the list of Sterilization companies used. New format for the presentation of the catalogue numbers.
23 August 2004	EQ 10059974	Shelf Life extension to 3 years and revision of history to remove items prior to first issue under CE 69002.
31 March 2006	EQ 10078108	Changes to wildcards.
08 June 2007	EQ 10088941	Change in pouch heat seal coating from CR 27 (ex. Perfecseal) and 703 HSC (ex. Mangar) to PTH 025 (ex. Mangar).
01 August 2007	EQ 10089895	Add pouch with RLE004 PET/PE film PTH 034 heat seal coating, and Tyvek 1073B.
31 August 2007	EQ 10089893	Certificate renewal.
16 August 2012	10136333	Certificate renewal Modified Standards: SMXXXX and SMXXXXX added as they were inadvertently omitted when CE 69002 was split from CE 01110 under EQ 10040583.

First Issued: **2002-08-19**

Date: **2017-07-31**

Expiry Date: **2022-08-18**

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# EC Design-Examination Certificate

## Supplementary Information to CE 69002

Issued To:

**Cordis Corporation**  
**14201 North West 60th Avenue**  
**Miami Lakes**  
**Florida**  
**33014**  
**USA**

## Certificate History

Date	Reference Number	Action
04 February 2016	10160465	Change affecting DuPont Tyvek 1073B packaging material – all product codes are affected.
Current	8763074	Certificate Renewal. Removed Envoy® Guiding Catheter from certificate scope and product catalogue.

First Issued: **2002-08-19**

Date: **2017-07-31**

Expiry Date: **2022-08-18**

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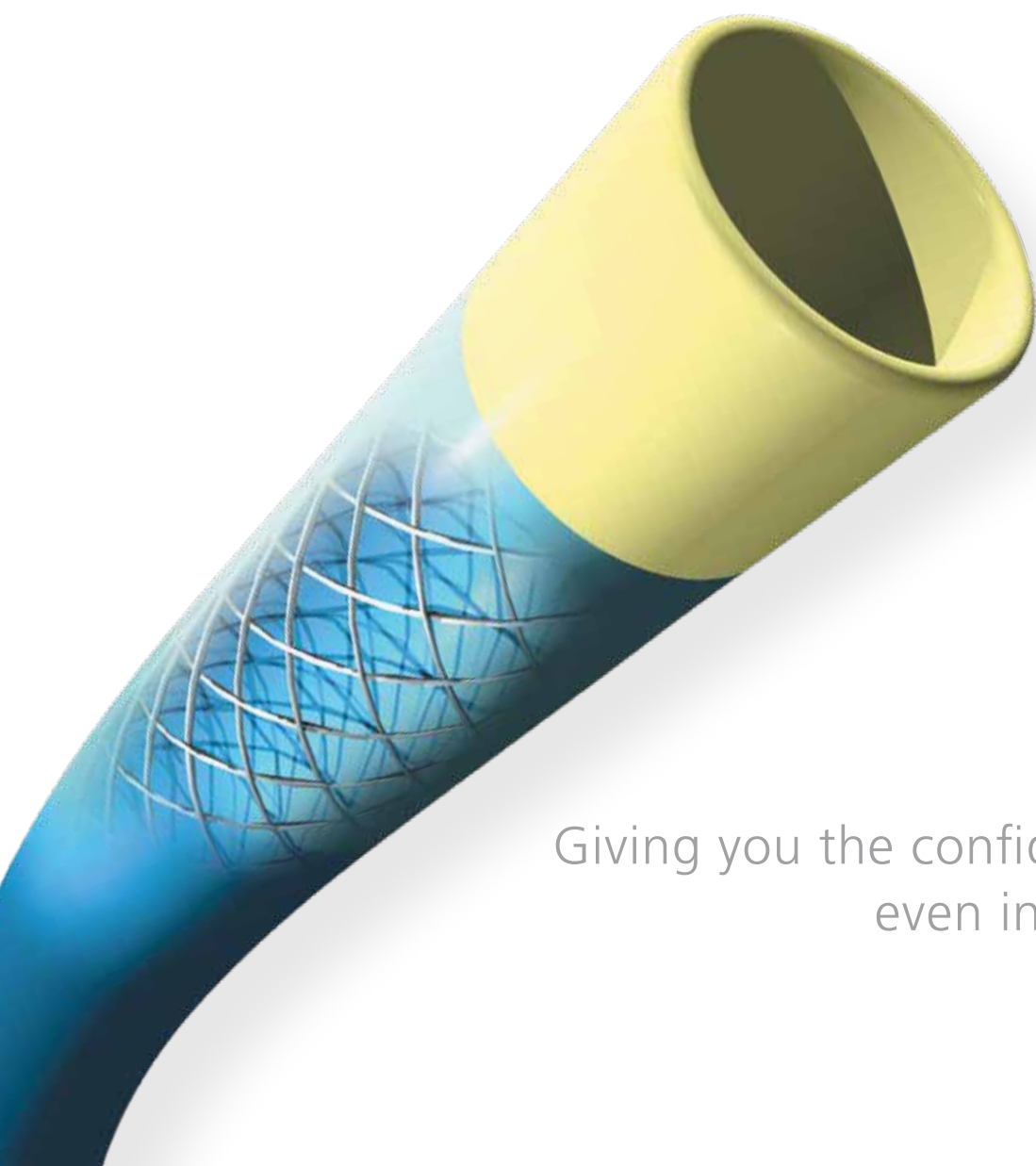
Page 4 of 4

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.

# Cordis **VISTA BRITE TIP**<sup>™</sup>

Guiding Catheter

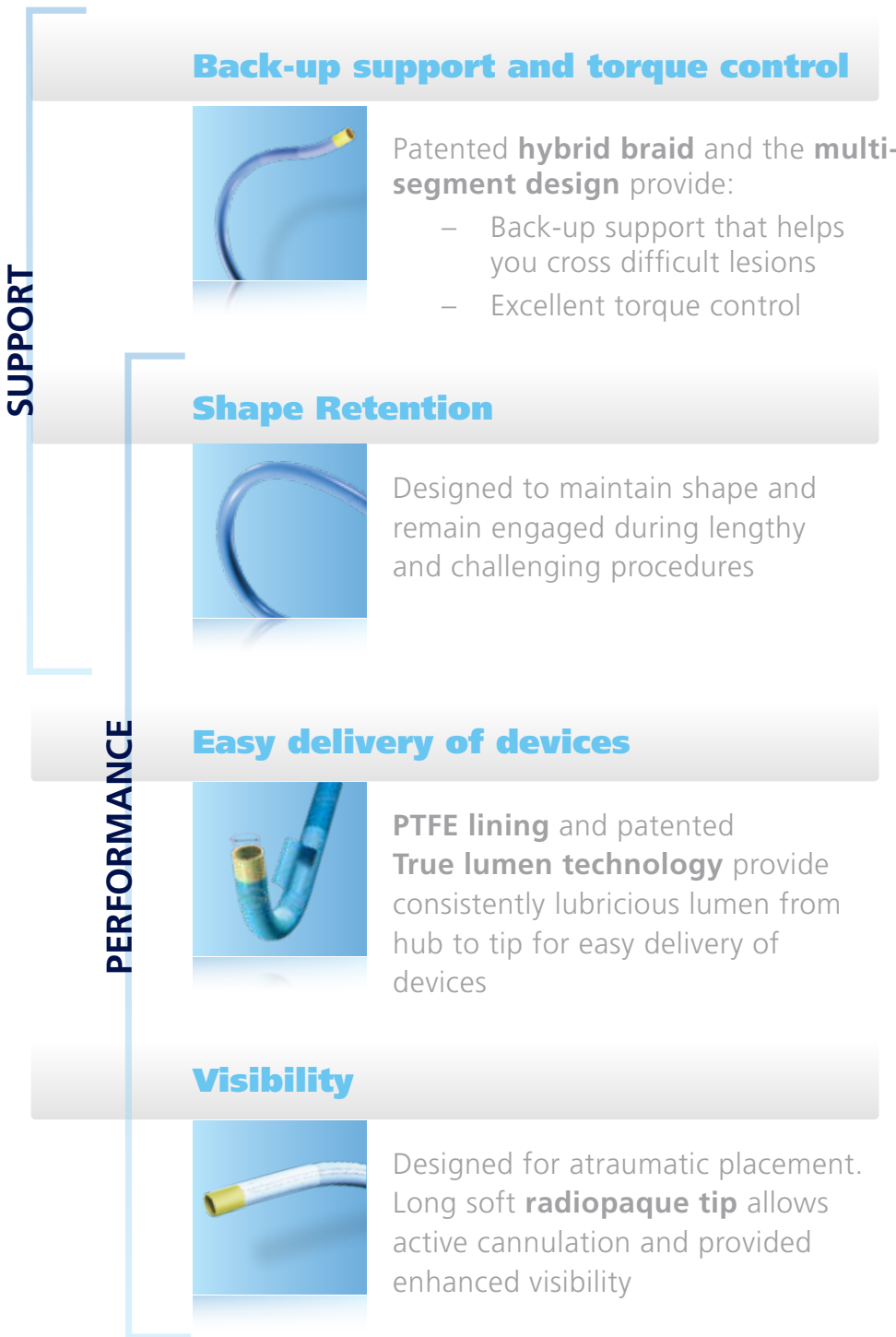
Designed for  
**support and  
performance**



Giving you the confidence and support  
even in challenging cases

# Guiding Catheters

## Designed for support and performance



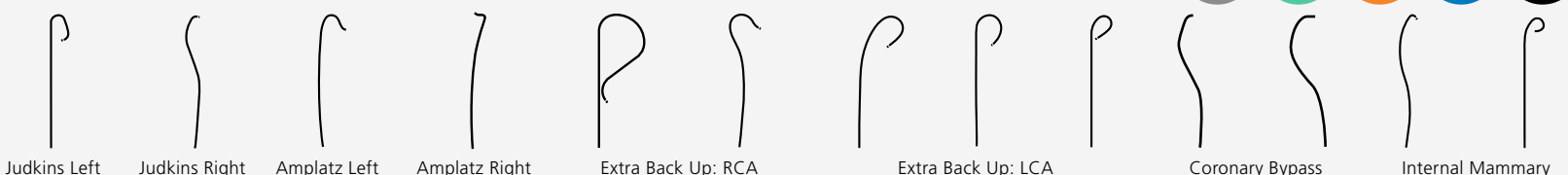
**Hybrid braid**

**Multi-segment design / radiopaque tip**

**PTFE liner / True lumen technology**

**Guiding Catheters** are available in a wide range of shapes and configurations.

- 5F.056"
- 6F.070"
- 7F.078"
- 8F.088"
- 9F.098"



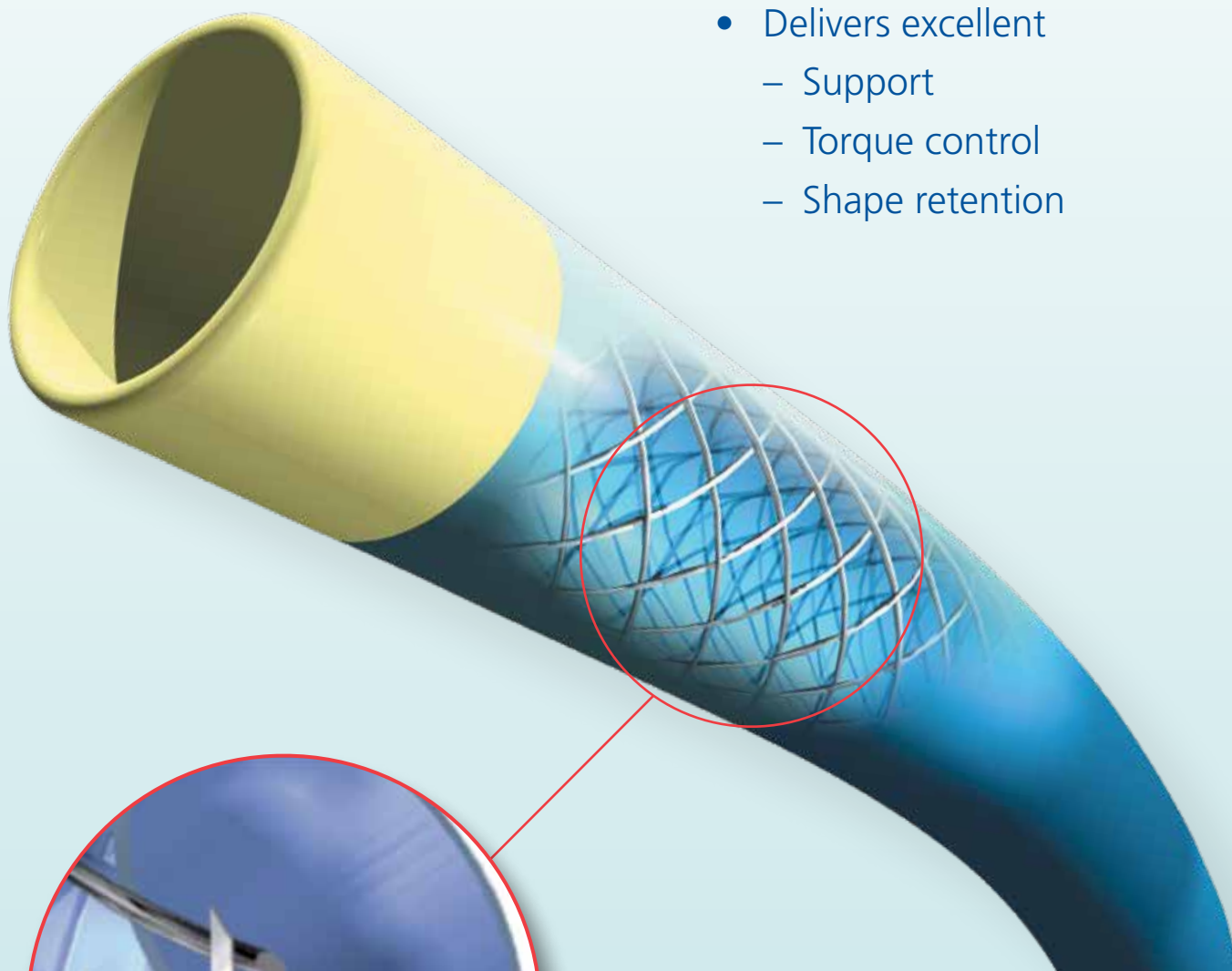


# Cordis **VISTA BRITE TIP™**

Guiding Catheter – Designed for support and performance

## Hybrid Braid Construction

- Patented hybrid braiding
- Allows for a thin wall without sacrificing support
- Delivers excellent
  - Support
  - Torque control
  - Shape retention



**Back-up support and torque control**  
**Shape retention**



# Cordis **VISTA BRITE TIP™**

Guiding Catheter – Designed for support and performance

## Multi-Segment Design

A variation of design and materials to balance strength and flexibility promoting:

- Coaxial alignment
- Kink resistance
- Support

### Kink Resistant Segment

The segment absorbs the kink forces between the firm shaft and the soft distal segments.

### The Bright Tip

The Bright Tip is ultra-soft to ensure safe engagement.

### Coaxial Segment

This soft braided segment optimizes tip flexibility and provides gentle cannulation.

### Torque/Support Segment

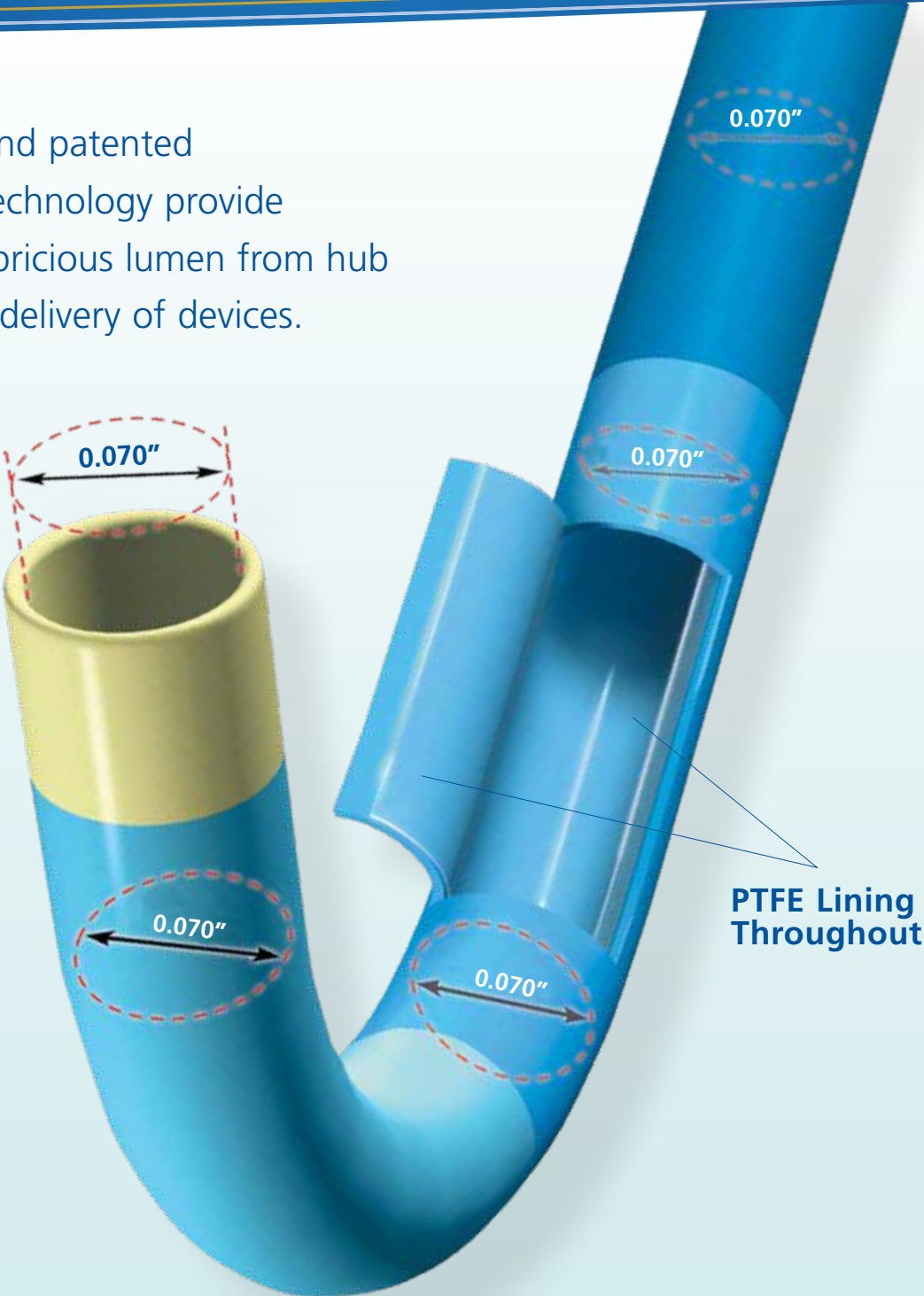
This segment delivers a 1:1 transfer of torsional and lateral force from hub to distal end. Moreover, it ensures a solid foundation for support.

**Back-up support and torque control**

**Shape retention**

**Excellent visibility**

**PTFE Lining** and patented **True lumen** Technology provide consistently lubricious lumen from hub to tip for easy delivery of devices.



**Easy delivery of devices**

### **True lumen technology**

Guarantees precise diameters from hub to tip (0.070" for 6F)

# Cordis **VISTA BRITE TIP™**

Guiding Catheter – Designed for support and performance

## **Long VISTA BRITE TIP™**

Guiding Catheter

Provides additional support and stability.

- 16 mm tip, flexible and atraumatic
- Deep intubation for active support
- Conformity with the anatomy of the vessels

**16 mm  
ultra soft tip  
facilitates  
active support**

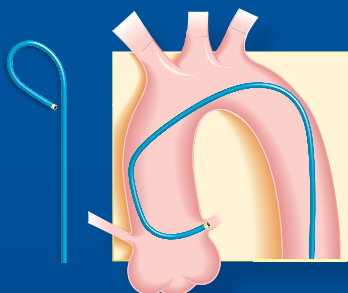


**Long VISTA BRITE TIP™**  
Guiding Catheter

# Cordis Offers a Complete Line of **Extra Back-up**

## Guides For Both the Left and Right Coronary Arteries

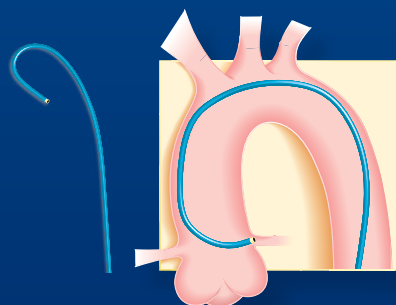
### LCA



#### **XB**

First choice guiding catheter, adapted to most anatomies which allows very good coronary support and with minimal trauma.

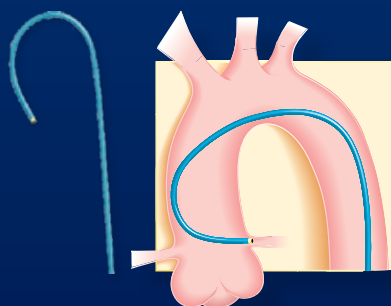
- More backup support than JL
- Allows good coaxial alignment to intubate the circumflex and left anterior descending (LAD) arteries
- Adapted for normal ostium take-off
- 1/2 size down from JL standard (XB 3.5 = JL4)
- Suited for transradial procedures, including XB-2.5



#### **XBC**

An extra backup shape for the left coronary and adapted to a short or absent left main and to a very angular CX origin.

- More backup support than JL
- Adapted for normal, superior or inferior aortic take-offs
- 1/2 size down from JL standard (XBC 3.5 = JL4)
- Suited for transradial procedures

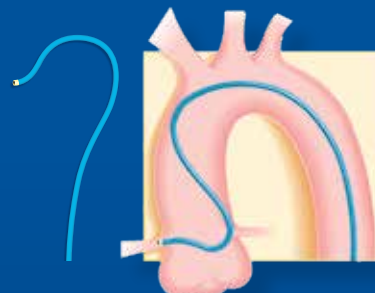


#### **XBLAD**

Extra-support for the intubation of the left coronary and more specifically designed for the LAD.

- More support than a JL4 and enables extra support for LAD
- Adapted for superior aortic take-offs
- 1/2 size down from JL standard (XBLAD 3.5 = JL4)
- Suited for transradial procedures

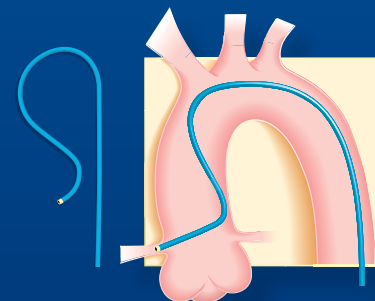
### RCA



#### **XBRCa**

The Extra Back up shape designed for the Right Coronary.

- More support than an Amplatz or JR shapes
- Adapted for normal or superior aortic take-offs



#### **XBR**

Another Extra Back up shape designed for the Right Coronary.

- More support than an Amplatz or JR shapes
- Adapted for normal and inferior take-offs
- XBR1 for normal aortas and XBR2 for dilated aortas



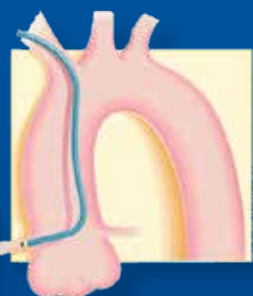
**Extra-Back up**  
shapes available

# Cordis **VISTA BRITE TIP™**

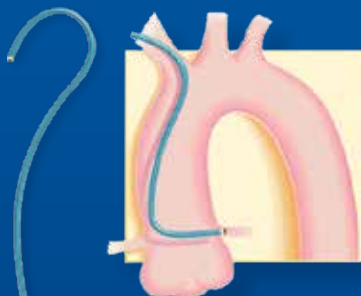
Guiding Catheter – Designed for support and performance

## Extra Back-up in Transradial Interventions

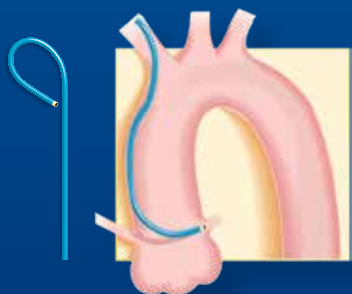
### Judkins Fajadet Right (JFR)



### Judkins Fajadet Left (JFL)



A modification of the Judkins catheters especially developed for giving extra back up during transradial procedures.



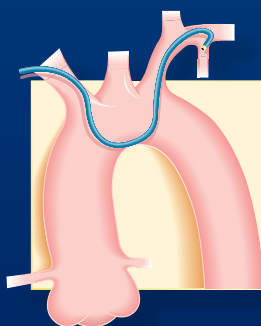
### XB 2.5

In general, engagement of the left coronary artery requires smaller catheters (i.e. a JL 3.5 compared with a JL 4) compared with those used for femoral or left radial approaches. XB-2.5 is a smaller curve of the best selling XB family. Suitable for aortas in which JL-3.0 would be needed radially.

## IM Options via Radial

### Barbeau IM Curve

Coronarography and angioplasty via right radial approach of left and right internal mammary arteries.



### 3D LIMA 90 Curve

Coronarography and angioplasty via right radial approach of left and right internal mammary arteries.

Angioplasty of the renal artery using right or left radial approach.

## LONG Catheters

Cordis offers a number of guiding catheters longer than the standard 100 cm for:

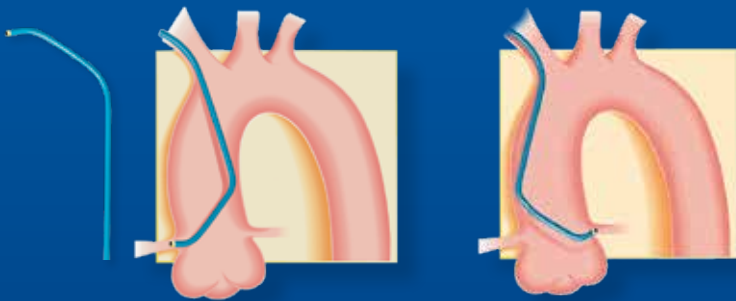
- very tall patients
- tortuous anatomy
- angioplasty of the renal artery using right or left radial approach



# Radial Solutions: Special Radial Shapes

## Radial Bi-Lateral / Multipurpose

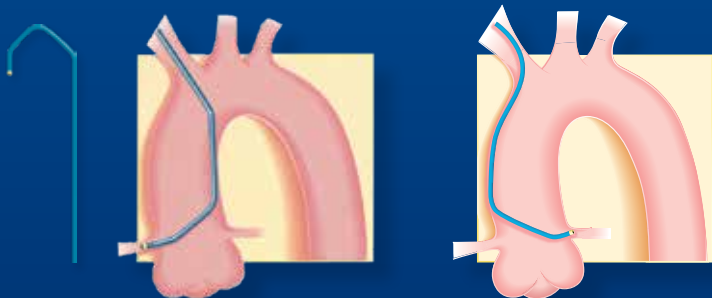
Cordis offer a series of catheter choices to cannulate both the LCA and RCA.



### Barbeau

Coronary catheterisation via right radial access of the left and right coronary arteries.

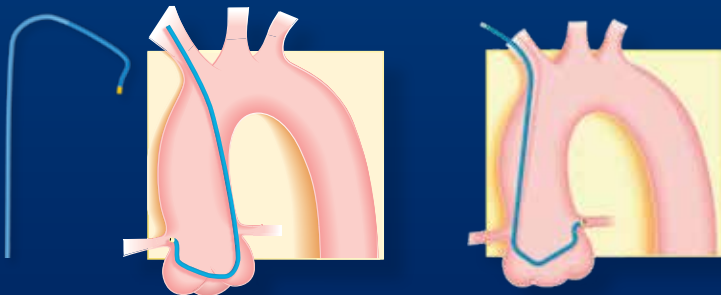
- Primary curve of 135 degrees added to an MPA catheter (Multipurpose A)
- Can be used for the right and left ostium cannulation
- Curvature very suitable for the right coronary artery
- If the left coronary artery is difficult to cannulate use a XB catheter



### Radial Brachial (RB)

Designed to perform the right transradial Kimmy Technique, can be used to engage both the left and right coronary arteries.

The shape is designed with three angles that allow contralateral wall support and tip engagement.



### Brachial left (BL) (Tilon)

Coronary catheterisation via right radial access of the left and right coronary arteries.

- Allows effective cannulation of the left coronary artery
- Allows easy and effective cannulation of the right coronary artery when the ostium is at the same level as the left ostium



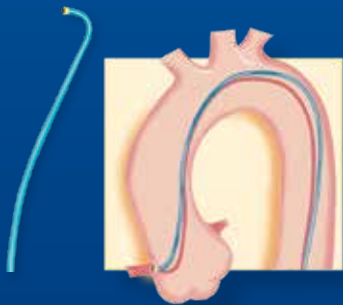
## Angioplasty of renal artery using left or right radial access



### MPA 115 cm – 125 cm Curve / JR4 125 cm

- Allows cannulation of ostiums of descending arteries
- Alternative for patients with no femoral access

## Other shapes

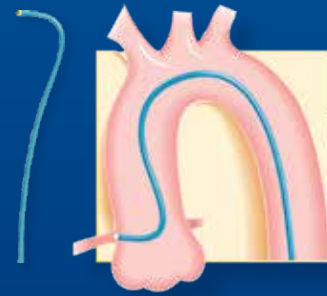


### 3DRC (Williams Technique)

A popular choice of guiding catheter, suitable for most anatomies of the right coronary artery.

Three-dimensional curve allows for limited torque needed for its insertion in the right coronary artery. Suitable for:

- ostial lesions
- right and left internal mammary arteries



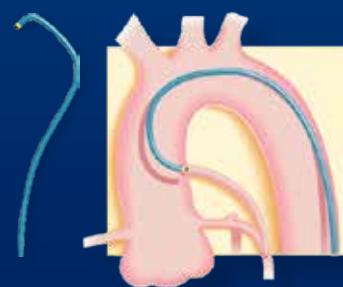
### Hockey Stick – HS Curve

Guiding catheter which are able to catheterise the right coronary artery and right saphenous vein bypass grafts.

The HS offers more support than a Judkins right (JR) and can be a first choice catheter.

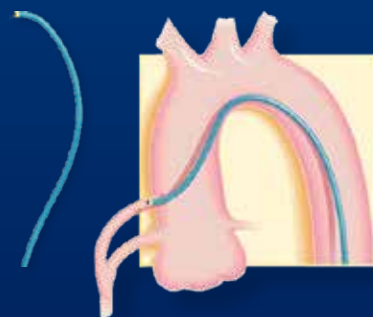
Adapted to radial approach.

## Other Options for PCI in Coronary Bypass



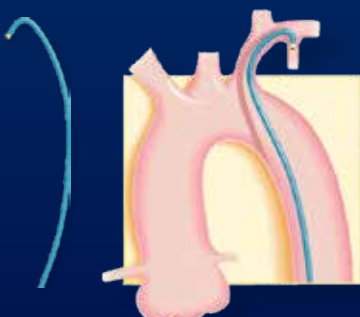
### LCB

Left Coronary Artery via Femoral.



### RCB

Right Coronary Artery via Femoral.



### IM

Internal mammary femoral access.

# Cordis **VISTA BRITE TIP**<sup>™</sup>

Guiding Catheter Designed for support and performance

- 1. Back-up support and torque control**
- 2. Shape retention**
- 3. Easy delivery of devices**
- 4. Excellent visibility**

Giving you the confidence and support even in challenging cases

## Cordis **VISTA BRITE TIP**<sup>™</sup>


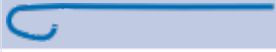






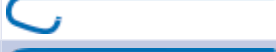















Guiding Catheter

Available in a wide variety of shapes, including transradial-specific, and from 5F to 9F




# Guiding Catheters

## Left Coronary Judkins Technique

### JUDKINS LEFT

SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
JL 3				670-000-00	778-000-00	588-812
JL 3 SH		2 side holes			778-001-00	
JL 3.5				670-002-00	778-002-00	588-851
JL 3.5 LBT		Long VISTA BRITE TIP™	556-002-0L			
JL 3.5 ST		short tip		670-012-00	778-012-00	
JL 3.5 SH		2 side holes		670-003-00	778-003-00	588-832
JL 4				670-004-00 670-004-0E	778-004-00	588-823
JL 4		90 cm		670-004-90		
JL 4 LBT		Long VISTA BRITE TIP™	556-004-0L	670-004-0L		
JL 4 ST		short tip		670-014-00	778-014-00	
JL 4 SH		2 side holes		670-005-00	778-005-00	588-834
JL 4 ST SH		short tip, 2 side holes			778-015-00	
JL 4		125 cm		SM7435*	SM6987*	
JL 4 SH		125 cm, 2 side holes				SM7128*
JL 4.5				670-006-00	778-006-00	588-852
JL 4.5 LBT		Long VISTA BRITE TIP™	SM7329*			
JL 4.5 ST		short tip		670-016-00		
JL 4.5 SH		2 side holes			778-007-00	588-810
JL 5				670-008-00	778-008-00	588-853
JL 5 LBT		Long VISTA BRITE TIP™	556-008-0L			
JL 5 SH		2 side holes			778-009-00	588-800
JL 5		125 cm		SM7361*	SM6731*	
JL 6				670-010-00	778-010-00	588-854
JL 6		125 cm			SM7445*	

### JUDKINS CURVED LEFT



JCL 3.5				670-026-00		
JCL 3.5 SH		2 side holes		670-027-00		
JCL 4				670-028-00		

\* Please note that the modified standard catheters will be produced on special request and are subject to longer delivery times and list prices.

# Guiding Catheters

## Left Coronary Extra Back-Up Shapes

### EXTRA BACK-UP


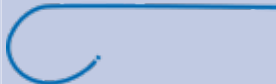



SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
XB 2.5				SM7465*		
XB 3				670-052-00	778-052-00	588-829
XB 3 LBT		Long VISTA BRITE TIP™	SM7328*			
XB 3 SH		2 side holes		670-053-00	778-053-00	588-875
XB 3.5				670-054-00	778-054-00	588-882
XB 3.5		90 cm		670-054-90		
XB 3.5 LBT		Long VISTA BRITE TIP™	556-054-0L	670-054-0L		
XB 3.5 SH		2 side holes		670-055-00	778-055-00	588-885
XB 3.5 LBT		Long VISTA BRITE TIP™, 120 cm	SM7400*			
XB 3.5		125 cm		SM7437*	SM6991*	
XB 4				670-056-00	778-056-00	588-894
XB 4		125 cm		SM7363*		
XB 4 LBT		Long VISTA BRITE TIP™	556-056-0L			
XB 4 SH		2 side holes		670-057-00	778-057-00	588-896
XB 4.5				670-058-00	778-058-00	
XB 4.5 SH		2 side holes		670-059-00	778-059-00	
XBC 3				670-070-00		
XBC 3 SH		2 side holes		670-071-00		
XBC 3.5				670-072-00		
XBC 3.5 LBT		Long VISTA BRITE TIP™	SM7466			
XBC 3.5 SH		2 side holes		670-073-00		
XBC 4				670-074-00		
XBC 4.5 SH		2 side holes		670-077-00		
XBLAD 3				670-066-00		
XBLAD 3 SH		2 side holes		670-067-00		
XBLAD 3.5				670-060-00	778-060-00	588-8100

\* Please note that the modified standard catheters will be produced on special request and are subject to longer delivery times and list prices.

# Guiding Catheters

## Left Coronary Extra Back-Up Shapes

### EXTRA BACK-UP

SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
XBLAD 3.5 LBT		Long VISTA BRITE TIP™	556-060-0L			
XBLAD 3.5 SH		2 side holes		670-061-00	778-061-00	588-8103
XBLAD 4				670-062-00	778-062-00	588-8101
XBLAD 4 SH		2 side holes		670-063-00	778-063-00	
XBLAD 4.5				670-064-00		

## Left Coronary Amplatz Technique

### AMPLATZ LEFT

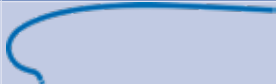






SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
AL .75				670-034-00	778-034-00	588-890
AL .75 SH		2 side holes		670-035-00		
AL 1				670-036-00	778-036-00	588-843
AL 1 LBT		Long VISTA BRITE TIP™	SM7331*	SM7389*		
AL 1 ST		short tip		670-044-00	778-044-00	588-870
AL 1 SH		2 side holes		670-037-00	778-037-00	588-847
AL 1 ST SH		short tip, 2 side holes			778-045-00	
AL 1		125 cm		SM7438*	SM7115*	
AL 1.5				670-038-00	778-038-00	
AL 1.5 SH		2 side holes			778-039-00	588-878
AL 2				670-040-00	778-040-00	588-844
AL 2		90 cm				588-844T
AL 2		125 cm		SM7279*		

\* Please note that the modified standard catheters will be produced on special request and are subject to longer delivery times and list prices.

# Guiding Catheters








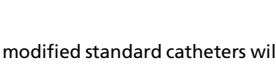

## Left Coronary Amplatz Technique

### AMPLATZ LEFT

SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
AL 2 LBT		Long VISTA BRITE TIP™	556-040-0L	670-040-0L		
AL 2 ST		short tip			778-048-00	
AL 2 SH		2 side holes		670-041-00	778-041-00	588-848
AL 3				670-042-00	778-042-00	588-849
AL 3		125 cm			SM6988*	
AL 3 LBT		Long VISTA BRITE TIP™	SM7332*			
AL 3 SH		2 side holes			778-043-00	588-891

## Right Coronary Judkins Technique

### JUDKINS RIGHT

SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
JR 3.5				670-080-00	778-080-00	588-855
JR 3.5 LBT		Long VISTA BRITE TIP™	556-080-0L	SM7390*		
JR 3.5 SH		2 side holes		670-081-00	778-081-00	588-828
JR 4				670-082-00	778-082-00	588-830
JR 4		90 cm		670-082-90		
JR 4 LBT		Long VISTA BRITE TIP™	556-082-0L	670-082-0L		
JR 4 LBT		110 cm	SM7426*			
JR 4 ST		short tip		670-090-00	778-090-00	
JR 4 SH		2 side holes		670-083-00	778-083-00	588-831
JR 4		125 cm		SM7436*		
JR 4 SH		125 cm, 2 side holes			SM7444*	
JR 4.5 ST		short tip			778-092-00	





\* Please note that the modified standard catheters will be produced on special request and are subject to longer delivery times and list prices.



# Guiding Catheters





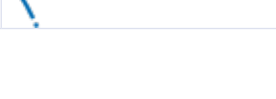
## Right Coronary Judkins Technique

### JUDKINS RIGHT




SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
JR 5				670-084-00	778-084-00	588-856
JR 5		125 cm		SM7359*		
JR 5 LBT		Long VISTA BRITE TIP™	SM7330			
JR 5 SH		2 side holes			778-085-00	

## Right Coronary Extra Back-Up Shapes

### RIGHT CORONARY EXTRA BACK-UP SHAPES

SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
XBR 1				670-122-00		
XBR 1 SH		2 side holes		670-123-00		
XBR 2				670-124-00		
XBRCA				670-126-00		
XBRCA SH		2 side holes		670-127-00		

### WILLIAMS TECHNIQUE









SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
3DRC				670-130-00		
3DRC LBT		Long VISTA BRITE TIP™	SM7599*			
3DRC SH		2 side holes		670-131-00		

\* Please note that the modified standard catheters will be produced on special request and are subject to longer delivery times and list prices.

# Guiding Catheters

## Right Coronary Amplatz Technique




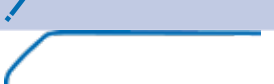








### AMPLATZ RIGHT

SHAPE						
Name	Picture	Observation	5F	6F	7F	8F
AR 1				670-110-00	778-110-00	588-845
AR 1 LBT		Long VISTA BRITE TIP™	SM7333	670-110-0L		
AR 1 SH		2 side holes			778-111-00	588-836
AR 1		125 cm			SM7296*	
AR 2				670-112-00	778-112-00	588-846
AR 2		125 cm		SM7360*		
AR 2 LBT		Long VISTA BRITE TIP™	556-112-0L	670-112-0L		
AR 2 SH		2 side holes		670-113-00	778-113-00	588-837

# Guiding Catheters

## Transradial / Brachial Technique

### TRANSRADIAL TECHNIQUE


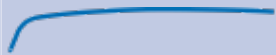







SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
RBL 4				SM7717*		
CAS 2				SM6877*		
CAS 3				SM7066*		
SON 1				SM7166*		
RB		Kimny Technique	556-172-0L	670-172-00		
Barbeau			556-174-0L	670-174-00		
Barbeau		125 cm		SM7713*		
3D LIMA 90				SM7501*		
IM Barbeau			SM7641	SM7638*		
JFL			556-162-0L	670-162-00		
JFR			556-168-0L	670-168-00		
XB 2.5				SM7465*		






# Guiding Catheters

## Multipurpose

### MULTIPURPOSE




SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
MPA 1 LBT		Long VISTA BRITE TIP™ 100 cm	556-270-0L			
MPA 1				670-270-00	778-270-00	588-842
MPA 1 LBT		Long VISTA BRITE TIP™		670-270-0L		
MPA 1 SH		2 side holes		670-271-00	778-271-00	588-892
MPA 1		125 cm		SM7477*	SM7206*	
MPA 1 SH		125 cm, 2 side holes			SM7482*	
MPA 2		125 cm		SM7394*		
MPB 1				670-272-00		
MPB 1 SH		2 side holes			778-273-00	

### HOCKEY STICK

SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
H-STICK				670-278-00	778-278-00	588-841
H-STICK LBT		Long VISTA BRITE TIP™	556-278-0L	670-278-0L		
H-STICK SH		2 side holes		670-279-00	778-279-00	588-850

## Bypass

### LEFT CORONARY BYPASS



SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
LCB				670-180-00	778-180-00	588-815
LCB LBT		Long VISTA BRITE TIP™	SM7327*			
LCB SH		2 side holes		670-181-00	778-181-00	

\* Please note that the modified standard catheters will be produced on special request and are subject to longer delivery times and list prices.





# Guiding Catheters

## Bypass

### RIGHT CORONARY BYPASS

SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
RCB				670-182-00	778-182-00	588-816
RCB SH		2 side holes		670-183-00	778-183-00	

### INTERNAL MAMMARY

SHAPE			5F	6F	7F	8F
Name	Picture	Observation				
IM				670-190-00	778-190-00	588-817
IM		90 cm		670-190-90		
IM SH		2 side holes		670-191-00	778-191-00	588-820
IM LBT		Long VISTA BRITE TIP™	556-190-0L			

## Long Catheters

### Long Catheters

Name	Observation	5F	6F	7F	8F
AL 1	125 cm		SM7438*	SM7115*	
AL 2	125 cm		SM7279*		
AL 3	125 cm			SM6988*	
AR 1	125 cm			SM7296*	
AR 2	125 cm		SM7360*		
BARBEAU	125 cm		SM7713*		
IM	125 cm		SM7370*		
JL 4	125 cm		SM7435*	SM6987*	
JL 4	125 cm 2 side holes				SM7128*
JL 5	125 cm		SM7361*	SM6731*	
JR 4	125 cm		SM7436*		
JR 4	125 cm 2 side holes				SM 7444*
JR 4	110 cm Long Brite Tip	SM7426*			
MPA 1	125 cm		SM7477*	SM7206*	
MPA 1	125 cm 2 side holes			SM7482*	
MPA 2	125 cm		SM7394*		
XB 3	125 cm			SM7395*	
XB 3.5	125 cm			SM6991*	
XB 3.5	120 cm Long Brite Tip	SM7400*			
XB 4	125 cm		SM7363*		

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# Guiding Catheters

## Long VISTA BRITE TIP™

### Long VISTA BRITE TIP™

- Available in 6F .070" & 5F .056"
- Active back up support through deep seating
- Atraumatic ostial coaxial alignment by the excellent tip conformability
- Good tip visibility
- Atraumatic TIP

## LEFT CORONARY JUDKINS TECHNIQUE

### JUDKINS LEFT

Name	Observation	5F	6F	7F	8F
JL 3.5		556-002-0L			
JL 4		556-004-0L	670-004-0L		
JL 4.5		SM7329			
JL 5		556-008-0L			

## LEFT CORONARY EXTRA BACK-UP SHAPES

### EXTRA BACK-UP

Name	Observation	5F	6F	7F	8F
XB 3.0		SM7328			
XB 3.5		556-054-0L	670-054-0L		
XBLAD 3.5		556-060-0L			
XB 4		556-056-0L			

## LEFT CORONARY AMPLATZ TECHNIQUE

### AMPLATZ LEFT

Name	Observation	5F	6F	7F	8F
AL 1		SM7331	SM7389*		
AL 2		556-040-0L	670-040-0L		
AL 3		SM7332			

## RIGHT CORONARY JUDKINS TECHNIQUE

### JUDKINS RIGHT

Name	Observation	5F	6F	7F	8F
JR 3.5		556-080-0L	SM7390*		
JR 4		556-082-0L	670-082-0L		
JR 4	110 cm	SM7426*			
JR 5		SM7330*			

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# Guiding Catheters

## Long VISTA BRITE TIP™

### RIGHT CORONARY AMPLATZ TECHNIQUE

#### AMPLATZ RIGHT

Name	Observation	5F	6F	7F	8F
AR 1		SM7333*	670-110-0L		
AR2		556-112-0L	670-112-0L		

### TRANSRADIAL / BRACHIAL TECHNIQUE

Name	Observation	5F	6F	7F	8F
JFL		556-162-0L			
JFR		556-168-0L			
RB		556-172-0L			
BARBEAU		556-174-0L			

### MULTIPURPOSE

#### MULTIPURPOSE A 1

Name	Observation	5F	6F	7F	8F
MPA 1	90 cm	556-270-0L			
MPA 1			670-270-0L		

#### HOCKEY STICK

Name	Observation	5F	6F	7F	8F
H-STICK LBT		556-278-0L	670-278-0L		

### BYPASS

#### INTERNAL MAMMARY

Name	Observation	5F	6F	7F	8F
IM		556-190-0L			

#### LEFT CORONARY BY PASS

Name	Observation	5F	6F	7F	8F
LCB		SM7327*			

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# Guiding Catheters

## ECO-PAC FIVE PACS

### LEFT CORONARY JUDKINS TECHNIQUE

Name	Observation	5F	6F	7F	8F
JL 4			670-004-0E		

### LEFT CORONARY EXTRA BACK-UP SHAPES

Name	Observation	5F	6F	7F	8F
XB 3.5			670-054-0E		

### RIGHT CORONARY JUDKINS TECHNIQUE

Name	Observation	5F	6F	7F	8F
JR 4			670-082-0E		

For more information please visit [www.cardinalhealth.co.uk](http://www.cardinalhealth.co.uk)



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