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Case Report

Distal Stent Delivery With Guideliner Catheter: First in Man Experience

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Failure to deliver stents is one of the commonest causes of procedural failure in contemporary PCI practice. We describe successful use of the Guideliner Catheter, the first purpose designed FDA and CE marked device delivery catheter in 13 complex cases in native coronary vessels and bypass grafts performed via the radial route to enable distal stent delivery following failure of conventional techniques. We discuss how the Guideliner catheter may be used to facilitate difficult radial cases. © 2010 Wiley-Liss, Inc.

Key words: TRAD; transradial cath; PCI; percutaneous coronary intervention; ANGO; angiography; coronary

INTRODUCTION

Failure to deliver stents during percutaneous coronary interventions (PCI) is one of the major causes of procedural failure that may occur in up to 5% of cases in contemporary PCI practice [1,2]. We have previously described use of the Terumo 5F Heartrail II catheter within a standard 6F guiding catheter (so called "five-in-six" system) to aid stent delivery. Extra deep coronary intubation using this catheter increases backup support and bypasses proximal points of obstruction to enable distal stent delivery in both native coronary vessels and coronary artery bypass grafts [3,4].

The Terumo "five-in-six" Heartrail II system was developed for use in chronic total occlusion PCI cases in order to increase back-up support [5]. Conversely, the Guideliner catheter (Vascular Solutions, MN) that has now been both CE marked and FDA approved has been developed more specifically with device delivery in mind. The Guideliner "five-in-six" catheter (Vascular Solutions, MN) is essentially a rapid exchange or monorail equivalent of the "five-in-six" Heartrail II catheter that consists of a short guide catheter extension connected to an introducer rod, and so is potentially easier to use than the Heartrail II catheter. In this case series we describe our initial experience with the use of this catheter for stent delivery and backup support in a series of challenging cases performed transradially, and discuss its potential utility in complex radial PCI cases.

METHOD OF INTRODUCTION

The 5-in-6 Guideliner catheter is a 20 cm soft tipped 5F catheter with an internal diameter (ID) of 0.056″ connected via a metal collar to a 115 cm stainless steel shaft to a proximal positioning tab (Fig. 1A). At any time, following placement of the mother guide catheter and coronary wire in the target vessel, the 20 cm Guideliner catheter can be advanced over the wire through the haemostatic valve without the need to disconnect this from the mother guide. The catheter tip is then advanced beyond the tip of the mother guide into the coronary vessel by pushing on the proximal tab. The interventional procedure is performed in the usual manner through the haemostatic valve (Fig. 1B and C).

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Conflict of interest: Nothing to report.

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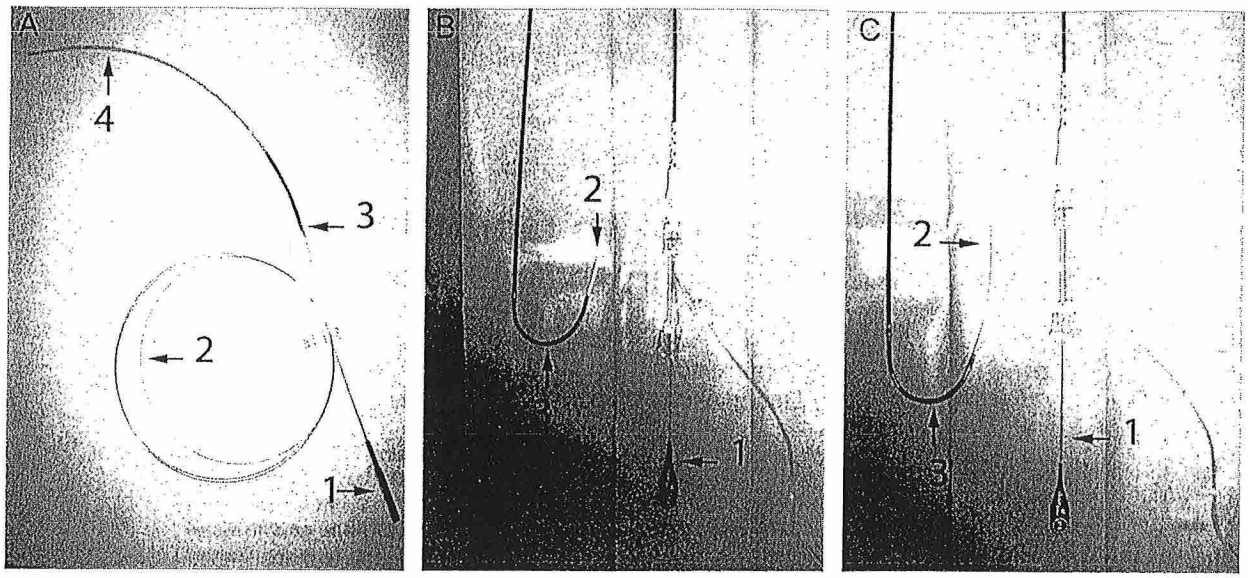

Fig. 1. A: The 6Fr Guideliner catheter is a 20 cm soft tipped catheter (Arrow 4) connected via a metal collar (Arrow 3) to a 115 cm stainless steel shaft (Arrow 2) with a large proximal tab (Arrow 1) for accurate positioning of the device within the coronary system. B: Guideliner catheter setup. The Guideliner is passed through the haemostatic valve over a guidewire. The proximal tab (Arrow 1) is attached to the 115 cm stainless steel shaft that attaches to the 20 cm soft tipped catheter (Arrow 2) seen to extend from the guide catheter (Arrow 3). The proximal tab can be used to position the 20 cm soft tip catheter more distally into the vessel (C).

Frequently, placement would follow predilation of the target vessel and prior attempts at stent placement.

Conversely, introduction of the much longer 120 cm Heartrail II catheter requires removal of the haemostatic valve followed by advancement over the coronary wire into and through the mother guide, with subsequent reconnection of the haemostatic valve to the proximal end of the Heartrail catheter [3,4,6]. Again, this is frequently performed following predilation and prior attempts at stent placement. When complete removal of the Heartrail catheter is required, the haemostatic valve needs to be removed and reconnected to the mother guide, and may dislodge the coronary wires if these are not docked. Conversely, removal of the Guideliner catheter can be performed without repositioning of the haemostatic valve or docking the wires in a similar fashion to removal of a monorail balloon. Consequently, advancement, positioning, and removal of the Guideliner catheter is potentially greatly simplified in comparison to the Heartrail catheter.

Case 1

A 48-year-old female with significant exertional angina and good left ventricular function underwent attempted recanalisaton of a chronically occluded LAD artery (Fig. 2A). Access was from the right radial artery with a 6F Cordis extra backup guiding catheter. Wire crossing was rapidly achieved using a whisper wire to negotiate a visible microchannel connecting the proximal and distal lumens (Fig. 2B). However, subsequent passage of either a Finecross microcatheter or a low profile 1.25-mm balloon (Riujn, Terumo) was unsuccessful due to marked resistance at the entry to the microchannel. A Guideliner catheter was therefore introduced over the coronary wire, through the guiding catheter. This was advanced 4 cm beyond the tip of the guide catheter into the LAD, up to the point of occlusion. Subsequent passage of a Quickcross microcatheter across the occlusion was achieved (Fig. 2C), and the Whisper wire was exchanged for a super support Mailman wire. Subsequent introduction of a 1.25 mm balloon allowed expansion of the microchannel, with successful further balloon dilation and finally stenting using a 2.5 × 38 mm Xience (Fig. 2D) and 3 × 28 mm Promus stents. These stents were further expanded with 2.75 and 3 mm balloons to high pressure with an excellent angiographic result (Fig. 2E).

Case 2

A 79-year-old lady with good resting left ventricular function was admitted with an NSTEMI associated with critical single vessel disease of a large RCA. The RCA was heavily calcified with 95% stenoses of the mid vessel and distal vessel at the crux extending into PDA and PLV branches with TIMI 2 flow (Fig. 3A). Access was from the right radial artery using a JR4 guiding catheter. Two Choice floppy wires (Boston Scientific) were advanced into the PDA and PLV

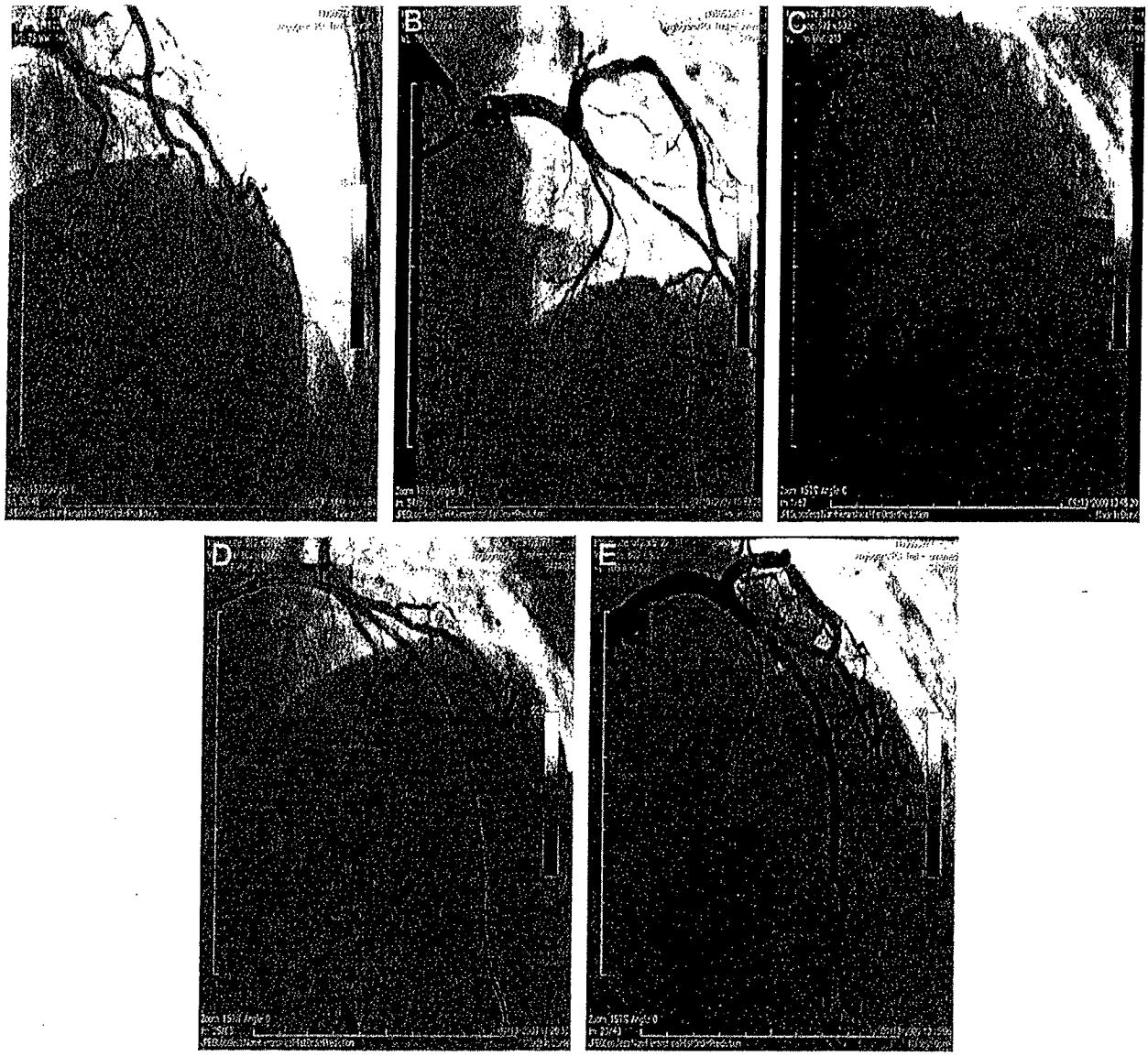

Fig. 2. Chronically occluded LAD (A) and subsequent crossing of the lesion with whisper wire (B). (C) illustrates positioning of the Guideliner catheter into the LAD (second vertical arrow) and the position of the guide catheter is shown by the first arrow. The horizontal arrow illustrates the Quickcross microcatheter used to exchange the whisper wire for a more supportive mailman wire. (D) positioning of xience stent and final result (E).

branches respectively and both lesions were predilated with 2.5-mm compliant and 3-mm angiosculpt balloons (Pyromed). However, stent delivery across the proximal lesion was not possible due to significant calcification and resistance to stent passage hence a Guideliner catheter was advanced into the RCA. To aid deep intubation of the catheter a 2.5-mm balloon was inflated in the distal RCA lesion and a combination of gentle traction on inflated balloon and push on the Guideliner catheter allowed passage of the Guideliner beyond the midvessel lesion. A 4 × 23-cm Biomatrix stent was then advanced without resistance through the midvessel lesion within the Guideliner catheter and on into the distal vessel (Fig. 3B). The Guideliner was then brought back into the proximal vessel and the stent was brought back into the mid vessel stenosis were it was inflated with good strut expansion. Again, using an inflated balloon in the distal lesion as an anchor, the Guideliner was advanced through the deployed stent into the distal vessel. A Triton bifurcation stent was then advanced to the distal vessel through the Guideliner catheter and was deployed across the crux into

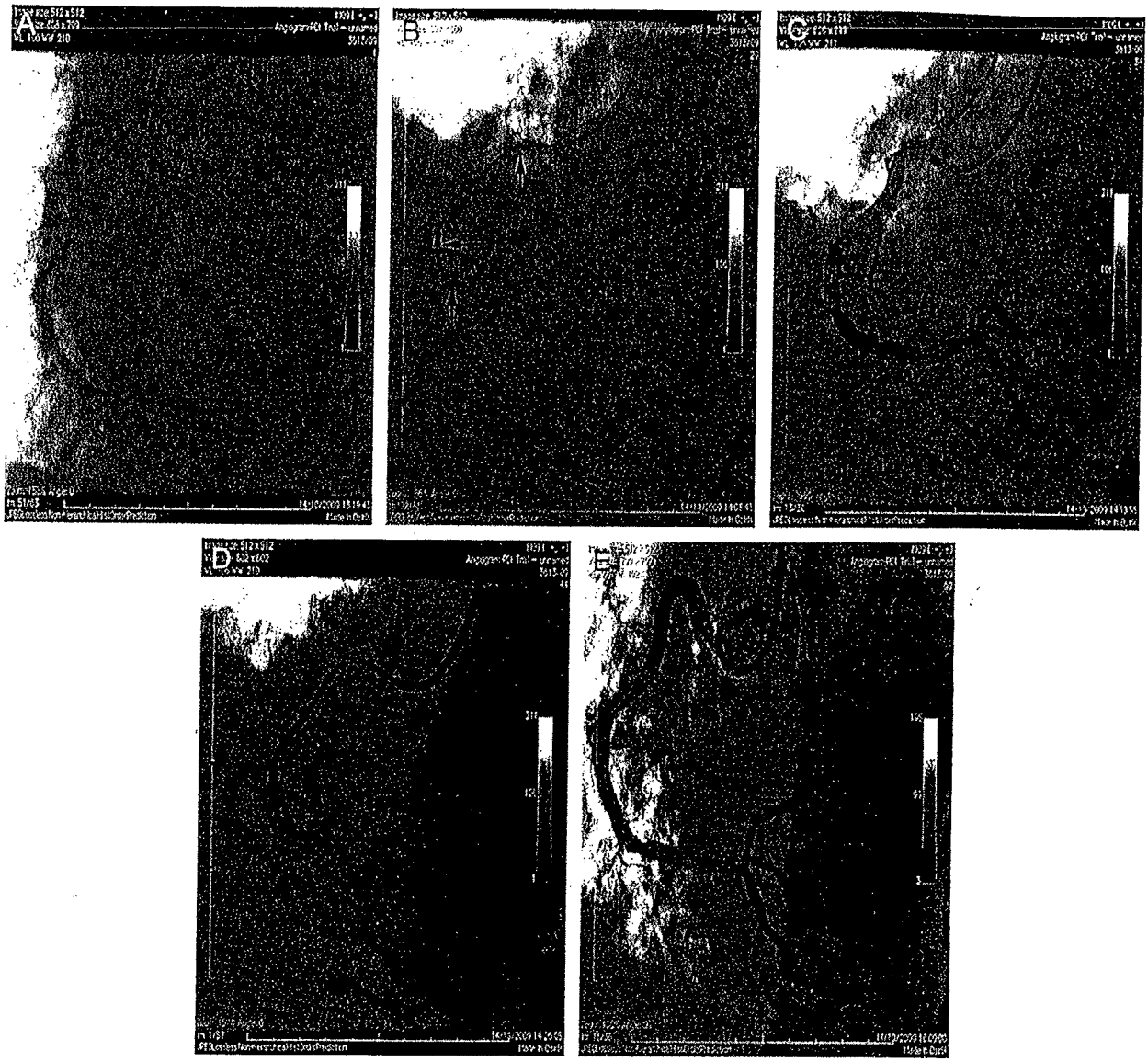

Fig. 3. A: RCA at start of case. B: Guideliner catheter (Horizontal arrow) used to bypass proximal point of obstruction enabling delivery of biomatrix stent (Vertical arrow). The guide catheter is illustrated by vertical arrow at top of figure. C: opacification of RCA following stenting of proximal and mid RCA. D: Triton bifurcation stent (Vertical arrow) delivered into PLV branch of RCA through Guideliner catheter (Horizontal arrow) passed through previously deployed proximal stents. E: Final result.

the PLV branch. Further stents were then placed in the PLV branch distal to the crux and from the distal RCA into the PDA. A final kissing balloon from the distal RCA into the PDA and PLV branches completed the procedure with an excellent angiographic result.

Case 3

A 76-year-old male with good left ventricular function and previous CABG was scheduled for PCI of the native RCA due to ongoing ischaemia at rest in this territory that had no graft supply. The RCA was diffusely diseased from the proximal to the distal vessel with heavy calcification, marked tortuousity and subtotal occlusion of the midvessel (Fig. 4A). We proceeded from the right radial artery using a 6F JR4 catheter and successfully crossed into the distal vessel using a Whisper wire. The mid and proximal RCA was dilated with 1.5, 2.5, and 2.75 mm balloons (Maverick, Boston), however stent passage was unsuccessful due to

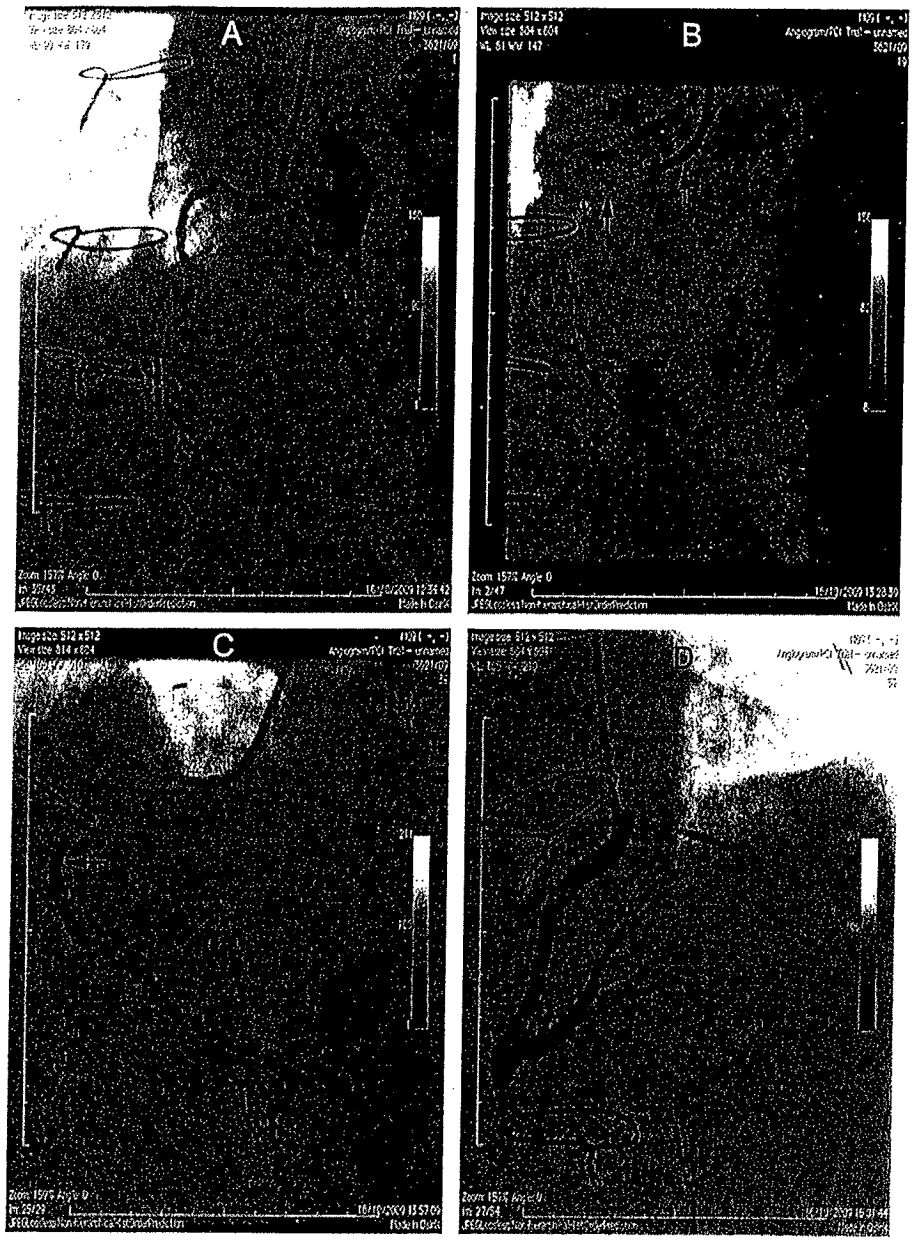

Fig. 4. A: Angiographic appearance of RCA at start of case. B: Positioning of initial Promus stent (Horizontal arrow). The Guideliner catheter and guide catheter are shown by vertical arrows. C: Passage of Guideliner catheter through the proximally deployed stents and opacification of the distal vessel demonstrating further disease. Distal end of Guideliner highlighted by horizontal arrow. D: Final result.

heavy calcification and tortuosity. The Guideliner catheter was then advanced 3.5 cm into the proximal RCA, enabling deployment of a 2.5 by 18 mm Promus stent to the site of subtotal occlusion in the mid RCA (Fig. 4B). Again with the aid of deep intubation an overlapping 3 × 28 mm Promus stent could then placed proximally extending from the first stent to the proximal RCA. This allowed visualization of the distal RCA that had two further severe stenoses together with a severe stenosis of the proximal PDA. To treat these lesions a 2.5-mm balloon was inflated in the distal RCA and the Guideliner catheter advanced through the stented segments into the distal RCA (Fig. 4C). Following predilation this allowed easy passage of a 2.25 × 23 mm Promus stent that extended from the RCA into the PLV and a further 3 × 28 mm Promus stent that

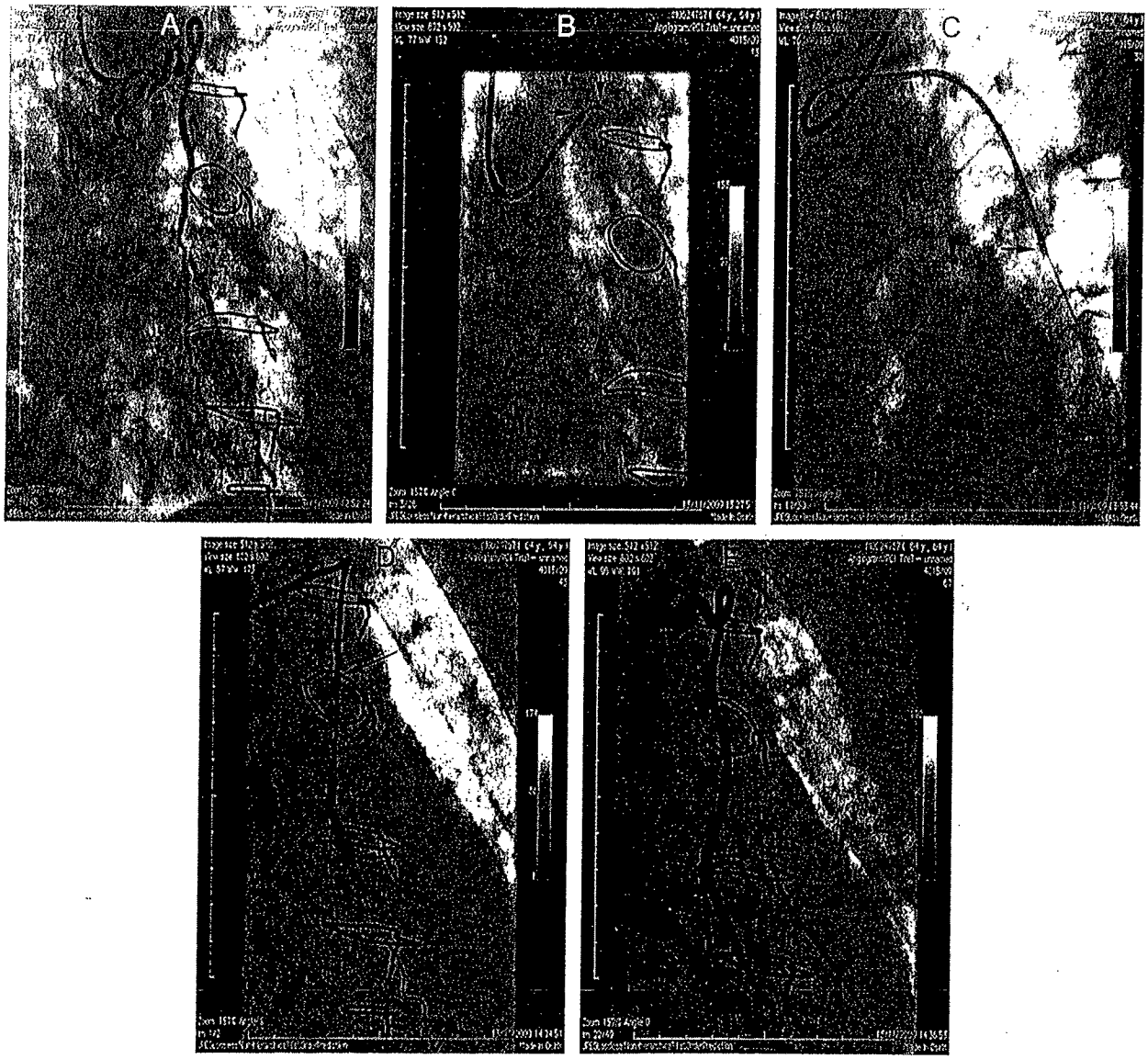

Fig. 5. A: Angiographic appearance of SVG at the start of case. B: Guideliner catheter (Horizontal arrow) used to increase backup support to enable proximal stent delivery (Vertical arrow). C: Guideliner (Horizontal arrow) used to deeply intubate SVG. D: Deployment of distal Promus stent (Horizontal arrow). The position of Guideliner catheter is illustrated by oblique arrow. E: Final result.

overlapped this stent and the first stent placed. Following post dilation of the RCA stents to 3 mm and stenting of the proximal RCA with two 3.5 × 8 mm Promus stents, an excellent angiographic result was achieved (Fig. 4D).

Case 4

A 64-year-old male with Re-do CABG and aortic and mitral valve replacement was admitted for elective PCI due to significant limiting angina to an OM_1 graft with two proximal hair pin loops with a severe lesion at the apex of the first loop and a more distal lesion at the distal end of the graft with further disease within the native vessel (Fig. 5A). We proceeded from the left radial artery using an AL-1 guide. The graft was wired using a whisper wire, however due to the severe tortuosity of the graft we were unable to deliver a balloon for predilation. The Guideliner catheter was therefore advanced into the asending limb of the hair pin loop to increase backup support and a 3-mm balloon was passed relatively easily into the lesion to allow

predilation. The proximal lesion was stented with a 3.5 × 8 mm Promus stent (Fig. 5B) overlapping with a 3 × 15 mm Promus stent. Because of severe tortuosity and the proximally deployed stents, we were unable to pass further stents/balloons distally to treat the vein graft/native vessel disease. The Guideliner catheter was therefore used to bypass this area of extreme tortuosity with the previously deployed stents achieving extra deep intubation of the vein graft (7 cm) allowing distal balloon/stent delivery (Fig. 5C). The distal vein graft lesion was predilated and stented using a 2.75 × 23 mm Promus stent proximally (Fig. 5D) and a 2.25 × 23 mm stent distally into the native vessel. The stents were post dilated at high pressure and an excellent angiographic result was obtained (Fig. 5E). The patient remains angina free at one-month follow up.

A further 10 cases were performed (total of 13 cases) and these are summarized in Table I. All cases were performed via the radial route using conventional 6F guiding catheters.

DISCUSSION

To the best of our knowledge, for the first time in the literature we report the successful use of the Guideliner catheter for distal stent delivery in a series of 13 highly complex cases, with a mean stent length of more than 44 mm (range, 15–105 mm) and either severe tortuosity and/or calcification, or chronic occlusion in every case. The Guideliner catheter was used for stent delivery following prior failure using conventional techniques or upfront use due to anticipated failure (cases 9 and 10). Balloon and stent delivery was successfully achieved in all cases and the device was simple both to deploy and remove and was not associated with a procedural complication in any case. This was achieved using the Guideliner catheter by both increasing backup support and crossing proximal points of obstruction. The catheter can cross points of proximal obstruction where a stent gets stuck due to the greater flexibility and smoother surface of the catheter than a stent. In addition, distal balloon anchoring to deliver the Guideliner is more readily achieved than distal balloon anchoring to deliver a stent within a 6F guiding catheter. The main limitation of the device that we have observed was stent damage due to trauma entering the catheter portion of the device at the metal collar occurring in two cases (two of the 32 stents delivered; 6.2%) and failure to pass a 4-mm stent due to resistance at this point in 1 case (1 stent out of 32; 3.1%).

In most cases the Guideliner catheter was advanced over a coronary wire into the distal vessel. In some cases, additional techniques were used to aid Guideliner and then stent delivery in this series. In cases 2 and 3 advancement of the Guideliner catheter was associated with initial resistance. This was overcome by anchoring a balloon catheter in the distal vessel by inflating it within a distal target lesion followed by with gentle traction on the balloon during advancement of the Guideliner catheter (anchor balloon technique). In case 2, a severe proximal stenosis that had been predilated could not be crossed with a stent but was crossed with the Guideliner catheter enabling a stent to be delivered distal to the lesion within the catheter and then drawn back proximally into the lesion. In this case, crossing of the lesion with the Guideliner catheter was possible due to a good result from predilation; failure to cross the lesion directly with a stent was due to calcification and tortuousity at the lesion site. In cases 2, 3, 4, and 13 severe distal disease was stented following stenting of severe proximal disease. As well as facilitating proximal stenting in several of these cases, the Guideliner was deeply intubated through the stented proximal disease to gain direct access to the distal vessel to facilitate stenting of the distal disease.

Anchor balloon techniques using a conventional guide catheter have been used to facilitate stent delivery as well as wire and balloon passage in CTO lesions [7]. These techniques include both sidebranch anchor and distal main vessel anchor techniques. Whilst successful, these techniques usually require use of a 7F or larger guide, as smaller guides will not accommodate a stent with a conventional balloon catheter already in place. Placing the stent in the proximal vessel first could overcome this but would be technically demanding. This limits the applicability of these techniques to radial access when a 6F guide will be used in most cases. Conversely, using a distal anchor balloon to deliver the Guideliner catheter can easily be performed using a 6F guide. We have previously described this technique to aid delivery of the Heartrail 5-in-6 catheter [4]. We have always deployed the anchor balloon at a distal lesion site that we intend to stent, both to help to lock the balloon more successfully and to avoid trauma to an undiseased coronary segment.

Conventional stenting is performed from distal to proximal vessel in most cases, mainly due to the potential difficulty of crossing a deployed stent in the proximal vessel in the setting of vessel tortuousity. However, use of the Guideliner catheter overcomes this restriction because of the ease with which the Guideliner catheter will pass through even very tortuous stented segments (in some cases aided by a distal balloon anchor). In the four cases using this technique in this series, passage of the Guideliner catheter into the distal vessel through stented proximal disease was performed without complication and greatly facilitated distal stent delivery. We believe this technique of

TABLE I. Summary of Cases Performed Using Guideliner Catheter

Case	Age	Access Site	Vessel	Obstruction	Mechanism	Indication	Intubation depth (cm)	Stents deployed (lengths in mm)	Stent damage/Failure to deliver stent
1	43	Radial	LAD	CTO lesion	Backup	Balloon and stent delivery	3 cm	2.5 × 38 Xience	
								3 × 28 Promus	
2	79	Radial	RCA	Tortuous calcified	Backup	Stent delivery	6 cm	4.0 × 18 Biomatrix	4 × 23 Biomatrix Damaged
					Cross obstruction			2.5/3.5 ×19 Tryton	
								3.0 × 24 Biomatrix	
								2.5 × 18 Biomatrix	
								2.5 × 18 Biomatrix	
3	76	Radial	RCA	Tortuous calcified	Backup	Stent delivery	6 cm	2.5 × 18 Promus	
					Cross obstruction			3 × 28 Promus	
								2.25 × 23 Promus	
								3 × 28 Promus	
4	64	Radial	OM VG	Extreme tortuousity	Backup	Stent delivery	7 cm	3.5 × 8 Promus	
					Cross obstruction			2.5 × 28 Promus	
5	61	Radial	LAD	Tortuous calcified	Backup	Stent delivery	3 cm	3 × 28 Promus	
								2.5 × 28 Nobori	2.5 × 28 Nobori Damaged
6	87	Radial	RCA	Tortuous calcified	Backup	Stent delivery	6 cm	3 × 28 Nobori	
					Cross obstruction			3.5 × 33 Xience	4 × 28 mm Biomatrix would not enter
7	50	Radial	RCA	Tortuous calcified	Backup	Stent delivery	6 cm	3.5 × 15 mm Promus	
					Cross obstruction			3.5 × 20 Promus	
8	71	Radial	OM	Tortuous calcified	Backup	Stent delivery	4 cm	3.0 × 16 Promus	
9	74	Radial	Left PDA	Tortuous	Backup	Stent delivery (anticipated)	10 cm	2.75 × 28 Promus	
10	76	Radial	LAD	calcified	Backup	Stent delivery (anticipated)	3 cm	2.75 × 28 Promus	
								2.5/3.5 ×19 Tryton	
11	60	Radial	PLV	Tortuous	Backup	Stent delivery	10 cm	3.5 × 28 Nobori	
12	72	Radial	Cx	Tortuous calcified	Backup	Stent delivery	3 cm	3.5 × 20 Promus	
					Cross obstruction			3.0 × 15 Promus	
13	55	Radial	RCA	Tortuous calcified	Backup	Stent delivery	8 cm	3.5 × 38 Xience	
				CTO case	Cross obstruction			3.0 × 38 Xience	
								3.5 × 18 Promus	

proximal to distal stenting using the Guideliner catheter is an important new technique in the setting of highly complex proximal and distal disease.

In the treatment of tortuous and calcified disease it is failure to deliver a stent to the target lesion that remains one of the major causes of procedural failure. Improvements in stent design over time have been matched by increasing case complexity. Failure to deliver a stent occurs in up to 5% of cases in contemporary PCI practice [1,2] and is associated with in-hospital MACE rates of up to 19% [8]. Conventional techniques previously described to overcome problems of stent delivery include use of buddy wires and support wires to reduce tortuosity [9,10], use of rotational atherectemy or balloon dilation in calcified vessels to reduce friction [11], use of smaller sized stents [12] or increased backup support by deep intubation of the guide catheter, use of the anchor balloon techniques or exchange to a larger sized guide catheter [7]. In this series, stent delivery had failed in cases 1 to 8 and cases 11–13 despite predilation and the use of either support or buddy wires. We have demonstrated that successful stent delivery using the Heartrail catheter may be achieved in up to 90% of cases in which stent delivery had failed using conventional techniques [4]. More recently others have also adapted the Proxis proximal embolic protection catheter to facilitate distal stent delivery by deep intubation [13]. In the former series stent delivery was achieved in all cases when intubation depth of the Heartrail catheter exceeded 2 cm. However, stent delivery into very proximal lesions was not successful due to failure to intubate the device sufficiently. In this series, intubation depth exceeded 2 cm in all cases, and stent delivery was achieved in all cases.

Large bore guides provide greater passive backup support and permit a greater range of interventional techniques [7]. However, these may be poorly tolerated via the radial artery. For example, in a study of 250 patients, Saito et al. [14] demonstrated that the radial artery diameter was smaller than the outer diameter of a 7F Terumo (Terumo Co, Tokyo, Japan) introducer sheath in 28.5% of males and 59.7% of females. This may therefore contribute to procedural failure in complex cases performed through the transradial route, for example in a recent series of 2100 transradial PCI procedures, 36% of procedural failures were due to inadequate guide catheter support [15]. Use of Sheathless guide catheters may in part address this problem in the future [16] although their use is not currently widespread and they are still an evolving technology [17].

All of our cases were performed successfully despite highly complex disease via the radial artery using 6F guides with back-up support augmented using deep intubation of the Guideliner catheter. Deep intubation using such a system increases backup support dramatically. Using an arterial model Takahashi et al. [5] demonstrated that 5mm of intubation using a Heartrail catheter within a 6F guide produced 20% greater backup support than a 7 Fr guide catheter and 20-mm intubation produced greater back-up support approaching that of an 8Fr guide catheter. In this series, the mean intubation depth was 57.7 mm (range, 30–100 mm) therefore the additional support provided by the Guideliner catheter is likely to have been substantial. Consequently in transradial cases in which backup support is likely to be important such as CTO cases, or during cases where backup support is inadequate, the Guideliner catheter can be used upfront or as a bale out device. Backup support may be particularly poor using conventional guiding catheters for the treatment of vein graft lesions [15]. Backup using a Guideliner catheter to achieve deep graft intubation, as in case 4, may therefore be very useful also in transradial vein graft PCI.

The Guideliner was developed with stent delivery in mind and is able to deliver stents with similar effectiveness to the Heartrail catheter, although is easier to use but associated with a small but significant risk of stent damage. Advantages of the Guideliner include not needing to remove and reconnect the Y connector, less risk of air embolism, easier control of the mother catheter, easier advancement and removal, and ability to advance a stent further distal beyond the catheter tip.

Limitations of the Technique

Stent damage occurred in a total of two out of 32 stents used (6.3%) within the 6F mother guides. This occurred exclusively with the use of the bulkier Nobori (1/4 stents used) or Biomatrix stents (1/6 stents used) rather than lower profile Xience/Promus stents (0/20 stents used). It was also related to stent size with failure to pass 2/3 4 mm or larger Biomatrix or Nobori stents. In some cases it was clear that guide wire wrap around the Guideliner stainless steel introducer shaft had caused the stent to catch at the collar resulting in significant resistance to stent passage and damage.

CONCLUSION

The Guideliner is an easy to use guide catheter extension that greatly facilitates backup support and stent delivery, significantly extending the scope of coronary intervention possible within a 6F mother guide catheter. It should be considered either to increase backup support or enable stent delivery when problems are encountered using conventional techniques, or

upfront in the setting of very complex disease. Performance is similar to the 5-in-6 Heartrail II catheter, whilst ease of use is significantly improved. The main limitation however is that there is a small risk that large/bulky stents can get damaged entering the metal collar, and caution should be exercised particularly when resistance to the passage of a stent is felt whilst within the Guideliner catheter since excess force may not only lead to damage of the stent but also to potential stent loss. We would currently recommend the use of low profile stents with this system since this appears to limit the potential for stent damage in our series and would caution the Guideliner for stent delivery of stents $\geq$4 mm in diameter. Future catheter design modifications, particularly at the steel collar may reduce the small risk of stent damage that we have observed. This device will be useful for both transfemoral and transradial procedures in which backup support and stent delivery difficulties are encountered, and may be of especial interest to radial interventionalists taking on complex disease. Early or upfront use in highly complex cases should be considered.

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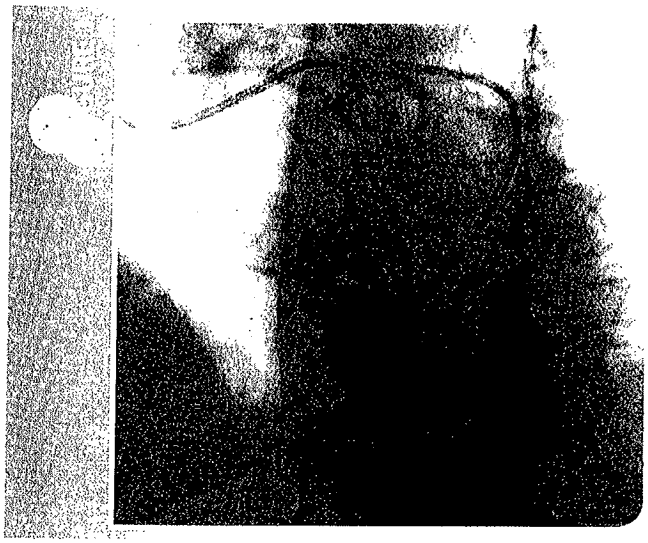
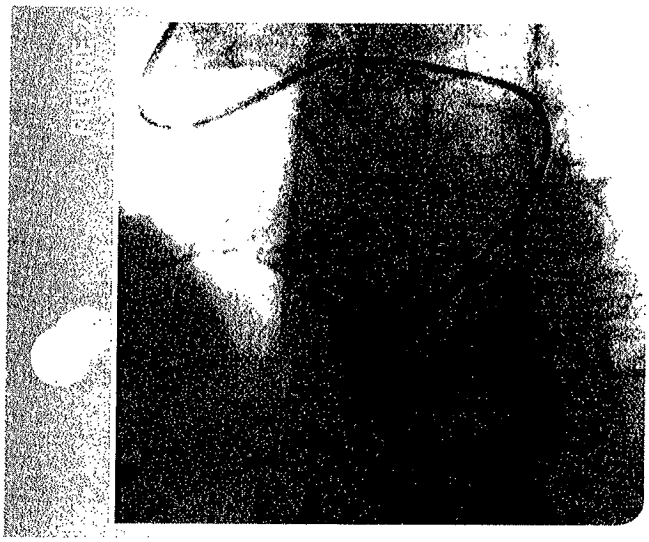
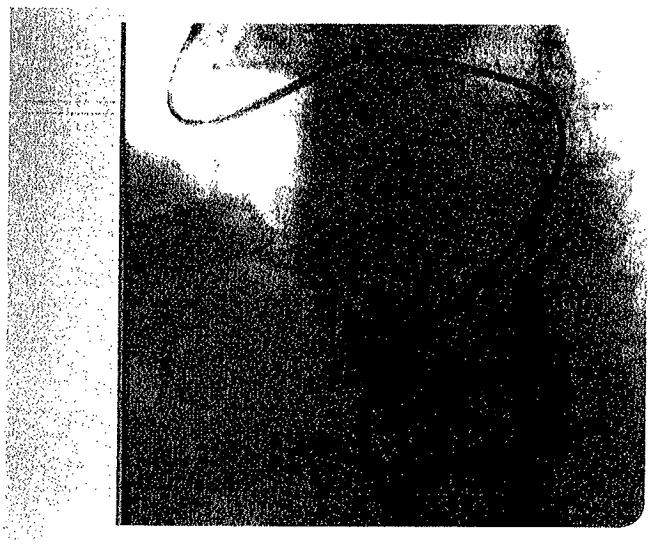
Exhibit 14







GuideLiner® is useful both for support and to minimize contrast load by super-selective injections in a high-risk chronic renal failure patient

PHYSICIANS

Dr. Paolo Danna
Dr. Alessandra Dozio

LOCATION

Sacco Hospital of Milan, Italy

PRESENTATION

A.T. is an 80-year-old male with polycystic kidney disease and stage 4 chronic renal failure; his cardiovascular history is significant for ventricular arrhythmia, syncope, hypertension and hyperlipidaemia.

He was admitted to the hospital after a syncopal episode with post-traumatic renal and retroperitoneal hematoma, which was treated with selective embolization of the lower branch of left renal artery.

Several complications occurred during hospitalization: progressive bleeding needing several transfusions, ventricular tachycardia (VT), acute pulmonary oedema and non-ST elevation myocardial infarction. An echocardiogram showed hypokinetic cardiomyopathy with severe reduction of ejection fraction (EF) and a mild-to-moderate mitral regurgitation.

ANGIOGRAPHIC FINDINGS

After the stabilization of his hemodynamic state, the patient was brought to the cath lab, where coronary angiography showed a three-vessel disease. The RCA showed extensive disease and a small calibre, the LCx showed subcritical stenosis of the ostium and mid-segment and a severe lesion in its distal part involving the PDA, and the LAD exhibited focal proximal disease.

INITIAL TREATMENT

The patient was treated via PCI through the right radial approach using a 6F guiding catheter. The angioplasty of the LAD was optimized with a NO-eluting stent.

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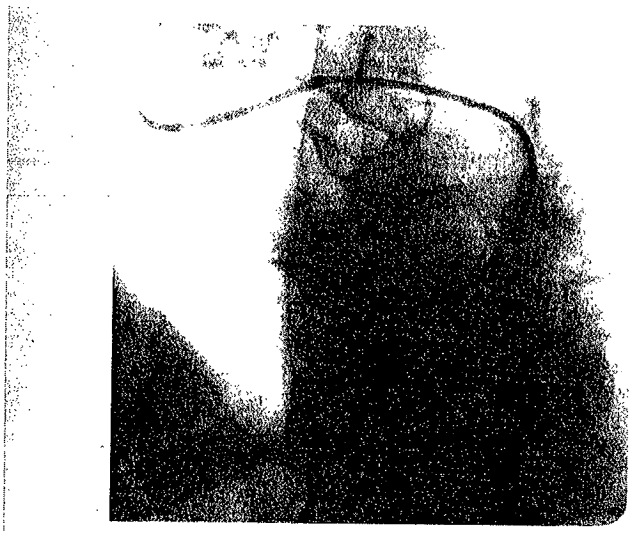

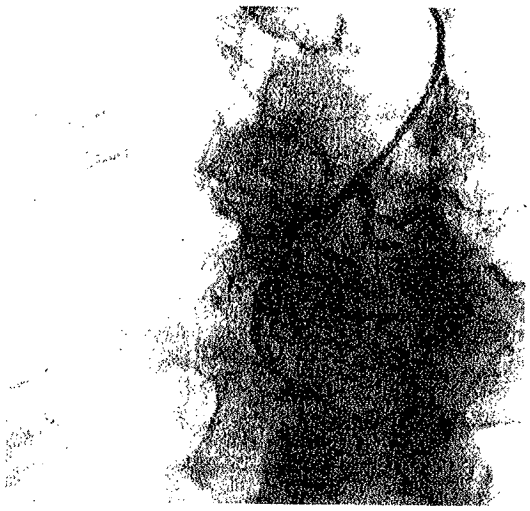

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TREATMENT WITH GUIDELINER

The PDA was studied with a GuideLiner catheter (Figures 1, 2 & 3) as the instrument for a selective and minimized injection of contrast media. Afterwards, the same system was used to support and stabilize the implantation of an everolimus-eluting stent (Figures 4, 5 & 6). FFR of LCx was > 0.8, so the vessel was not treated.

AFTER PCI

Renal function was unchanged (serum creatinine, 2.2 mg/100ml) during the whole post-procedural stay. ECG monitoring showed a reduction in ventricular ectopic activity and subsequent evaluation showed the absence of active kidney bleeding.

CONCLUSIONS

This case report shows an adjunctive advantage of the GuideLiner: minimization of contrast load in by super-selective coronary injections, thereby potentially helping in preventing contrast-induced nephropathy.

In our patient, the use of the GuideLiner system allowed the reduction of the amount of contrast medium thanks to super-selective and optimized injection. This is potentially useful to preserve renal function in patients with chronic renal failure or other kidney disease undergoing angiographic procedures.

It is also important to consider the benefit of this system in urgent/emergent coronary procedures and in patients without adequate preparation against contrast-induced nephropathy.

The GuideLiner system improves the selective evaluation of coronary anatomy, supports the deliverability of stents, and optimizes the use of contrast medium by minimizing its total volume with a possible consequent reduction in adverse renal events.

Dr. Paolo Danna
Director, Cardiac Catheterization Laboratory,
Ospedale Luigi Sacco, Milano, Italy.

Dr. Alessandra Dozio
Fellow in Cardiology,
Ospedale Luigi Sacco, Milano, Italy.

GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guidewires and other interventional devices.
Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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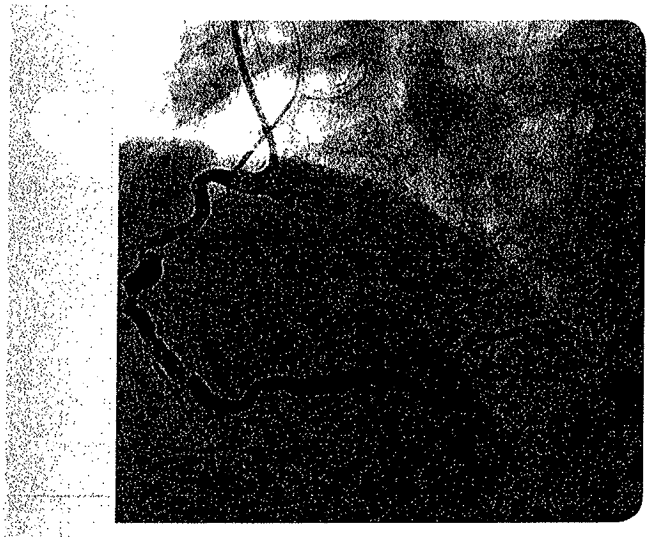

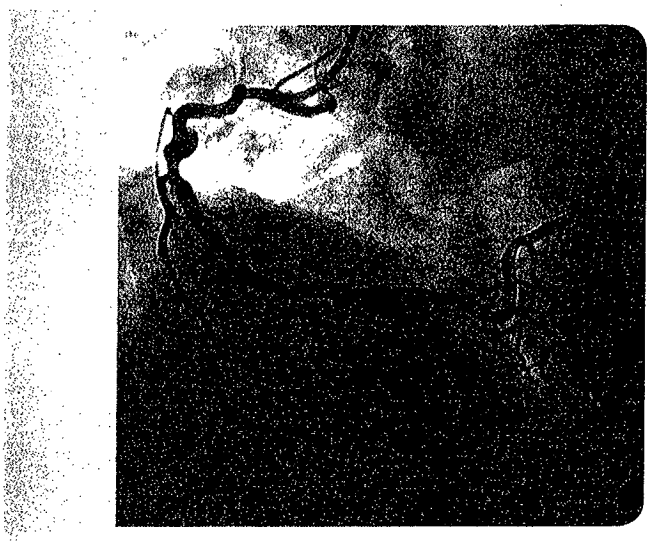

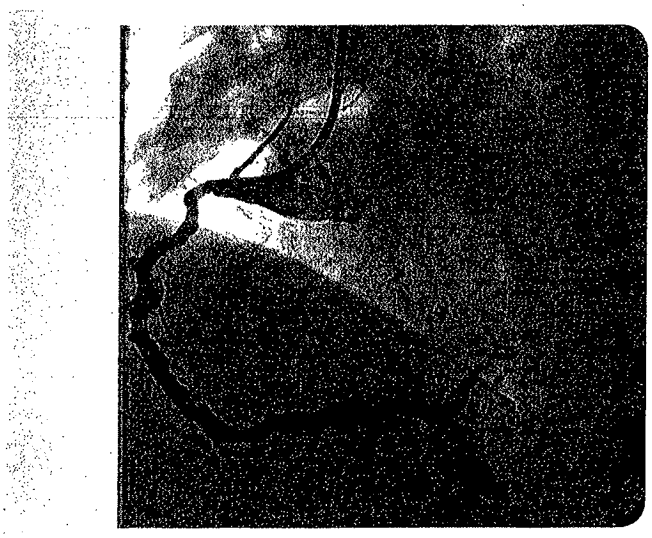

Successful use of the GuideLiner® catheter to facilitate stent delivery across a tortuous aneurysmal right coronary artery to the second postero-lateral coronary artery

PHYSICIAN

Islam A. Bolad, MD, FESC, FACC

LOCATION

Roudebush VA Medical Center, Indianapolis, Indiana, USA

PRESENTATION

This is a 59 year old Caucasian male with hypertension, hyperlipidemia and peripheral vascular disease who sustained NSTEMI perioperatively following non-cardiac surgery.

ANGIOGRAPHIC FINDINGS

Coronary angiography showed a tortuous, aneurysmal right coronary artery (RCA) with multiple stenoses accounting for the acute coronary syndrome, and a chronically occluded posterior descending artery (Figure 1). The left anterior descending and circumflex arteries had mild non obstructive coronary disease and the LV systolic function was preserved.

INITIAL TREATMENT

The RCA was engaged using a 6F AL 0.75 guide catheter. The lesions were crossed using a BMW™ angioplasty wire. The proximal RCA stenotic lesions, proximal and distal to the aneurysmal segment, were angioplastied using a 2.5mm x 15mm Maverick® balloon. A clot then embolized and lodged in the distal RCA aneurysmal segment (Figure 2). An Export® aspiration catheter would not pass to the distal RCA to facilitate clot aspiration. The distal RCA was then angioplastied using a 3.5mm x 15mm Maverick balloon, and that resulted in clot embolization and occlusion of PLA 2 (Figure 3). Multiple angioplasty attempts of PLA 2 to restore flow were unsuccessful, and so were attempts to deliver a 2.25mm x 12mm ION™ drug eluting stent.

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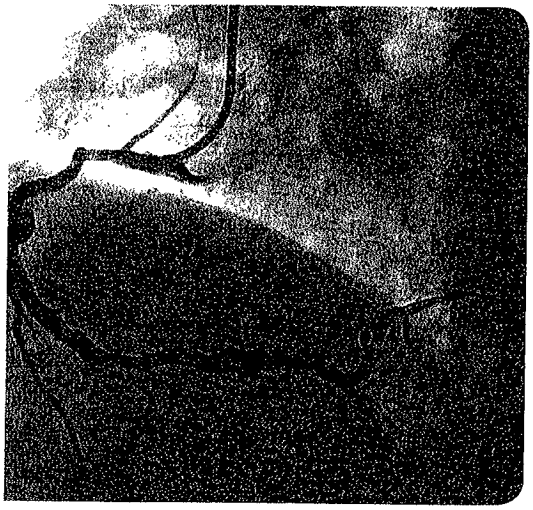

Successful use of the GuideLiner® catheter to facilitate stent delivery across a tortuous aneurysmal right coronary artery to the second postero-lateral coronary artery

TREATMENT WITH GUIDELINER

A 6F GuideLiner was then railed over an anchoring 3.5mm x 15mm Maverick balloon to the distal RCA past the distal RCA aneurysm (Figure 4). The 2.25mm x 12mm ION drug eluting stent was then delivered to the occluded PLA2 and deployed, and that restored flow (Figure 5). A 3.5mm x 16mm ION drug eluting stent was then delivered through the GuideLiner catheter to the mid RCA lesion, the GuideLiner catheter was withdrawn and the stent deployed. Similarly, the proximal RCA lesion was stented using a 3.5mm x 38mm ION stent. Good angiographic result was achieved (Figure 6).

CONCLUSION

The GuideLiner catheter was an essential component in the successful revascularization of this RCA and it facilitated deliver of multiple drug eluting stents in this tortuous and aneurysmal artery, without which, revascularization of this vessel would have likely been unsuccessful.

Islam A. Bolad, MD
Interventional Cardiologist, Krannert Institute of Cardiology
Indiana University School of Medicine
Fellow of the American College of Cardiology
Fellow of the European Society of Cardiology

GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guidewires and other interventional devices.
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Complex Primary PCI For ST Elevation Myocardial Infarction Facilitated By The GuideLiner® Catheter

PHYSICIAN

Islam A. Bolad, MD

LOCATION

Roudebush VA Medical Center, Indianapolis, Indiana, USA

PRESENTATION

A 58 year old gentleman with hypertension presented to our emergency room with inferior STEMI. He was taken emergently to the cardiac catheterization laboratory for coronary angiography and primary PCI.

INITIAL FINDINGS

Coronary angiography showed a tortuous right coronary artery (RCA) with an occlusive thrombus in the mid to distal coronary segment (Figure 1). The left coronary system was unremarkable.

TREATMENT

The ostium of the RCA was engaged using a 6F ART 3.5 guide catheter. A BMW™ guidewire would not advance past the proximal RCA segment. A polymer covered ChoICE® PT floppy guidewire with balloon support crossed the thrombotic lesion into the distal RCA (Figure 2). A 3 x 15mm Trek™ balloon was passed with difficulty into the lesion and angioplasty performed. Attempts to pass a 4 x 23mm Xience V® drug eluting stent were unsuccessful and the stent would not pass through the proximal RCA.

A 6F GuideLiner was then used, the tip of which was positioned in the distal RCA using the 3mm Trek as an anchoring balloon (Figures 3 & 4). The 4 x 23mm Xience V stent was then delivered to the lesion site, the GuideLiner catheter withdrawn, and the stent deployed (Figure 5). An excellent angiographic result was obtained (Figure 6).

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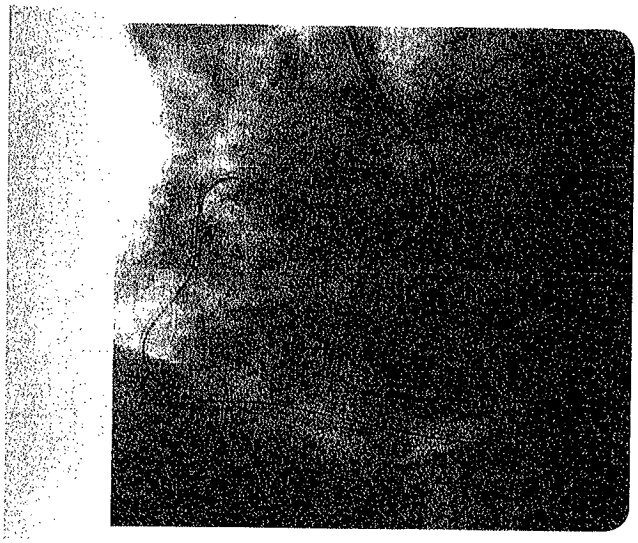

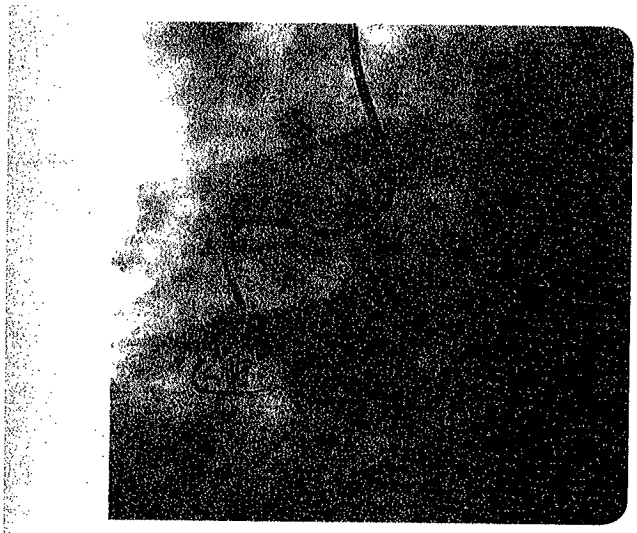

Complex Primary PCI For ST Elevation Myocardial Infarction Facilitated By The GuideLiner Catheter

CONCLUSION & POST PROCEDURE

The GuideLiner catheter is a new tool which facilitates complex primary PCI in STEMI patients. It saves critical time in this patient subset. It makes the difference between success and failure and converts an impossible case to a possible one.

SUMMARY

The GuideLiner catheter allowed the delivery of a large drug eluting stent through a very tortuous artery to the lesion site. Importantly, the pressure from the tip of the GuideLiner catheter showed that flow was maintained normally with no ventriculization or damping, and angiographically it was noted that the GuideLiner conformed to the vessel tortuosity and did not kink the vessel, which would have occurred if stiff wires were used to facilitate delivery of the stent.

Islam A. Bolad, MD

Interventional Cardiologist, Krannert Institute of Cardiology
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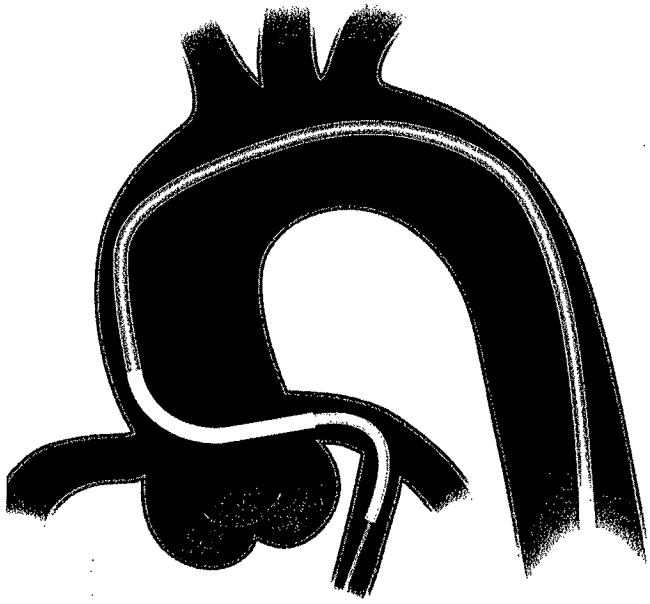
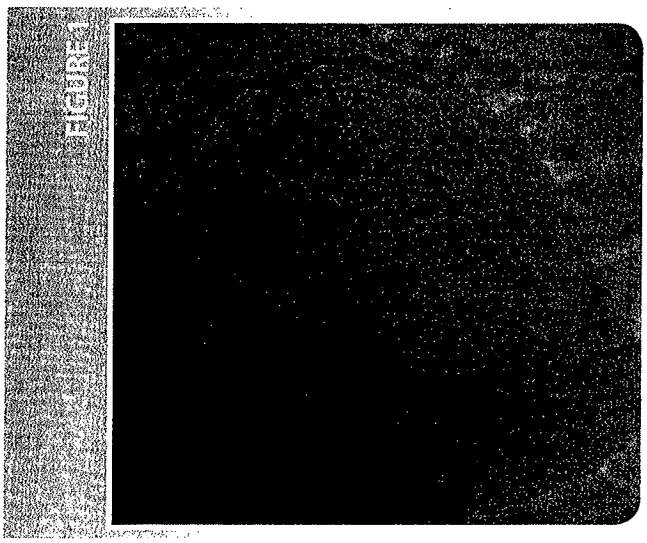
GuideLiner® Catheter Facilitates Treatment of Calcific Ostial Circumflex Artery Despite Severe Retroflexion





PHYSICIAN

Barry S. Weinstock, MD, FACC

LOCATION

South Lake Hospital, Clermont, Florida

PRESENTATION

The patient is an 83 year old woman with extensive cardiovascular history including prior CABG, porcine aortic valve replacement, chronic atrial fibrillation with AV node failure and subsequent permanent pacemaker placement. She also has hypertension, diabetes, and a history of stroke. Due to severe left hip pain from degenerative joint disease, she was electively admitted for total hip arthroplasty. Post-operatively, she developed congestive heart failure and cardiac enzymes were consistent with a small peri-operative myocardial infarction. Cardiac catheterization was advised for further evaluation of her cardiac status.

ANGIOGRAPHIC FINDINGS

The patient underwent diagnostic catheterization (Figure 1) which demonstrated a patent left main coronary artery without significant disease. The left anterior descending artery had severe disease proximally with competitive flow from a bypass graft noted distal to the origin of a patent diagonal branch, which itself had severe ostial segment stenosis of 80-90%. The left circumflex artery had severe proximal tortuosity with retroflexion and a critical 95% stenosis at the origin followed by moderately severe disease proximally. A large 1st obtuse marginal branch had 70% proximal stenosis while a small 2nd obtuse marginal branch had 90% ostial segmental stenosis. The RCA had diffuse disease. The LIMA graft to the LAD was normal but all of the saphenous vein grafts were occluded. LV function was remarkably well preserved with EF of 55% with no significant wall motion abnormality. The culprit lesion for her MI was thought to be the critical ostial left circumflex stenosis and the patient was referred for intervention.

INITIAL TREATMENT

The ostial circumflex stenosis was approached using a 7F XB 3.5 guide catheter and the patient was anti-coagulated with bivalirudin. The circumflex was initially wired using a 0.014" Whisper Extra-Support wire. The ostial stenosis was dilated using a 3.0 x 15mm Trek® PTCA balloon. A Promus® 4.0 x 28mm drug-eluting stent was inserted, but could be advanced only partially into the circumflex despite aggressive guide catheter positioning. The stent was removed and additional angioplasty was performed using a 3.5 x 20mm Apex® balloon catheter.

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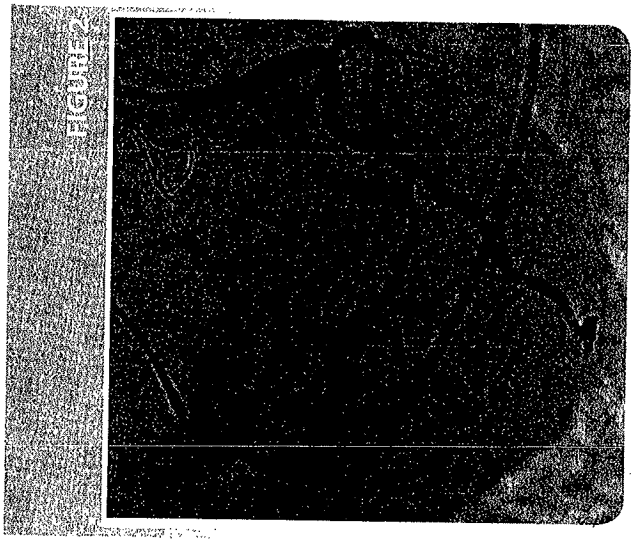

A second 0.014" ChoICE® PT Extra Support guidewire was delivered and the stent was re-advanced over the ChoICE PT wire. Again, it was not possible to pass the stent into the circumflex despite dee, throating the guide catheter. The first guidewire was removed, and a 7F-compatible GuideLiner® was advanced without difficulty to the proximal circumflex artery. The 4.0 x 28mm stent was then advanced easily into the circumflex and the GuideLiner was removed. The stent was positioned at the ostium of the vessel and deployed. The 1st OM branch was then dilated using a 3.0 x 20mm Apex angioplasty balloon catheter which resulted in a moderate dissection. An attempt was made to pass a 3.0 x 23mm Promus stent into the OM branch but the stent would not pass through the ostial circumflex stent due to interaction with the stent struts. The stent was removed and the GuideLiner was re-advanced to the mid-circumflex artery. The 3.0 x 23mm Promus stent was then easily advanced into the OM branch and deployed.

Additional views of the left main coronary artery revealed mid-distal dissection, likely due to aggressive "deep-throating" of the guide catheter. The GuideLiner was re-advanced to the proximal circumflex and a 4.0 x 18mm Promus stent was advanced to the left main coronary artery with overlap distally into the ostial circumflex stent and deployed. The GuideLiner was removed and the left main artery and ostial / proximal circumflex were post-dilated using a 5.0 x 12mm NC Quantum™ Apex balloon catheter. Final angiography confirmed excellent angiographic results in the left main, circumflex and first OM branch (Figure 2). The severe disease at the ostium of the small second OM branch was not treated.

SUMMARY

This patient had failure of all but one bypass graft and was extremely close to acutely occluding a large circumflex artery at its origin. The vessel's tortuosity, retroflexion and calcification combined to make stenting virtually impossible, despite use of a very strong guide catheter position and two extra-support wires. Using the GuideLiner device, it was possible to stent the ostial / proximal circumflex, a large OM branch after a balloon angioplasty-induced dissection, and the protected left main coronary artery with highly important overlap of the ostial circumflex stent. This challenging case highlights the utility of the GuideLiner, a device which clearly was the difference between this procedure's failure and success.

Physician Profile

Dr. Weinstock trained at Yale School of Medicine before completing his residency in internal medicine at the Hospital of the University of Pennsylvania. He completed his cardiology fellowship at Cedars-Sinai Medical Center and has been in practice as an interventional cardiologist since 1993. He currently practices with Mid-Florida Cardiology Specialists in Orlando and performs interventional procedures at three hospitals in the central Florida area.

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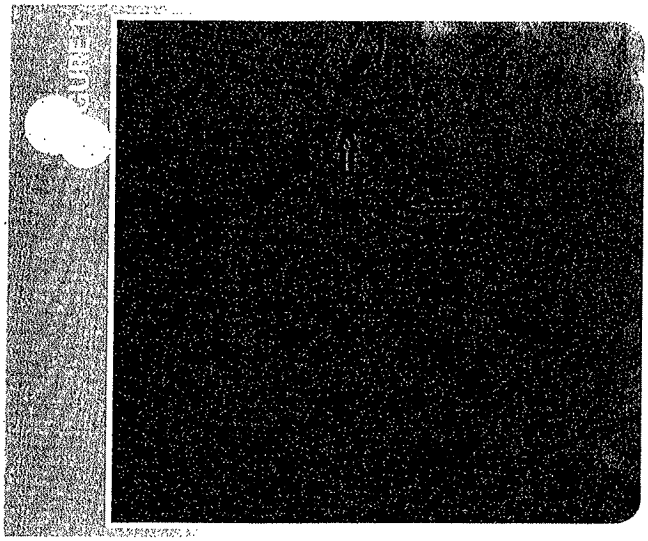

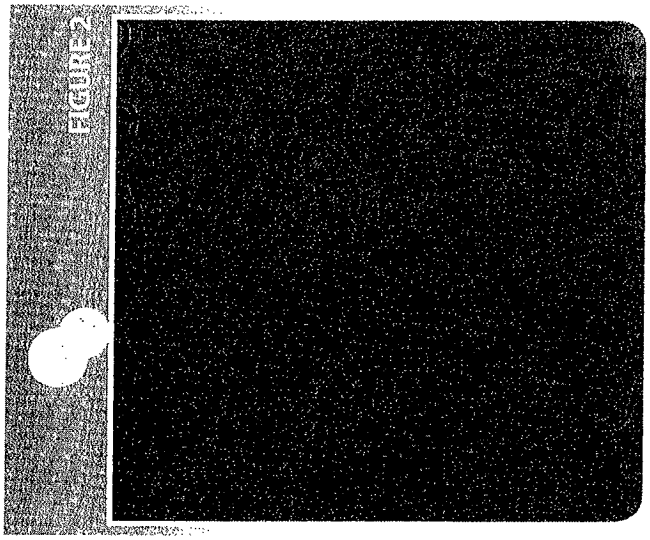

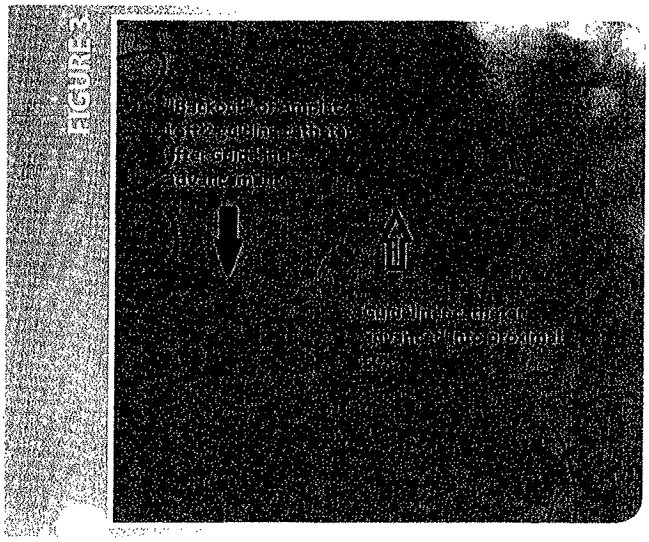

The "Child-in-Mother" Technique: Successful Transradial Use of the GuideLiner® catheter in a Heavily Calcified Circumflex Artery

PHYSICIAN

Jack P. Chen, MD, FACC, FSCAI

LOCATION

Saint Joseph's Heart and Vascular Institute, Atlanta, GA

PRESENTATION

A 63-year-old patient had undergone robotic totally endoscopic coronary artery bypass (TECAB) involving the left internal mammary artery (LIMA) to the left anterior descending artery (LAD) 2 years prior. Subsequently, the patient developed distal LIMA anastomotic stenosis, as well as severe progression of disease in the left circumflex artery (LCX) and right coronary artery (RCA).

At repeat bypass surgery (with sternotomy), saphenous vein grafts (SVGs) were anastomosed to the LAD, first obtuse marginal branch (OM1), and right posterior descending artery (PDA). The LIMA was tied off at the distal anastomosis to enhance SVG-LAD flow.

The patient recently developed recurrent angina.

INITIAL FINDINGS

Transradial cardiac catheterization revealed patent SVGs to the OM1 and PDA. However, the SVG to the LAD was occluded ostially. The native LCX was a calcified vessel, with a very angulated origin from the left main artery. There were stenoses in the proximal and distal LCX (Figure 1). The native OM1 was totally occluded proximal to the anastomosis, and there was no retrograde perfusion of the LCX. The LAD had a chronic total occlusion proximally, as did the RCA. The LIMA was not imaged.

INITIAL TREATMENT

It was decided to proceed with hybrid TECAB-LAD and stent-LCX. Transradial PCI was performed with initial balloon predilatation with a 2.0mm x 15mm Sprinter® balloon (Figure 2). However, the marked LM-LCX angulation and severe arc (270°), coupled with marked calcification, prevented stent advancement despite use of a stiff wire. A 6F compatible GuideLiner catheter, likewise, could not be advanced into the proximal arc.

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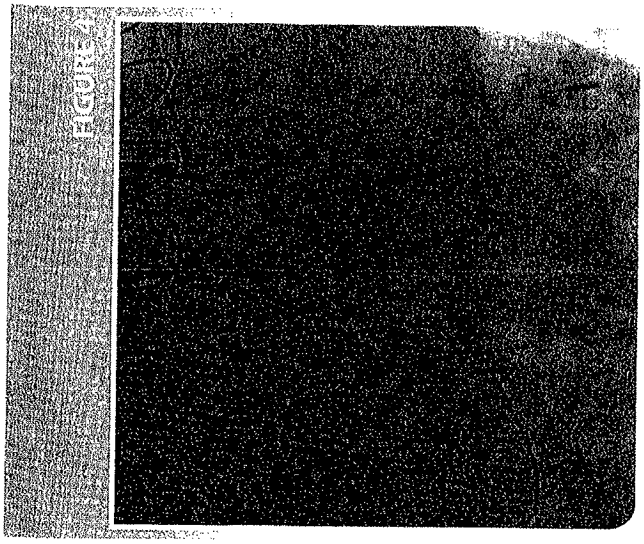

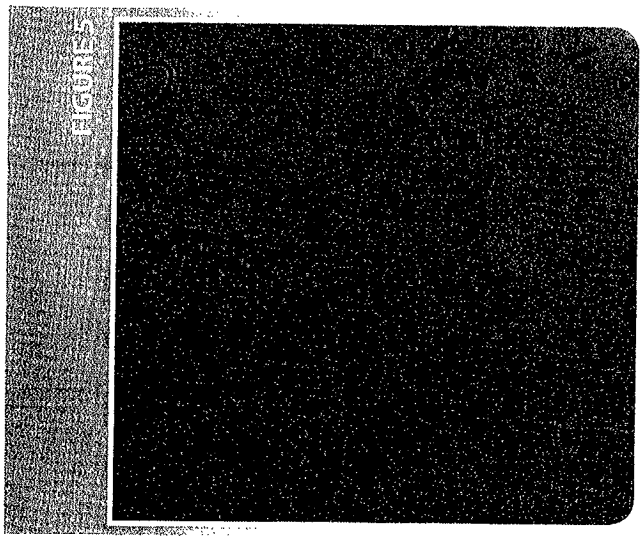

TREATMENT OF CIRCUMFLEX ARTERY

The original balloon was re-advanced through the GuideLiner into the distal vessel; the GuideLiner was subsequently inserted slowly into the proximal LCX, using sequential short, firm advancements.

Once the GuideLiner was positioned in the proximal LCX, two 3.5mm x 18mm Driver® bare metal stents were deployed in the mid and proximal lesions without a problem (Figures 3 & 4). However, the intervening vessel segment now appeared narrowed.

A third 3.5mm x 18mm Driver stent would not traverse the previously deployed proximal stent. The GuideLiner catheter was once again advanced, this time through the proximal stent to avoid "stent-on-stent" friction. The third stent was easily deployed after advancing through the GuideLiner, between the two previous stents (Figure 5). The final result was excellent (Figure 6).

The patient subsequently underwent uneventful repeat TECAB utilizing a free right internal mammary artery segment as a "jump graft" anastomosed to and bridging the distal LIMA and the mid-LAD. Unfortunately, this free RIMA graft segment also developed diffuse stenosis a few months subsequently, necessitating further DES implantation via the LIMA graft.

CONCLUSION

This case illustrates the value of the "child-in-mother" technique of deep catheter engagement to facilitate difficult device advancement.

Advancement of additional stents through a previously deployed proximal stent can be challenging. When positioned through a deployed stent, the GuideLiner acted as a smooth sleeve or inner lining allowing passage of the new stent.

Additionally, it is not uncommon to observe concomitant guide catheter disengagement or back-out from the coronary ostium with GuideLiner advancement. This is not a concern, as the intracoronary GuideLiner offers substantial back-up support.

Physician Profile

Dr. Chen received his M.D. from Weill-Cornell Medical College. He completed his Cardiology fellowship at New York-Presbyterian Hospital. As an Interventional Cardiologist, Dr. Chen serves as the Medical Director of Cardiology at Northside Hospital and is the Director for Cardiac Studies at Saint Joseph's Translational Research Institute (Saint Joseph's Hospital) in Atlanta, Georgia.

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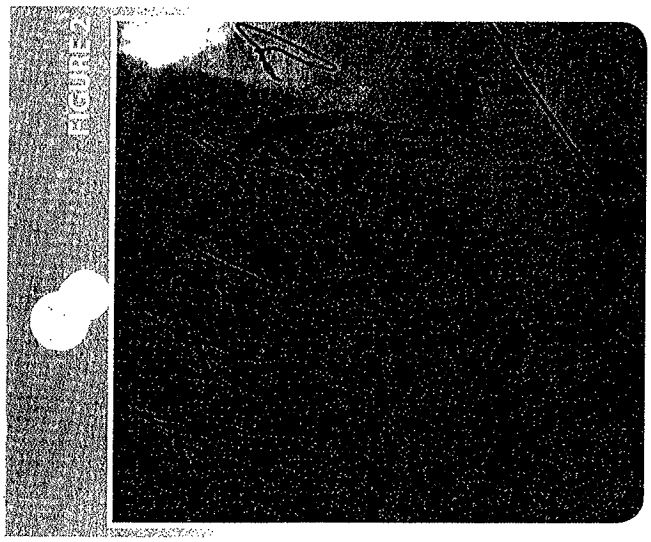

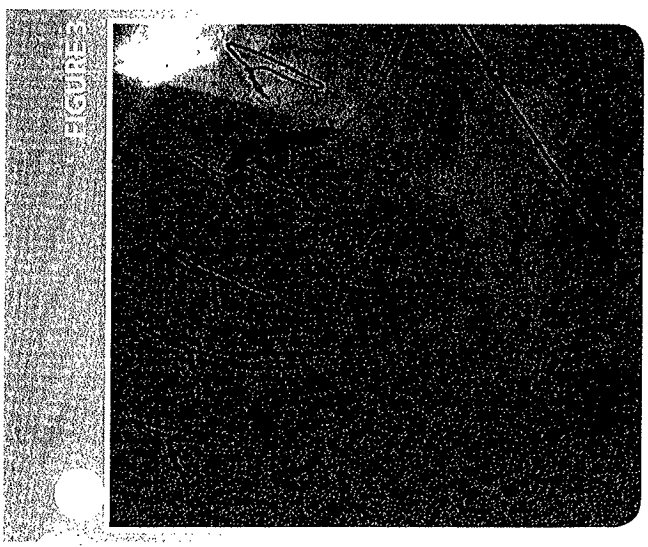

GuideLiner® Catheter Used for Proximal to Distal Stent Technique

PHYSICIAN

Steven S. Roh, MD, FACC
North Memorial Heart and Vascular Institute
Robbinsdale, Minnesota

PRESENTATION

A 56 year old male was admitted to the hospital with refractory Canadian Class IV angina. He had undergone a previous 5 vessel CABG in 1997 and was studied by angiography six months earlier. On his previous study, he had native three vessel coronary artery disease. His LIMA to LAD, SVG to diagonal, and SVG to PDA were patent. His posterior and lateral walls were vulnerable to ischemia due to his occluded sequential SVG to the OM and posterolateral branches. He was treated with medical management but continued to have life limiting angina despite his maximum antianginal therapy. His angina continued to crescendo until his day of admission. In the week prior to his admission, he had taken up to twenty sublingual nitroglycerin tablets.

INITIAL FINDINGS

Coronary and graft angiography performed during the most recent admission was without change from the previous study. The patient had clearly failed medical therapy. The source of his ischemia was the posterolateral wall due to limited native flow from the RCA and limited retrograde filling from the SVG to the PDA. Angiography suggested that he would benefit from revascularization of the posterolateral branch of the RCA.

TREATMENT

The diagnostic angiogram of the RCA demonstrated a technically challenging PCI due to the numerous acute bends within the RCA, including the greater than 90 degree angle from the distal RCA to the posterolateral branch, and the severe diffuse disease within the entire RCA (Figure 1). Even the initial guide selection was a challenge due to the significant lesion in the ostial and proximal RCA. As a result, a 6F JR4 guide was chosen to cannulate the RCA to allow for the necessary guide manipulations. A 300 cm ChoICE® PT guidewire was advanced into the distal PLA. The lesion in the distal RCA/proximal PLA was predilated (with great difficulty) with a 1.5 x 20 mm OTW balloon (Figure 2). The first challenge in the case came from the deep seating of the guide catheter to provide the support for advancing the OTW balloon catheter across the chronically occluded distal RCA/proximal PLA branch.

With the necessary deep seating of the guide there was ulceration of the proximal RCA and acute vessel occlusion (Figure 3). To resolve this, the proximal RCA was stented.

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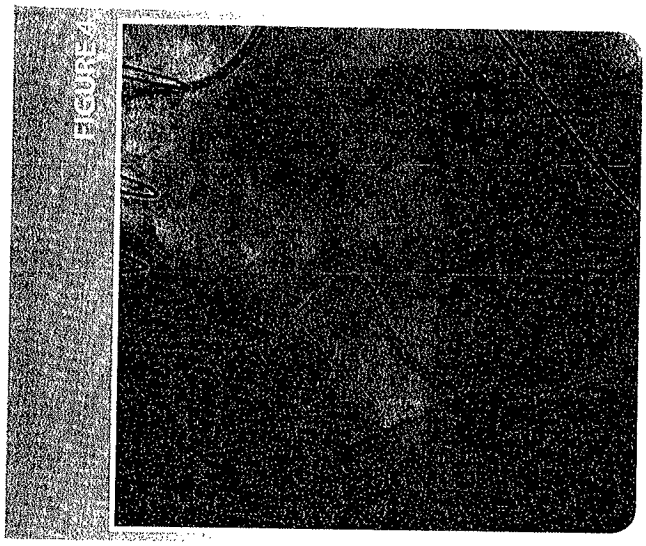
FIGURE 4

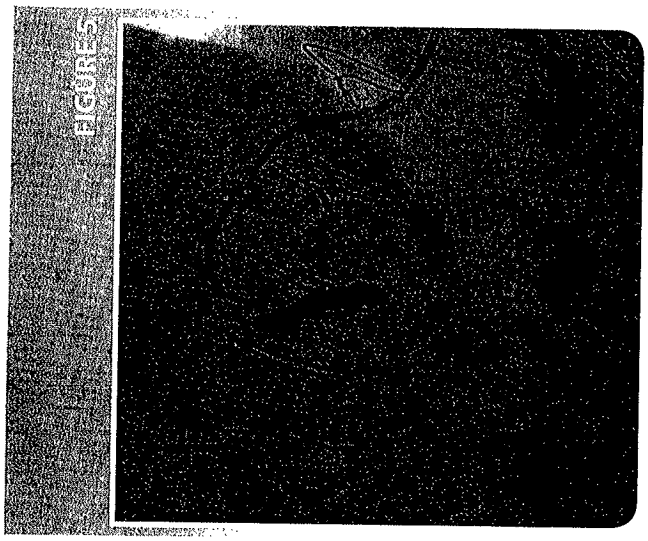
FIGURE 5

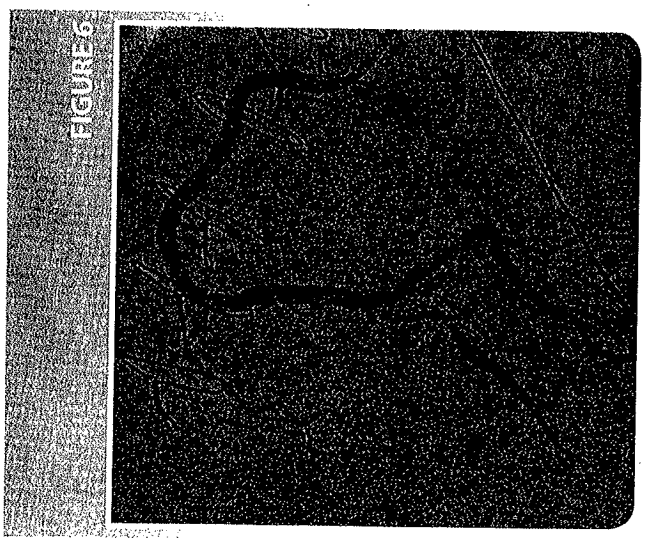
FIGURE 6

TREATMENT (continued)

The fact that there were freshly laid stent struts in the proximal RCA of this tortuous vessel would have prevented delivery of the distal stents, especially within a 6 French system. Therefore, the GuideLiner was advanced past the freshly laid stent struts into the distal RCA. Then, using the GuideLiner and the guidewire as a "rail", the JR4 guide catheter was advanced into the mid RCA to provide greater backup for delivery of the distal coronary stent past the numerous acute angles. The GuideLiner was the pivotal tool needed to achieve the necessary backup and delivery of the distal stents into proximal and mid PLA. Following these manipulations and maneuvers, a 2.5 x 28 mm PROMUS® DES was easily delivered to the proximal to mid PLA (Figure 4). A subsequent DES was delivered proximally through the GuideLiner. Once the stent was positioned, the GuideLiner was pulled back to "unsheath" the stent at the site of the lesion (Figure 5). GuideLiner was the pivotal tool to achieve the successful percutaneous revascularization of this technically difficult vessel (Figure 6).

CONCLUSION

Upon the three month follow up visit, the patient's angina significantly improved so much so that the patient has resumed exercising on his treadmill and has just built a garage for his home. The GuideLiner catheter provided the necessary support to stay within a 6F guide system and successfully revascularize a highly tortuous, chronically occluded, distal RCA. First, the GuideLiner catheter provided the necessary "rail" to successfully deep seat a guide catheter into the mid segment of the highly tortuous RCA. The GuideLiner catheter then provided the support necessary to deliver a "long" stent across a greater than 90 degree bend, in the distal segment of a tortuous vessel. In summary, the GuideLiner is a novel tool to support stent delivery, which may be used to facilitate proximal to distal deployment or to "unsheath" a stent within a coronary lesion rather than pushing the exposed stent across the lesion.

Physician Profile

Steven S. Roh, MD, FACC has his ABIM Certification in Interventional Cardiology and Cardiovascular Diseases as well as his CBNC Certification in Nuclear Cardiology. He attended medical school at Indiana University School of Medicine and his residency was at the University of Minnesota Hospital and Clinics. He studied Cardiology at Oregon Health Sciences University and Interventional Cardiology at the University of Wisconsin. His specialties are Interventional Cardiology, Nuclear Cardiology and General Cardiology. His current location is North Memorial Heart and Vascular Institute in Robbinsdale, Minnesota.

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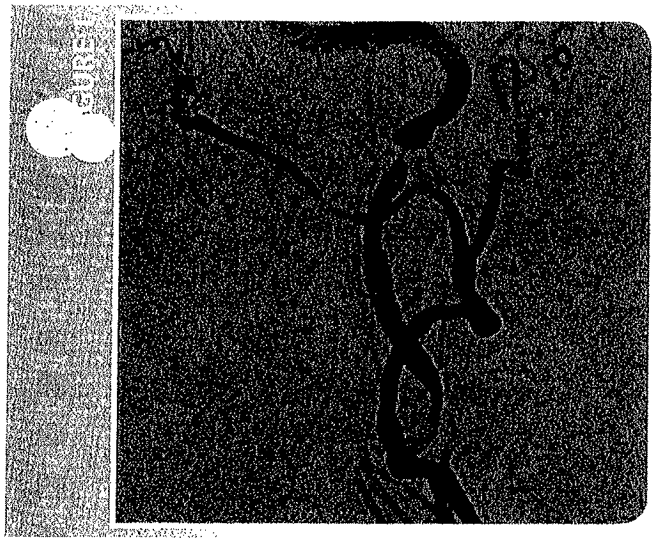

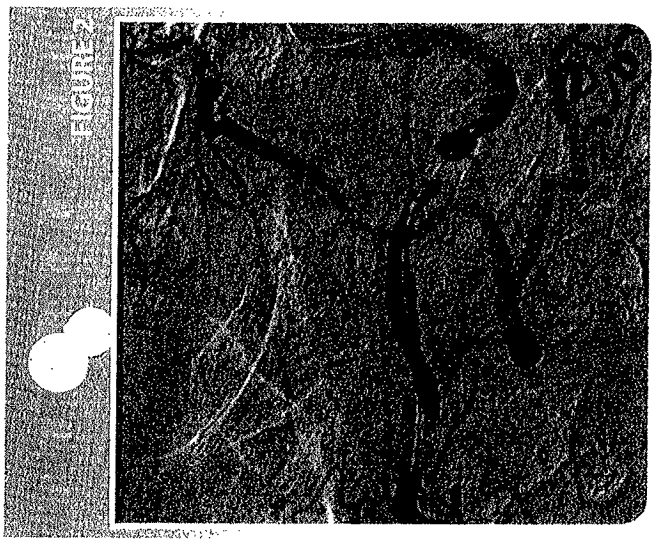

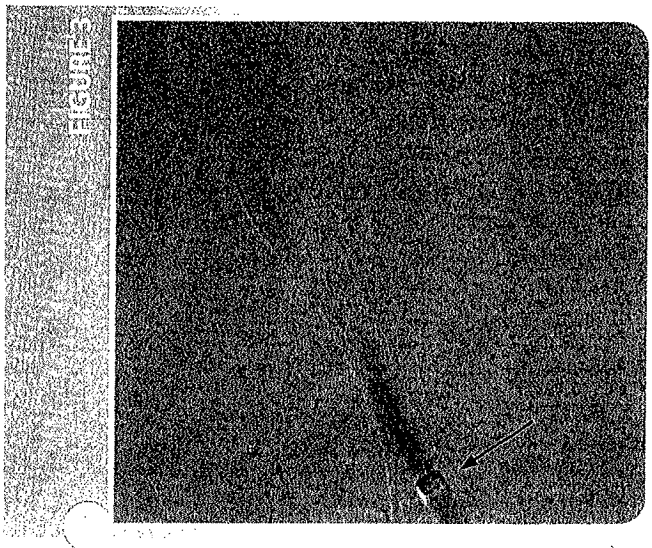

Successful Use of the GuideLiner® catheter to Treat Sequential Distal Carotid Artery Stenoses

PHYSICIAN

George Petrossian, M.D.

LOCATION

St. Francis Hospital, Roslyn, New York

PRESENTATION

The patient is a 68 year-old man with a history of hypertension and hypercholesterolemia. He has a remote history of neck surgery for a parotid tumor, followed by radiation.

Five months ago he presented with a left hemispheric CVA, with moderate residual arm weakness. Angiography demonstrated a 50% ulcerated right internal carotid stenosis. The left carotid contained a proximal 90% stenosis at the origin, an 80% tubular mild left ICA stenosis distal to an angulated segment, and an 80% stenosis in the distal left ICA (petrous segment). At that time, an 8mm x 10mm, tapered Xact® stent was placed at the proximal stenosis with distal protection.

Two weeks ago the patient developed one hour of severe right arm weakness which resolved. He then underwent repeat carotid angiography.

INITIAL FINDINGS

Carotid angiography demonstrated a stable 50% ulcerated plaque within the right ICA. The left ICA proximal stent was widely patent. The mid left ICA contained an 80% tubular stenosis and the distal left ICA (petrous segment) had progressed and contained a 95% stenosis (Figure 1).

INITIAL TREATMENT

Without distal protection, a 3mm x 15mm balloon was used to perform PTA of the 2 distal stenoses (Figure 2). A 7mm x 20mm Xact stent would not cross the distal lesion, and was deployed at the more proximal lesion, with a similar 7mm x 20mm stent placed just proximally. A significant residual stenosis was present at the distal stent margin as well as the distal most lesion in the petrous segment. Further attempts to cross the remaining lesions with a 2.0mm balloon over a 0.014" wire were unsuccessful.

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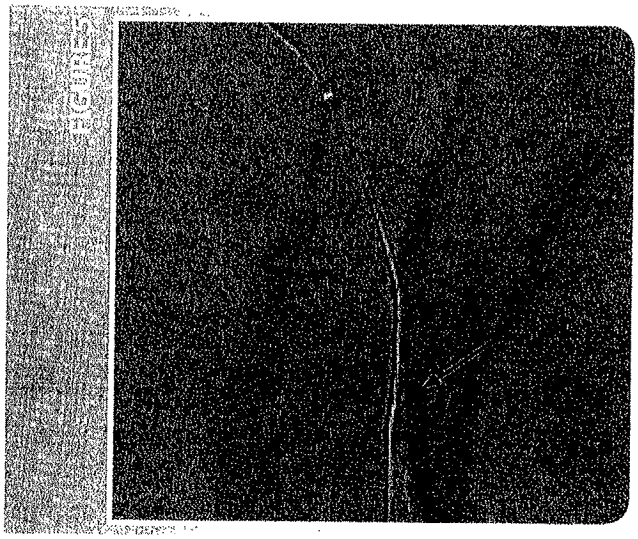
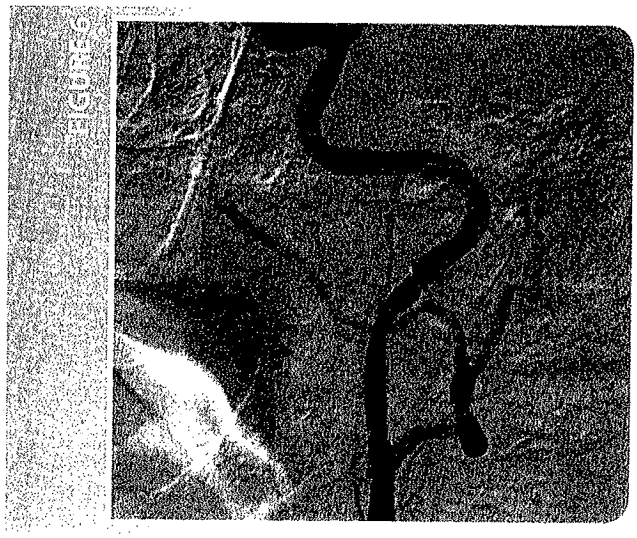




Successful Use of the GuideLiner® catheter to Treat Sequential Distal Carotid Artery Stenoses

TREATMENT WITH GUIDELINER CATHETER

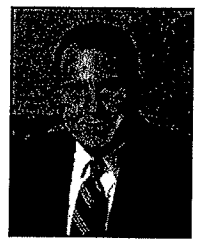
A 0.014" BMW 300cm guidewire was placed distally in the left ICA and the GuideLiner catheter was advanced into the stented segment of the left ICA (Figure 3). A 2mm x 15mm OTW balloon crossed the distal lesion with GuideLiner support and a 300cm Wiggle™ wire was placed distally after removal of the BMW guidewire.

A 3.5mm x 15mm bare metal stent and a 4.5mm x 18mm bare metal stent were deployed distally (Figure 4) within the left ICA and post dilated (Figure 5). The end result was a widely patent left ICA (figure 6).

CONCLUSION

The GuideLiner catheter provided the support necessary to advance balloon and stent catheters to the distal left ICA in a patient with prior radiation, vessel tortuosity and prior stent implantation. Without the GuideLiner catheter, this procedure would have been unsuccessful.

Physician Profile



Dr. Petrossian received his M.D. from The Mount Sinai School of Medicine. He completed his Medical and Cardiology training at Columbia Presbyterian Hospital, New York and his Interventional Cardiology training at Massachusetts General Hospital. He is the Director of Interventional Cardiovascular Procedures, St. Francis Hospital, The Heart Center, Roslyn, NY.

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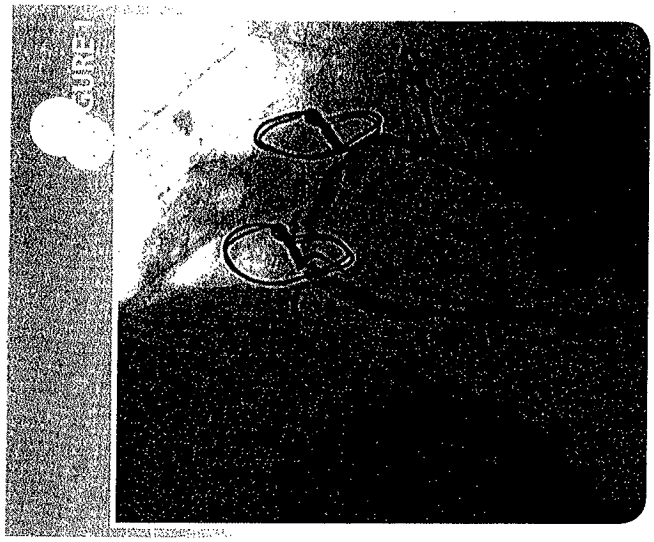

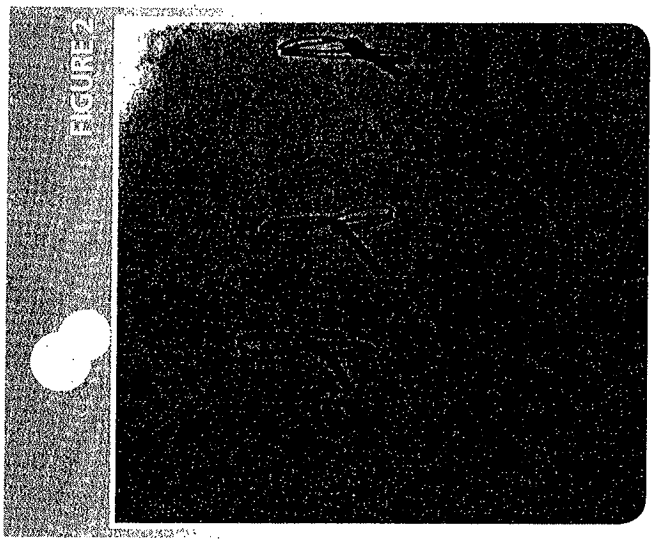

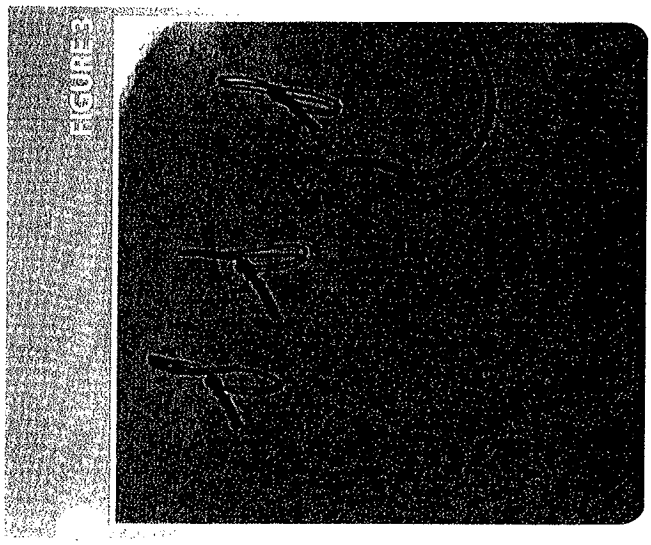

Successful Treatment of Heavily Calcified Right Coronary Artery from the Right Radial Artery Approach using the GuideLiner® catheter

PHYSICIANS

Aseem Vashist, M.D., FACC, FSCAI
Michael Azrin, M.D., FACC, FSCAI

LOCATION

University Of Connecticut School Of Medicine
Farmington, Connecticut

PRESENTATION

The patient is a 65-year old male with a history of coronary artery bypass grafting surgery, hypertension and hyperlipidemia who presented with chest tightness and dyspnea on exertion over the past few months. A stress test revealed inferior ischemia.

ANGIOGRAPHIC FINDINGS

Cardiac catheterization confirmed multiple severely calcified stenoses of the right coronary artery (figure 1) and calcified stenosis of the ostium of the circumflex artery. The vein grafts to the RCA and the circumflex were both occluded.

INITIAL TREATMENT

A 6F Amplatz AL1 catheter was inserted via the right radial artery access. The RCA lesions were treated with multiple passes using 1.25mm and 1.5mm Rotablator® burrs (figure 2). After adequate lesion modification, multiple balloon inflations were performed as part of an aggressive pre-dilation strategy (figure 3). In spite of multiple attempts, stents could not be delivered to the mid and distal segments of the RCA.

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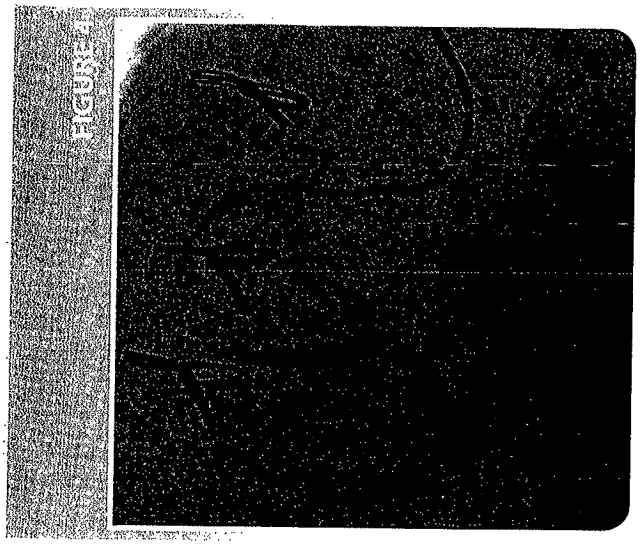


FIGURE 4

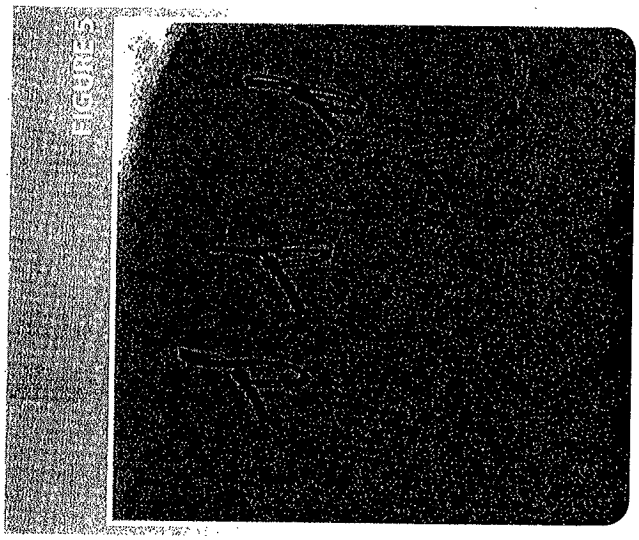


FIGURE 5

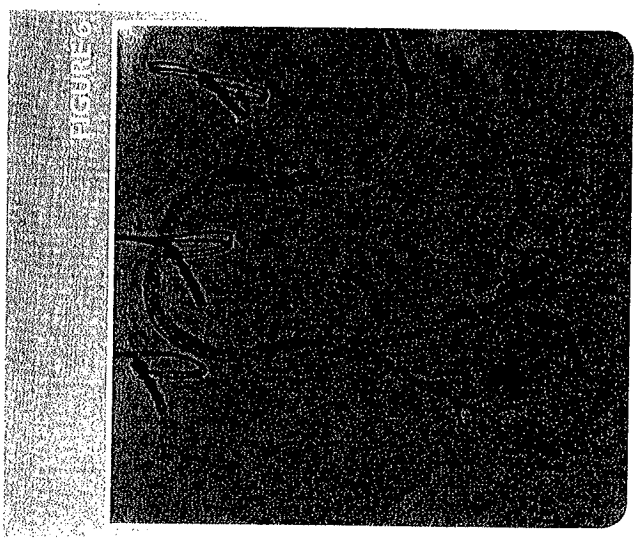


FIGURE 6

Successful Treatment of Heavily Calcified Right Coronary Artery from the Right Radial Artery Approach using the GuideLiner® catheter

TREATMENT WITH GUIDELINER CATHETER

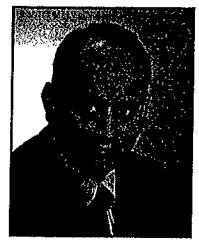
A 6F GuideLiner catheter was gently advanced over a balloon catheter into the distal right coronary artery and a 3.0mm x 18mm Everolimus drug eluting stent was delivered to the distal RCA through the GuideLiner catheter without any resistance or difficulty (figure 4). Next, a 3.5mm x 28mm Everolimus drug eluting stent stent was delivered through the GuideLiner catheter without difficulty to the mid-RCA (figure 5). The proximal and ostial RCA were then stented with a 3.5mm x 28mm Everolimus drug eluting stent. Final angiography demonstrated an excellent result (figure 6).

CONCLUSION

This case highlights certain technical challenges involved in treating calcified and tortuous arteries. Specifically, in this case it was difficult to deliver stents in spite of adequate lesion modification with rotational atherectomy, aggressive guide support positioning and multiple balloon inflations as part of the pre-dilation strategy. Using the GuideLiner catheter, the stents were delivered without difficulty. The GuideLiner catheter facilitated successful completion of this procedure.

Physician Profile

Dr. Vashist is Assistant Clinical Professor of Medicine at the University Of Connecticut School Of Medicine in Farmington, CT.



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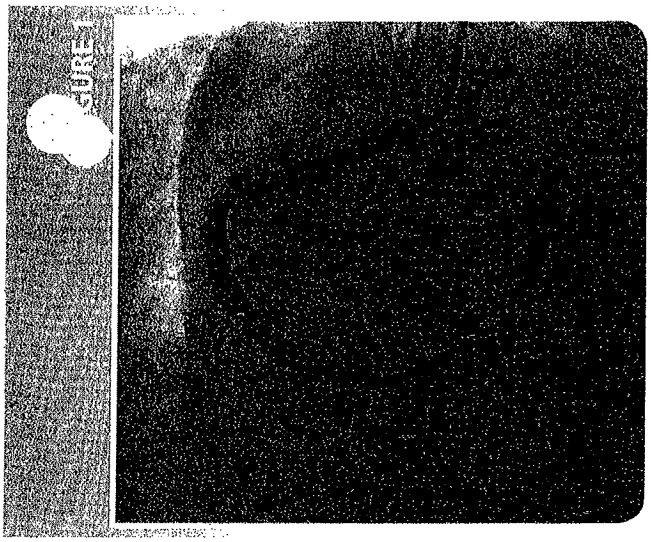

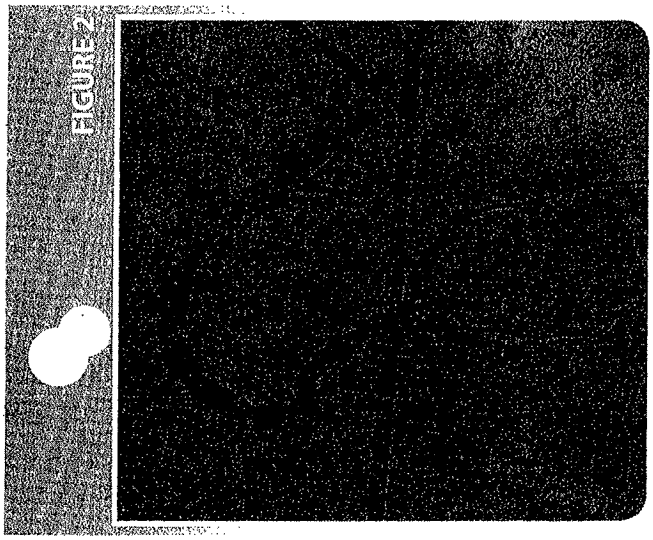

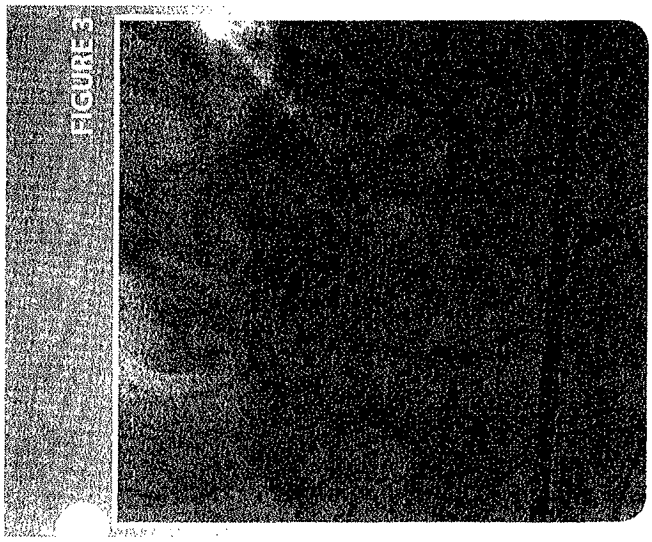

Successful Multi-Stent Delivery in a Heavily Calcified Right Coronary Artery Using the GuideLiner® catheter

PHYSICIAN

Patrizia Presbitero, MD
Chief of Interventional Cardiology Department

LOCATION

Hospital Humanitas Rozzano-Milano

PRESENTATION

The patient is a 63 year-old male, with a relevant medical history consisting of diabetes mellitus, hypertension and hyperlipidemia. Three years prior to this visit the patient presented with acute coronary syndrome and underwent PCI with rotablation and stenting of the LAD. At that time, treatment of a stenosed, heavily calcified right coronary artery was also attempted with rotablation and POBA, but it was impossible to position the stent due to the tortuosity and calcification of the artery.

Three years later, due to increasing exertional angina, he was reconsidered for coronary angiography and eventually PCI.

ANGIOGRAPHIC FINDINGS

Coronary angiography demonstrated patency of the previously treated LAD, and a heavily calcified circumflex artery with occlusion of a small marginal branch. The dominant right coronary artery was tortuous and completely calcified all along its course. Critical stenoses were present in the proximal and mid-distal (tandem lesion) right coronary artery with diffuse disease of IVP (Figure 1). Left ventricular function was preserved.

INITIAL TREATMENT

A 7F amplatz left guiding catheter was positioned at the ostium of the right coronary artery. After positioning two Balanced Heavyweight 0.014" guidewires in the IVP and PL, we attempted to pass a microcatheter to the distal vessel with the intent to place a Rotablator® guidewire that was impossible to advance otherwise. The maneuver was unsuccessful due to the failure to advance the microcatheter (Figure 2).

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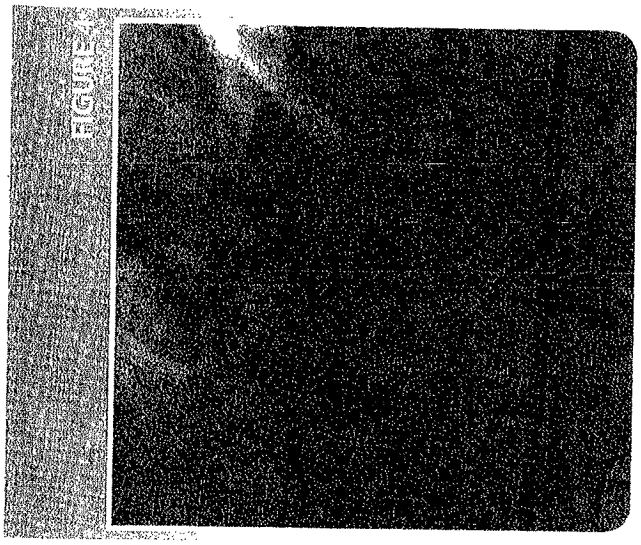

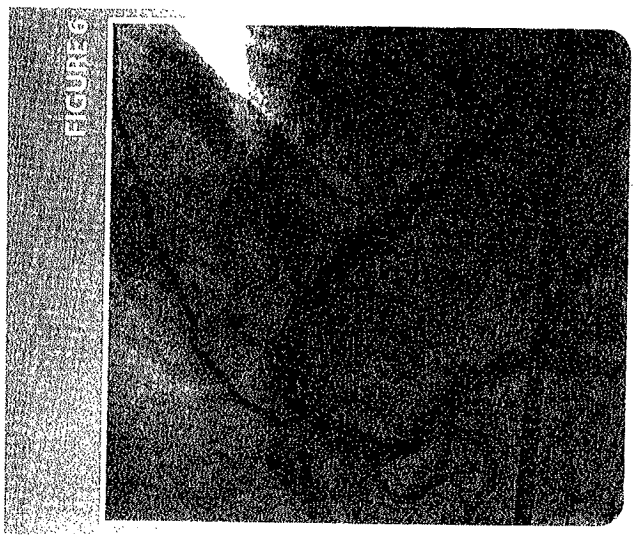

Successful Multi-Stent Delivery in a Heavily Calcified Right Coronary Artery Using the GuideLiner® catheter

TREATMENT OF RIGHT CORONARY ARTERY WITH GUIDELINER CATHETER

After removing one of the guidewires, a 6F GuideLiner catheter was inserted over the remaining Balanced Heavyweight guidewire and advanced to the proximal portion of the right coronary. It was then possible for a 2.5mm x 3.0mm balloon to reach the distal lesions and to dilate it. In order to deliver the stent, it was necessary to further advance the Guideliner catheter. In order to do so a 3.0 balloon was inflated distally and kept inflated, acting as an anchor so that the GuideLiner catheter could be pushed over the balloon and positioned right in front of the distal lesion (Figure 3). After removing the balloon, 3.5mm x 12mm and 3.5mm x 15mm Xience™ stents were advanced through the GuideLiner catheter, positioned and deployed in the middle distal right coronary (Figure 4). After withdrawing the GuideLiner catheter to a more proximal location, a 4mm x 12 mm Xience stent was positioned proximally (Figure 5). Final dilatation with 3.5mm and 4mm high pressure balloons was performed while using the GuideLiner catheter in order to position the balloon distally. Good results were obtained (Figure 6).

CONCLUSION

In this case, by enabling distal stent delivery within a heavily calcified vessel, the GuideLiner catheter made it possible to treat previously unreachable lesions.

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Successful Distal Stent Delivery Past Multiple Previous Stents Made Possible by the GuideLiner® catheter

FIGURE 1

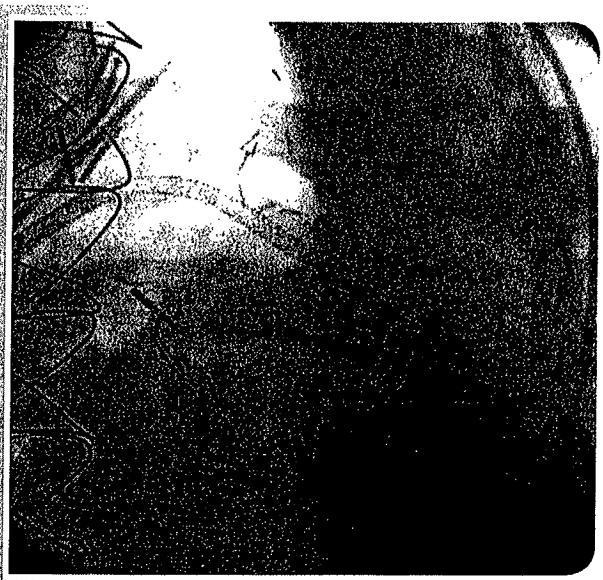
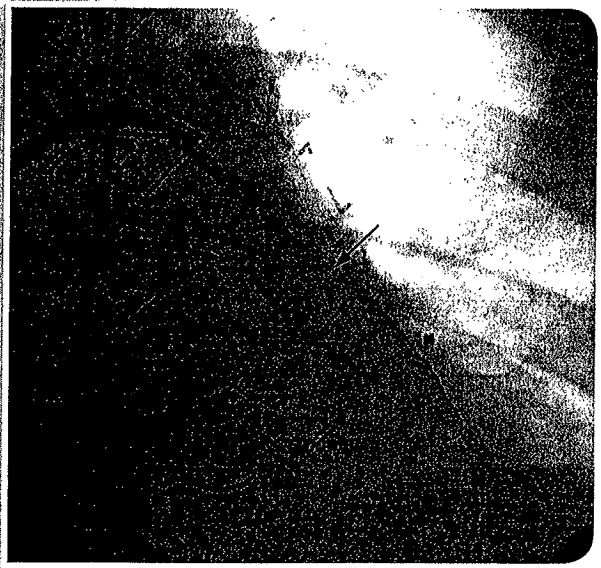


FIGURE 2



PHYSICIANS

Binita Shah, M.D.
Chad Kliger, M.D.
John Coppola, M.D.

LOCATION

New York University Medical Center, New York

PRESENTATION

The patient is a 62 year old male with a history of diabetes mellitus, hyperlipidemia, hypertension and coronary artery disease. He has undergone a 4 vessel coronary artery bypass grafting and has had multiple interventions on a saphenous vein graft to the Ramus, with implantation of bare metal and drug-eluting stents (figure 1). He returned for treatment after developing disabling angina.

INITIAL FINDINGS

Coronary angiography confirmed a lesion at the distal stent edge, beyond multiple previously placed stents, within the vein graft, extending into the native vessel (figure 2).

INITIAL TREATMENT OF SVG TO RAMUS

The distal graft lesion was treated with balloon angioplasty. Multiple attempts made to advance a stent to the distal lesion were unsuccessful, despite the use of a Wiggle™ wire for buddy wire support. The procedure was completed with balloon dilation only.

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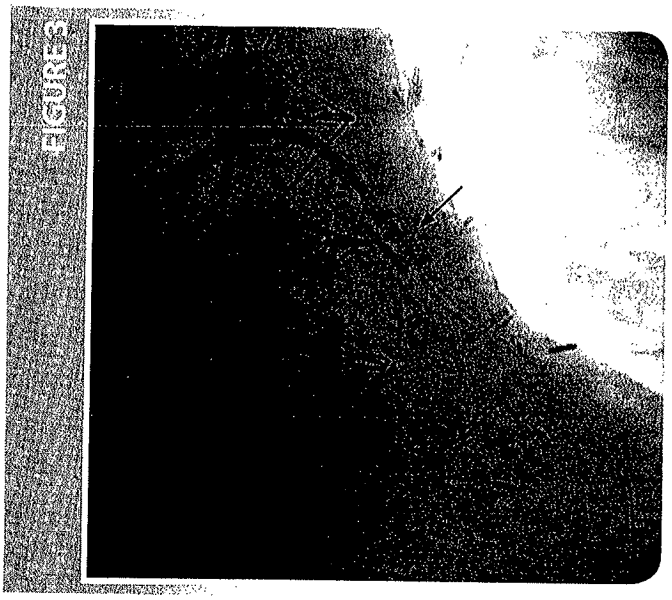

FIGURE 3

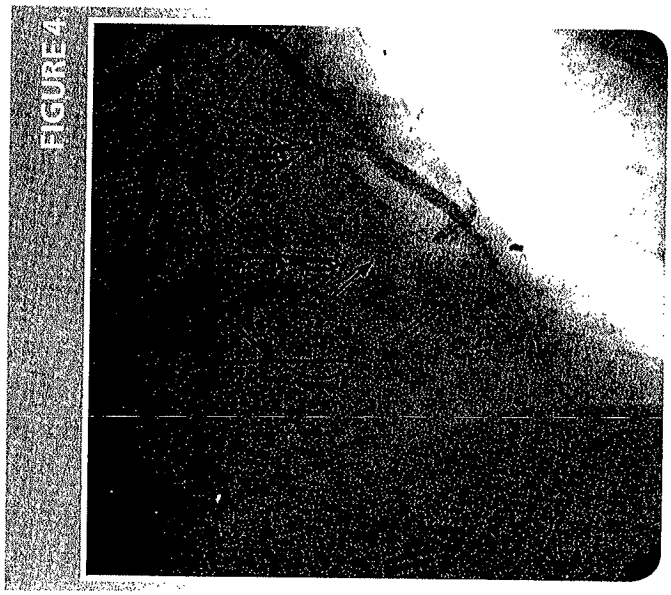

FIGURE 4

Successful Distal Stent Delivery Past Multiple Previous Stents Made Possible by the GuideLiner® catheter

SUBSEQUENT TREATMENT OF THE SVG WITH GUIDELINER

Two months after the balloon angioplasty was performed, the patient returned with recurrent angina. The SVG to the Ramus was cannulated with an AL1 guide catheter. The GuideLiner was advanced through the guide catheter and a Prowater™ wire was advance to the lesion through the GuideLiner. A 2.5mm x 12mm Sprinter® balloon was placed at the distal lesion and inflated. With the distal anchor balloon inflated, the GuideLiner was advanced into the vein graft through the prior areas of stented graft that had given so much difficulty passing on the previous procedures (figure 3). With the GuideLiner in place, a Promus® stent passed easily to the distal lesion and was successfully deployed at 18 atms. A good angiographic result and positive patient outcome was achieved. (figure 4)

SUMMARY

1. By allowing the delivery of a stent through a saphenous vein graft with multiple previous stent implantations, the GuideLiner made possible the treatment of this difficult and persistent distal lesion.
2. The GuideLiner enabled deep seating within a vessel, even past previous stents and atherosclerotic plaque.

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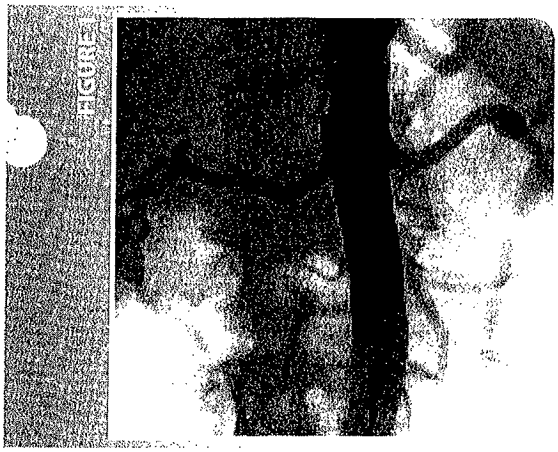

Novel Use of the Guideliner® Catheter in Accessing a Tortuous Renal Artery for Renal Denervation

PHYSICIAN

Martin W. Bergmann, M.D.

LOCATION

St. Georg Hospital, Hamburg, Germany

INITIAL FINDINGS

The patient is a 71 year old female with persistent hypertension already taking three oral antihypertensive medications and not tolerant to additional medication. Routine testing procedures were performed and subsequent diagnosis made. Initial angiography revealed the superior take-off of the right renal artery with some proximal tortuosity (figure 1).

TREATMENT

Rather than the usual 5F guide catheter through a shorter 8F guide catheter maneuver to deliver the renal denervation catheter to the distal portion of the renal artery, a 6F (5-in-6) GuideLiner catheter was advanced into the right renal artery and positioned at the mid-vessel (figure 2). The denervation catheter was then easily delivered through the GuideLiner to the desired location within the renal artery (figure 3). With the ease of delivery, the renal artery was treated accordingly with the denervation catheter.

CONCLUSION

The GuideLiner allowed advancement of the renal denervation catheter without engaging the renal artery with the 8F guide catheter. The smooth tip of the GuideLiner reduced the risk of vessel dissection as it was delivered distally through a tortuous renal artery.

SUMMARY

The denervation catheter moved freely through the GuideLiner to the desired vascular location and the entire procedure was simplified due to the benefits of the GuideLiner.

PHYSICIAN PROFILE

Dr. Bergmann studied at the University of Kiel. As an Interventional Cardiologist and Heart Failure practitioner, Dr. Bergmann currently acts as the Deputy of the Cardiology department at St. Georg hospital in Hamburg, Germany.

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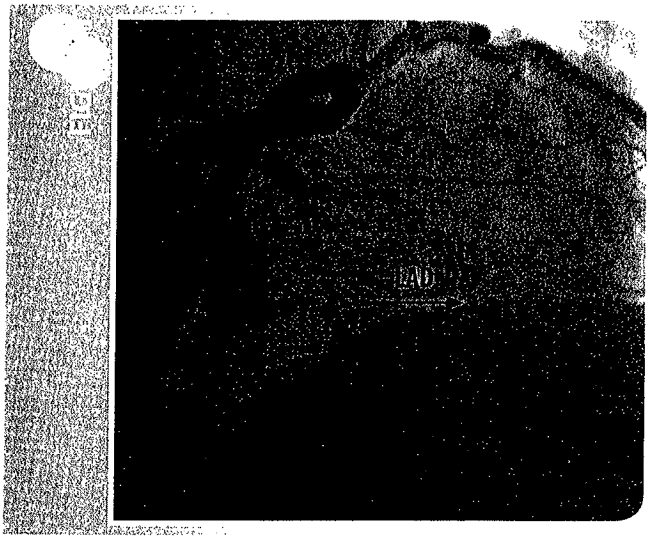
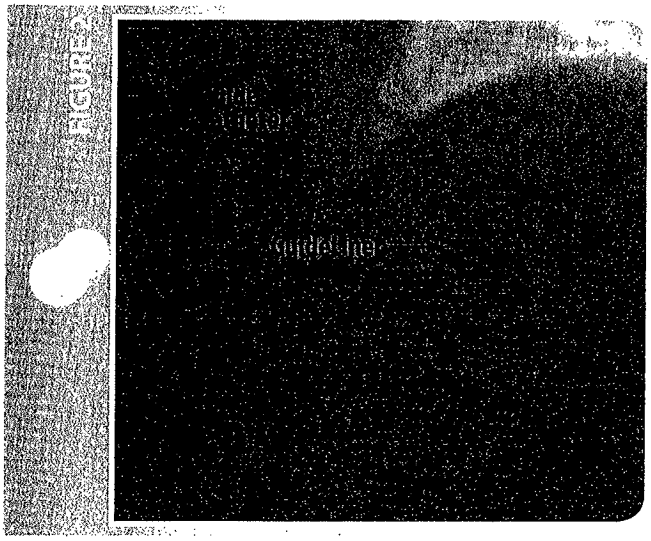
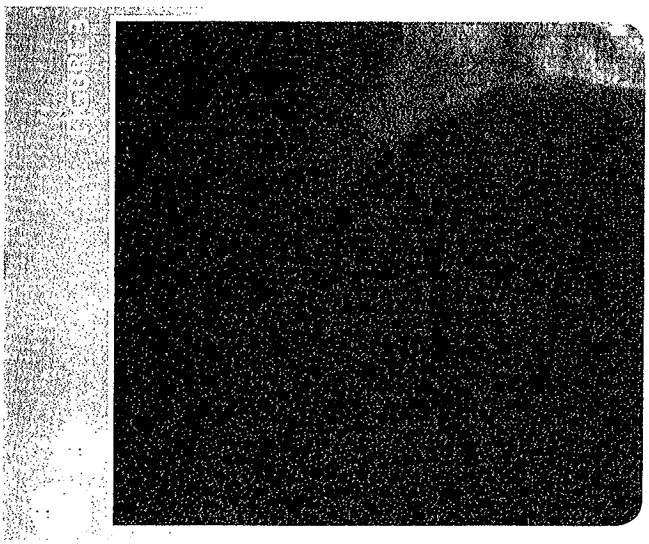






Successful Transradial Use of the GuideLiner™ Catheter to Selectively Treat Severe Disease in the LAD

PHYSICIAN

Mark Spence, MB BCh BAO Honours, MRCP (Edinburgh), MD
Colm Hanratty, MD, FRCPI

LOCATION

Royal Victoria Hospital, Belfast, Northern Ireland

PRESENTATION

The patient is a 73-year-old male who presented with an acute coronary syndrome and uncontrolled atrial fibrillation. The patient has a medical history of hypertension and hyperlipidemia. He presented with Inferolateral ST depression on 12-lead ECG; troponin level T 0.05. An echocardiogram showed asymmetrical septal hypertrophy and inferior hypokinesis.

INITIAL FINDINGS

Coronary angiography confirmed severe ostial disease in the RCA, extending into the proximal segment of the artery and a long segment of heavily calcified disease in the mid-LAD (Figure 1). The LCX showed minimal disease and overall LV function was mildly impaired (LVEDP 16mmHg).

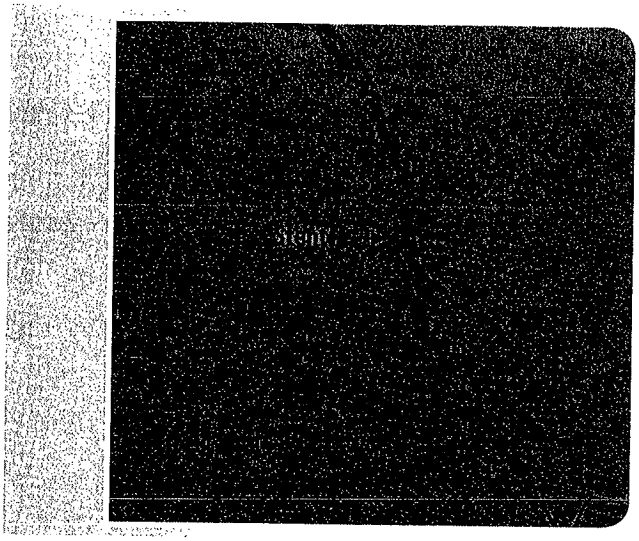
INITIAL TREATMENT

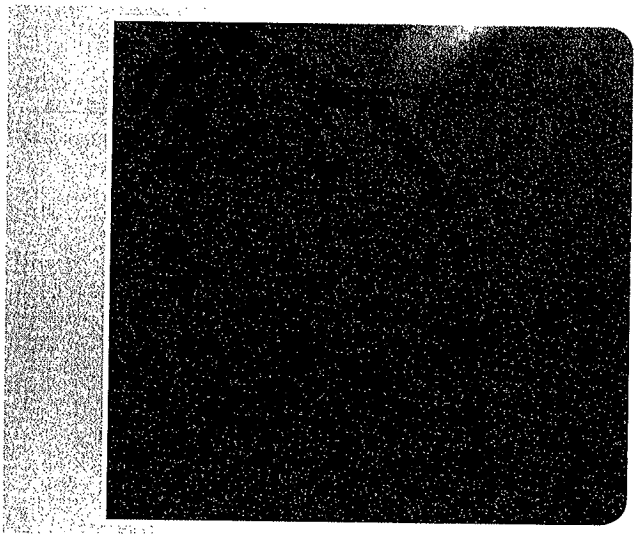
The RCA was treated satisfactorily with a Liberté® 3.0 x 12mm bare-metal stent. Initial access to treat the LAD was obtained through the transradial approach using a 7F JL3.5 Asahi sheathless guide catheter. A 1.5mm Rotablator® burr was used to modify the calcified LAD. The lesion was predilated serially with an Apex® 3.0 x 20mm balloon. Due to the friction encountered in the proximal LAD and guide catheter back out, a 3.0 x 38mm Taxus® stent could not be delivered to the target lesion.

TREATMENT OF THE LAD WITH GUIDELINER

A 6F GuideLiner catheter was inserted over the in-place .014" guidewire and easily passed through the proximal lesion and into the mid-LAD (Figure 2). Selective contrast injection improved visualization of the target vessel (Figure 3) and facilitated accurate stent sizing and positioning.

(continued on back)





Successful Transradial Use of the GuideLiner Catheter to Selectively Treat Severe Disease in the LAD

TREATMENT CONTINUED ...

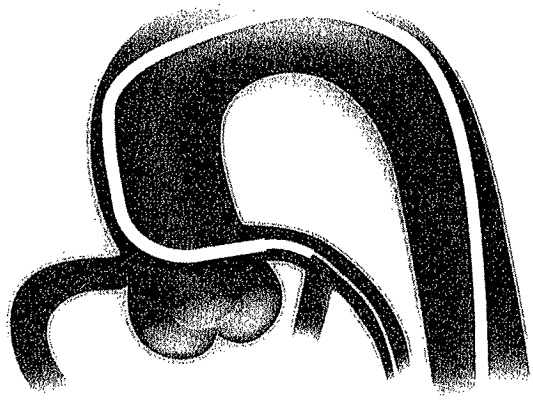
The GuideLiner catheter was used to successfully deliver a 3.0 x 38mm Taxus stent to the mid-LAD, which was subsequently overlapped with an additional 4.0 x 24mm Taxus stent proximally (Figure 4). The GuideLiner catheter was then used to deliver a 4.0 x 15mm Quantum™ balloon for post-dilatation stent expansion.

CONCLUSION

There was a good angiographic end result (Figure 5), following stenting and post-dilatation. IVUS confirmed the stent was apposed and optimally sized and deployed. The patient was discharged well, without complication the following day and was asymptomatic at 8 week review.

By overcoming resistance in the proximal LAD, the GuideLiner catheter enabled successful delivery of interventional equipment to the heavily calcified mid-vessel.

The facility for selective contrast injection via the GuideLiner catheter into the target vessel improved visualization facilitating optimal stent sizing and placement with limited total contrast volume.



PHYSICIAN PROFILES

Dr. Spence received his MD from Queen's University Belfast in Northern Ireland, UK and is an Honorary Senior Lecturer at the University. Dr. Spence completed an interventional cardiology fellowship, specializing in Coronary and Structural Heart Disease, at Royal Jubilee Hospital in Vancouver, British Columbia, Canada. In addition, Dr. Spence completed a fellowship in Congenital Heart Disease Intervention at Royal Brompton Hospital and Guy's and St. Thomas' Hospitals in London, UK. He now practices at Royal Victoria Hospital in Belfast as a Consultant Interventional Cardiologist.

Dr. Hanratty received his MD from Queen's University Belfast in Northern Ireland, UK followed by a fellowship at North Shore Hospital in Sydney, Australia. He now practices with the Belfast Trust as a Consultant Interventional Cardiologist.

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Exhibit 15

Vascular SOLUTIONS

To: Dr. Doug Fraser, Manchester Heart Centre, Manchester, United Kingdom
From: Joan Will, Director of Marketing Communications
Date: December 3, 2009
Subject: Testimonial Authorization

I hereby grant permission to Vascular Solutions, Inc. to quote the comments made by me regarding the Vascular Solutions' products listed below. My quoted comments may be included in any of Vascular Solutions' materials, including advertisements, websites, direct mailings, or other promotional materials for its products and accessories. The comments may be edited by Vascular Solutions to fit the available space in the document so long as the substantive meaning of my comments is unchanged.

This authorization shall continue unless and until I provide written notice of revocation of this authorization to the Director of Marketing Communications of Vascular Solutions at the address set forth below.

Signature	D.G.W. Fraser
Name (printed)	**D G W Fraser**
Date	**9 / 12 / 09**
Vascular Solutions' Product	**GuideLiner™ Catheter**

Quotation as follows:

"Deep intubation of the GuideLiner catheter within a soft 6F guide provides better backup support and is less traumatic than using stiff 7F and 8F guides that were previously required in complex disease. Furthermore, the soft and very flexible tip will often cross tortuous disease where a stent gets stuck, enabling delivery of stents and other equipment directly to the target lesion. The GuideLiner is as easy to insert as a standard rapid exchange balloon catheter and has quickly become a routine part of my angioplasty practice."

Return to Joan Will via fax (763.656.4254) or email jwill@vascularsolutions.com

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PHONE: 763/656-4300 ◆ FAX: 763/656-4254 ◆ www.vascularsolutions.com

reference

Vascular SOLUTIONS

To: Dr. Matthew Price
From: Joan Will, Director of Marketing Communications
Date: December 9, 2010
Subject: Testimonial Authorization

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This authorization shall continue unless and until I provide written notice of revocation of this authorization to the Director of Marketing Communications of Vascular Solutions at the address set forth below.

"The GuideLiner has become an indispensible part of my tool kit for complex PCI. Simply put, it's a game changer."

Matthew Price, MD, FACC, FSCAI ~~Scripps Green Hospital, La Jolla, CA~~ Scripps Clinic, La Jolla CA

Signature	
Name (printed)	*Matthew Price, MD, FACC, FSCAI*
Institution	~~*Scripps Green Hospital*~~ Scripps Clinic
Date	*December 9, 2010*
Vascular Solutions' Product	*GuideLiner® catheter*

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Vascular SOLUTIONS

To:
From: Joan Will, Director of Marketing Communications
Date:
Subject: Testimonial Authorization

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This authorization shall continue unless and until I provide written notice of revocation of this authorization to the Director of Marketing Communications of Vascular Solutions at the address set forth below.

Quotation:

The Guideliner is an important tool that all interventional Cardiologist shoud be familiar with - It can really Save you one day!

Signature	Mehdi Shishehbor
Name (printed)	Mehdi Shishehbor
Date	08/14/2010
Vascular Solutions' Product	Guideliner

Return to Joan Will via fax (763.656.4254) or email jwill@vascularsolutions.com

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Vascular SOLUTIONS

To: Dr. Ashish Pershad
From: Joan Will, Director of Marketing Communications
Date: December 16, 2010
Subject: Testimonial Authorization

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This authorization shall continue unless and until I provide written notice of revocation of this authorization to the Director of Marketing Communications of Vascular Solutions at the address set forth below.

"The GuideLiner allows me to successfully complete previously unimaginable interventions."

Ashish Pershad, M.D., F.A.C.C., F.S.C.A.I.
Heart and Vascular Center of Arizona, Phoenix, AZ

Signature	
Name (printed)	*Dr. Ashish Pershad*
Institution	*Heart and Vascular Center of Arizona*
Date	*December 16, 2010*
Vascular Solutions' Product	*GuideLiner® catheter*

Return to Joan Will via fax (763.656.4254) or email jwill@vascularsolutions.com

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Exhibit 16

Core Businesses

Our products and technologies are used to diagnose or treat a wide range of medical conditions, including heart, digestive, pulmonary, vascular, urological, women's health, and chronic pain conditions. We continue to innovate in these areas and are extending our innovations into new geographies and high-growth adjacency markets.

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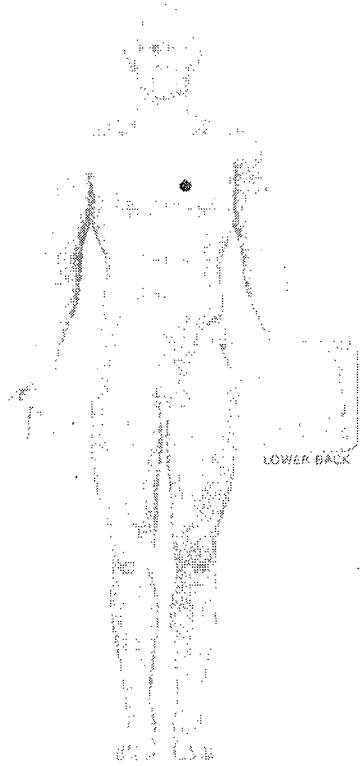

CARDIAC RHYTHM MANAGEMENT

Solutions for treating irregular heart rhythms and heart failure, and protecting against sudden cardiac arrest.

Medical Conditions Treated:

- Cardiac Arrhythmias
- Sudden Cardiac Arrest
- Heart Failure
- Heart Rhythm Disorders

Our Solutions:

- Pacemakers
- Implantable Cardioverter Defibrillators (ICDs)
- Cardiac Resynchronization Therapy (CRT) Devices
- Remote Monitoring Systems
- Pericardiocentesis
- Pacing Leads and ICD Leads

NEXT: LEARN ABOUT OUR LEADERS

Core Businesses

Our products and technologies are used to diagnose or treat a wide range of medical conditions, including heart, digestive, pulmonary, vascular, urological, women's health, and chronic pain conditions. We continue to innovate in these areas and are extending our innovations into new geographies and high-growth adjacency markets.

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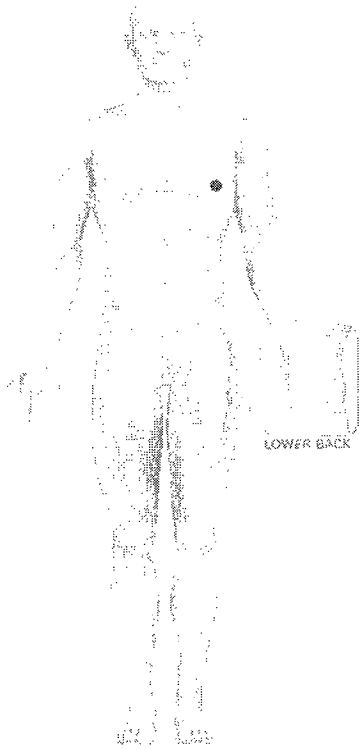

ELECTROPHYSIOLOGY

Technologies, such as mapping catheters, radiofrequency energy, and cryogenics, for diagnosing and treating heart rhythm disorders.

Medical Conditions Treated:

- Cardiac Arrhythmias
- Heart Rhythm Disorders

Our Solutions:

- Cardiac Tissue Ablation
- Cardiac Mapping
- Cardiac Catheterization
- Sheaths
- Diagnostic Catheters

NEXT: LEARN ABOUT OUR LEADERS

Core Businesses

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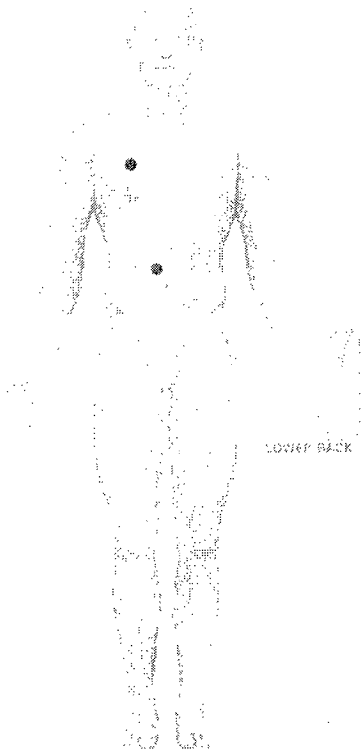

ENDOSCOPY

Technologies for diagnosing and treating diseases of the **digestive system, airway and lungs.**

Medical Conditions Treated:

- Malignant & Benign Tumors
- Gastrointestinal Diseases
- Pulmonary Diseases
- Gastrointestinal Cancers
- Abscesses

Our Solutions:

- Balloon Dilation
- Stenting
- ERCP/Cholangioscopy
- Biliary
- Biopsy and Polypectomy
- Hemostasis
- Radio Frequency Ablation
- Enteral Feeding

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Core Businesses

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INTERVENTIONAL CARDIOLOGY

Technologies for diagnosing and treating coronary artery disease and other cardiovascular disorders.

Medical Conditions Treated:

- Cardiovascular Diseases
- Coronary Artery Disease
- Acute Myocardial Infarction

Our Solutions:

- Drug-Eluting Stents
- Bare-Metal Stents
- Catheters, Balloons
- Guide Wires
- Coronary Atherectomy
- Coronary Intravascular Ultrasound

NEXT: LEARN ABOUT OUR LEADERS

Core Businesses

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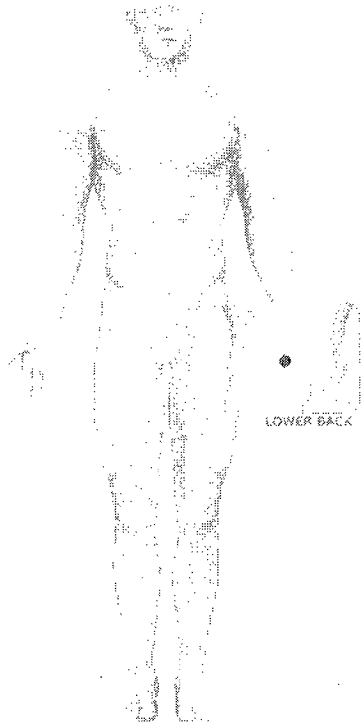

NEUROMODULATION

Microelectronic implantable technologies for managing chronic neuropathic pain and neurological diseases.

Medical Conditions Treated:

- Chronic Pain

Our Solutions:

- Neurostimulation
- Rechargeable Spinal Cord Stimulators
- Microstimulators

NEXT: LEARN ABOUT OUR LEADERS

Core Businesses

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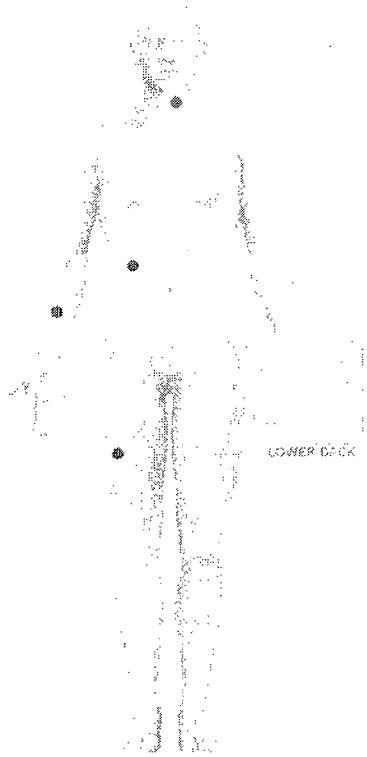

PERIPHERAL INTERVENTIONS

Products that treat vascular system blockages in areas such as the carotid and renal arteries and the lower extremities.

Medical Conditions Treated:

- Peripheral Vascular Diseases
- Pulmonary Embolisms

Our Solutions:

- Carotid Artery Stenting
- Embolic Protection Balloon Catheters
- Vascular Protection
- Iliac Solutions
- Renal Solutions

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Core Businesses

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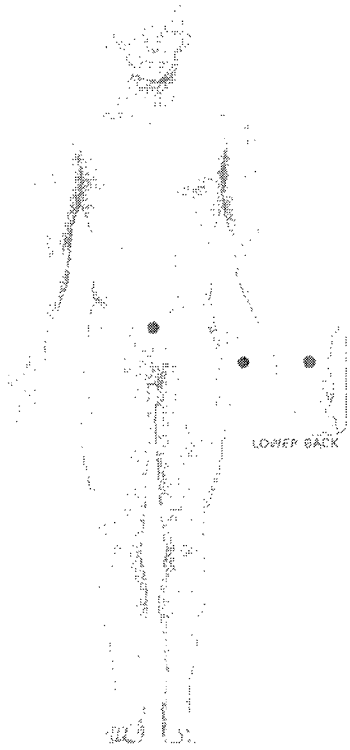

UROLOGY & WOMEN'S HEALTH

Solutions for treating urological and gynecological disorders like kidney and bladder stones, stress urinary incontinence, pelvic organ prolapse, and excessive uterine bleeding.

Medical Conditions Treated:

- Urinary Stone Disease
- Benign Prostatic Hyperplasia
- Urinary Incontinence
- Pelvic Organ Prolapse
- Menorrhagia

Our Solutions:

- Endometrial Ablation
- Holmium Laser Ablation of the Prostate (HoLAP)
- Stone Retrieval/Lithotripsy
- Pelvic Floor Reconstruction
- Mid-Urethral Slings
- Urethral Bulking

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Embolic Protection
Guide Catheters
Guide Wires
Imaging Catheters
Imaging System
Plaque Modification

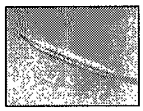
Balloon Catheters

Apex® PTCA Dilatation Catheter

The Apex Balloon Catheter offers a new shaft and tip technology along with an expanded size matrix which optimizes the balance between trackability and pushability.

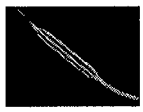
Emerge™ PTCA Dilatation Catheter

Emerge™ PTCA Dilatation Catheter - Lead the Way.



Maverick® PTCA Balloon Catheters

Maverick Balloon Catheter technologies deliver the exceptional performance needed to succeed in demanding cases.



NC Quantum Apex™ PTCA Dilatation Catheter

The NC Quantum Apex Catheter is a high-performance, post-dilatation balloon catheter developed specifically to address physicians' needs in optimizing coronary stent deployment.

Quantum™ Maverick® Balloon Catheters

The Quantum Maverick Balloon Catheter provides a unique balance of dilatation force and exceptional deliverability to meet the needs of the interventional cardiologist in the drug-eluting world.

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Bare-Metal Stents

VeriFLEX® Bare-Metal Coronary Stent System

The VeriFLEX Bare-Metal Stent is engineered to maximize radial strength and minimize recoil while providing exceptional deliverability.

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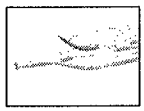
Plaque Modification

CTO System

CrossBoss® CTO Catheter

The CrossBoss Coronary Catheter is designed to quickly and safely deliver a guidewire via true lumen or subintimal pathways.



Stingray® CTO System

The Stingray Coronary System (catheter and guidewire) is designed to accurately target and re-enter the true lumen from a subintimal position.

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Guide Catheters
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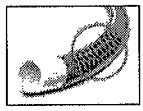
Imaging Catheters
Imaging System
Plaque Modification

Diagnostic Catheters

Expo® Diagnostic Catheter

Designed to promote quick, safe vessel engagement and reliable performance for a smooth diagnostic procedure.



Impulse® Diagnostic Catheter

Flextrusion technology for a smooth transition from stiff proximal shaft to soft distal segment.

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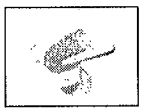
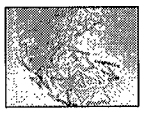
Guide Wires
Imaging Catheters
Imaging System
Plaque Modification

Drug-Eluting Stents

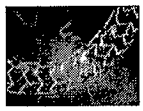
ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System
The ION Paclitaxel-Eluting Platinum Chromium Coronary Stent System sets a new standard in strength, deliverability and visibility with the innovation of Platinum Chromium (PtCr) and a new stent design.



PROMUS Element™ Plus Everolimus-Eluting Platinum Chromium Stent System
The PROMUS Element Everolimus-Eluting Platinum Chromium Coronary Stent System establishes a new standard of drug-eluting stent performance.

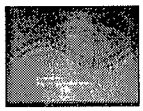


PROMUS® 2.25 Drug-Eluting Coronary Stent System
Not All Olimus Stents Are Created Equal...for Small Vessels
The PROMUS 2.25 mm Stent System combines a highly deliverable platform with an effective drug and polymer design to provide an optimal olimus, from a partner you trust.

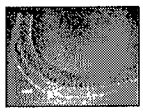


PROMUS® Everolimus-Eluting Coronary Stent System
The PROMUS Everolimus-Eluting Coronary Stent System is 'olimus made deliverable' with a powerful neointimal suppressor designed to provide impressive clinical results.

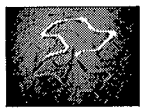
TAXUS Express² Coronary Stent System
The ability to reduce restenosis, treat a variety of lesions and achieve safe, predictable outcomes for patients.



TAXUS® Liberté® Atom™ Paclitaxel-Eluting Coronary Stent System
The TAXUS Liberté Atom Stent System, a 2.25mm drug-eluting stent (DES), is engineered for consistent drug delivery in small vessels.



TAXUS® Liberté® Long Paclitaxel-Eluting Coronary Stent System
The TAXUS Liberté Long Stent System is the only 38mm length drug-eluting stent (DES) approved for use in the United States.



TAXUS® Liberté® Paclitaxel-Eluting Coronary Stent System
The TAXUS Liberté Paclitaxel-Eluting Coronary Stent System is engineered for consistent drug elution and impressive performance. Enhanced deliverability features allow access to the target lesion, because first you have to get there.

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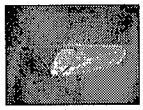
Diagnostic Catheters
Drug-Eluting Stents
Embolic Protection
Guide Catheters
Guide Wires
Imaging Catheters
Imaging System
Plaque Modification

Embolic Protection



FilterWire EZ™ Embolic Protection System

With its advanced technology designed for simplicity and effectiveness, the FilterWire EZ Embolic Protection System is intended to deliver efficient, predictable protection.

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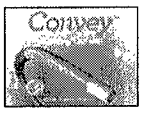
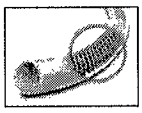
- Guide Wires
- Imaging Catheters
- Imaging System
- Plaque Modification

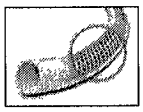
Guide Catheters



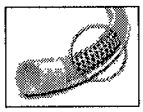
Convey™ Guiding Catheter
The Convey™ Guiding Catheter provides controlled deliverability and critical back-up support.



Mach 1® Guide Catheter
A large lumen and optimal shaft performance offers precise handling, device delivery options and clinical versatility.



RunWay® Guide Catheter
High-performance design for exceptional support, strength and control in case after case.



Wiseguide® Guide Catheter
SmartShapes™ Curves for excellent interventional performance and back-up support.

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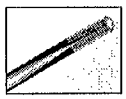
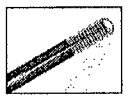
Imaging System
Plaque Modification

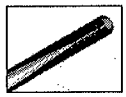
Guide Wires



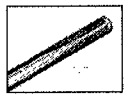
ChoICE® Extra Support Guide Wire
Provides the extra support and smooth device tracking required for device delivery.



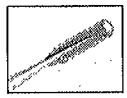
ChoICE® Floppy Guide Wire
Combines a hydrophilic-coated polymer sleeve with a soft tip and flexible body - excellent for frontline and tortuous anatomy cases.



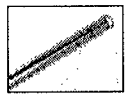
ChoICE® PT Extra Support Guide Wire
Provides excellent access with a high level of support designed for easier device delivery in highly resistant lesions and extra support cases.



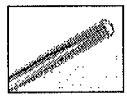
ChoICE® PT Floppy Guide Wire
Combines a hydrophilic-coated polymer sleeve with an intermediate tip and flexible body – excellent for tortuous anatomy and resistant lesion cases.



Forté® Extra Support Guide Wire
Combines a silicone coating and extra rail support to provide smooth device tracking and control in cases with challenging device delivery.

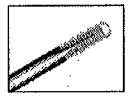


Forté® Floppy Guidewire and Forté® Floppy Marker Wire
Forté® Floppy is designed to provide enhanced steering for frontline cases with a soft tip, silicone coating and unibody stainless steel core. Forté® Floppy Marker integrates a precise lesion measurement system without compromising performance.

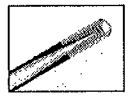


Forté® Moderate Support Guidewire and Forté® Moderate Support Marker Wire
Forté® Moderate Support Guidewire offers the torque response and support needed to deliver most interventional devices. Forté® Moderate Support Marker Wire integrates a precise lesion measurement system without compromising performance.

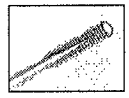
Kinetix™ Guidewire
The Kinetix Guidewire is a revolutionary new class of workhorse technology designed to improve your procedural efficiency through enhanced precision and control with a micro-cut nitinol sleeve and turn-for-turn torque response.



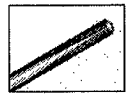
Luge™ Guide Wire
Delivers optimal torque response and the support required for device delivery in challenging anatomy.



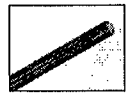
Mailman™ Guide Wire
Offers our highest level of rail support with a hydrophilic-coated polymer sleeve for smooth device delivery and vessel wall interaction



Platinum Plus™ Guide Wire
A vessel-straightening guide wire for challenging cases where torque response, very high rail support and significant pushability are required.



PT Graphix™ Intermediate Guide Wire
Designed to help steer, cross and deliver devices in tortuous anatomy and highly resistant lesion cases.



PT®® Light Support Guide Wire
A resilient yet flexible guide wire designed to help navigate in cases of tortuous anatomy and highly resistant lesions.

PT®® Moderate Support Guide Wire
Offers increased resiliency with the ability to help steer and deliver devices in tortuous anatomy and highly resistant lesions.

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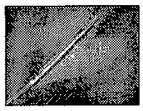
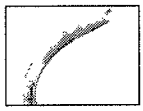
Imaging System
Plaque Modification

Imaging Catheters



iCross® Coronary Imaging Catheter
The iCross Catheter offers substantial deliverability without sacrificing image quality.



OptiCross™ Coronary Imaging Catheter
The IVUS Catheter that Delivers Confidently

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Imaging System
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Imaging System

iLab® Ultrasound Imaging System

Look to the intuitive iLab® System to deliver excellent IVUS images. This convenient-to-use installed system with tableside controller helps you see what matters.

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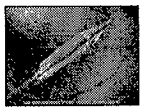
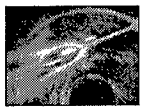


Flextome® Cutting Balloon® Dilatation Device

Flextome Cutting Balloon Device's mechanism of action and improved deliverability will enhance your ability to treat resistant lesions.



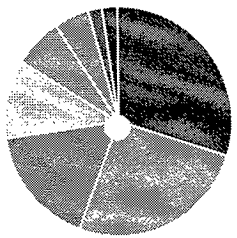
Rotablator® Rotational Atherectomy System

The standard in rotational atherectomy, The Rotablator System provides an excellent option for treating calcified lesions, with a complete family of products.

Exhibit 17

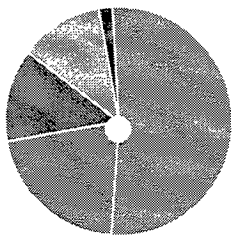
Boston Scientific
Advancing science for life™
We are advancing science for life.
2012 ANNUAL REPORT

FINANCIAL HIGHLIGHTS



2012 Sales by Product Category

(Dollars in millions)	2012	
Interventional Cardiology	$ 2,179	30%
Cardiac Rhythm Management	1,908	26%
Endoscopy	1,252	17%
Peripheral Interventions	774	11%
Urology/Women's Health	500	7%
Neuromodulation	367	5%
Electrophysiology	147	2%
	7,127	
Divested Businesses[2]	122	2%
	$ 7,249	100%



2012 Sales by Geographic Segment

(Dollars in millions)	2012	
U.S.	$ 3,756	52%
EMEA	1,568	21%
Japan	931	13%
Inter-Continental	872	12%
	7,127	
Divested Businesses[2]	122	2%
	$ 7,249	100%

2 Sales from divested businesses include those generated by the Company's former Neurovascular business, sold to Stryker Corporation in January 2011.
3 Constant currency growth rates are non-GAAP measures; see reconciliation to GAAP growth rates on page 17.
4 Company estimates as of December 2012.
5 Adjusted earnings per share is a non-GAAP measure; see reconciliation to GAAP earnings (loss) per share on page 17.
6 In the U.S., this device is investigational and is not available for use or sale.
7 This is an investigational device worldwide and is not available for use or sale.

TO OUR EMPLOYEES AND STOCKHOLDERS:

New leadership, a global strategy and a continued commitment to meaningful innovation set the stage for a new era of growth for Boston Scientific.

Stronger execution during 2012 in many areas of our company, fueled by meaningful innovation and the dedication and winning spirit of our global employees, has set the stage for Boston Scientific to return to growth.

Guided by a clear global strategy and a committed, seasoned leadership team, our company took important steps in 2012 to stabilize and strengthen its core businesses while expanding into new, higher-growth market adjacencies and emerging geographies.

And while there remain areas we must continue to address in order to improve our overall performance and strengthen our growth profile, we believe we have the right formula to achieve our goals. As we move forward, we expect to become a high performance leader that honors its 35-year heritage of saving and improving lives while transforming millions more around the world.

Highlights of 2012

- Our company delivered sales of $7.249 billion. While overall global revenue declined three percent on a constant currency basis, driven by challenging end markets for our Interventional Cardiology and Cardiac Rhythm Management business units, we gained share in several of our businesses, including Endoscopy, Peripheral Interventions, Neuromodulation and Urology.[3]

ITEM 1. BUSINESS

The Company

Boston Scientific Corporation is a worldwide developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. Our mission is to transform lives through innovative medical solutions that improve the health of patients around the world. When used in this report, the terms "we," "us," "our" and "the Company" mean Boston Scientific Corporation and its divisions and subsidiaries.

Our history began in the late 1960s when our co-founder, John Abele, acquired an equity interest in Medi-tech, Inc., a research and development company focused on developing alternatives to surgery. In 1969, Medi-tech introduced a family of steerable catheters used in some of the first less-invasive procedures performed. In 1979, John Abele joined with Pete Nicholas to form Boston Scientific Corporation, which indirectly acquired Medi-tech. This acquisition began a period of active and focused marketing, new product development and organizational growth. Since then, we have advanced the practice of less-invasive medicine by helping physicians and other medical professionals treat a variety of diseases and conditions and improve patients' quality of life by providing alternatives to surgery and other medical procedures that are typically traumatic to the body.

Our net sales have increased substantially since our formation over thirty years ago. Our growth has been fueled in part by strategic acquisitions designed to improve our ability to take advantage of growth opportunities in the medical device industry. Our strategic acquisitions have helped us to add promising new technologies to our pipeline and to offer one of the broadest product portfolios in the world for use in less-invasive procedures. We believe that the depth and breadth of our product portfolio has also enabled us to compete more effectively in the current healthcare environment of cost containment, managed care, large buying groups, government contracting, hospital consolidation, and international expansion and will generally assist us in navigating through the complexities of the global healthcare market, including healthcare reform.

Business Strategy

The following are our five strategic imperatives:

- **Strengthen Execution to Grow Share**

  We believe that our success will be driven by our ability to consistently deliver initiatives that grow profitability and market share. We are focused on improving the speed and performance of our business units by adding new capabilities, processes, and innovative technologies.

- **Expand into High Growth Adjacencies**

  We seek to diversify our product portfolio by realigning our research and development spend and focusing our business development investment toward higher growth opportunities. We are focused on executing on our committed growth adjacencies while increasing our access to developing technologies. Through this diversification we expect to increase our opportunity for growth in areas that complement our core businesses.

- **Drive Global Expansion**

  We are focused on expanding into the emerging markets. By expanding our global commercial presence, we seek to increase revenue and market share, and strengthen our relationships with leading physicians and their clinical research programs. We are focused on building new capabilities in countries whose economies and healthcare sectors are growing rapidly. We have local leadership teams with extensive in-country experience to help strengthen our position in these fast growing regions.

- **Fund the Journey to Fuel Growth**

  We are driving continuous improvement to expand our profitability, optimizing our manufacturing cost structure, reducing our corporate infrastructure and re-allocating spending to support our growth initiatives.

- **Develop Key Capabilities**

  We intend to develop key capabilities by providing economic and customer focused solutions so that our product portfolio is aligned to the needs of the market place and by developing core internal skills to better manage our business in a dynamic and evolving environment. We are globally focused on building a culture of empowerment and engagement while improving our diversity.

We believe that our execution of these strategic imperatives will drive innovation, accelerate profitable revenue growth and increase stockholder value.

Products

During 2012, our products were offered for sale by seven core businesses - Interventional Cardiology, Cardiac Rhythm Management (CRM), Endoscopy, Peripheral Interventions, Urology/Women's Health, Neuromodulation, and Electrophysiology. In

January 2011, we closed the sale of our Neurovascular business to Stryker Corporation. We continue to generate sales from the Neurovascular business pursuant to our supply and distribution agreements with Stryker; however, these sales are at significantly lower levels and at reduced gross profit margins as compared to periods prior to the divestiture.

During 2012, we derived 30 percent of our sales from our Interventional Cardiology business, 26 percent of our sales from our CRM business, 17 percent of our sales from our Endoscopy business, 11 percent of our sales from our Peripheral Interventions business, seven percent of our sales from our Urology/Women's Health business, five percent of our sales from our Neuromodulation business, and two percent of our sales from our Electrophysiology business. Approximately two percent of our 2012 sales were derived from the Neurovascular business that we sold to Stryker Corporation.

The following section describes certain of our product offerings:

Endoscopy

Gastroenterology

We market a broad range of products to diagnose, treat and ease a variety of digestive diseases, including those affecting the esophagus, stomach, liver, pancreas, duodenum, and colon. Common disease states include esophagitis, portal hypertension, peptic ulcers as well as esophageal, biliary, pancreatic and colonic cancer. We offer the Radial Jaw® 4 Single-Use Biopsy Forceps, which are designed to enable collection of large high-quality tissue specimens without the need to use large channel therapeutic endoscopes. Our exclusive line of RX Biliary System™ devices are designed to provide greater access and control for physicians to diagnose and treat challenging conditions of the bile ducts, such as removing gallstones, opening obstructed bile ducts and obtaining biopsies in suspected tumors. We also market the Spyglass® Direct Visualization System for direct imaging of the pancreatico-biliary system. The Spyglass® System is the first single-operator cholangioscopy device that offers clinicians a direct visualization of the pancreatico-biliary system and includes supporting devices for tissue acquisition, stone management and lithotripsy. Our products also include the WallFlex® family of stents, in particular, the WallFlex® Biliary line and WallFlex® Esophageal line; and in 2012, we launched our WallFlex® Biliary Transheptic stent system for treatment of biliary strictures. In addition, we continue to see growth of our hemostasis franchise on the continued adoption and utilization of our Resolution® Clip Device for gastrointestinal bleeding. In December of 2012, the first patient enrolled in our study comparing the WallFlex® Biliary RX Fully Covered self-expanding metal stent (SEMS) to plastic stents for the treatment of benign bile duct strictures caused by chronic pancreatitis. SEMS, which have a significantly larger diameter than plastic biliary stents, have long been the standard of care for palliation of malignant biliary strictures. This study is evaluating the benefits of using a SEMS in benign biliary strictures, with an objective to demonstrate stricture resolution in fewer procedures.

Interventional Bronchoscopy

We market devices to diagnose, treat and ease pulmonary disease systems within the airway and lungs. Our products are designed to help perform biopsies, retrieve foreign bodies from the airway, open narrowings of an airway, stop internal bleeding, and ease symptoms of some types of airway cancers. Our product line includes pulmonary biopsy forceps, transbronchial aspiration needles, cytology brushes and tracheobronchial stents used to dilate narrowed airway passages or for tumor management. In October 2010, we completed our acquisition of Asthmatx, Inc., which adds to our Endoscopy portfolio a less-invasive, catheter-based bronchial thermoplasty procedure for the treatment of severe persistent asthma. The Alair® Bronchial Thermoplasty System, developed by Asthmatx, has both Conformite Europeenne (CE) Mark and U.S. Food and Drug Administration (FDA) approval and is the first device-based asthma treatment approved by the FDA. In the third quarter of 2012, the America Medical Association (AMA) Current Procedural Terminology (CPT) editorial panel assigned category I CPT codes specifically for bronchial thermoplasty beginning January 1, 2013. Once recognized, the Category I CPT procedure codes will be available for all public and private health insurance payers in the United States, which will allow physicians and hospitals to seek reimbursement for bronchial thermoplasty procedures. We believe these codes will provide greater access to treatment for patients with poorly controlled severe asthma, help facilitate claims processing and help private payers' approve coverage for this form of treatment. We continue to focus on driving commercialization and increased awareness of the Alair® System.

Peripheral Interventions (PI)

We sell various products designed to treat patients with peripheral disease (disease which appears in blood vessels other than in the heart and in the biliary tree), including a broad line of medical devices used in percutaneous transluminal angioplasty (PTA) and peripheral vascular stenting. Our peripheral product offerings include stents, balloon catheters, wires, peripheral embolization

devices and vena cava filters. We launched three new peripheral angioplasty balloons in 2011, including our next-generation Mustang™ percutaneous transluminal angioplasty balloon, our Coyote™ balloon catheter, a highly deliverable and ultra-low profile balloon dilatation catheter designed for a wide range of peripheral angioplasty procedures and our Charger™ PTA Balloon Catheter, a 0.035" percutaneous transluminal angioplasty balloon catheter designed for post-stent dilatation as well as conventional balloon angioplasty to open blocked peripheral arteries. With our Coyote, Mustang and Charger devices, we offer balloons across all size platforms. In 2012, we launched our EPIC™ self-expanding nitinol stent system in the U.S. and certain international markets, the Carotid WALLSTENT® stent system in Japan, and Innova™ self-expanding bare metal stent system in Europe and certain international markets.

In February 2011, we announced the acquisitions of S.I. Therapies and ReVascular Therapeutics, Inc., which added to our PI portfolio a re-entry catheter and intraluminal chronic total occlusion (CTO) crossing device, enabling endovascular treatment in cases that typically cannot be treated with standard endovascular devices. In 2011, we commenced a limited market release of our OFF-ROAD™ re-entry catheter system in certain international markets, and in February 2012, we launched our TRUEPATH™ intraluminal CTO device in the U.S., EMEA, and other international markets. We believe that offering these devices will enhance our position in assisting physicians in addressing the challenges of treating complex peripheral lesions. In the fourth quarter of 2012, we acquired Vessix Vascular, Inc., a developer of catheter-based renal denervation systems for the treatment of uncontrolled hypertension. We expect to launch this platform commercially in Europe and other international markets in 2013.

We also sell products designed to treat patients with non-vascular disease (disease that appears outside the blood system). Our non-vascular suite of products includes biliary stents, drainage catheters and micro-puncture sets designed to treat, diagnose and ease various forms of benign and malignant tumors. We continue to market our extensive line of Interventional Oncology product solutions, including the recently launched Renegade® HI-FLO™ Fathom® microcatheter and guidewire system and Interlock™ - 35 Fibered IDC™ Occlusion System for peripheral embolization.

Neuromodulation

Within our Neuromodulation business, we market the Precision® Spinal Cord Stimulation (SCS) system, used for the management of chronic pain. This system delivers pain management by applying an electrical signal to mask pain signals traveling from the spinal cord to the brain. In addition, during the fourth quarter of 2012 we received CE Mark approval for the Precision Spectra™ Spinal Cord Stimulator System and began a European market launch of this technology. The Precision Spectra system is the world's first and only SCS system with 32 contacts and 32 dedicated power sources and is designed to provide improved pain relief to a wide range of patients who suffer from chronic pain. In 2011, we launched our Clik™ Anchor for our Precision® Plus™ SCS System, the world's first rechargeable SCS device for chronic pain management. In the fourth quarter of 2011, we received FDA approval for and launched the Infinion™ 16 Percutaneous Lead, the world's first and only 16-contact percutaneous lead. We also market the Linear™ 3-4 and Linear 3-6 Percutaneous Leads for use with our SCS systems, which are designed to provide physicians more treatment options for their chronic pain patients. These leads provide the broadest range of percutaneous lead configurations in the industry.

We believe that we continue to have a technology advantage compared to our competitors with proprietary features such as Multiple Independent Current Control, which is intended to allow the physician to target specific areas of pain more precisely. We are looking to strengthen the clinical evidence with spinal cord stimulation and are committed to studies designed to demonstrate cost effectiveness or demonstrate the value of proprietary features in our SCS system.

In January 2011, we completed the acquisition of Intelect Medical, Inc., a development-stage company developing advanced visualization and programming for the Vercise™ system. We believe this acquisition leverages the core architecture of our Vercise™ platform and will advance our technology in the field of deep-brain stimulation. During the third quarter of 2012, we received CE Mark approval for the use of our Vercise™ Deep Brain Stimulation (DBS) System for the treatment of Parkinson's disease in Europe. We believe we have an exciting opportunity in DBS with our ability to customize the field designed to precisely stimulate the target without extraneous stimulation of adjacent areas that may cause unwanted side effects.

Urology/Women's Health

Our Urology/Women's Health division develops, manufactures and sells devices to treat various urological and gynecological disorders. Within our Urology business, we sell a variety of products designed to treat patients with urinary stone disease and benign prostatic hyperplasia (BPH). We offer a full line of stone management products, including ureteral stents, wires, lithotripsy devices, stone retrieval devices, sheaths, balloons and catheters. Within our Women's health business, we market a range of devices for the treatment of conditions such as female urinary incontinence, pelvic floor reconstruction (rebuilding of the anatomy to its original state), and menorrhagia (excessive menstrual bleeding). We offer a full breadth of mid-urethral sling products, sling materials, graft materials, pelvic floor reconstruction kits, and suturing devices. We market our Genesys Hydro ThermAblator® (HTA) system, a next-generation endometrial ablation system designed to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia. The Genesys HTA System features a smaller and lighter console, simplified set-up requirements, and an enhanced graphic user interface and is designed to improve operating performance.

Electrophysiology

Within our Electrophysiology business, we develop less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart. Included in our product offerings are radio frequency (RF) generators, steerable RF ablation catheters, intracardiac ultrasound catheters, diagnostic catheters, delivery sheaths, and other accessories. Our leading products include the Blazer® and Blazer Prime® line of temperature ablation catheters, designed to deliver enhanced performance, responsiveness, and durability. Our cooled ablation portfolio includes the only closed-loop irrigated catheter on the market, the Chilli II® cooled ablation catheter, and the newly launched Blazer™ Open-Irrigated ablation catheter with a unique Total Tip Cooling™ Design. In 2012, we received Health Canada and CE Mark approval of the Blazer™ Open-Irrigated Catheter, our latest radiofrequency ablation (RFA) catheter designed to treat a variety of arrhythmias such as atrial fibrillation, atrial flutter, ventricular tachycardia and other supraventricular tachycardias.

Additionally, on October 9, 2012, we acquired Rhythmia Medical, Inc., a developer of next-generation mapping and navigation solutions for use in cardiac catheter ablations and other electrophysiology procedures, including atrial fibrillation and atrial flutter. We believe that this acquisition, as well as the recent and expected product launches, will help to position us to competitively participate in the fast-growing Electrophysiology market.

Cardiac Rhythm Management

We develop, manufacture and market a variety of implantable devices that monitor the heart and deliver electricity to treat cardiac abnormalities, including:

- Implantable cardioverter defibrillator (ICD) systems used to detect and treat abnormally fast heart rhythms (tachycardia) that could result in sudden cardiac death, including the world's first and only commercially available subcutaneous implantable cardioverter defibrillator—the S-ICD® System, and implantable cardiac resynchronization therapy defibrillator (CRT-D) systems used to treat heart failure; and
- Implantable pacemaker systems used to manage slow or irregular heart rhythms (bradycardia), including implantable cardiac resynchronization therapy pacemaker (CRT-P) systems used to treat heart failure.

A key component of many of our implantable device systems is our remote LATITUDE® Patient Management System, which enables physicians to monitor device performance remotely while patients are in their homes, allowing for more frequent monitoring in order to guide treatment decisions.

In the first half of 2012, we launched our INGENIO™ family of pacemaker systems in the U.S. and EMEA, and in the third quarter of 2012, we received CE Mark approval for use of our INGENIO™ and ADVANTIO™ pacemakers in patients in need of a magnetic resonance imaging (MRI) scan, which we believe represents a significant advancement to our family of pacemaker devices. In the second quarter of 2012, we received FDA approval for our INVIVE™ cardiac resynchronization therapy pacemakers (CRT-Ps). INVIVE™ is built on the same platform as our high voltage cardiac resynchronization therapy defibrillator (CRT-Ds), is enabled for remote patient monitoring, and includes features that promote ease of use. Also during the first half of 2012, we completed the acquisition of Cameron Health, Inc. (Cameron). Cameron developed the world's first and only commercially available subcutaneous implantable cardioverter defibrillator—the S-ICD® System, which we believe is a differentiated technology that will provide us the opportunity to both increase our market share in the existing ICD market and expand that market over

time. The S-ICD® system has CE Mark approval and is available in EMEA. In addition, during the third quarter of 2012 we received FDA approval for the S-ICD® system and commenced a limited commercial launch in the U.S. With this approval, we are now able to offer our U.S. physician customers an entirely new option to treat their patients who are at risk for sudden cardiac arrest. We believe the recent product developments noted above will help to better position us within the CRM market.

Interventional Cardiology

Coronary Stent Systems

Our broad, innovative product offerings have enabled us to become a leader in the interventional cardiology market. This leadership is due in large part to our coronary stent product offerings. Coronary stents are tiny, mesh tubes used in the treatment of coronary artery disease, which are implanted in patients to prop open arteries and facilitate blood flow to and from the heart. We believe we have further enhanced the outcomes associated with the use of coronary stents, particularly the processes that lead to restenosis (the growth of neointimal tissue within an artery after angioplasty and stenting), through dedicated internal and external product development, strategic alliances and scientific research of drug-eluting stent systems. We market our internally-developed and self-manufactured PROMUS® Element™ everolimus-eluting stent platform in all major markets worldwide, as well as our TAXUS® paclitaxel-eluting stent line, including our third-generation TAXUS® Element™ stent system. We are the only company in the industry to offer a two-drug platform strategy with our paclitaxel-eluting and everolimus-eluting stent system offerings, and we offer a broad range of stent sizes. In addition, during the fourth quarter of 2012, we received CE Mark approval for the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System featuring an ultra-thin abluminal (outer) bioabsorbable polymer coating. The SYNERGY Stent is unique in that its proprietary polymer and everolimus drug coating dissipate by three months. This innovation has the potential to improve post-implant vessel healing and will eliminate long-term polymer exposure, a possible cause of late adverse events. In the first quarter of 2013, we also received CE Mark approval and launched our next-generation Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System in Europe and other select geographies.

Core Coronary Technology

We market a broad line of products used to treat patients with atherosclerosis, a principal cause of coronary artery obstructive disease which is characterized by a thickening of the walls of the coronary arteries and a narrowing of arterial openings caused by the progressive development of deposits of plaque. Our product offerings include balloon catheters, rotational atherectomy systems, guide wires, guide catheters, embolic protection devices, and diagnostic catheters used in percutaneous transluminal coronary angioplasty (PTCA) procedures, as well as intravascular ultrasound (IVUS) imaging system. In addition, in October 2012, we completed the acquisition of BridgePoint Medical, Inc., a developer of proprietary, catheter-based systems to treat coronary chronic total occlusions (CTOs). Through this acquisition we expect to augment our current portfolio of Interventional Cardiology products, which we believe will enable us to be a single-source supplier for complex PCI procedures. During 2012 we received FDA clearance for our Emerge™ Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Dilatation Catheter and began marketing the device in the United States. The Emerge Catheter is a next-generation pre-dilatation balloon catheter designed specifically to offer exceptional deliverability for physicians to address challenging lesions in coronary arteries. Both the Monorail® and Over-The-Wire (OTW) options are available. The Emerge Catheter has been commercially available in CE Mark countries since the second quarter of 2012.

Intraluminal Ultrasound Imaging

We market a family of intraluminal catheter-directed ultrasound imaging catheters and systems for use in coronary arteries and heart chambers as well as certain peripheral vessels. The iLab® Ultrasound Imaging System continues as our flagship console and is compatible with our full line of imaging catheters. This system is designed to enhance the diagnosis and treatment of blocked vessels and heart disorders. Further, iLab systems have been placed in cardiology labs worldwide which provide an installed base through which we expect to launch new products, including an improved line of coronary Intravascular Vessel Imaging catheters and an integrated Fractional Flow Reserve (FFR) device. Following regulatory approval, these Imaging products would provide our cardiology sales force with a differentiated product offering in one of the fastest growing segments of interventional cardiology.

Structural Heart Therapy

In January 2011, we completed the acquisition of Sadra Medical, Inc. (Sadra). Through the acquisition of Sadra, we are developing a fully repositionable and retrievable device for transcatheter aortic valve replacement (TAVR) to treat through patients with severe aortic stenosis. The Lotus™ Valve System consists of a stent-mounted tissue valve prosthesis and catheter delivery system for guidance and placement of the valve. The low-profile delivery system and introducer sheath are designed to enable accurate positioning, repositioning and retrieval at any time prior to release of the aortic valve implant. We believe TAVR is one of the fastest growing medical device markets.

In March 2011, we completed the acquisition of Atritech, Inc. (Atritech). Atritech developed a novel device designed to close the left atrial appendage in patients with atrial fibrillation (AF) who are at risk for ischemic stroke. The WATCHMAN® Left Atrial Appendage Closure Technology (WATCHMAN® LAA), developed by Atritech, is the first device proven in a randomized clinical trial to offer an alternative to anticoagulant drugs, and is approved for use in CE Mark countries. Additionally in August 2012, European regulators approved an expanded indication for the WATCHMAN® LAA Closure Device. The new indication offers patients with AF, and a contraindication to warfarin and the newer oral anti-coagulants, a new treatment option for stroke reduction.

Innovation

Our approach to innovation combines internally-developed products and technologies with those we may obtain externally through strategic acquisitions and alliances. Our research and development efforts are focused largely on the development of next-generation and novel technology offerings across multiple programs and divisions. In addition, we have undertaken strategic acquisitions to help enable us to continue to be a leader in the medical device industry. We expect to continue to invest in our core franchises, and also investigate opportunities to further expand our presence in, and diversify into, strategic growth adjacencies. We have closed several acquisitions targeting many of these areas. In 2011, we completed the acquisitions of Sadra Medical, Inc., Intelect Medical, Inc., and Atritech, Inc., and in 2012, we completed the acquisitions of Cameron Health Inc., BridgePoint Medical, Inc., Rhythmia Medical Inc., and Vessix Vascular Inc., all discussed above. There can be no assurance that technologies developed internally or acquired through acquisitions and alliances will achieve technological feasibility, obtain regulatory approvals or gain market acceptance, and any delay in the development or approval of these technologies may adversely impact our ability to drive future growth.

Research and Development

Our investment in research and development is critical to driving our future growth. We expended $886 million on research and development in 2012, $895 million in 2011 and $939 million in 2010, representing approximately 12 percent of our net sales each year. Our investment in research and development reflects:

- regulatory compliance, clinical science, and internal research and development programs, as well as other programs obtained through our strategic acquisitions and alliances; and
- engineering efforts which incorporate customer feedback into continuous improvement efforts for currently marketed and next-generation products.

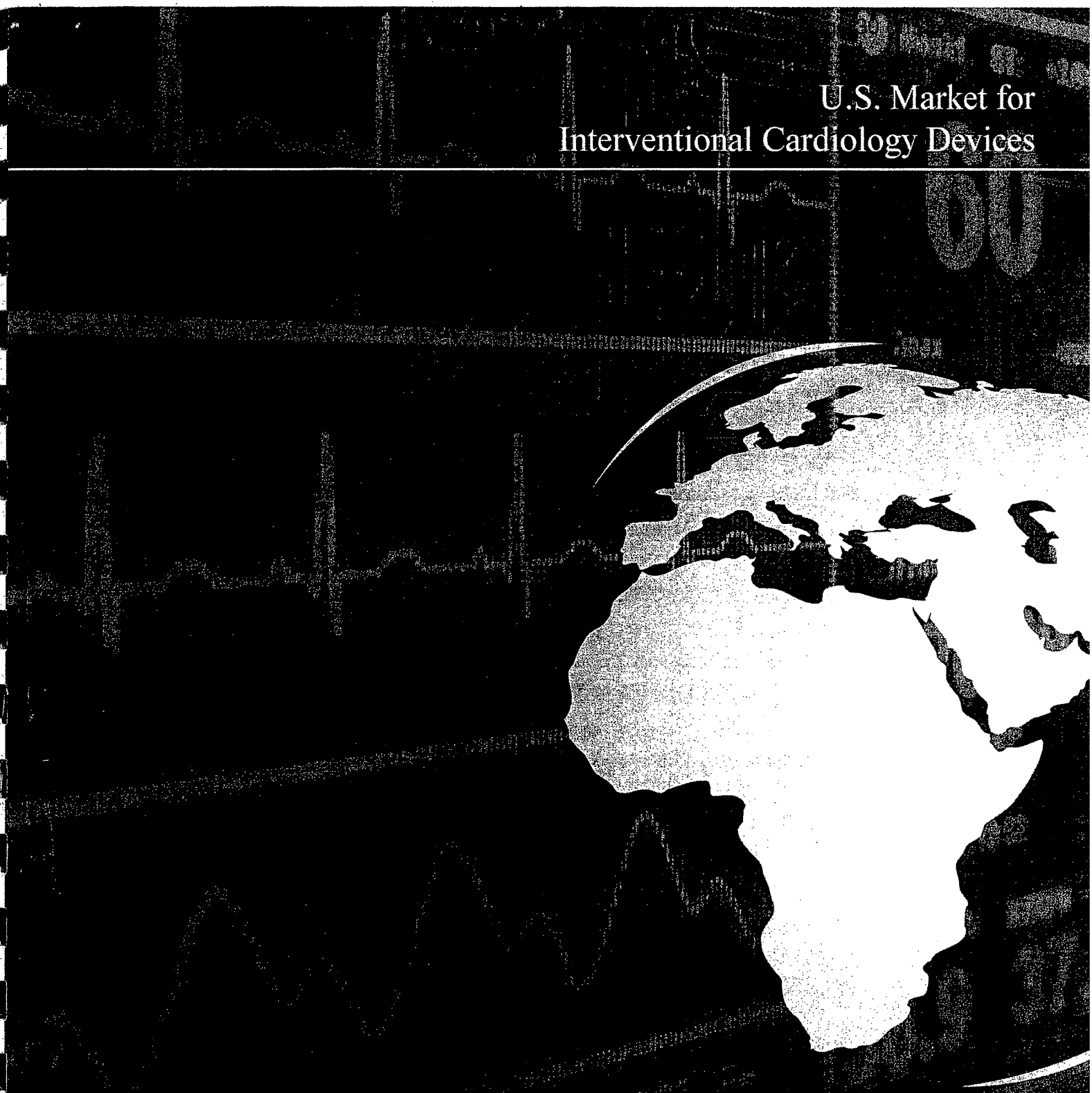
We have directed our development efforts toward regulatory compliance and innovative technologies designed to expand current markets or enter adjacent markets. We are transforming the way we conduct research and development and are scrutinizing our cost structure, which we expect will enhance our overall efficiency and effectiveness. Our approach to new product design and development is through focused, cross-functional teams. We believe that our formal process for technology and product development aids in our ability to offer innovative and manufacturable products in a consistent and timely manner. Involvement of the research and development, clinical, quality, regulatory, manufacturing and marketing teams early in the process is the cornerstone of our product development cycle. This collaboration allows these teams to concentrate resources on the most viable and clinically relevant new products and technologies, and focus on bringing them to market in a timely and cost-effective manner. In addition to internal development, we work with hundreds of leading research institutions, universities and clinicians around the world to develop, evaluate and clinically test our products. We believe our future success will depend upon the strength of these development efforts.

Marketing and Sales

During 2012, we marketed our products to over 13,000 hospitals, clinics, outpatient facilities and medical offices in nearly 100 countries worldwide. The majority of our net sales are derived from countries in which we have direct sales organizations. We also have a network of distributors and dealers who offer our products in certain countries and markets, which accounts for our remaining sales. We expect to continue to leverage our infrastructure in markets where commercially appropriate and use third parties in those markets where it is not economical or strategic to establish or maintain a direct presence. We are not dependent on any single institution and no single institution

Exhibit 18

U.S. Market for Interventional Cardiology Devices



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INTELLIGENCE BEHIND THE RESEARCH

3.6 Competitive Analysis

Boston Scientific

In 2010, Boston Scientific was the leading competitor in the U.S. market for interventional cardiology, with a 39.6% market share, as shown in Figure 3-9 and Chart 3-7. Boston Scientific was the market leader in several segments including drug-eluting stents, PTCA and cutting balloon catheters, angioplasty accessory kits, coronary embolic protection devices and coronary atherectomy devices. Boston Scientific's wide range of devices and complementary products for interventional cardiology combined with their international sales team has allowed them to maintain their dominant position.

Abbott Laboratories

Abbott Laboratories was the second leading competitor in the U.S. interventional cardiology market in 2010, with 20.7% market share. Abbott has gained market share in the drug-eluting stent segment since the introduction of their *Xience*™ stent in 2008 and in 2010, they controlled 21.4% of that market. Abbott also led the bare-metal stent market in 2010 and the interventional coronary guidewire market, where they controlled more than half of each market. Although they did not have the dominant market share, Abbott also had strong sales in the PTCA balloon catheter and angioplasty accessory kit markets.

Medtronic

Medtronic was the third leading competitor in the interventional cardiology market, with an overall market share of 11% in 2010. While Medtronic did not have the leading position in any of the market segments, they were involved in over half of the markets, holding either the third or fourth position in those markets. Medtronic has gained considerable market share since 2007 through aggressive research and marketing campaigns and acquiring smaller companies with newer technologies. In 2010, Medtronic acquired Italian based Invatec, which should allow them to expand their market share in the coronary and peripheral vascular device markets.

Cordis

Cordis was the fourth leading competitor in 2010 with a total market share of 10.3%. Cordis has been a major competitor in the interventional cardiology market for many years and in the past, competed vigorously with Boston Scientific for dominance on the market. With the rise of companies such as Abbott and Medtronic as well as Cordis moving their focus to other medical device markets, the company has lost some of their interventional cardiology market over the past few years. However, Cordis was still the market leader in the interventional coronary guidewire and diagnostic coronary catheter markets in 2010, where they had market shares of 46.3% and 43.2%, respectively.

St. Jude Medical

St. Jude Medical accounted for 8.2% market share in the interventional cardiology device market in 2010. This market share was due to their leading market shares of 65.3% in the coronary vascular closure device market and 54.6% in the fractional flow reserves (FFR) guidewire market. St. Jude has been able to increase their market share in these segments through the acquisition of companies such as Radi Medical Systems and Datascope.

Volcano Therapeutics

Volcano Therapeutics was the market leader in the rapidly growing IVUS catheter market, with 58.4% market share. This leading position combined with a 45.4% share of the FFR guidewire market corresponded to 2.2% of the total interventional cardiology device market. In addition, Volcano is developing products for OCT and vulnerable plaque screening, which are markets that have the potential to grow rapidly once the first devices and procedures are approved in the United States.

Other Notable Competitors

Other notable competitors in the interventional cardiology market included AccessClosure with 1.7% market share, Merit Medical Systems with 1.3% and Cook Medical with 0.9%.

Figure 3-9: Leading Competitors, Interventional Cardiology Device Market, U.S., 2010 (Part 1 of 2)

Company	Bare-Metal Stent Market Share	Drug-Eluting Stent Market Share	PTCA and Cutting Balloon Catheter Market Share	Balloon-Inflation Syringe Market Share	Angioplasty Accessory Kit Market Share	Interventional Coronary Catheter Market Share	Interventional Coronary Guidewire Market Share	Coronary Embolic Protection Device Market Share	Coronary Atherectomy Device Market Share
Boston Scientific	25.4%	49.2%	60.9%	30.7%	37.8%	20.2%	23.8%	69.8%	89.9%
Abbott Laboratories	58.7%	21.4%	25.4%	7.9%	16.0%	15.6%	57.5%	–	–
Medtronic/Invatec	13.8%	15.1%	9.3%	4.8%	–	14.4%	8.1%	7.2%	–
Cordis	2.1%	13.9%	3.8%	–	–	46.3%	9.5%	–	–
St. Jude Medical	–	–	–	–	–	–	–	12.9%	–
Volcano Therapeutics	–	–	–	–	–	–	–	–	–
AccessClosure	–	–	–	–	–	–	–	–	–
Merit Medical Systems	–	–	–	47.5%	22.6%	–	–	–	–
Cook Medical	–	–	–	–	–	–	–	–	–
Vascular Solutions	–	–	–	–	–	–	–	–	–
MEDRAD Interventional/Possis	–	–	–	–	–	–	–	–	–
Terumo	–	–	–	–	–	–	–	–	–
ev3	–	–	–	–	–		–	10.1%	–
Galt Medical	–	–	–	–	–		–	–	–
AngioDynamics	–	–	–	–	–		–	–	–
Spectranetics	–	–	–	–	–	3.5%	–	–	10.1%
Argon Medical	–	–	–	3.1%	–	–	–	–	–
B. Braun	–	–	–	2.7%	8.3%	–	–	–	–
C. R. Bard	–	–	–	1.2%	–	–	–	–	–
Marine Polymer Technologies	–	–	–	–	–	–	–	–	–
Smiths Medical	–	–	–	2.1%	9.4%	–	–	–	–
Teleflex Medical	–	–	–	–	–	–	–	–	–
AngioScore	–	–	0.3%	–	–	–	–	–	–
FlowCardia	–	–	–	–	–	–	–	–	–
Asahi Medical	–	–	–	–	–	–	–	–	–
Others	0.0%	0.4%	0.3%	0.0%	5.9%	0.0%	1.1%	0.0%	0.0%
Total	100%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (US$M)	$244.7	$2,124.6	$326.3	$63.4	$24.7	$64.4	$98.9	$97.0	$25.9

1) The market share of market leader in each segment is highlighted.
2) Others include: AccessClosure, Abbott Laboratories, AngioDynamics, Asahi Medical, B. Braun, Boston Scientific, Cook Medical, Cordis, C. R. Bard, ev3, FlowCardia, Galt Medical, Kensey Nash, Marine Polymer Technologies, MEDRAD Interventional/Possis, Medtronic/Invatec, Merit Medical Systems, Smiths Medical, Spectranetics, St. Jude Medical, Teleflex Medical, Terumo, Volcano Therapeutics

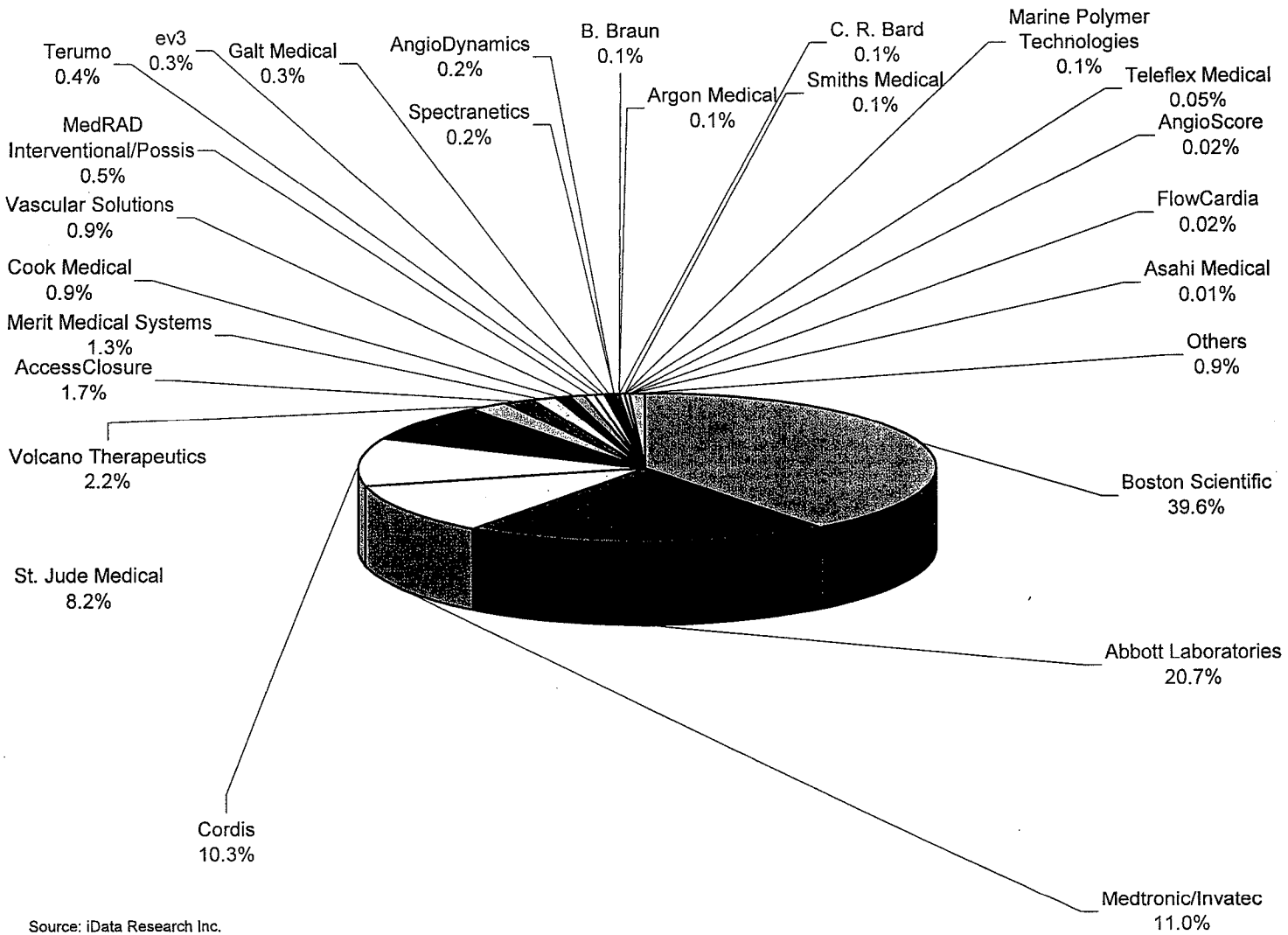
Source: iData Research Inc.

Figure 3-10: Leading Competitors, Interventional Cardiology Device Market, U.S., 2010 (Part 2 of 2)

Company	Coronary Thrombectomy Market Share	Coronary Chronic Total Occlusion Device Market Share	Coronary Introducer Sheath Market Share	Coronary Vascular Closure Device Market Share	Diagnostic Coronary Catheter Market Share	Diagnostic Coronary Guidewire Market Share	FFR Guidewire Market Share	IVUS Catheter Market Share	Total Market Share
Boston Scientific	–	–	1.1%	–	36.3%	17.9%	–	41.6%	39.6%
Abbott Laboratories	–	–	–	11.6%	–	–	–	–	20.7%
Medtronic/Invatec	17.1%	–	2.3%	–	–	13.0%	–	–	11.0%
Cordis	–	–	13.3%	–	43.2%	18.2%	–	–	10.3%
St. Jude Medical	–	–	7.5%	65.3%	–	–	54.6%	–	8.2%
Volcano Therapeutics	–	–	–	–	–	–	45.4%	58.4%	2.2%
AccessClosure	–	–	–	15.7%	–	–	–	–	1.7%
Merit Medical Systems	–	–	10.5%	–	4.7%	7.3%	–	–	1.3%
Cook Medical	–	–	31.3%	–	–	19.4%	–	–	0.9%
Vascular Solutions	34.0%	–	3.6%	3.8%	–	–	–	–	0.9%
MEDRAD Interventional/Possis	43.6%	–	–	–	–	–	–	–	0.5%
Terumo	–	–	12.4%		–	6.1%	–	–	0.4%
ev3	–	–			–	–	–	–	0.3%
Galt Medical	–	–	11.3%		–	–	–	–	0.3%
AngioDynamics	–	–	4.9%		–	4.0%	–	–	0.2%
Spectranetics	4.7%	2.2%	–		–	–	–	–	0.2%
Argon Medical	–	–	–		–	–	–	–	0.1%
B. Braun	–	–	–		–	–	–	–	0.1%
C. R. Bard	–	–	–		–	14.1%	–	–	0.1%
Marine Polymer Technologies	–	–	–	1.0%	–	–	–	–	0.1%
Smiths Medical	–	–	–	–	–	–	–	–	0.1%
Teleflex Medical	–	–	1.9%	–	–	–	–	–	0.05%
AngioScore	–	–	–	–	–	–	–	–	0.02%
FlowCardia	–	61.5%	–	–	–	–	–	–	0.02%
Asahi Medical	–	36.3%	–	–	–	–	–	–	0.01%
Others	0.6%	0.0%	0.0%	2.6%	15.8%	0.0%	0.0%	0.0%	0.9%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Market Value (US$M)	$44.6	$1.6	$99.0	$409.9	$71.3	$28.3	$52.9	$104.8	$3,882.4

1) The market share of market leader in each segment is highlighted.
2) Others include: AccessClosure, Abbott Laboratories, AngioDynamics, Asahi Medical, B. Braun, Boston Scientific, Cook Medical, Cordis, C. R. Bard, ev3, FlowCardia, Galt Medical, Kensey Nash, Marine Polymer Technologies, MEDRAD Interventional/Possis, Medtronic/Invatec, Merit Medical Systems, Smiths Medical, Spectranetics, St. Jude Medical, Teleflex Medical, Terumo, Thomas Medical, Volcano Therapeutics
Source: iData Research Inc.

Chart 3-7: Leading Competitors, Interventional Cardiology Device Market, U.S., 2010



Source: iData Research Inc.

Exhibit 19

PTO Form 1478 (Rev 9/2006)
OMB No. 0651-0009 (Exp 12/31/2014)

Trademark/Service Mark Application, Principal Register

Serial Number: 85542098
Filing Date: 02/14/2012

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85542098
MARK INFORMATION	
***MARK**	GUIDEZILLA
STANDARD CHARACTERS	YES
USPTO-GENERATED IMAGE	YES
LITERAL ELEMENT	GUIDEZILLA
MARK STATEMENT	The mark consists of standard characters, without claim to any particular font, style, size, or color.
REGISTER	Principal
APPLICANT INFORMATION	
***OWNER OF MARK**	Boston Scientific Scimed, Inc.
***STREET**	One Scimed Place
***CITY**	Maple Grove
***STATE (Required for U.S. applicants)**	Minnesota
***COUNTRY**	United States
***ZIP/POSTAL CODE (Required for U.S. applicants only)**	55311
PHONE	612-331-1464
FAX	612-331-2239
EMAIL ADDRESS	michelle@nrslaw.com
LEGAL ENTITY INFORMATION	
TYPE	corporation
STATE/COUNTRY OF INCORPORATION	Minnesota

GOODS AND/OR SERVICES AND BASIS INFORMATION	
INTERNATIONAL CLASS	010
*IDENTIFICATION	Medical Guide Catheters
FILING BASIS	SECTION 1(b)
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PHONE	612-331-1464
FAX	612-331-2239
EMAIL ADDRESS	michelle@nrslaw.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
OTHER APPOINTED ATTORNEY	Lawrence M. Nawrocki and Richard C. Stempkovski, Jr.
CORRESPONDENCE INFORMATION	
NAME	Wayne A. Sivertson
FIRM NAME	Nawrocki, Rooney & Sivertson, P.A.
INTERNAL ADDRESS	Suite 401, Broadway Place East
STREET	3433 Broadway Street Northeast
CITY	Minneapolis
STATE	Minnesota
COUNTRY	United States
ZIP/POSTAL CODE	55413
PHONE	612-331-1464
FAX	

FAX	612-331-2239
EMAIL ADDRESS	michelle@nrslaw.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
FEE INFORMATION	
NUMBER OF CLASSES	1
FEE PER CLASS	325
***TOTAL FEE DUE**	325
***TOTAL FEE PAID**	325
SIGNATURE INFORMATION	
SIGNATURE	/WAS316/
SIGNATORY'S NAME	Wayne A. Sivertson
SIGNATORY'S POSITION	Partner and Attorney
DATE SIGNED	02/14/2012

PTO Form 1478 (Rev 9/2006)
OMB No. 0651-0009 (Exp. 12/31/2014)

Trademark/Service Mark Application, Principal Register

Serial Number: 85542098
Filing Date: 02/14/2012

To the Commissioner for Trademarks:

MARK: GUIDEZILLA (Standard Characters, see mark)
The literal element of the mark consists of GUIDEZILLA.
The mark consists of standard characters, without claim to any particular font, style, size, or color.

The applicant, Boston Scientific Scimed, Inc., a corporation of Minnesota, having an address of
One Scimed Place
Maple Grove, Minnesota 55311
United States

requests registration of the trademark/service mark identified above in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq.), as amended, for the following:

International Class 010: Medical Guide Catheters
Intent to Use: The applicant has a bona fide intention to use or use through the applicant's related company or licensee the mark in commerce on or in connection with the identified goods and/or services. (15 U.S.C. Section 1051(b)).

The applicant's current Attorney Information:
Wayne A. Sivertson and Lawrence M. Nawrocki and Richard C. Stempkovski, Jr. of Nawrocki, Rooney & Sivertson, P.A.

Suite 401, Broadway Place East
3433 Broadway Street Northeast
Minneapolis, Minnesota 55413
United States
The attorney docket/reference number is 55913.375101.
The applicant's current Correspondence Information:
Wayne A. Sivertson
Nawrocki, Rooney & Sivertson, P.A.
Suite 401, Broadway Place East
3433 Broadway Street Northeast
Minneapolis, Minnesota 55413
612-331-1464(phone)
612-331-2239(fax)

michelle@nrslaw.com (authorized)

A fee payment in the amount of $325 has been submitted with the application, representing payment for 1 class(es).

Declaration

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements, and the like, may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true.

Declaration Signature

Signature: /WAS316/ Date: 02/14/2012
Signatory's Name: Wayne A. Sivertson
Signatory's Position: Partner and Attorney
RAM Sale Number: 10783
RAM Accounting Date: 02/14/2012

Serial Number: 85542098
Internet Transmission Date: Tue Feb 14 13:26:24 EST 2012
TEAS Stamp: USPTO/BAS-63.87.126.58-20120214132624761
762-85542098-490c41684369f8b024dba6b05f8
cd460fd-CC-10783-20120214131056849983

GUIDEZILLA

Exhibit 20

Vascular SOLUTIONS

October 16, 2012

Mr. Kevin Ballinger
President, Interventional Cardiology Division
Boston Scientific
Attn: Mail Stop A225
One Scimed Place
Maple Grove, MN 55311

Dear Kevin,

It was a pleasure to meet you at the LifeScience Alley event on October 2 for Sens. Amy Klobuchar and Chris Coons. Following up on our conversation about "Guidezilla" guide catheters after that event, I wanted to make you aware of a U.S. patent that will be issued on October 23, 2012 and assigned to Vascular Solutions, Inc. concerning guide extensions (US 8,292,850). This is in addition to two U.S. patents already issued and assigned to Vascular Solutions, Inc. in this same area (US 8,048,032 and US 8,142,413). I have included copies of both of these two issued patents and a copy of the issue notification of the most recent patent.

If you have any questions concerning these patents, please do not hesitate to give me a call.

Best regards,

Howard Root
Chief Executive Officer

Encl.
HR/mw

VASCULAR SOLUTIONS, INC.
6464 Sycamore Court • Minneapolis, Minnesota 55369
PHONE: 763/656-4300 • FAX: 763/656-4250 • www.vascularsolutions.com

Exhibit 21

Traditional 510(k) Submission
GUIDEZILLA™ Guide Extension Catheter

MAR 19 2013

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Holly Ramirez Phone: 763-494-2113 Fax: 763-494-2222 e-mail: Holly.Holmes@BSCI.com
Prepared	06 December 2012
Proprietary Name	GUIDEZILLA™ Guide Extension Catheter
Common Name	Guide Catheter
Product Code	DQY
Classification	Class II, 21 CFR Part 870.1250
Predicate Devices	GuideLiner® V2 Catheter K112082 01 December 2011
Device Description	The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter. GUIDEZILLA consists of a proximal stainless steel hypotube with a tab used for device identification and a distal guide catheter segment through which interventional devices may be delivered. The guide catheter segment incorporates two radiopaque marker bands to aid in positioning the device during the procedure. A hydrophilic coating is applied to the distal polymer segment of the device. GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter. The effective length of the device is 145 cm.
Intended Use / Indications for Use	The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.
Comparison of Technological Characteristics	The GUIDEZILLA™ Guide Extension Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as the GuideLiner® V2 (K112082).

Performance Data

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

The following biocompatibility tests were completed on the GUIDEZILLA™ Guide Extension Catheter:

Cytotoxicity	Direct Contact Hemolysis
Sensitization	Hemolysis Extract
Intracutaneous Reactivity	Complement Activation
Acute Systemic Toxicity	Partial Thromboplastin Time
Materials Mediated Pyrogenicity	In Vitro Hemocompatibility
USP Physicochemical	Latex

The following in-vitro performance tests were completed of the GUIDEZILLA™ Guide Extension Catheter:

Effective Length	Radiopacity
Outer Diameter	Dye Flow
Inner Diameter	Coating Integrity
Full Unit Tensile	Particulate Evaluation
Kink Resistance	Corrosion Resistance
Tip Deflection	Device Compatibility
Torque Strength	Packaging Integrity

Clinical Testing

Clinical Evaluation was not required for these devices.

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the GUIDEZILLA™ Guide Extension Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the GuideLiner® V2 (K112082).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2013

Boston Scientific Corporation
C/O Holly Ramirez
One Scimed Place
Maple Grove, MN 55311

Re: K123765
Trade/Device Name: Guidezilla™ Guide Extension Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 15, 2013
Received: February 19, 2013

Dear Ms. Ramirez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram Zuckerman, M.D.
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123765

Device Name: GUIDEZILLA™ Guide Extension Catheter

Indications for Use:

The Guidezilla guide extension catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G Hillebrenner

Exhibit 22

Vascular SOLUTIONS

April 25, 2013

Mr. Kevin Ballinger
President, Interventional Cardiology Division
Boston Scientific
Attn: Mail Stop A225
One Scimed Place
Maple Grove, MN 55311

Dear Kevin,

Following up on my letter to you dated October 16, 2012 (to which I never received a reply), it has come to my attention that Boston Scientific has commenced clinical uses in the U.S. of the Guidezilla guide extension catheter. I once again remind you of the three U.S. patents owned by Vascular Solutions on the concept of guide extension (US 8,048,032, US 8,142413 and US 8,292,850).

By this letter, I request that you provide me with a sample of the Guidezilla catheter (for which I will pay the normal retail price) to examine in light of Vascular Solutions' patents. Furthermore, if you have an analysis of the applicability or inapplicability of these patents to your Guidezilla catheter, I would request that you provide that to me for my review. Finally, I am willing to sit down with you or any other Boston Scientific representative to discuss this issue at a mutually convenient place and time.

Please reply to my requests at your earliest convenience.

Best regards,

Howard Root
Chief Executive Officer

VASCULAR SOLUTIONS, INC.
6464 Sycamore Court • Minneapolis, Minnesota 55369
PHONE: 763/656-4300 • FAX: 763/656-4250 • www.vascularsolutions.com

Exhibit 23

Boston Scientific

May 3, 2013

Mr. Howard Root
Chief Executive Officer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Dear Howard,

I am responding to your letter of April 25, 2013. First, as to your letter of October 16, 2012, I did not respond because it was merely informational and no response was requested.

As to your current letter, I have forwarded it to legal for review. They will contact you following their review.

Best Regards,

Kevin Ballinger
Global President, Cardiology

Exhibit 24

Boston Scientific

Guidezilla™

Guide Extension Catheter (5-in-6)

6F

Catéter guía con extensión (5 en 6), Cathéter d extension de guide (5 dans 6), Verlängerungs-Führungskatheter (5-in-6), Prolunga del catetere guida (5-in-6), Geleideverlengkatheter (5 F in 6 F), ガイド・エクステンション・カテーテル (5-in-6), Ledekateterforlængelse (5 i 6), Καθετήρας επέκτασης οδηγού καθετήρα (5 F εντός 6 F), Cateter-guia de Extensão (5 em 6), Förlängningsstyrkateter (5 F för 6 F), Vezetőhosszabbító katéter (5 F méretű, amely 6 F méretű vezetőkatéterrel használható), Prodlužovací zaváděcí katétr (5 v 6), Przedłużający cewnik prowadzący (5 w 6), Ledekateterforlengelse (5-i-6), Kılavuz Uzatma Kateteri (6'da 5)

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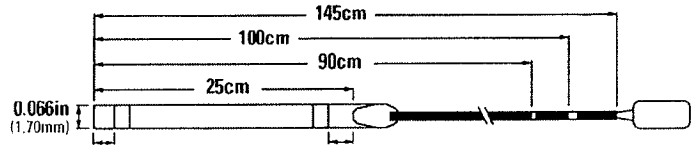
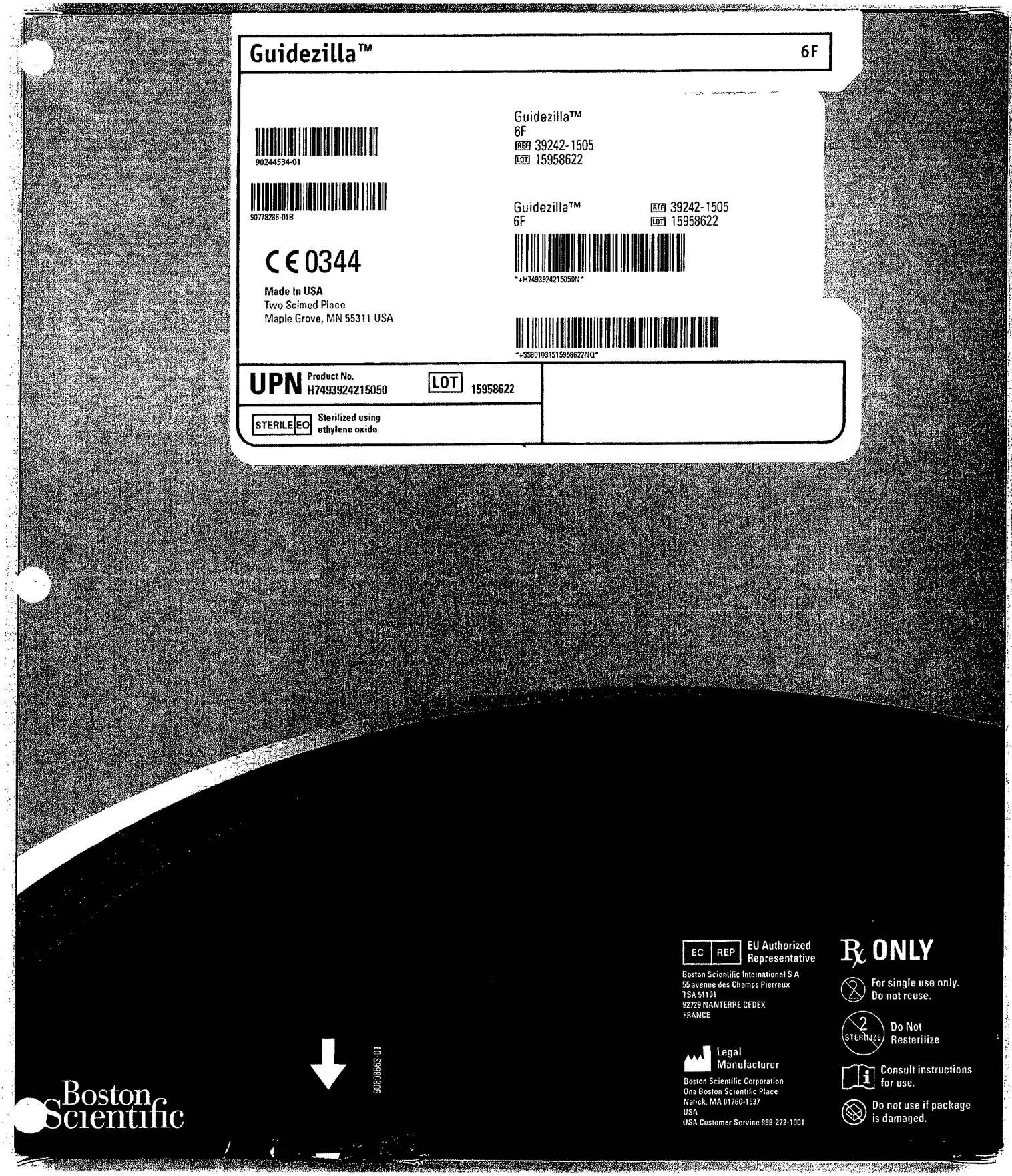


ID 0.057in (1.45mm) Inner Diameter

ID ≥ 0.070in (1.78mm) Guide Catheter Inner Diameter

REF Catalog No.	39242-1505
Use By	2015-03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90244534-01
90778286-01B
Guidezilla™
6F
REF 39242-1505
LOT 15958622
Guidezilla™ 6F
REF 39242-1505
LOT 15958622
+H7493924215050N
+$$8010315159586222NQ
CE 0344
Made In USA
Two Scimed Place
Maple Grove, MN 55311 USA
UPN Product No. H7493924215050
LOT 15958622
STERILE EO Sterilized using ethylene oxide.
EC REP EU Authorized Representative
Boston Scientific International S A
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE
Legal Manufacturer
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001
Rx ONLY
For single use only. Do not reuse.
Do Not Resterilize
Consult instructions for use.
Do not use if package is damaged.
Boston Scientific
90808663-01

Boston Scientific

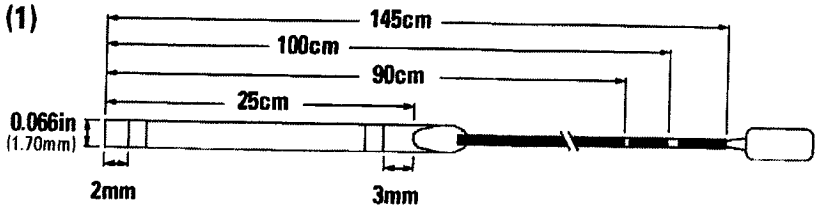
6F

Guidezilla™

Guide Extension Catheter (5-in-6)

Catéter guía con extensión (5 en 6), Cathéter d'extension de guide (5 dans 6), Verlängerungs-Führungskatheter (5-in-6), Prolunga del catetere guida (5-in-6), Geleideverlengkatheter (5 F in 6 F), ガイド・エクステンション・カテーテル（5-in-6）, Ledekateterforlængelse (5 i 6), Καθετήρας επέκτασης οδηγού καθετήρα (5 F εντός 6 F), Cateter-guia de Extensão (5 em 6), Förlängningsstyrkateter (5 F för 6 F), Vezetőhosszabbító katéter (5 F méretű, amely 6 F méretű vezetőkatéterrel használható), Prodlužovací zaváděcí katétr (5 v 6), Przedłużający cewnik prowadzący (5 w 6), Ledekateterforlengelse (5-i-6), Kılavuz Uzatma Kateteri (6'da 5)

Contents (1)



ID 0.057in (1.45mm) Inner Diameter

ID ≥ 0.070in (1.78mm) Guide Catheter Inner Diameter

REF Catalog No. 39242-1505

Use By 2015-03

UPN Product No. H7493924215050

LOT 15960140

STERILE EO Sterilized using ethylene oxide.

90244533-01

90778284-01B

CE 0344

Made In USA
Two Scimed Place
Maple Grove, MN 55311 USA

Guidezilla™
6F
REF 39242-1505
LOT 15960140

+H7493924215050N

+S$$01031515960140NE

Exhibit 25

Boston Scientific

Guidezilla™

Guide Extension Catheter (5-in-6)

Guidezilla™

Guide Extension Catheter (5-in-6)

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Guidezilla guide extension catheter is a single lumen rapid exchange catheter npatible with 6F guide catheters and may be placed over an exchanged length 180 cm guidewire. The 145 cm device has a stainless steel proximal shaft with a 25 cm single lumen distal guide segment with a hydrophilic coating.

The Guidezilla device has two platinum-iridium marker bands, which enable visibility while using standard fluoroscopic methods. The distal marker band is located 2 mm from the distal tip. The proximal marker band is located 3 mm distal to the opening of the guide segment. The device has two positioning marks located at 90 cm (single mark) and 100 cm (double mark) from the distal tip, respectively.

The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter. The Guidezilla device has a proximal tab which indicates inner diameter and guide catheter compatibility.

Table 1. Compatibility Information

Model	Compatible Guidewire	Compatible Guide Catheter	Guidezilla Min. I.D.
6F (5-in-6)	≤ 0.014 in (0.36 mm)	≥ 6F / ≥ 0.070 in I.D. (1.78 mm)	.057 in (1.45 mm)

CONTENTS

Qty	Material
One (1)	Single-use Guidezilla guide extension catheter

INTENDED USE/INDICATIONS FOR USE

The Guidezilla guide extension catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

CONTRAINDICATIONS

- Vessels less than 2.5 mm in diameter.
- Vessels in the neurovasculature and the venous system.

WARNINGS

- Use prior to the "use by" date as indicated on the label.
- Never advance the Guidezilla device into a vessel without a leading guidewire or without confirming location using fluoroscopic guidance. Vessel dissection or perforation may result.
- Due to the size and non-tapered tip of the Guidezilla device, extreme care must be taken to avoid vessel ischemia or vascular damage.
- Where there is limited clearance between interventional devices and the distal guide segment lumen, those devices must be advanced and withdrawn slowly with the hemostasis valve open to reduce the risk of embolism.
- This is a non-torqueable device. Torqueing the device may result in wire wrap or damage to the device or vessel.
- Never advance the Guidezilla device into a vessel with an effective diameter less than 2.5 mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting the Guidezilla catheter, withdraw the Guidezilla catheter until the pressure returns to normal.

PRECAUTIONS

- Inspect the device prior to use for any bends or kinks. Any device damage may decrease the desired performance characteristics.
- The device lumen should be thoroughly flushed with heparinized saline prior to use.
- This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. Use of systemic heparinization and heparinized sterile solution should be considered.
- Exercise care in handling of the device during a procedure to reduce the possibility of accidental breakage, bending or kinking.
- When the device is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the device without observing the resultant tip response.
- Never advance the Guidezilla device more than 15 cm beyond the tip of the guide catheter. Further distal advancement of the Guidezilla device could cause the entire guide segment to track outside of the guide catheter and impede withdrawal of the device.
- If strong resistance is encountered during manipulation of the devices, do not force passage. Determine the cause of the resistance before proceeding. If the cause cannot be removed, withdraw all devices simultaneously.

ADVERSE EVENTS

The adverse events include, but are not limited to:

- Vessel trauma (e.g., perforation, dissection)
- Vascular complication (e.g., puncture site complication)
- Thrombus
- Renal failure
- Slow-flow/occlusion
- Allergic reaction
- Death
- Emboli
- Hemorrhage/hematoma (e.g., vascular access complication)
- Infection
- Myocardial infarction
- Arterial spasm
- Intimal disruption

HOW SUPPLIED

Packaging is designed to maintain sterility according to expiration date on the label. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Other items required but not provided:

- Guide catheter with an inner diameter large enough to accommodate the Guidezilla™ device
- Y-adaptor with hemostasis valve

  Guidewire with diameter ≤ 0.014 in (0.36 mm)
- Sterile syringe (for system flushing)
- Sterile heparinized saline (for system flushing)

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Preparations for Use

1. Prior to use, carefully inspect the Guidezilla device packaging and components for damage.
2. Using sterile technique, transfer the protective tubing with the Guidezilla device into the sterile field.
3. Carefully remove the Guidezilla device from its protective tubing. Do not bend or kink the device during removal.
4. Immerse the distal guide segment in heparinized saline solution.

Delivery Procedure

Deliver the Guidezilla device according to the following steps:

1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve.
2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter.
3. Under fluoroscopy, advance the Guidezilla device up to a maximum of 15 cm beyond the distal tip of the guide catheter and into the desired location within the vessel.

Warning: Due to the size and non-tapered tip of the Guidezilla device, extreme care must be taken to avoid vessel occlusion and damage to the wall of the vessels through which this catheter passes.

Warning: Never advance the Guidezilla device into a vessel with an effective diameter less than 2.5 mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting the Guidezilla catheter, withdraw the Guidezilla catheter until the pressure returns to normal.

4. Using fluoroscopy, confirm the desired position of the Guidezilla device in the vessel.
5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device into the desired vascular space.

Note: Use caution when advancing the interventional device into the distal guide segment.

6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guidezilla device to prevent back-bleeding.
7. Perform the catheterization procedure. After completing the procedure, remove the Guidezilla device prior to removing the guide catheter from the vessel.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Guidezilla™

Catéter guía con extensión (5 en 6)

℞ ONLY

Precaución: las leyes federales de los Estados Unidos sólo permiten la venta de este dispositivo bajo prescripción facultativa.

ADVERTENCIA

El contenido se suministra ESTÉRIL mediante óxido de etileno (OE). No usar si la barrera estéril está dañada. Si se encuentran daños, llamar al representante de Boston Scientific.

Para un solo uso. No reutilizar, reprocesar o reesterilizar. La reutilización, el reprocesamiento o la reesterilización pueden comprometer la integridad estructural del dispositivo y/o causar su fallo, lo que a su vez puede resultar en lesiones al paciente, enfermedad o la muerte. La reutilización, el reprocesamiento o la reesterilización pueden también crear el riesgo de contaminación del dispositivo y/o causar infección o infección cruzada al paciente, que incluye, entre otros, la transmisión de enfermedades infecciosas de un paciente a otro. La contaminación del dispositivo puede causar lesiones, enfermedad o la muerte del paciente.

Después de su uso, desechar el producto y su envase de acuerdo a las normas del hospital, administrativas y/o de las autoridades locales.

DESCRIPCIÓN DEL DISPOSITIVO

El catéter guía con extensión Guidezilla es un catéter de intercambio rápido de un solo lumen compatible con catéteres guía de 6 F y puede colocarse sobre una guía de 180 cm o de longitud intercambiable. El dispositivo de 145 cm tiene un cuerpo proximal de acero inoxidable con un segmento guía distal de un solo lumen de 25 cm y revestimiento hidrófilo.

El dispositivo Guidezilla tiene dos bandas marcadoras de platino-iridio, que le proporcionan visibilidad durante la utilización de métodos fluoroscópicos estándar. La banda marcadora distal está situada a 2 mm de la punta distal. La banda marcadora proximal está situada a 3 mm de la abertura del segmento guía. El dispositivo dispone de dos marcas de posición situadas a 90 cm (marca única) y 100 cm (marca doble) de la punta distal, respectivamente.

El dispositivo Guidezilla se introduce a través de un catéter guía, dando lugar a un diámetro interno de aproximadamente 1 French menos que el catéter guía. El dispositivo Guidezilla tiene una lengüeta proximal que indica el diámetro interno y la compatibilidad del catéter guía.

Tabla 1. Información sobre compatibilidad

Modelo	Guía compatible	Catéter guía compatible	D.I. mín. de Guidezilla
6 F (5 en 6)	≤ 0,014 in (0,36 mm)	≥ 6 F / ≥ D.I. de 0,070 in (1,78 mm)	0,057 in (1,45 mm)

CONTENIDO

Cant.	Material
Un (1)	catéter guía con extensión de un solo uso Guidezilla

USO INDICADO / INDICACIONES DE USO

El catéter guía con extensión Guidezilla está indicado para utilizarse junto con catéteres guía para acceder a regiones aisladas de la vasculatura periférica o coronaria, y para facilitar la colocación de dispositivos quirúrgicos.

CONTRAINDICACIONES

- Vasos de diámetro inferior a 2,5 mm.
- Vasos de la neurovasculatura y del sistema venoso.

ADVERTENCIAS

- Utilice este producto antes de la fecha de caducidad indicada en la etiqueta.
- No haga avanzar nunca un dispositivo Guidezilla en un vaso sin una guía de dirección o sin confirmar la ubicación mediante orientación fluoroscópica. Puede provocar disección o perforación vascular.
- Debido al tamaño y la punta no cónica del dispositivo Guidezilla, se debe actuar con suma precaución para evitar daños o isquemias vasculares.
- Cuando el espacio existente entre los dispositivos quirúrgicos y el lumen del segmento guía distal es limitado, dichos dispositivos deben hacerse avanzar y retirarse lentamente con la válvula hemostática abierta para reducir el riesgo de embolia.
- Este dispositivo no se puede torcer. La torsión del dispositivo puede provocar el enroscamiento de la guía o daños en el dispositivo o vaso.
- No introduzca nunca el dispositivo Guidezilla en un vaso de diámetro efectivo inferior a 2,5 mm. Puede ocasionarse una lesión, isquemia y/u oclusión vascular. Si la presión de un vaso desciende después de insertar el catéter Guidezilla, extráigalo hasta que la presión vuelva a ser normal.

PRECAUCIONES

- Inspeccione el dispositivo antes de utilizarlo para verificar que no tiene pliegues ni acodamientos. Cualquier daño en el dispositivo puede disminuir el rendimiento del procedimiento.
- El lumen del dispositivo debe irrigarse completamente con solución salina heparinizada antes de utilizarse.
- Solo los médicos debidamente preparados en la realización de intervenciones y técnicas percutáneas e intravasculares deben utilizar este dispositivo.
- Cuando se usen catéteres en el sistema vascular, deberán tomarse precauciones para evitar o reducir la coagulación. Debe considerarse el uso de heparinización sistémica y solución salina heparinizada.
- Manipule el dispositivo con cuidado durante la intervención para reducir la posibilidad de acodamientos, dobleces o roturas accidentales.
- Cuando el dispositivo esté dentro del cuerpo, solo debe manipularse bajo fluoroscopia. No intente mover el dispositivo sin observar la respuesta correspondiente de la punta.
- No haga avanzar nunca el dispositivo Guidezilla más de 15 cm más allá de la punta del catéter guía. Si el dispositivo Guidezilla se hace avanzar a más profundidad en dirección distal, el segmento guía completo podría soltarse del catéter guía e impedir la extracción del dispositivo.

- Si se percibe una fuerte resistencia durante la manipulación de los dispositivos, no fuerce su introducción. Antes de proceder, es necesario determinar la causa de dicha resistencia. Si la causa no se puede eliminar, retire todos los dispositivos de forma simultánea.

EPISODIOS ADVERSOS

Entre los episodios adversos se incluyen:

- Traumatismo vascular (p. ej., perforación o disección)
- Complicaciones vasculares (p. ej., complicaciones en el lugar de la punción)
- Trombos
- Insuficiencia renal
- Flujo lento/oclusión
- Reacción alérgica
- Muerte
- Émbolos
- Hemorragia/hematoma (p. ej., complicaciones de acceso vascular)
- Infección
- Infarto de miocardio
- Espasmo arterial
- Ruptura de la íntima

PRESENTACIÓN

El envase está diseñado para proporcionar la esterilidad según figura en la fecha de caducidad de la etiqueta. No utilizar si el envase está abierto o dañado. No utilizar si la etiqueta está incompleta o ilegible.

os elementos necesarios que no se suministran:

- Catéter guía con diámetro interno lo suficientemente grande para albergar el dispositivo Guidezilla™
- Adaptador en Y con válvula hemostática
- Guía con diámetro ≤ 0,014 in (0,36 mm)
- Jeringa estéril (para irrigar el sistema)
- Solución salina heparinizada estéril (para irrigar el sistema)

Manipulación y almacenamiento

Almacenar en un lugar oscuro, seco y fresco.

INSTRUCCIONES DE FUNCIONAMIENTO

Preparación para el uso

1. Antes de utilizar, inspeccione cuidadosamente el envase y los componentes del dispositivo Guidezilla para verificar que no existe ningún daño.
2. Con una técnica estéril, transfiera el dispositivo Guidezilla en el tubo protector a un entorno estéril.
3. Extraiga cuidadosamente el dispositivo Guidezilla del tubo protector. No doble ni tuerza el dispositivo durante la extracción.
4. Introduzca el segmento guía distal en la solución salina heparinizada.

Procedimiento de introducción

Introduzca el dispositivo Guidezilla siguiendo los pasos que se indican a continuación:

1. Asegure la guía insertada previamente, cargue la punta distal del dispositivo Guidezilla en la guía desde la parte posterior y haga que avance hasta que el dispositivo se encuentre en posición proximal con respecto a la válvula hemostática.
2. Abra la válvula hemostática y haga avanzar el dispositivo Guidezilla a través de la válvula hemostática hasta el catéter guía.
3. Bajo fluoroscopia, haga avanzar el dispositivo Guidezilla hasta un máximo de 15 cm más allá de la punta distal del catéter guía, en el lugar deseado del vaso.

Advertencia: debido al tamaño y la punta no cónica del dispositivo Guidezilla, se debe actuar con suma precaución para evitar daños en las paredes y oclusiones vasculares por donde pasa el catéter.

Advertencia: no introduzca nunca el dispositivo Guidezilla en un vaso de diámetro efectivo inferior a 2,5 mm. Puede ocasionarse una lesión, isquemia y/u oclusión vascular. Si la presión de un vaso desciende después de insertar el catéter Guidezilla, extráigalo hasta que la presión vuelva a ser normal.

4. Bajo fluoroscopia, confirme la posición deseada del dispositivo Guidezilla en el vaso.
5. Si se lleva a cabo un procedimiento quirúrgico, cargue el dispositivo quirúrgico desde la parte posterior sobre la guía y haga que avance hasta el espacio vascular deseado a través del catéter guía y del dispositivo Guidezilla.

Nota: haga avanzar el dispositivo quirúrgico en el segmento guía distal con precaución.

6. Apriete el adaptador en Y de la válvula hemostática y asegúrelo al cuerpo proximal del dispositivo Guidezilla para evitar el sangrado retrógrado.
7. Realice el procedimiento de cateterismo. Tras completar el procedimiento, extraiga el dispositivo Guidezilla antes de retirar el catéter guía del vaso.

GARANTÍA

Boston Scientific Corporation (BSC) garantiza que se ha puesto un cuidado razonable en el diseño y la fabricación de este instrumento. **Esta garantía sustituye a cualquier otra que no se mencione expresamente en este documento, ya sea de forma explícita o implícita por ley o de otro modo, incluida, entre otras, cualquier garantía implícita de comerciabilidad o de adecuación para un fin concreto.** La manipulación, el almacenamiento, la limpieza y la esterilización de este instrumento, así como otros aspectos relacionados con el paciente, el diagnóstico, el tratamiento, las intervenciones quirúrgicas y cualquier otro aspecto ajeno al control de BSC afectan directamente a este instrumento y a los resultados que puedan obtenerse de su uso. La responsabilidad de BSC en virtud de esta garantía se limita a la reparación o sustitución de este instrumento y BSC no asumirá responsabilidad alguna por pérdidas accidentales o consecuentes, por daños ni por gastos directos o indirectos que pueda ocasionar el uso de este instrumento. BSC tampoco asume ninguna otra obligación o responsabilidad relacionada con este instrumento ni autoriza a ninguna persona a que lo haga en su nombre. **BSC rechaza cualquier responsabilidad con respecto a instrumentos reutilizados, reprocesados o reesterilizados y, respecto a los mismos, no ofrece garantía alguna, ya sea explícita o implícita, incluyendo entre otras la de comerciabilidad y adecuación para un fin concreto.**

Guidezilla™

Cathéter d'extension de guide (5 dans 6)

℞ ONLY

Avertissement : Selon la loi fédérale américaine, ce dispositif ne peut être vendu que sur prescription d'un médecin.

MISE EN GARDE

Contenu STÉRILISÉ à l'oxyde d'éthylène (OE). Ne pas utiliser si l'emballage stérile est endommagé. Si le produit est endommagé, contacter le représentant de Boston Scientific.

À usage unique. Ne pas réutiliser, retraiter ou restériliser. La réutilisation, le retraitement ou la restérilisation de ce dispositif risquent de compromettre son intégrité structurelle et/ou d'entraîner son dysfonctionnement, risquant de provoquer des blessures, des maladies ou le décès du patient. De plus, une telle action risque d'entraîner la contamination du dispositif et/ou l'infection croisée du patient, y compris la transmission de maladies infectieuses d'un patient à un autre. La contamination du dispositif peut causer des blessures, des maladies ou le décès du patient.

Après utilisation, éliminer le produit et l'emballage conformément au règlement de l'établissement, de l'administration et/ou du gouvernement local.

DESCRIPTION DU DISPOSITIF

Le cathéter d'extension de guide Guidezilla est un cathéter à lumière unique à échange rapide compatible avec des cathéters-guides de 6 F qui peut être placé sur une longueur d'échange ou sur un guide de 180 cm. Le dispositif de 145 cm est constitué d'un corps proximal en acier inoxydable avec segment de guide distal à lumière unique de 25 cm recouvert d'un revêtement hydrophile.

Le dispositif Guidezilla comporte deux repères en platine iridié, qui permettent de le visualiser lors de l'utilisation de méthodes radioscopiques standard. Le repère distal est situé à 2 mm de l'extrémité distale. Le repère proximal se trouve 3 mm en aval de l'ouverture du segment de guide. Le dispositif comporte deux repères de positionnement situés à 90 cm (repère unique) et 100 cm (repère double) de l'extrémité distale, respectivement.

Le dispositif Guidezilla est mis en place à l'aide d'un cathéter-guide et a un diamètre interne qui est environ 1 French inférieur à celui du cathéter-guide. Le dispositif Guidezilla comporte une languette proximale qui indique le diamètre interne et la compatibilité avec le cathéter-guide.

Tableau 1. Informations relatives à la compatibilité

Modèles	Guide compatible	Cathéter-guide compatible	Ø int. min. Guidezilla
6 F (5 dans 6)	≤ 0,014 in (0,36 mm)	Ø int. ≥ 6 F / ≥ 0,070 in (1,78 mm)	0,057 in (1,45 mm)

CONTENU

Qté	Matériel
Un (1)	Cathéter d'extension de guide Guidezilla à usage unique

UTILISATION/INDICATIONS

Le cathéter d'extension de guide Guidezilla est destiné à être utilisé en conjonction avec des cathéters-guides pour accéder à des sites particuliers du système vasculaire coronaire et/ou périphérique et pour faciliter la mise en place de dispositifs interventionnels.

CONTRE-INDICATIONS

- Vaisseaux de diamètre inférieur à 2,5 mm.
- Vaisseaux du système neuro-vasculaire et veineux.

MISES EN GARDE

- Utiliser avant la date limite d'utilisation figurant sur l'étiquette.
- Ne jamais faire progresser le dispositif Guidezilla dans un vaisseau sans guide ou sans confirmer l'emplacement sous surveillance radioscopique, au risque d'entraîner une dissection ou une perforation du vaisseau.
- En raison de la taille et de l'extrémité non effilée du dispositif Guidezilla, faire preuve d'extrême précaution pour éviter une ischémie du vaisseau ou des dommages vasculaires.
- S'il existe un espace réduit entre les dispositifs interventionnels et la lumière du segment de guide distal, faire avancer ou retirer ces dispositifs lentement avec la valve hémostatique ouverte pour réduire le risque d'embolie.
- Ce dispositif ne peut pas être tordu. Une torsion du dispositif peut causer un enroulement du guide ou endommager le vaisseau ou le dispositif.
- Ne jamais faire progresser un cathéter Guidezilla dans un vaisseau présentant un diamètre efficace inférieur à 2,5 mm, au risque d'entraîner des lésions vasculaires, une ischémie et/ou une occlusion. Si la pression diminue au sein d'un vaisseau après insertion du cathéter Guidezilla, retirer le cathéter Guidezilla jusqu'au rétablissement de la pression normale.

PRÉCAUTIONS

- Avant toute utilisation, vérifier que le dispositif n'est ni plié ni courbé. L'efficacité du dispositif peut être compromise s'il est endommagé.
- La lumière du dispositif doit être complètement rincée avec du sérum physiologique hépariné avant utilisation.
- Ce dispositif ne doit être utilisé que par des médecins dûment formés aux techniques et procédures intravasculaires percutanées.
- Des précautions doivent être prises pour éviter ou réduire la formation de caillots lors de l'utilisation de tout cathéter dans le système vasculaire. Le recours à une héparinisation systémique et l'utilisation de sérum physiologique hépariné doivent être envisagés.
- Ne manipuler le dispositif pendant une procédure qu'avec beaucoup de précaution pour éviter de le casser, de le courber ou de le plier.
- Une fois le dispositif introduit dans l'organisme, ne le manipuler que sous radioscopie. Ne pas tenter de déplacer le dispositif sans observer la réaction de l'extrémité.
- Ne jamais faire progresser le dispositif Guidezilla plus de 15 cm au-delà de l'extrémité du cathéter-guide. Une progression distale plus avancée du dispositif Guidezilla pourrait entraîner la totalité du segment de guide hors du cathéter-guide, ce qui pourrait empêcher le retrait du dispositif.
- En cas de forte résistance lors de la manipulation des dispositifs, ne pas forcer le passage. Déterminer la cause de la résistance avant de continuer.

Si la résistance en cause ne peut pas être résolue, retirer tous les dispositifs simultanément.

ÉVÉNEMENTS INDÉSIRABLES

Les événements indésirables incluent notamment :

- Lésion vasculaire (par exemple, dissection, perforation)
- Complication vasculaire (par exemple, complication au site de ponction)
- Thrombus
- Insuffisance rénale
- Débit lent/occlusion
- Réaction allergique
- Décès
- Embolie
- Hémorragie/hématome (par exemple, complication de l'accès vasculaire)
- Infection
- Infarctus du myocarde
- Spasme artériel
- Rupture intimale

PRÉSENTATION

Cet emballage est conçu pour préserver la stérilité du produit jusqu'à la date de péremption indiquée sur l'étiquette. Ne pas utiliser si l'emballage est ouvert ou endommagé. Ne pas utiliser si l'étiquetage est incomplet ou illisible.

Autre matériel requis, mais non fourni :

Cathéter-guide de diamètre interne de taille suffisante pour admettre le dispositif Guidezilla™

- Adaptateur en Y avec valve hémostatique
- Guide de diamètre ≤ 0,014 in (0,36 mm)
- Seringue stérile (pour le rinçage du système)
- Sérum physiologique stérile hépariné (pour le rinçage du système)

Manipulation et stockage

Conserver dans un endroit sec, à l'abri de la lumière et de la chaleur.

INSTRUCTIONS D'UTILISATION

Préparation

1. Avant toute utilisation, inspecter soigneusement l'emballage et les composants du dispositif Guidezilla à la recherche de dommages éventuels.
2. En utilisant une technique stérile, transférer le tube de protection contenant le dispositif Guidezilla dans le champ stérile.
3. Retirer avec précaution le dispositif Guidezilla de son tube de protection. Ne pas courber ou tordre le dispositif lors du retrait.
4. Immerger le segment de guide distal dans du sérum physiologique hépariné.

Procédure de mise en place

Mettre en place le dispositif Guidezilla selon les étapes suivantes :

1. Fixer le guide introduit précédemment et insérer l'extrémité distale du dispositif Guidezilla sur le guide, puis faire progresser le dispositif jusqu'à ce qu'il se trouve juste en amont de la valve hémostatique.
2. Ouvrir la valve hémostatique et faire progresser le dispositif Guidezilla par la valve hémostatique et dans le cathéter-guide.
3. Sous radioscopie, faire progresser le dispositif Guidezilla jusqu'à un maximum de 15 cm au-delà de l'extrémité distale du cathéter-guide et à l'emplacement souhaité dans le vaisseau.

Mise en garde : En raison de la taille et de l'extrémité non effilée du dispositif Guidezilla, faire preuve d'extrême précaution pour éviter une occlusion du vaisseau et des lésions des parois vasculaires lors du passage du cathéter.

Mise en garde : Ne jamais faire progresser un cathéter Guidezilla dans un vaisseau présentant un diamètre efficace inférieur à 2,5 mm, au risque d'entraîner des lésions vasculaires, une ischémie et/ou une occlusion. Si la pression diminue au sein d'un vaisseau après insertion du cathéter Guidezilla, retirer le cathéter Guidezilla jusqu'au rétablissement de la pression normale.

4. Sous radioscopie, confirmer la position souhaitée du dispositif Guidezilla dans le vaisseau.
5. Dans le cas d'une procédure interventionnelle, insérer le dispositif interventionnel sur le guide et faire progresser le dispositif par le cathéter-guide et le dispositif Guidezilla dans l'espace vasculaire désiré.

Remarque : Faire preuve de prudence lors de la progression du dispositif interventionnel dans le segment de guide distal.

6. Serrer la valve hémostatique de l'adaptateur en Y sur le corps proximal du dispositif Guidezilla pour éviter tout reflux de sang.
7. Effectuer la procédure de cathétérisme. Une fois la procédure terminée, retirer le dispositif Guidezilla avant de retirer le cathéter-guide du vaisseau.

GARANTIE

Boston Scientific Corporation (BSC) garantit que cet instrument a été conçu et fabriqué avec un soin raisonnable. **Cette garantie remplace et exclut toute autre garantie non expressément formulée dans le présent document, qu'elle soit explicite ou implicite en vertu de la loi ou de toute autre manière, y compris notamment toute garantie implicite de qualité marchande ou d'adaptation à un usage particulier.** La manipulation, le stockage, le nettoyage et la stérilisation de cet instrument ainsi que les facteurs relatifs au patient, au diagnostic, au traitement, aux procédures chirurgicales et autres domaines hors du contrôle de BSC, affectent directement l'instrument et les résultats obtenus par son utilisation. Les obligations de BSC selon les termes de cette garantie sont limitées à la réparation ou au remplacement de cet instrument. BSC ne sera en aucun cas responsable des pertes, dommages ou frais accessoires ou indirects découlant de l'utilisation de cet instrument. BSC n'assume, ni n'autorise aucune tierce personne à assumer en son nom, aucune autre responsabilité ou obligation supplémentaire liée à cet instrument. **BSC ne peut être tenu responsable en cas de réutilisation, de retraitement ou de restérilisation des instruments et n'assume aucune garantie, explicite ou implicite, y compris notamment toute garantie de qualité marchande ou d'adaptation à un usage particulier concernant ces instruments.**

Guidezilla™

Verlängerungs-Führungskatheter (5-in-6)

℞ ONLY

Vorsicht: Laut Bundesgesetz der USA darf diese Vorrichtung ausschließlich an einen Arzt oder auf dessen Anordnung verkauft werden.

WARNHINWEIS

Der Inhalt wurde mit Ethylenoxid (EO) STERILISIERT. Bei beschädigtem sterilen Verpackungssiegel nicht verwenden. Im Falle von Beschädigungen Kontakt mit einem Vertreter von Boston Scientific aufnehmen.

Für den einmaligen Gebrauch. Nicht wiederverwenden, wiederaufbereiten oder resterilisieren. Die Wiederverwendung, Wiederaufbereitung oder Resterilisation kann eine Beeinträchtigung der strukturellen Unversehrtheit der Vorrichtung und/oder ein Versagen der Vorrichtung zur Folge haben, was wiederum zu Erkrankungen, Verletzungen oder zum Tod des Patienten führen kann. Eine Wiederverwendung, Wiederaufbereitung oder Resterilisation der Vorrichtung erhöht ebenfalls das Kontaminationsrisiko bzw. das Risiko einer Infektion des Patienten oder einer Kreuzinfektion. Hierzu gehört u. a. die Übertragung von Infektionskrankheiten von Patient zu Patient. Eine Kontamination der Vorrichtung kann zu Verletzungen, Erkrankungen oder zum Tod des Patienten führen.

Nach dem Gebrauch das Produkt und die Verpackung gemäß den Bestimmungen des Krankenhauses, administrativen und/oder örtlichen Regelungen entsorgen.

BESCHREIBUNG DER VORRICHTUNG

Der Guidezilla Verlängerungs-Führungskatheter ist ein Rapid Exchange-Katheter mit einem einzelnen Lumen, der mit 6 F Führungskathetern kompatibel ist, und kann über einen Führungsdraht mit Wechsellänge oder einen Führungsdraht von 180 cm Länge platziert werden. Die 145 cm lange Vorrichtung hat einen proximalen Edelstahlschaft mit einem 25 cm langen distalen Einzellumen-Führungssegment mit hydrophiler Beschichtung.

Die Guidezilla Vorrichtung verfügt über Platin-Iridium-Markierungsbänder, die die Sichtbarkeit bei der Verwendung fluoroskopischer Standardmethoden ermöglichen. Das distale Markierungsband befindet sich 2 mm von der distalen Spitze. Das proximale Markierungsband befindet sich 3 mm distal der Öffnung des Führungssegments. Die Vorrichtung hat zwei Positionierungsmarkierungen, die sich 90 cm (einfache Markierung) bzw. 100 cm (doppelte Markierung) von der distalen Spitze befinden.

Die Guidezilla Vorrichtung wird über einen Führungskatheter eingeführt, was einen Innendurchmesser ergibt, der etwa 1 French-Größe kleiner ist als der Führungskatheter. Die Guidezilla Vorrichtung verfügt über einen proximalen Streifen, der die Kompatibilität von Innendurchmesser und Führungskatheter anzeigt.

Tabelle 1: Kompatibilitätsinformationen

Modell	Kompatibler Führungsdraht	Kompatibler Führungskatheter	Guidezilla Min. ID
6 F (5-in-6)	≤ 0,014 in (0,36 mm)	≥ 6 F / ≥ 0,070 in ID (1,78 mm)	0,057 in (1,45 mm)

INHALT

Anz. Material

Ein (1) Guidezilla Verlängerungs-Führungskatheter für den einmaligen Gebrauch

VERWENDUNGSZWECK/INDIKATIONEN

Der Guidezilla Verlängerungs-Führungskatheter dient zur Verwendung in Verbindung mit Führungskathetern für den Zugang zu diskreten Bereichen der Koronar- und/oder peripheren Gefäße und zur einfacheren Platzierung interventioneller Vorrichtungen.

KONTRAINDIKATIONEN

- Gefäße mit einem Durchmesser von weniger als 2,5 mm
- Gefäße im neurovaskulären Bereich oder im venösen System

WARNHINWEISE

- Vor dem auf dem Produktetikett angegebenen Verfallsdatum („Verwendbar bis") verwenden.
- Die Guidezilla Vorrichtung niemals ohne einen leitenden Führungsdraht oder ohne Bestätigung der Position unter Röntgendurchleuchtung in ein Gefäß vorschieben. Andernfalls kann es zu Gefäßdissektion oder -perforation kommen.
- Aufgrund der Größe und der nicht konischen Spitze der Guidezilla Vorrichtung muss äußerst vorsichtig vorgegangen werden, um eine Gefäßischämie oder -verletzung zu vermeiden.
- Wenn nur ein geringer Abstand zwischen der interventionellen Vorrichtung und dem distalen Lumen des Führungssegments vorliegt, muss diese Vorrichtung bei geöffnetem Hämostaseventil langsam vorgeschoben bzw. zurückgezogen werden, um das Embolierisiko zu verringern.
- Die Vorrichtung ist nicht torsionsstabil. Ein Torquieren der Vorrichtung kann zu einer Wicklung des Drahts oder einer Beschädigung von Vorrichtung oder Gefäß führen.
- Die Guidezilla Vorrichtung niemals in ein Gefäß mit einem effektiven Durchmesser von weniger als 2,5 mm vorschieben. Dies kann zu einer Gefäßverletzung, Ischämie und/oder Okklusion führen. Wenn der Druck in einem Gefäß nach dem Einführen des Guidezilla Katheters abnimmt, den Guidezilla Katheter zurückziehen, bis der Druck wieder normal ist.

VORSICHTSMASSNAHMEN

- Vorrichtung vor Verwendung auf Verbiegungen und Knicke prüfen. Eine beschädigte Vorrichtung kann die gewünschte Leistung beeinträchtigen.
- Das Vorrichtungslumen vor Verwendung sorgfältig mit heparinisierter Kochsalzlösung spülen.
- Die Vorrichtung darf nur von Ärzten verwendet werden, die in perkutanen intravaskulären Techniken und Verfahren gründlich geschult wurden.

- Beim Einsatz von Kathetern sind Vorsichtsmaßnahmen zur Verhinderung bzw. Reduzierung der Blutgerinnung im Gefäßsystem zu treffen. Eine allgemeine Heparinisierung und die Anwendung von heparinisierter Kochsalzlösung sind zu erwägen.
- Die Vorrichtung während des Eingriffs vorsichtig handhaben, um das Risiko einer versehentlichen Bruchstelle, Biegung oder Knickbildung zu vermeiden.
- Wenn sich die Vorrichtung im Körper befindet, darf sie nur unter Röntgendurchleuchtung manipuliert werden. Die Vorrichtung nicht bewegen, ohne dabei die resultierende Bewegung der Spitze zu beobachten.
- Die Guidezilla™ Vorrichtung niemals mehr als 15 cm über die Spitze des Führungskatheters vorschieben. Ein weiteres distales Vorschieben der Guidezilla Vorrichtung kann dazu führen, dass das gesamte Führungssegment aus der Spur des Führungskatheters heraus bewegt wird, wodurch das Zurückziehen der Vorrichtung verhindert wird.
- Wenn bei der Manipulation der Vorrichtung starker Widerstand spürbar wird, die Passage nicht erzwingen. Vor dem Fortfahren die Ursache für den Widerstand feststellen. Wenn die Ursache nicht behoben werden kann, alle Vorrichtungen gemeinsam zurückziehen.

UNERWÜNSCHTE EREIGNISSE

Unter anderem können folgende unerwünschte Ereignisse auftreten:

- Gefäßtrauma (z. B. Perforation, Dissektion)
- Vaskuläre Komplikationen (z. B. Komplikationen an der Punktionsstelle)
- Thrombus
- Nierenversagen
  Geringer Blutfluss/Okklusion
  Allergische Reaktion
- Tod
- Emboli
- Blutungen/Hämatome (z. B. Komplikationen beim Gefäßzugang)
- Infektion
- Myokardinfarkt
- Arterienspasmus
- Dissektion der Intima

LIEFERFORM

Die Verpackung garantiert Sterilität gemäß dem Haltbarkeitsdatum auf dem Etikett. Bei geöffneter oder beschädigter Verpackung nicht verwenden. Bei unvollständigem oder unleserlichem Etikett nicht verwenden.

Weitere erforderliche, aber nicht im Lieferumfang enthaltene Elemente:

- Führungskatheter mit einem Innendurchmesser, der groß genug ist, um die Guidezilla Vorrichtung aufzunehmen
- Y-Adapter mit Hämostaseventil
- Führungsdraht mit Durchmesser ≤ 0,014 in (0,36 mm)
- Sterile Spritze (zum Spülen des Systems)
- Sterile heparinisierte Kochsalzlösung (zum Spülen des Systems)

Handhabung und Lagerung

Kühlen, trocken und vor Lichteinfall geschützt aufbewahren.

BEDIENUNGSANLEITUNG

Vorbereitung vor dem Gebrauch

1. Vor der Verwendung die Verpackung der Guidezilla Vorrichtung und die einzelnen Komponenten auf Beschädigungen untersuchen.
2. Unter Verwendung eines sterilen Verfahrens die Schutzhülle mit der Guidezilla Vorrichtung in das sterile Feld übertragen.
3. Die Guidezilla Vorrichtung vorsichtig aus der Schutzhülle entnehmen. Die Vorrichtung beim Auspacken nicht biegen oder knicken.
4. Das distale Führungssegment in heparinisierte Kochsalzlösung eintauchen.

Applikationsverfahren

Die Guidezilla Vorrichtung unter Befolgung der folgenden Schritte einführen:

1. Den zuvor eingeführten Führungsdraht fixieren und die distale Spitze der Guidezilla Vorrichtung von hinten auf den Führungsdraht führen und vorschieben, bis sich die Vorrichtung unmittelbar proximal des Hämostaseventils befindet.
2. Hämostaseventil öffnen und Guidezilla Vorrichtung durch das Hämostaseventil in den Führungskatheter vorschieben.
3. Guidezilla Vorrichtung unter Röntgendurchleuchtung bis maximal 15 cm über die distale Spitze des Führungskatheters an die gewünschte Stelle im Gefäß vorschieben.

Warnhinweis: Aufgrund der Größe und der nicht konischen Spitze der Guidezilla Vorrichtung muss äußerst vorsichtig vorgegangen werden, um eine Gefäßokklusion und eine Beschädigung der Gefäßwand, durch die der Katheter geführt wird, zu vermeiden.

Warnhinweis: Die Guidezilla Vorrichtung niemals in ein Gefäß mit einem effektiven Durchmesser von weniger als 2,5 mm vorschieben. Dies kann zu einer Gefäßverletzung, Ischämie und/oder Okklusion führen. Wenn der Druck in einem Gefäß nach dem Einführen des Guidezilla Katheters abnimmt, den Guidezilla Katheter zurückziehen, bis der Druck wieder normal ist.

4. Die gewünschte Position der Guidezilla Vorrichtung im Gefäß unter Röntgendurchleuchtung bestätigen.
5. Bei Durchführung eines interventionellen Verfahrens die interventionelle Vorrichtung von hinten über den Führungsdraht führen, die Vorrichtung durch den Führungskatheter vorschieben und die Guidezilla Vorrichtung in den gewünschten vaskulären Raum einführen.

Hinweis: Beim Vorschieben der interventionellen Vorrichtung in das distale Führungssegment vorsichtig vorgehen.

6. Das Hämostaseventil des Y-Adapters sicher auf dem proximalen Schaft der Guidezilla Vorrichtung festziehen, um Rückblutungen zu vermeiden.
7. Das Katheterisierungsverfahren durchführen. Nach Abschluss des Verfahrens die Guidezilla Vorrichtung entfernen, bevor der Führungskatheter aus dem Gefäß entfernt wird.

GARANTIE

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Guidezilla™

Prolunga del catetere guida (5-in-6)

℞ ONLY

Attenzione: la legge federale degli Stati Uniti autorizza la vendita di questo prodotto esclusivamente su prescrizione medica.

AVVERTENZA

Il contenuto è STERILIZZATO mediante ossido di etilene (EO). Non utilizzare se la barriera sterile è stata compromessa. In caso si rilevino danni, rivolgersi al rappresentante Boston Scientific.

Esclusivamente monouso. Non riutilizzare, ritrattare o risterilizzare. Tali processi potrebbero compromettere l'integrità strutturale del dispositivo e/o provocarne il guasto, con conseguente rischio di lesioni, malattia o morte del paziente. Potrebbero inoltre creare rischi di contaminazione del dispositivo e/o causare infezioni del paziente o infezioni crociate, inclusa, in modo non limitativo, la trasmissione di malattie infettive da un paziente all'altro. La contaminazione del dispositivo può inoltre provocare lesioni, malattia o la morte del paziente.

Dopo l'uso, eliminare il prodotto e la confezione in conformità ai protocolli ospedalieri, alle normative amministrative e/o alle leggi locali vigenti.

DESCRIZIONE DEL DISPOSITIVO

La prolunga del catetere guida Guidezilla è un catetere a cambio rapido, a lume singolo, compatibile con cateteri guida da 6 F per il posizionamento su una lunghezza di scambio o su un filoguida da 180 cm. Il dispositivo da 145 cm presenta un corpo prossimale di acciaio inossidabile con un segmento della guida distale a lume singolo da 25 cm provvisto di rivestimento idrofilo.

Il dispositivo Guidezilla è dotato di due fasce di marker in platino-iridio, che permettono la visualizzazione fluoroscopica in base ai metodi standard. La fascia di marker distale si trova a 2 mm dalla punta distale. La fascia di marker prossimale si trova a 3 mm in posizione distale rispetto all'ingresso del segmento della guida. Sul dispositivo sono presenti due contrassegni di posizionamento, ubicati rispettivamente a 90 cm (contrassegno singolo) e a 100 cm (contrassegno doppio) dalla punta distale.

Il dispositivo Guidezilla viene rilasciato attraverso un catetere guida e presenta un diametro interno inferiore all'incirca di 1 French rispetto al diametro interno del catetere guida. Il dispositivo Guidezilla è dotato di una linguetta prossimale indicante il diametro interno e la compatibilità del catetere guida.

Tabella 1. Informazioni sulla compatibilità

Modello	Filoguida compatibile	Catetere guida compatibile	D.I. min. Guidezilla
6 F (5-in-6)	≤ 0,014 in (0,36 mm)	D.I. ≥ 6 F / ≥ 0,070 in (1,78 mm)	0,057 in (1,45 mm)

CONTENUTO

Qtà	Materiale
Una (1)	prolunga del catetere guida Guidezilla monouso

USO PREVISTO/INDICAZIONI PER L'USO

La prolunga del catetere guida Guidezilla è indicata per l'uso con i cateteri guida per consentire l'accesso a regioni discrete del sistema vascolare coronarico e/o periferico e per agevolare il posizionamento di dispositivi interventistici.

CONTROINDICAZIONI

- Vasi con diametro inferiore a 2,5 mm.
- Vasi appartenenti all'albero vascolare del sistema nervoso centrale.

AVVERTENZE

- Utilizzare il prodotto prima della data di scadenza riportata sull'etichetta.
- Non far mai avanzare il dispositivo Guidezilla all'interno di un vaso senza l'ausilio di un filoguida o senza confermarne la posizione in fluoroscopia, per evitare rischi di dissezione o perforazione del vaso.
- Prestare la massima attenzione a evitare l'ischemia del vaso o danni vascolari, a causa delle dimensioni e della punta non rastremata del dispositivo Guidezilla.
- In presenza di uno spazio ridotto tra i dispositivi interventistici e il lume del segmento della guida distale, fare avanzare e retrarre lentamente tali dispositivi con la valvola emostatica aperta, per ridurre il rischio di embolia.
- Non è possibile torcere questo dispositivo. La torsione del dispositivo è infatti in grado di provocare l'attorcigliamento del filo o danni al dispositivo o al vaso.
- Non far mai avanzare il dispositivo Guidezilla all'interno di un vaso con diametro effettivo inferiore a 2,5 mm in quanto ciò può provocare una lesione, ischemia e/o un'occlusione del vaso. Se la pressione in un vaso diminuisce dopo l'introduzione del catetere Guidezilla, retrarre il catetere Guidezilla finché la pressione non torna al livello normale.

PRECAUZIONI

- Prima dell'uso controllare che il dispositivo non presenti piegature o attorcigliamenti. Eventuali danni al dispositivo possono comprometterne le prestazioni.
- Prima dell'uso, il lume del dispositivo deve essere accuratamente irrigato con soluzione fisiologica eparinizzata.
- Questo dispositivo deve essere usato solamente da personale medico altamente qualificato ed esperto in tecniche e procedure percutanee e intravascolari.
- Indipendentemente dal tipo di catetere utilizzato, è necessario prendere le dovute precauzioni per prevenire o ridurre la formazione di coaguli nell'albero vascolare. Considerare l'uso di eparinizzazione sistemica e di soluzione fisiologica eparinizzata.
- Nel corso della procedura maneggiare il dispositivo con estrema cautela, per ridurre il rischio di rotture, piegature e attorcigliamenti accidentali.
- Una volta introdotto, il dispositivo deve essere manovrato esclusivamente in fluoroscopia. Non effettuare movimenti del dispositivo senza controllare la risposta della punta.
- Non far mai avanzare il dispositivo Guidezilla più di 15 cm oltre la punta del catetere guida. Un ulteriore avanzamento distale del dispositivo Guidezilla potrebbe comportare la fuoriuscita dal catetere guida dell'intero segmento della guida, impedendo la retrazione del dispositivo.

- Qualora si avverta una forte resistenza nel corso della manipolazione del dispositivo, non forzarne il passaggio. Prima di proseguire, determinare la causa della resistenza. Se non è possibile eliminare tale causa, retrarre tutti i dispositivi contemporaneamente.

EFFETTI INDESIDERATI

Tra i possibili effetti indesiderati rientrano, in modo non limitativo:

- Trauma del vaso (come dissezione e perforazione)
- Complicanze vascolari (come complicanze presso il sito della puntura)
- Trombo
- Insufficienza renale
- Flusso rallentato/occlusione
- Reazione allergica
- Morte
- Emboli
- Emorragia/ematoma (come complicazioni presso il sito di accesso)
- Infezione
- Infarto miocardico
- Spasmo dell'arteria
- Trauma intimale

MODALITÀ DI FORNITURA

La confezione è ideata per mantenere la sterilità fino alla data di scadenza sull'etichetta. Non usare il prodotto se la confezione è danneggiata o aperta. Non usare il prodotto se le etichette sono incomplete o illeggibili.

Altri articoli necessari ma non forniti:

- Catetere guida con diametro interno di dimensioni sufficienti ad alloggiare il dispositivo Guidezilla™
- Adattatore a Y con valvola emostatica
- Filoguida con diametro ≤ 0,014 in (0,36 mm)
- Siringa sterile (per l'irrigazione del sistema)
- Soluzione fisiologica eparinizzata sterile (per l'irrigazione del sistema)

Manipolazione e conservazione

Conservare in un luogo fresco e asciutto e al riparo dalla luce.

ISTRUZIONI PER IL FUNZIONAMENTO

Preparazione per l'uso

1. Prima dell'uso, ispezionare attentamente la confezione del dispositivo Guidezilla e i relativi componenti per accertarsi che non presentino danni.
2. Avvalendosi di tecnica sterile, trasferire il tubo di protezione con il dispositivo Guidezilla all'interno del campo sterile.
3. Rimuovere con cautela il dispositivo Guidezilla dal proprio tubo protettivo. Non provocare piegature o attorcigliamenti del dispositivo.
4. Immergere il segmento della guida distale in soluzione fisiologica eparinizzata.

Procedura di rilascio

Rilasciare il dispositivo Guidezilla attenendosi alla seguente procedura:

1. Fissare il filoguida precedentemente inserito, quindi posizionare la punta distale del dispositivo Guidezilla sul filoguida, facendola avanzare fino a quando il dispositivo si trova in posizione appena prossimale alla valvola emostatica.
2. Aprire la valvola emostatica e far avanzare il dispositivo Guidezilla attraverso la valvola e nel catetere guida.
3. Far avanzare il dispositivo Guidezilla in fluoroscopia, fino a un massimo di 15 cm oltre la punta distale del catetere guida e nella posizione desiderata all'interno del vaso.

Avvertenza: prestare la massima attenzione a evitare l'occlusione del vaso e danni alla parete dei vasi attraversati dal catetere, a causa delle dimensioni e della punta non rastremata del dispositivo Guidezilla.

Avvertenza: non far mai avanzare il dispositivo Guidezilla all'interno di un vaso con diametro effettivo inferiore a 2,5 mm in quanto ciò può provocare una lesione, ischemia e/o un'occlusione del vaso. Se la pressione in un vaso diminuisce dopo l'introduzione del catetere Guidezilla, retrarre il catetere Guidezilla finché la pressione non torna al livello normale.

4. Confermare il raggiungimento della posizione desiderata all'interno del vaso da parte del dispositivo Guidezilla per mezzo di fluoroscopia.
5. Se si effettua una procedura interventistica, inserire il dispositivo interventistico sopra il filoguida, quindi far avanzare il dispositivo nel catetere guida e il dispositivo Guidezilla nello spazio vascolare prescelto.

Nota: usare cautela durante l'avanzamento del dispositivo interventistico nel segmento della guida distale.

6. Serrare a fondo la valvola emostatica dell'adattatore a Y sul corpo prossimale del dispositivo Guidezilla per evitare il riflusso ematico.
7. Eseguire la procedura di cateterizzazione. Ultimata la procedura, rimuovere il dispositivo Guidezilla prima della rimozione del catetere guida dal vaso.

GARANZIA

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Guidezilla™

Geleideverlengkatheter (5 F in 6 F)

℞ ONLY

Let op: De Amerikaanse federale wetgeving bepaalt dat dit hulpmiddel slechts door of namens een arts kan worden gekocht.

WAARSCHUWING

De inhoud is gesteriliseerd volgens een ethyleenoxide(EO)-proces en wordt STERIEL geleverd. Niet gebruiken indien de steriele barrière is beschadigd. Neem contact op met uw Boston Scientific-vertegenwoordiger als er schade wordt aangetroffen.

Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken, verwerken of steriliseren. Opnieuw gebruiken, verwerken of steriliseren kan de structurele integriteit van het hulpmiddel aantasten en/of het defect raken van het hulpmiddel tot gevolg hebben, hetgeen kan resulteren in letsel, ziekte of de dood van de patiënt. Opnieuw gebruiken, verwerken of steriliseren brengt tevens het gevaar van verontreiniging van het hulpmiddel met zich mee en/of kan infectie of kruisinfectie van de patiënt veroorzaken, met inbegrip van, maar niet beperkt tot, overdracht van (een) besmettelijke ziekte(s) tussen patiënten. Verontreiniging van het hulpmiddel kan letsel, ziekte of de dood van de patiënt veroorzaken.

Werp dit product en het verpakkingsmateriaal na gebruik weg volgens het hiervoor geldende beleid van de instelling en de overheid.

.SCHRIJVING VAN HULPMIDDEL

De Guidezilla-geleideverlengkatheter is een snel verwisselbare katheter met enkel lumen die compatibel is met geleidekatheters van 6 F en over een verwisselde lengte of voerdraad van 180 cm kan worden geplaatst. Dit hulpmiddel van 145 cm heeft een roestvaststalen proximale schacht met een 25 cm lang distaal geleidesegment met enkel lumen, dat een hydrofiele coating bevat.

Het Guidezilla-hulpmiddel bevat twee markeringsbanden van platina/iridium die de zichtbaarheid tijdens het toepassen van standaard fluorescopische methoden vergroten. De distale markeringsband bevindt zich op 2 mm voor de distale tip. De proximale markeringsband bevindt zich op 3 mm distaal van de opening van het geleidesegment. Het hulpmiddel bevat twee positiemarkeringen die zich respectievelijk op 90 cm (enkele markering) en 100 cm (dubbele markering) van de distale tip bevinden.

Het Guidezilla-hulpmiddel wordt opgevoerd door een geleidekatheter, waardoor er een binnendiameter ontstaat die ongeveer 1 French kleiner is dan de geleidekatheter. Het Guidezilla-hulpmiddel bevat een proximaal lipje dat de compatibiliteit van de binnendiameter en de geleidekatheter aangeeft.

Tabel 1. Informatie met betrekking tot compatibiliteit

Model	Compatibele voerdraad	Compatibele geleidekatheter	Guidezilla min. binnendiameter
6 F (5 F in 6 F)	≤ 0,014 in (0,36 mm)	≥ 6 F / ≥ 0,070 in binnendiameter (1,78 mm)	0,057 in (1,45 mm)

INHOUD

Aantal	Materiaal
Een (1)	Guidezilla-geleideverlengkatheter voor eenmalig gebruik

BEOOGD GEBRUIK/INDICATIES VOOR GEBRUIK

De Guidezilla-geleideverlengkatheter is bedoeld voor gebruik in combinatie met geleidekathers voor toegang tot afzonderlijke delen van het coronaire en/of perifere vaatstelsel, en om het plaatsen van interventiehulpmiddelen te vergemakkelijken.

CONTRA-INDICATIES

- Vaten met een diameter kleiner dan 2,5 mm.
- Vaten in de neurovasculair systeem en het veneus systeem.

WAARSCHUWINGEN

- Gebruiken voor de uiterste gebruiksdatum op het etiket van de verpakking.
- Het opvoeren van het Guidezilla-hulpmiddel in een vat dient altijd te gebeuren met een geleidevoerdraad en tevens moet eerst de locatie worden bevestigd met behulp van fluorescopie, anders kan vaatdissectie of -perforatie het resultaat zijn.
- Als gevolg van de afmeting en de niet-spitse tip van het Guidezilla-hulpmiddel moet er extreme zorg worden betracht om vaatisschemie of vaatletsel te voorkomen.
- Als er weinig ruimte is tussen de interventiehulpmiddelen en het distale lumen van het geleidesegment moeten die hulpmiddelen langzaam worden opgevoerd en teruggetrokken met een openstaande hemostaseklep zodat het risico van embolie wordt verminderd.
- Dit is een niet-draaibaar hulpmiddel. Draaien van het hulpmiddel kan leiden tot verdraaiing van de draad of schade aan het hulpmiddel of het vat.
- Voer het Guidezilla-hulpmiddel nooit op in een vat met een effectieve diameter die kleiner is dan 2,5 mm. Vaatletsel, ischemie en/of occlusie kunnen het gevolg zijn. Als de druk in een vat daalt nadat de Guidezilla-katheter is ingebracht, dient u de Guidezilla-katheter terug te trekken totdat de normale druk is hersteld.

VOORZORGSMAATREGELEN

- Inspecteer het hulpmiddel voor gebruik op verbuigingen of knikken. Beschadigingen aan het hulpmiddel kunnen de gewenste prestatiekenmerken negatief beïnvloeden.
- Het hulpmiddel moet voor gebruik grondig worden gespoeld met geheparinisеerde zoutoplossing.
- Dit hulpmiddel mag alleen worden gebruikt door artsen die zijn opgeleid in percutane, intravasculaire technieken en procedures.
- Bij gebruik van katheters in het vaatstelsel moeten voorzorgsmaatregelen worden genomen om de vorming van bloedklonters te voorkomen of te beperken. Gebruik van systemische heparinisatie en geheparinisеerde steriele oplossing moet worden overwogen.
- Wees voorzichtig wanneer u het hulpmiddel tijdens een ingreep hanteert, om het risico van onvoorzien breken, verbuigen of knikken te beperken.
- Als het hulpmiddel zich in het lichaam bevindt, dient dit uitsluitend onder fluorescopie te worden gemanipuleerd. Probeer niet het hulpmiddel te bewegen zonder de daaruit voortvloeiende beweging van de tip te observeren.

- Voer het Guidezilla™-hulpmiddel nooit meer dan 15 cm op voorbij de tip van de geleidekatheter. Als het Guidezilla-hulpmiddel verder distaal wordt opgevoerd, kan dit ertoe leiden dat het volledige geleidesegment buiten de geleidekatheter terechtkomt, wat het terugtrekken van het hulpmiddel belemmert.
- Als u sterke weerstand voelt tijdens het manoeuvreren van de hulpmiddelen, forceer het opvoeren dan niet. Bepaal de oorzaak van de weerstand voordat u verder gaat. Als de oorzaak niet kan worden verwijderd, trek dan alle hulpmiddelen gelijktijdig terug.

COMPLICATIES

De complicaties omvatten onder meer, maar zijn niet beperkt tot:

- vaattrauma (bijv. dissectie en perforatie)
- vaatcomplicaties (complicaties op de punctieplaats)
- trombus
- nierfalen
- lage stroom/occlusie
- allergische reactie
- overlijden
- embolie
- hemorragie/hematoom (complicatie vasculaire toegang)
- infectie
- myocardinfarct
- arterieel spasme
- verstoring van de intima

VERING

De verpakking is zodanig ontworpen dat de steriliteit gehandhaafd blijft tot de uiterste houdbaarheidsdatum op het etiket. Niet gebruiken als de verpakking open of beschadigd is. Niet gebruiken als de etikettering onvolledig of onleesbaar is.

Andere, niet-meegeleverde benodigdheden:

- een geleidekatheter waarvan de binnendiameter groot genoeg is voor het Guidezilla-hulpmiddel
- Y-adapter met hemostaseklep
- voerdraad met diameter ≤ 0,014 in (0,36 mm)
- steriele injectiespuit (voor spoelen van het systeem)
- steriele geheparinisеerde zoutoplossing (voor spoelen van het systeem)

Hantering en opslag

Koel, droog en donker bewaren.

BEDIENINGSINSTRUCTIES

Voorbereiden voor gebruik

1. Inspecteer voor gebruik de verpakking van het Guidezilla-hulpmiddel en de componenten op beschadiging.
2. Breng de beschermslang met het Guidezilla-hulpmiddel met een steriele techniek over naar het steriele veld.
3. Verwijder het Guidezilla-hulpmiddel voorzicht uit de beschermslang. Buig en knik het hulpmiddel niet tijdens het uitpakken.
4. Dompel het distale geleidesegment onder in geheparinisеerde zoutoplossing.

Inbrengprocedure

Breng het Guidezilla-hulpmiddel volgens de volgende stappen in:

1. Zet de eerder ingebrachte voerdraad vast en schuif de distale tip van het Guidezilla-hulpmiddel over de voerdraad en voer het op totdat het hulpmiddel zich net proximaal van de hemostaseklep bevindt.
2. Open de hemostaseklep en voer het Guidezilla-hulpmiddel door de hemostaseklep op de geleidekatheter in.
3. Voer onder fluorescopie het Guidezilla-hulpmiddel op tot maximaal 15 cm voorbij de distale tip van de geleidekatheter naar de gewenste locatie binnen het vat.

Waarschuwing: als gevolg van de afmeting en de niet-spitse tip van het Guidezilla-hulpmiddel moet er extra zorg worden betracht om vaatocclusie en schade aan de vaatwanden waardoor deze katheter wordt opgevoerd, te voorkomen.

Waarschuwing: Voer het Guidezilla-hulpmiddel nooit op in een vat met een effectieve diameter die kleiner is dan 2,5 mm. Vaatletsel, ischemie en/of occlusie kunnen het gevolg zijn. Als de druk in een vat daalt nadat de Guidezilla-katheter is ingebracht, dient u de Guidezilla-katheter terug te trekken totdat de normale druk is hersteld.

4. Bevestig met toepassing van fluorescopie de gewenste positie van het Guidezilla-hulpmiddel in het vat.
5. Indien u een interventionele ingreep uitvoert, schuift u het interventiehulpmiddel over de voerdraad en voert u het hulpmiddel door de geleidekatheter en het Guidezilla-hulpmiddel op in de gewenste vasculaire ruimte.

Opmerking: wees voorzichtig bij het opvoeren van het interventiehulpmiddel in het distale geleidesegment.

6. Bevestig de hemostaseklep met Y-adapter goed op de proximale schacht van het Guidezilla hulpmiddel om terugstromen te voorkomen.
7. Voer de katherisatieprocedure uit. Verwijder na voltooiing van de procedure het Guidezilla-hulpmiddel voordat u de geleidekatheter uit het vat verwijdert.

GARANTIE

Boston Scientific Corporation (BSC) garandeert dat er redelijke zorg is betracht bij het ontwerpen en vervaardigen van dit instrument. **Deze garantie vervangt en ontkracht alle andere garanties die hier niet worden vermeld, hetzij uitdrukkelijk, hetzij impliciet door de werking van de wet of anderszins, met inbegrip van, maar niet beperkt tot, geïmpliceerde garanties van verkoopbaarheid of geschiktheid voor een bepaald doel.** Hanteren, opslag, schoonmaken en sterilisatie van dit instrument alsmede andere factoren in verband met de patiënt, diagnose, behandeling, chirurgische ingrepen en andere zaken die buiten de macht van BSC vallen, zijn direct van invloed op het instrument en de resultaten die ermee worden verkregen. De aansprakelijkheid van BSC volgens deze garantievoorwaarden is beperkt tot het repareren of vervangen van dit instrument; BSC aanvaardt geen aansprakelijkheid voor incidentele of bijkomende schade die direct dan wel indirect voortvloeit uit gebruik van dit instrument. BSC aanvaardt geen, en geeft niemand de bevoegdheid tot het in naam van BSC aanvaarden van, andere of aanvullende aansprakelijkheid of verantwoordelijkheid in verband met dit instrument. **BSC aanvaardt geen aansprakelijkheid voor instrumenten die opnieuw zijn gebruikt, verwerkt of gesteriliseerd en biedt geen uitdrukkelijke dan wel impliciete garanties in verband met zulke instrumenten, met inbegrip van, maar niet beperkt tot, garanties van verkoopbaarheid of geschiktheid voor een bepaald doel.**

Guidezilla™

Cateter-guia de Extensão (5 em 6)

℞ ONLY

Cuidado: A lei federal (EUA) só permite a venda deste dispositivo sob receita médica.

ADVERTÊNCIA

O conteúdo é fornecido ESTERILIZADO por óxido de etileno (EO). Não utilize se o selo de esterilização estiver danificado. Se verificar a presença de quaisquer danos no produto, contacte o seu representante da Boston Scientific.

Apenas para uma única utilização. Não reutilize, reprocesse nem reesterilize. A reutilização, o reprocessamento ou a reesterilização podem comprometer a integridade estrutural do dispositivo e/ou provocar a sua falha, o que, por sua vez, pode causar lesões, doença ou a morte do paciente. A reutilização, o reprocessamento ou a reesterilização também acarretam o risco de contaminação do dispositivo e/ou o risco de infecção no paciente ou infecção cruzada incluindo mas não se limitando à transmissão de doença(s) contagiosa(s) de um paciente para outro. A contaminação do dispositivo pode causar lesões, doença ou a morte do paciente.

Depois de utilizar, deite fora o produto e a embalagem de acordo com a política do hospital, administrativa e/ou do governo local.

¿SCRIÇÃO DO DISPOSITIVO

O cateter-guia de extensão Guidezilla é um cateter de troca rápida de lúmen único compatível com cateteres-guia de 6 F e que pode ser colocado sobre um fio-guia de troca ou 180 cm de comprimento. O dispositivo de 145 cm possui um corpo proximal de aço inoxidável com um segmento-guia distal de lúmen único de 25 cm, com um revestimento hidrofílico.

O dispositivo Guidezilla possui duas bandas marcadoras de platina/irídio, que permitem visualizar o dispositivo aquando da utilização de métodos fluoroscópicos padrão. A banda marcadora distal está localizada a uma distância de 2 mm da ponta distal. A banda marcadora proximal está localizada a uma distância de 3 mm distalmente em relação à abertura do segmento-guia. O dispositivo possui duas marcas de posicionamento localizadas a uma distância de 90 cm (marcação única) e 100 cm (marcação dupla) da ponta distal, respectivamente.

O dispositivo Guidezilla é introduzido através de um cateter-guia, resultando num diâmetro interno que é aproximadamente 1 tamanho French mais pequeno em relação ao cateter-guia. O dispositivo Guidezilla possui uma patilha proximal que indica a compatibilidade entre o diâmetro interno e o cateter-guia.

Tabela 1. Informações sobre compatibilidade

Modelo	Fio-guia compatível	Cateter-guia compatível	D.I. mín. Guidezilla
6 F (5 em 6)	≤ 0,014 in (0,36 mm)	≥ 6 F / ≥ 0,070 in de D.I. (1,78 mm)	0,057 in (1,45 mm)

CONTEÚDO

Qtd	Material
Um (1)	cateter-guia de extensão Guidezilla de utilização única

UTILIZAÇÃO PREVISTA/INDICAÇÕES DE UTILIZAÇÃO

O cateter-guia de extensão Guidezilla destina-se a ser utilizado em conjunto com cateteres-guia para aceder a regiões distintas da vasculatura coronária e/ou periférica e para facilitar a colocação de dispositivos de intervenção.

CONTRA-INDICAÇÕES

- Vasos com diâmetro inferior a 2,5 mm.
- Vasos na neurovasculatura e sistema venoso.

ADVERTÊNCIAS

- Utilize o produto antes do vencimento da data de validade indicada no rótulo.
- Nunca avance o dispositivo Guidezilla num vaso sem a orientação de um fio-guia ou sem confirmar a localização por intermédio de orientação fluoroscópica. Pode ocorrer uma dissecção ou perfuração do vaso.
- Devido à dimensão e ao facto da ponta do dispositivo Guidezilla não ser cónica, é necessário ter extremo cuidado para evitar uma isquemia do vaso ou lesões vasculares.
- Nos casos em que existe um espaço livre limitado entre os dispositivos de intervenção e o lúmen do segmento-guia distal, estes dispositivos devem ser avançados e retirados lentamente com a válvula hemostática aberta para reduzir o risco de embolia.
- Este dispositivo não é passível de torção. Qualquer torção do dispositivo pode resultar num enrolamento dos fios, danos no dispositivo ou lesões no vaso.
- Nunca faça avançar o dispositivo Guidezilla para dentro de um vaso com um diâmetro efectivo inferior a 2,5 mm. Poderão ocorrer lesões, isquemia e/ou oclusão do vaso. Se a pressão num vaso reduzir depois de inserir o cateter Guidezilla, retire o cateter Guidezilla até a pressão voltar ao normal.

PRECAUÇÕES

- Inspeccione o dispositivo antes da utilização para verificar se existem quaisquer dobras ou torções. Quaisquer danos no dispositivo podem diminuir as características de desempenho desejadas.
- O lúmen do dispositivo deve ser completamente irrigado com solução salina heparinizada antes da utilização.
- Este dispositivo só deve ser utilizado por médicos com bastante experiência em técnicas e procedimentos intravasculares percutâneos.
- Deverão ser tomadas as devidas precauções para evitar ou reduzir a coagulação durante a utilização de qualquer cateter no sistema vascular. Dever-se-á considerar a utilização de heparinização sistémica e solução salina heparinizada.
- Tenha cuidado ao manusear o dispositivo durante um procedimento, para reduzir a possibilidade de quebra, dobras ou torções acidentais.
- Quando o dispositivo estiver no corpo, só deverá ser manipulado sob fluoroscopia. Não tente mover o dispositivo sem observar a resposta produzida na ponta.

- Nunca avance o dispositivo Guidezilla™ mais de 15 cm para além da ponta do cateter-guia. Um maior avanço a nível distal do dispositivo Guidezilla poderia provocar um desalinhamento de todo o segmento-guia em relação ao cateter-guia, impedindo a remoção do dispositivo.
- Se sentir uma forte resistência durante a manipulação dos dispositivos, não force a passagem. Determine a causa da resistência antes de continuar. Caso não seja possível remover a causa, retire todos os dispositivos ao mesmo tempo.

EFEITOS INDESEJÁVEIS

Os efeitos indesejáveis incluem, entre outros:

- Traumatismo do vaso (por ex., perfuração, dissecção)
- Complicação vascular (por ex., complicação no local da punção)
- Trombo
- Insuficiência renal
- Fluxo lento/oclusão
- Reacção alérgica
- Morte
- Êmbolos
- Hemorragia/hematoma (por ex., complicação no acesso vascular)
- Infecção
- Enfarte do miocárdio
- Espasmo arterial
- Dissecção da íntima

FORMA DE APRESENTAÇÃO DO PRODUTO

A embalagem destina-se a manter a esterilidade em conformidade com a data de validade indicada no rótulo. Não utilize se a embalagem estiver aberta ou danificada. Não utilize se a etiquetagem estiver incompleta ou ilegível.

Outros itens necessários mas não fornecidos:

- Cateter-guia com um diâmetro interno suficientemente grande para acomodar o dispositivo Guidezilla
- Adaptador em Y com válvula hemostática
- Fio-guia com um diâmetro ≤ 0,014 in (0,36 mm)
- Seringa esterilizada (para irrigação do sistema)
- Solução heparinizada esterilizada (para irrigação do sistema)

Manuseio e armazenamento

Guarde num local fresco, seco e escuro.

INSTRUÇÕES DE OPERAÇÃO

Preparação para utilização

1. Antes de utilizar, inspeccione cuidadosamente a embalagem do dispositivo Guidezilla e respectivos componentes para verificar se apresentam danos.
2. Utilizando uma técnica asséptica, transfira a tubagem de protecção com o dispositivo Guidezilla para o campo esterilizado.
3. Com cuidado, remova o dispositivo Guidezilla da respectiva tubagem de protecção. Não dobre nem torça o dispositivo durante a remoção.
4. Mergulhe o segmento-guia distal em solução salina heparinizada.

Procedimento de introdução

Proceda à introdução do dispositivo Guidezilla de acordo com os passos seguintes:

1. Fixe o fio-guia previamente inserido e retrocarregue a ponta distal do dispositivo Guidezilla no fio-guia e avance até que o dispositivo fique numa posição imediatamente proximal em relação à válvula hemostática.
2. Abra a válvula hemostática e avance o dispositivo Guidezilla através da válvula hemostática e para dentro do cateter-guia.
3. Sob fluoroscopia, avance o dispositivo Guidezilla até, no máximo, 15 cm para além da ponta distal do cateter-guia e para a localização pretendida dentro do vaso.

Advertência: Devido à dimensão e ao facto da ponta do dispositivo Guidezilla não ser cónica, é necessário ter extremo cuidado para evitar a oclusão do vaso e lesões na parede dos vasos através da passagem deste cateter.

Advertência: Nunca faça avançar o dispositivo Guidezilla para dentro de um vaso com um diâmetro efectivo inferior a 2,5 mm. Poderão ocorrer lesões, isquemia e/ou oclusão do vaso. Se a pressão num vaso reduzir depois de inserir o cateter Guidezilla, retire o cateter Guidezilla até a pressão voltar ao normal.

4. Recorrendo a fluoroscopia, confirme a posição pretendida do dispositivo Guidezilla no vaso.
5. Caso esteja a ser efectuado um procedimento de intervenção, retrocarregue o dispositivo de intervenção pelo fio-guia e avance o dispositivo através do cateter-guia e o dispositivo Guidezilla no espaço vascular pretendido.

Nota: Tenha cuidado ao avançar o dispositivo de intervenção no segmento-guia distal.

6. Aperte devidamente a válvula hemostática do adaptador em Y no corpo proximal do dispositivo Guidezilla para evitar o refluxo de sangue.
7. Efectue o procedimento de cateterização. Uma vez concluído o procedimento, retire o dispositivo Guidezilla antes de remover o cateter-guia do vaso.

GARANTIA

A Boston Scientific Corporation (BSC) garante que foram tomados todos os cuidados devidos na concepção e fabrico deste instrumento. **Esta garantia substitui e exclui todas as outras aqui não expressamente mencionadas, explícitas ou implícitas por força de lei, ou de qualquer outra forma, incluindo, mas não se limitando a, quaisquer garantias implícitas de comercialização ou adequação para fins específicos.** O manuseio, o armazenamento, a limpeza e a esterilização deste instrumento, bem como os factores relacionados com o paciente, diagnóstico, tratamento, procedimentos cirúrgicos e outros assuntos fora do controlo da BSC afectam directamente o instrumento e os resultados obtidos pela sua utilização. A responsabilidade da BSC, de acordo com esta garantia, limita-se à reparação ou substituição deste instrumento e a BSC não se responsabiliza por quaisquer perdas, danos ou despesas incidentais ou consequenciais resultantes, directa ou indirectamente, da utilização deste instrumento. A BSC não assume, nem autoriza qualquer outra pessoa a assumir em seu nome, qualquer outra obrigação ou responsabilidade adicional em relação a este instrumento. **A BSC não assume nenhuma responsabilidade relativamente a instrumentos reutilizados, reprocessados ou reesterilizados e não estabelece quaisquer garantias, explícitas ou implícitas, incluindo mas não se limitando à comercialização ou adequação para fins específicos, em relação a estes instrumentos.**

REF
Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência

Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi
Gebrauchsanweisung beachten
Consultare le istruzioni per l'uso
Raadpleeg instructies voor gebruik.
Consulte as instruções de Utilização

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EC REP
EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

LOT
Lot
Lote
Lot
Charge
Lotto
Partij
Lote

UPN
Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

AUS
Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano

For single use only. Do not reuse.
Para un solo uso. No reutilizar.
A usage unique. Ne pas réutiliser
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken
Apenas para uma única utilização. Não reutilize

Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

Do not use if package is damaged.
No usar si el envase está dañado
Ne pas utiliser si l'emballage est endommagé
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd
Não utilize se a embalagem estiver danificada.

STERILE EO
Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide
Esterilizado por óxido de etileno

ID
Inner Diameter
Diámetro interno
Diamètre interne
Innendurchmesser
Diametro interno
Binnendiameter
Diâmetro Interno

ID
Guide Catheter Inner Diameter
Diámetro interno del catéter guía
Diamètre interne du cathéter guide
Innendurchmesser des Führungskatheters
Diametro interno del catetere guida
Binnendiameter geleidekatheter
Diâmetro Interno do Cateter-guia

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Free Fax 1800 836 666

Legal Manufacturer

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

CE 0344

2013-02

90830507-01

Exhibit 26

GuideLiner® V2 Catheter

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Minneapolis, MN 55369
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(888) 240-6001 USA
(763) 656-4300
(763) 656-4250
www.vasc.com

EC REP
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Newcastle Road
Galway
Ireland
Phone +353 91 861611
Fax +353 91 861612

CE 0344

GuideLiner® Catheter Instructions For Use

USA CAUTION

Federal law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The GuideLiner catheter is a single lumen rapid exchange catheter offered in sizes compatible with 6F, 7F, and 8F guide catheters and may be placed over an exchange length or 180cm guidewire. The larger sizes of GuideLiner catheters are intended to be used within the proximal portions of the coronary vasculature to provide support and/or facilitate use of multiple interventional devices. The 150cm device has a stainless steel shaft with a 25cm single lumen wiped with silicone.

The GuideLiner catheter has two platinum-iridium marker bands, which enable visibility while using standard fluoroscopic methods. The distal marker band is located 0.085" / 2.16mm from the distal tip. The proximal marker band is located 1cm from the collar. The device has two positioning marks located at 95cm (single mark) and 105cm (double mark) from the distal tip, respectively.

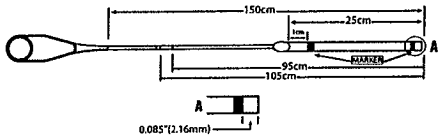
The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter. The GuideLiner catheter has a proximal tab which indicates guide catheter compatibility and the resulting GuideLiner catheter inner diameter.

The GuideLiner catheter has been sterilized with ethylene oxide.

STERILE EO

SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner Min. I.D.	GuideLiner Tip O.D.
5570 5.5F	≥ 6F (≥ 0.066" / 1.68mm I.D.)	0.051" / 1.30mm	0.063" / 1.60mm
5571 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm	0.067" / 1.70mm
5572 7F	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" / 1.57mm	0.075" / 1.90mm
5573 8F	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" / 1.80mm	0.085" / 2.16mm



INDICATIONS

GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guidewires and other interventional devices.

CONTRAINDICATIONS

The GuideLiner catheters are contraindicated in vessels less than 2.5mm in diameter, vessels in the neurovasculature and the venous system.

WARNINGS

The GuideLiner catheter is provided sterile for single use only. Reuse of single-use device creates a potential risk of patient or user infections. Contamination of the device may lead to illness or serious patient injury

Never advance the GuideLiner catheter into a vessel without a leading guidewire or without confirming location using fluoroscopic guidance. Vessel dissection or perforation may result.

Never advance the GuideLiner catheter into a vessel with an effective diameter less than 2.5mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting the GuideLiner catheter, withdraw the GuideLiner catheter until the pressure returns to normal.

Due to the size and non-tapered tip of the GuideLiner, extreme care must be taken to avoid vessel occlusion and damage to the wall of the vessels through which this catheter passes.

Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.

PRECAUTIONS

Do not use the GuideLiner catheter if the packaging has been damaged.

Inspect the GuideLiner catheter prior to use for any bends or kinks. Do not use a damaged catheter. Vessel damage and/or inability to advance or withdraw the catheter may occur.

The catheter lumen should be thoroughly flushed with heparinized saline prior to use to prevent clot formation.

The GuideLiner catheter deployment procedure should be performed by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. Use of systemic heparinization and heparinized sterile solution should be considered.

Exercise care in handling of the catheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.

When the catheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the catheter without observing the resultant tip response.

Never advance the GuideLiner catheter more than 15cm beyond the tip of the guide catheter as the GuideLiner catheter may become lodged in the guide catheter making it difficult to remove.

COMPLICATIONS

The following complications are generally associated with catheterization procedures and may occur when using the GuideLiner catheter:

- local or systemic infection
- air embolism
- intimal disruption
- arterial dissection
- perforation of the vessel wall
- vascular occlusion
- arterial thrombosis
- myocardial infarction
- arterial spasm

CLINICAL PROCEDURE

The GuideLiner catheter should be used by physicians trained on the procedures for which the device is intended. The techniques and procedures described do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient. All available data, including the patient's signs and symptoms and other diagnostic test results, should be considered before determining a specific treatment plan.

Package contains:

- Single-use disposable GuideLiner catheter

Other items required but not provided:

- Guide catheter with an inner diameter large enough to accommodate the specific model of GuideLiner catheter in use
- Y-adaptor with hemostasis valve (Tuohy-Borst type)
- Guidewire with diameter ≤ 0.014" / 0.36mm
- Sterile syringe (for system flushing)
- Sterile heparinized saline (for system flushing)

PREPARATIONS FOR USE

1. Prior to use, carefully inspect the GuideLiner catheter packaging and components for damage.
2. Using sterile technique, transfer the dispenser coil with the GuideLiner catheter into the sterile field.
3. Thoroughly flush the lumen of the GuideLiner catheter from the distal tip with heparinized saline solution.

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DEPLOYMENT PROCEDURE

Deploy the GuideLiner catheter according to the following steps:

1. Secure the previously inserted guidewire and backload the distal tip of the GuideLiner catheter onto the guidewire and advance until the catheter is just proximal to the hemostasis valve.
2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter.
3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel.

   Warning: Never advance the GuideLiner catheter into a vessel with an effective diameter less than 2.5mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting the GuideLiner catheter, withdraw the GuideLiner catheter until the pressure returns to normal.

   Warning: Due to the size and non-tapered tip of the GuideLiner, extreme care must be taken to avoid vessel occlusion and damage to the wall of the vessels through which this catheter passes.
4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel.
5. If performing an interventional procedure, backload the interventional device over the in place guidewire and advance the device through the guide catheter and GuideLiner catheter into the desired vascular space.
6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding.
7. Perform the catheterization procedure. After completing the procedure, remove the GuideLiner catheter prior to removing the guide catheter from the vessel.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the GuideLiner catheter is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product, which has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Vascular Solutions, Inc. shall not be liable for any incidental, special or consequential damages arising from the use of the GuideLiner catheter. Damage to the product through misuse, alteration, improper storage or improper handling shall void this limited warranty.

No employee, agent or distributor of Vascular Solutions, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Vascular Solutions, Inc.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF VASCULAR SOLUTIONS, INC.

PATENTS AND TRADEMARKS

US Patent 8048032, 8142413, 8292850.

GuideLiner® is a registered trademark of Vascular Solutions, Inc.

Katétr GuideLiner®
Návod k použití

UPOZORNĚNÍ PRO USA

Federální zákon (USA) omezuje prodej tohoto zařízení pouze na objednávky učiněné na předpis lékaře.

POPIS ZAŘÍZENÍ

Katétr GuideLiner je jednocestný katétr pro rychlou výměnu, dodávaný ve velikostech kompatibilních se zaváděcími katétry 6F, 7F a 8F, který může být nasunut na výměnný vodicí drát nebo na vodicí drát o délce 180 cm. Katétry GuideLiner větší velikosti jsou určeny ; použití v proximálních oddílech koronárních cév a .mají poskytovat podporu a usnadnit použití několika intervenčních zařízení. Zařízení o délce 150 cm má tělo z nerezové oceli s jediným luminem o délce 25 cm potaženým silikonem.

Na katétru GuideLiner jsou dvě značky z platiny-iridia, které při standardních skiaskopických metodách umožňují viditelnost. Distální značka je umístěna 2.16 mm od distální špičky. Proximální značka je umístěna 1 cm od kroužku. Na zařízení jsou také dvě značky pro určení polohy umístěné 95 cm (jednoduchá značka) a 105 cm (dvojitá značka) od distální špičky.

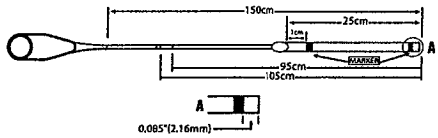
Katétr GuideLiner se zavádí zaváděcím katétrem, což znamená, že vnitřní průměr je přibližně o 1 French menší, než zaváděcí katétr. Na katétru GuideLiner je proximální štítek, na kterém je vyznačena kompatibilita se zaváděcím katétrem a výsledný vnitřní průměr katétru GuideLiner.

Katétr GuideLiner byl sterilizován etylénoxidem.

STERILE EO

SPECIFIKACE

Model	Kompatibilní zaváděcí katétr	Minimální vnitřní průměr katétru GuideLiner	Vnější průměr špičky katétru GuideLiner
5570 5,5F	≥ 6F (vnitřní průměr ≥ 0,066"/ 1,68 mm)	0,051"/ 1,30 mm	0,063"/ 1,60 mm
5571 6F	≥ 6F (vnitřní průměr ≥ 0,070"/ 1,78 mm)	0,056"/ 1,42 mm	0,067"/ 1,70 mm
5572 7F	≥ 7F (vnitřní průměr ≥ 0,078"/ 1,98 mm)	0,062"/ 1,57 mm	0,075"/ 1,90 mm
5573 8F	≥ 8F (vnitřní průměr ≥ 0,088"/ 2,24 mm)	0,071"/ 1,80 mm	0,085"/ 2,16 mm



INDIKACE

Katétry GuideLiner jsou určeny k použití společně se zaváděcími katétry při přístupu do přerušovaných oblastí koronárních nebo periferních cév a k usnadnění umístění a výměny vodicích drátů a jiných zařízení používaných při intervenčních výkonech.

KONTRAINDIKACE

Použití katétrů GuideLiner je kontraindikováno v cévách o průměru menším než 2,5 mm, v cévách zásobujících nervový systém a ve venózním systému.

VAROVÁNÍ

Katétr GuideLiner je dodáván sterilní a je určen pouze k jednorázovému použití. Opakované používání výrobku pro jednorázové použití vystavuje pacienta nebo uživatele potenciálnímu riziku infekce. Kontaminace zařízení může vést k onemocnění nebo k závažnému poškození pacienta

Katétr GuideLiner nikdy nezavádějte do cévy bez vedoucího vodicího drátu a aniž by byla potvrzena jeho poloha skiaskopickou kontrolou. Mohlo by dojít k disekci nebo perforaci cévy.

Katétr GuideLiner nikdy nezavádějte do cévy s efektivním průměrem menším než 2,5 mm. Mohlo by dojít k poranění, ischemii nebo okluzi cévy. Pokud se po zavedení katétru GuideLiner v cévě sníží tlak, vytáhněte katétr GuideLiner až do doby, kdy se tlak vrátí k normálu.

Vzhledem k tomu, že konec katétru GuideLiner není zúžený, a vzhledem k jeho velikosti je nutno postupovat s maximální opatrností, aby nedošlo k okluzi cévy a poškození stěny cévy, kterou katétr prochází.

Nikdy nezavádějte ani nevytahujte intravaskulární zařízení, cítíte-li odpor. Nejprve zjistěte příčinu odporu pomocí skiaskopie. Pohyb katétru nebo vodicího drátu proti odporu může vést k odtržení špičky katétru nebo vodicího drátu, k poškození katétru nebo k perforaci cévy.

BEZPEČNOSTNÍ OPATŘENÍ

Katétr GuideLiner nepoužívejte, pokud došlo k poškození obalu.

Před použitím katétr GuideLiner prohlédněte, zda není ohnutý nebo zauzlený. Poškozený katétr nepoužívejte. Mohlo by to vést k poškození cévy a/nebo k nemožnosti katétr zavést nebo vytáhnout.

Lumen katétru je nutno před použitím důkladně propláchnout heparinizovaným fyziologickým roztokem, aby se zabránilo srážení krve.

Umístění katétru GuideLiner by měl provádět lékař důkladně vyškolený v perkutánních intravaskulárních technikách a postupech.

Při používání jakéhokoli katétru v cévním systému musí být provedena opatření k prevenci nebo omezení srážení krve. Zvažte vhodnost systémové heparinizace a použití heparinizovaného sterilního roztoku.

Při manipulaci s katétrem během výkonu postupujte opatrně, abyste snížili riziko jeho náhodného přetržení, ohnutí nebo zauzlení.

Je-li katétr zaveden uvnitř těla, smí se s ním manipulovat pouze pod skiaskopickou kontrolou. Nepokoušejte se hýbat katétrem, aniž byste sledovali výsledný pohyb jeho špičky.

Nikdy nezavádějte katétr GuideLiner dále než 15 cm za špičku zaváděcího katétru, protože katétr GuideLiner se může zachytit v zaváděcím katétru a jeho vytažení může být obtížné.

KOMPLIKACE

Následující komplikace jsou obecně spojeny s katetrizačními výkony a může k nim dojít při používání katétru GuideLiner:

- lokální nebo systémová infekce
- vzduchová embolie
- natržení intimy
- arteriální disekce
- perforace cévní stěny
- cévní okluze
- arteriální trombóza
- infarkt myokardu
- arteriální spazmus

KLINICKÝ VÝKON

Katétr GuideLiner by měl používat pouze lékař školený k výkonům, pro něž je zařízení určeno. Popsané techniky a postupy nepředstavují VŠECHNYmedicínsky přijatelné protokoly, ani nenahrazují zkušenosti lékaře a jeho úsudek při léčbě konkrétních pacientů. Před rozhodnutím o příslušném plánu léčby je nutno uvážit všechny údaje, které jsou k dispozici, včetně známek a příznaků pacienta a výsledků dalších diagnostických vyšetření.

Balení obsahuje:

- Jednocestný katétr GuideLiner k jednomu použití

Ostatní potřebné položky, které nejsou součástí:

- Zaváděcí katétr s dostatečně velkým vnitřním průměrem, aby se do něj vešel příslušný model katétru GuideLiner, který má být použit
- Y-spojka s hemostatickým ventilem (typu Tuohy-Borst)
- Vodicí drát o průměru ≤ 0,36 mm
- Sterilní injekční stříkačka (k proplachování systému)
- Sterilní heparinizovaný fyziologický roztok (k proplachování systému)

PŘÍPRAVA K POUŽITÍ

1. Před použitím pečlivě prohlédněte obal katétru GuideLiner a jeho součásti, zda nejsou poškozeny.
2. Za použití sterilní techniky přeneste zásobník s katétrem GuideLiner do sterilního pole.
3. Důkladně propláchněte lumen katétru GuideLiner od distální špičky heparinizovaným fyziologickým roztokem.

POSTUP ZAVEDENÍ

Katétr GuideLiner zavádějte podle následujících kroků:

1. Dříve zavedený vodicí drát zajistěte, nasaďte distální špičku katétru GuideLiner na vodicí drát a zavádějte jej, až bude katétr proximálně téměř u hemostatického ventilu.
2. Otevřete hemostatický ventil a zaveďte katétr GuideLiner hemostatickým ventilem do zaváděcího katétru.
3. Za skiaskopické kontroly zavádějte katétr GuideLiner do vzdálenosti maximálně 15 cm za distální špičku zaváděcího katétru a do potřebného místa v cévě.

   Varování: Katétr GuideLiner nikdy nezavádějte do cévy s efektivním průměrem menším než

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2,5 mm. Mohlo by dojít k poranění, ischemii nebo okluzi cévy. Pokud se po zavedení katétru GuideLiner v cévě sníží tlak, potáhněte katétr GuideLiner zpět až do doby, kdy se tlak vrátí k normálu.

Varování: Vzhledem k tomu, že konec katétru GuideLiner není zúžený, a vzhledem k jeho velikosti je nutno postupovat s maximální opatrností, aby nedošlo k okluzi cévy a poškození stěny cévy, kterou katétr prochází.

4. Pomocí skiaskopie potvrďte, že je katétr GuideLiner v potřebné poloze v cévě.
5. Pokud provádíte intervenční výkon, nasaďte příslušné zařízení na umístěný vodicí drát a zavádějte zařízení zaváděcím katétrem a katétrem GuideLiner do potřebného prostoru v cévě.
6. Bezpečně upevněte hemostatický ventil s Y-spojkou na proximální část těla katétru GuideLiner, aby se zabránilo zpětnému krvácení.
7. Proveďte katetrizační výkon. Po dokončení výkonu vyjměte katétr GuideLiner dříve, než vytáhnete zaváděcí katétr z cévy.

OMEZENÁ ZÁRUKA

Společnost Vascular Solutions, Inc. zaručuje, že na katétru GuideLiner nebudou do uplynutí uvedené doby použitelnosti zpracovatelské ani materiálové vady. Odpovědnost podle této záruky je omezena na refundaci nebo výměnu jakéhokoli výrobku, u něhož byly ze strany společnosti Vascular Solutions, Inc. shledány zpracovatelské či materiálové vady. Společnost Vascular Solutions, Inc. nebude odpovídat za žádné náhodné, zvláštní či následné škody vzniklé při používání katétru GuideLiner. Poškození výrobku způsobená nesprávným použitím, pozměněním, nesprávným skladováním nebo nevhodnou manipulací ruší platnost této omezené záruky.

Žádný zaměstnanec, zástupce ani distributor společnosti Vascular Solutions, Inc. nemá v žádném ohledu žádnou pravomoc pozměnit či doplnit tuto omezenou záruku. Následky jakéhokoli záměrného pozměnění či doplnění nebudou u společnosti Vascular Solutions Inc. vymahatelné.

TATO ZÁRUKA JE POSKYTNUTA VÝSLOVNĚ NAMÍSTO VŠECH OSTATNÍCH VÝSLOVNÝCH NEBO NEPŘÍMÝCH ZÁRUK, VČETNĚ JAKÉKOLI ZÁRUKY UPLATNITELNOSTI NA TRHU NEBO VHODNOSTI KE KONKRÉTNÍMU ÚČELU NEBO JAKÉHOKOLI ZÁVAZKU SPOLEČNOSTI VASCULAR SOLUTIONS, INC.

PATENTY A OBCHODNÍ ZNAČKY

GuideLiner® je registrovaná obchodní značka společnosti Vascular Solutions, Inc.

GuideLiner®-kateter Brugsanvisning

ADVARSEL GÆLDENDE FOR USA

Ifølge amerikansk lovgivning må denne anordning kun sælges af eller på foranledning af en læge.

BESKRIVELSE AF ENHEDEN

GuideLiner-kateteret er et enkeltlumenkateter beregnet til hurtig udskiftning og leveres i størrelser, der er kompatible med 6F, 7F og 8F guide-katetre og kan placeres over en udvekslingslængde eller 180 cm guidewire. De større størrelser GuideLiner-katetre er beregnet til at blive anvendt inden for den proximale del af koronarvaskulaturen til at yde støtte og / eller lette brugen af flere interventionelle enheder. 150 cm anordningen har et skaft i rustfrit stål med et enkelt lumen på 25 cm, der er aftørret med silikone.

GuideLiner-kateteret har to platin-iridium markørbånd, der letter aflæsningen ved anvendelse af standard fluoroskopiske metoder. Det distale markørbånd sidder 2.16 mm fra den distale spids. Det proksimale markørbånd sidder 1 cm fra kraven. Anordningen har to placeringsmærker placeret henholdsvis 95 cm (enkelt mærkede) og 105 cm (dobbelt mærkede) fra den distale spids.

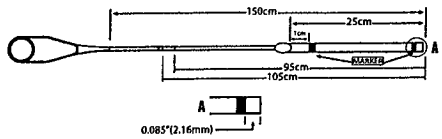
GuideLiner-kateteret leveres gennem et guide kateter, hvilket giver anledning til en indre diameter, der er ca. 1 french mindre end guide-kateteret. GuideLiner-kateteret har en proksimal tap, der angiver guide kateterets kompatibilitet og den deraf følgende indre diameter af GuideLiner-kateteret.

GuideLiner-kateteret er blevet steriliseret med ethylenoxid.

STERILE EO

SPECIFIKATIONER

Model	Kompatibelt guide-kateter	GuideLiner min. I.D.	GuideLiner spids O.D.
5570 5,5F	≥ 6F (≥ 0,066"/1,68 mm I.D.)	0,051"/ 1,30 mm	0,063"/ 1,60 mm
5571 6F	≥ 6F (≥ 0,070"/1,78 mm I.D.)	0,056"/1,42 mm	0,067"/1,70 mm
5572 7F	≥ 7F (≥ 0,078"/1,98 mm I.D.)	0,062"/1,57 mm	0,075"/1,90 mm
5573 8F	≥ 8F (≥ 0,088"/2,24 mm I.D.)	0,071"/1,80 mm	0,085"/2,16 mm



INDIKATIONER

GuideLiner-katetre er beregnet til anvendelse sammen med guide-katetre for at få adgang diskrete områder af koronar og/eller perifer vaskulatur og for at lette placering og udveksling af guidewirer og andre interventionelle enheder.

KONTRAINDIKATIONER

GuideLiner-katetre er kontraindiceret i kar, der er mindre end 2,5 mm i diameter, kar i neurovaskulaturen og i venesystemet.

ADVARSLER

GuideLine-kateteret leveres kun sterilt til engangsbrug. Genbrug af engangsenheder skaber en potentiel risiko for infektion af patienten eller brugeren. Kontaminering af anordningen kan medføre sygdom eller alvorlig patientskade.

Før aldrig GuideLiner-kateteret ind i et kar uden en ledeguidewire eller uden at kontrollere placeringen ved hjælp af fluoroskopi. Det kan give anledning til kardissektion eller perforation.

Før aldrig GuideLiner-kateteret ind i et kar med en effektiv diameter på under 2,5 mm. Det kan give anledning til karskade, iskæmi og/eller okklusion. Hvis trykket i et kar aftager, når GuideLiner-kateteret er ført ind, skal GuideLiner-kateteret trækkes ud, indtil trykket vender tilbage til det normale niveau.

På grund af GuideLiners størrelse og ikke-koniske spids skal du være meget forsigtig for at undgå karokklusion og skader på væggene i de kar, hvorigennem dette kateter passerer.

Før aldrig en intravaskulær enhed frem eller tilbage hvis den møder modstand, før årsagen til modstanden er fastlagt med fluoroskopi. Bevægelse af kateteret eller guidewiren ved modstand kan medføre, at kateteret eller guidewirens spids adskilles, at der opstår skade på kateteret eller en perforering af blodkar.

FORHOLDSREGLER

Anvend ikke GuideLiner, hvis emballagen er beskadiget.

Undersøg GuideLiner-kateteret for bukninger eller knæk før brugen. Anvend ikke et beskadiget kateter. Der kan opstå skade på blodkar og/eller det kan blive umuligt at fremføre eller trække kateteret tilbage.

Kateterets lumen skal skylles grundigt med heparineret saltvand før brugen for at forhindre koagulering.

GuideLiner-kateterets anlæggelsesprocedure skal udføres af læger med en omfattende træning i perkutane, intravaskulære teknikker og procedurer.

Der bør træffes forholdsregler for at forebygge eller mindske koagulation, når et kateter anvendes i det vaskulære system. Brug af systemisk heparinisering og heparineret steril opløsning bør overvejes.

Håndtér kateteret forsigtigt under proceduren for at reducere risikoen for at det knækker ved et uheld, bliver bøjet eller får et knæk.

Når kateteret er i kroppen, bør det kun håndteres under fluoroskopi. Forsøg ikke at bevæge kateteret uden at observere spidsens deraf følgende reaktion.

Fremfør aldrig GuideLiner-kateteret mere end 15 cm ud over spidsen af guidekateteret, da GuideLiner-kateteret kan blive fastklemt i guidekateteret og gøre det vanskeligt at fjerne.

KOMPLIKATIONER

Følgende komplikationer er generelt forbundet med kateterisationsprocedurer og kan forekomme, når du bruger GuideLiner-kateteret:

- lokal eller systemisk infektion
- luftemboli
- intimal forstyrrelse
- arteriel dissektion
- perforering af blodkarvæg
- vaskulær okklusion
- arteriel trombose
- myokardieinfarkt
- arteriel krampe

KLINISK PROCEDURE

GuideLiner-kateteret bør anvendes af læger, der er uddannet i de procedurer, som anordningen er beregnet til. De beskrevne teknikker og procedurer repræsenterer ikke ALLE lægeligt acceptable protokoller, og de er heller ikke beregnet som en erstatning for lægens erfaring og vurdering under behandling af en specifik patient. Alle tilgængelige data, herunder patientens tegn og symptomer og andre diagnostiske testresultater, bør tages med i betragtning før en specifik behandlingsplan fastsættes.

Pakken indeholder:

- GuideLiner-kateter til engangsbrug

Andre ting som kræves, men ikke medfølger:

- Guide-kateter med en indre diameter, der er stor nok til at have plads til den anvendte type model GuideLiner-kateter
- Y-adapter med hæmostaseventil (Tuohy-Borst typen)
- Guidewire med diameter ≤ 0,36 mm
- Steril sprøjte (til skylning af systemet)
- Sterilt hepariniseret saltvand (til skylning af systemet)

KLARGØRING TIL BRUG

1. Inspicer omhyggeligt GuideLiner-kateteret inden brug for beskadiget emballage og komponentskader.
2. Overfør, ved brug af sterile teknikker, udrulningsspiralen med GuideLiner-kateteret til det sterile område.
3. Skyl GuideLiner-kateterets lumen grundigt fra den distale spids med heparineret saltvand.

INDFØRINGSPROCEDURE

Brug GuideLiner-kateteret i henhold til følgende fremgangsmåde:

1. Fastgør den tidligere indsatte guidewire og sæt den distale spids af GuideLiner-kateteret fast på guidewiren og fremfør, indtil kateteret lige netop er proksimalt for hæmostaseventilen.
2. Åbn hæmostaseventilen og fremfør GuideLiner-kateteret gennem hæmostaseventilen og ind i guide-kateteret.
3. Før GuideLiner-kateteret under fluoroskopi op til højst 15 cm forbi guide-kateterets distale spids og ind i det ønskede sted i karret.

   Advarsel: Før aldrig GuideLiner-kateteret ind i et kar med en effektiv diameter på under 2,5 mm. Det kan give anledning til karskade, iskæmi og/eller okklusion. Hvis trykket i et kar aftager, når GuideLiner-kateteret er ført ind, skal GuideLiner-kateteret trækkes ud, indtil trykket vender tilbage til det normale niveau.

   Advarsel: På grund af GuideLiners størrelse og ikke-koniske spids skal du være meget forsigtig for at undgå karokklusion og skader på væggene i de kar, hvorigennem dette kateter passerer.passes
4. Kontrollér ved hjælp af fluoroskopi, at GuideLiner-kateteret sidder det ønskede sted i karret.
5. Hvis der udføres en interventionel procedure, sættes den interventionelle anordning over den anbragte guidewire og fremfør anordningen gennem guide-kateteret og GuideLiner-kateteret og ind i det ønskede vaskulære område.
6. Stram Y-adapter hæmostaseventilen til på GuideLiner-kateterets proksimale skaft for at forhindre tilbageluftning.
7. Udfør kateterisationsproceduren. Når proceduren er fuldført, tages GuideLiner-kateteret ud, inden guide-kateteret fjernes fra karret.

BEGRÆNSET GARANTI

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DENNE GARANTI ERSTATTER EKSPLICIT ALLE ANDRE GARANTIER, UDTRYKKELIGE ELLER IMPLICITTE, INKLUSIV ENHVER GARANTI VEDRØRENDE SALGBARHED ELLER EGNETHED TIL ET BESTEMT FORMÅL, ELLER ANDRE FORPLIGTIGELSER FOR VASCULAR SOLUTIONS, INC.

PATENTER OG VÆREMÆRKER

GuideLiner® er et registreret varemærke, der tilhører Vascular Solutions, Inc.

GuideLiner®-Katheter Gebrauchsanweisung

WARNUNG USA

Nach US-amerikanischem Bundesrecht darf dieses Gerät nur von einem Arzt oder auf dessen Anordnung hin verkauft werden.

BESCHREIBUNG

Der GuideLiner-Katheter ist ein einlumiger Schnellwechselkatheter, der in Größen angeboten wird, die mit Führungskathetern der Größe 6F, 7F und 8F kompatibel sind und über eine Wechsel- oder 180 cm langen Führungsdraht platziert werden kann. Die größeren GuideLiner-Katheter sind für den Gebrauch in den proximalen Bereichen des koronaren Gefäßsystems vorgesehen, um Unterstützung zu liefern und/oder den Gebrauch von multiplen interventionellen Vorrichtungen zu erleichtern. Die 150 cm lange Vorrichtung hat einen Edelstahlschaft mit einem mit Silikon ausgewischten Einzellumen von 25 cm.

Der GuideLiner-Katheter hat zwei Platin-Iridium-Markierungsstreifen, die Sichtbarkeit unter Standard-Fluoroskopiemethoden erlauben. Der distale Markierungsstreifen ist 2.16 mm von der distalen Spitze entfernt. Der proximale Markierungsstreifen ist 1 cm vom Kragen entfernt. Die Vorrichtung verfügt über zwei Positionsmarkierungen bei 95 cm (einzelne Markierung) bzw. bei 105 cm (doppelte Markierung) vor der distalen Spitze.

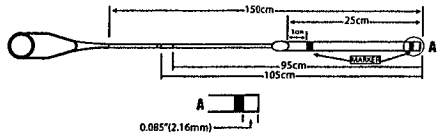
Der GuideLiner-Katheter wird über einen Führungskatheter abgegeben, was zu einem Innendurchmesser führt, der ca. 1 French kleiner ist als der Führungskatheter. Der GuideLiner-Katheter hat eine proximale Lasche, auf der die Kompatibilität des Führungskatheters und der resultierenden Innendurchmesser des GuideLiner-Katheters angegeben sind.

Der GuideLiner-Katheter wurde mit Ethylenoxid sterilisiert.

STERILE EO

TECHNISCHE DATEN

Modell	Kompatibler Führungs-katheter	GuideLiner Mindest-Innendurch-messer	Außen-durch-messer der GuideLiner-Spitze
5570 5,5F	≥ 6F (≥ 0,066"/1,68 mm Innendurch-messer)	0,051"/ 1,30 mm	0,063"/ 1,60 mm
5571 6F	≥ 6F (≥ 0,070"/1,78 mm Innendurch-messer)	0,056"/1,42 mm	0,067"/1,70 mm
5572 7F	≥ 7F (≥ 0,078"/1,98 mm Innendurch-messer)	0,062"/1,57 mm	0,075"/1,90 mm
5573 8F	≥ 8F (≥ 0,086"/2,24 mm Innendurch-messer)	0,071"/1,80 mm	0,085"/2,16 mm



HINWEISE

GuideLiner-Katheter sind für den Gebrauch zusammen mit Führungskathetern bestimmt, um unterschiedliche Bereiche des koronaren und/oder des peripheren Gefäßsystems zu erreichen und die Platzierung sowie den Austausch von Führungsdrähten und anderen interventionellen Vorrichtungen zu erleichtern.

GEGENANZEIGEN

Die GuideLiner-Katheter sind kontraindiziert in Gefäßen mit weniger als 2,5 mm Durchmesser sowie Gefäßen im Neurogefäßsystem und im venösen System.

ACHTUNG

Der GuideLiner-Katheter wird steril nur für den einmaligen Gebrauch geliefert. Mehrmaliger Gebrauch von Einweggeräten verursacht ein mögliches Risiko für Patienten- bzw. Bedienerinfektionen. Die Verunreinigung der Vorrichtung kann zu Erkrankung oder ernsthafter Verletzung des Patienten führen.

Den GuideLiner-Katheter niemals ohne einen Führungsdraht oder ohne Bestätigung der Lage unter fluoroskopischer Führung. Dies könnte zu Gefäßdissektion oder -perforation führen.

Den GuideLiner-Katheter niemals in ein Gefäß mit einem effektiven Durchmesser von weniger als 2,5 mm einführen. Dies könnte zu Gefäßverletzung, Ischämie und/oder Okklusion führen. Wenn der Druck in einem Gefäß nach der Einführung des GuideLiner-Katheters nachlässt, den GuideLiner-Katheter zurückziehen, bis sich der Druck normalisiert.

Aufgrund der Größe und nicht konischen Spitze des GuideLiner-Katheters ist sorgfältig darauf zu achten, in den Gefäßen, durch die dieser Katheter passiert, eine Gefäßokklusion und Schädigung der Gefäßwand zu vermeiden.

Intravaskuläre Vorrichtungen dürfen erst dann gegen Widerstand weitergeschoben oder herausgezogen werden, wenn die Ursache für den Widerstand durch eine Fluoroskopie geklärt ist. Die Bewegung von Katheter oder Führungsdraht gegen Widerstand kann zur Ablösung der Katheter- oder Führungsdrahtspitze, zur Beschädigung des Katheters sowie zur Perforation von Gefäßen führen.

SICHERHEITSHINWEISE

Den GuideLiner-Katheter nicht verwenden, wenn die Packung beschädigt ist.

Den GuideLiner-Katheter vor Gebrauch auf Knicke und Knickstellen untersuchen. Keinen beschädigten Katheter verwenden. Dies kann zu Schäden an Gefäßen führen und/oder das Weiterschieben bzw. Herausziehen des Katheters unmöglich machen.

Das Katheterlumen sollte vor Gebrauch gründlich mit heparinisierter Kochsalzlösung gespült werden, um Gerinnselbildung zu vermeiden.

Das Verfahren zur Einführung des GuideLiner-Katheters darf nur von Ärzten durchgeführt werden, die gründlich in der Durchführung perkutaner, intravaskulärer Techniken und Verfahren ausgebildet sind.

Beim Verwenden eines Katheters im vaskulären System sollten geeignete Vorsichtsmaßnahmen getroffen werden, um Gerinnungsbildung zu vermeiden oder zu reduzieren. Hierzu ist die Verwendung von systemischer Heparinisation und heparinisierter steriler Lösung in Betracht zu ziehen.

Während des Eingriffs den Katheter stets mit Sorgfalt handhaben, um keine unbeabsichtigte Beschädigung, Biegung oder Knickung des Katheters zu riskieren.

Wenn sich der Katheter im Körper befindet, sollte er nur unter Fluoroskopie gehandhabt werden. Den Katheter nur bewegen, wenn eine entsprechende Reaktion der Spitze beobachtet wurde.

Den GuideLiner-Katheter niemals mehr als 15 cm über die Spitze des Führungsdrahts hinaus vorschieben, da der GuideLiner-Katheter im Führungskatheter steckenbleiben und schwer zu entfernen sein könnte.

KOMPLIKATIONEN

Folgende Komplikationen, die sich generell bei Katheterbehandlungen ergeben können, können auch beim Verwenden des GuideLiner-Katheters auftreten:

- lokale oder systemische Infektion
- Luftembolie
- Intimariss
- arterielle Dissektion
- Perforation der Gefäßwand
- vaskuläre Okklusion
- arterielle Thrombose
- Myokardinfarkt
- arterieller Spasmus

KLINISCHES VORGEHEN

Der GuideLiner-Katheter ist für die Verwendung durch Ärzte vorgesehen, die in den für die bestimmungsgemäße Verwendung der Vorrichtung vorgesehenen Verfahren ausgebildet sind. Die beschriebenen Methoden und Verfahren repräsentieren nicht ALLE medizinisch zulässigen Protokolle und sollen nicht ärztliche Erfahrung und ärztliches Urteilsvermögen bei der individuellen Patientenbehandlung ersetzen. Alle verfügbaren Daten, einschließlich der Anzeichen und Symptome des Patienten und sonstiger diagnostischer Testergebnisse sollten berücksichtigt werden, bevor ein spezieller Behandlungsplan erstellt wird.

Der Verpackungsinhalt umfasst:

- GuideLiner-Katheter für den einmaligen Gebrauch

Weiteres erforderliches, aber nicht im Lieferumfang enthaltenes Material:

- Führungskatheter mit einem ausreichend großen Innendurchmesser für das zu verwendende GuideLiner-Kathetermodell
- Y-Adaptor mit Hämostaseventil (Art Tuohy-Borst)
- Führungsdraht mit Durchmesser von ≤ 0,36 mm
- Sterile Spritze (zur Spülung des Systems)
- Sterile heparinisierte Kochsalzlösung (zur Spülung des Systems)

VORBEREITUNG

1. Überprüfen Sie vor der Verwendung die Verpackung und Komponenten des GuideLiner-Katheters auf Schäden.
2. Steril arbeiten, die Dispenserspule mit dem GuideLiner-Katheter in den sterilen Bereich legen.
3. Das Lumen des GuideLiner-Katheters von der distalen Spitze gründlich mit heparinisierter Kochsalzlösung spülen.

ANWENDUNG

Bei der Einführung des GuideLiner-Katheters folgende Schritte beachten:

1. Den zuvor eingeführten Führungsdraht sichern und die distale Spitze des GuideLiner-Katheters auf den Führungsdraht zurückziehen und vorschieben, bis sich der Katheter sich unmittelbar proximal zum Hämostaseventil befindet.
2. Das Hämostaseventil öffnen und den GuideLiner-Katheter durch das Hämostaseventil in den Führungskatheter vorschieben.

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3. Den GuideLiner-Katheter unter Fluoroskopie bis maximal 15 cm über die distale Spitze des Führungskatheters hinaus und an die gewünschte Stelle im Gefäß vorschieben.

   Warnung: Den GuideLiner-Katheter niemals in ein Gefäß mit einem effektiven Durchmesser von weniger als 2,5 mm einführen. Dies könnte zu Gefäßverletzung, Ischämie und/oder Okklusion führen. Wenn der Druck in einem Gefäß nach der Einführung des GuideLiner-Katheters nachlässt, den GuideLiner-Katheter zurückziehen, bis sich der Druck normalisiert.

   Warnung: Aufgrund der Größe und nicht konischen Spitze des GuideLiner-Katheters ist sorgfältig darauf zu achten, in den Gefäßen, durch die dieser Katheter passiert, eine Gefäßokklusion und Schädigung der Gefäßwand zu vermeiden.

4. Mit Fluoroskopie die gewünschte Position des GuideLiner-Katheters im Gefäß bestätigen.
5. Bei einem interventionellen Verfahren die interventionelle Vorrichtung über den platzierten Führungsdraht zurückziehen und die Vorrichtung durch den Führungskatheter und GuideLiner-Katheter in den gewünschten Gefäßort vorschieben.
6. Den Y-Adaptor des Hämostaseventils sicher am proximalen Schaft des GuideLiner-Katheters festziehen, um eine Rückblutung zu verhindern.
7. Das Katheterisierungsverfahren durchführen. Nach Beendigung des Verfahrens den GuideLiner-Katheter entfernen, bevor der Führungskatheter aus dem Gefäß entfernt wird.

BESCHRÄNKTE GARANTIE

Vascular Solutions, Inc. garantiert, dass der GuideLiner-Katheter bis zum angegebenen Ablaufdatum frei von Fertigungs- und Materialdefekten ist. Die Haftung entsprechend dieser Garantie ist auf Rückvergütung oder Ersatz eines beliebigen Produkts beschränkt, das durch Vascular Solutions, Inc. hinsichtlich Fertigung oder Material für „defekt" befunden wurde. Vascular Solutions, Inc. ist für versehentliche, besondere oder Folgeschäden, die aus dem Einsatz des GuideLiner-Katheter entstehen, nicht haftbar. Beschädigung des Produkts durch Missbrauch, Veränderung, unsachgemäße Lagerung oder unsachgemäße Handhabung führen zum Erlöschen dieser beschränkten Garantie.

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PATENTE UND MARKEN

GuideLiner® ist eine eingetragene Marke von Vascular Solutions, Inc.

Καθετήρας GuideLiner® Οδηγίες χρήσης

ΠΡΟΣΟΧΗ (Η.Π.Α.)

Η Ομοσπονδιακή Νομοθεσία επιτρέπει την πώληση της συσκευής αυτής μόνο από ιατρό ή με εντολή ιατρού.

ΠΕΡΙΓΡΑΦΗ ΣΥΣΚΕΥΗΣ

Ο καθετήρας GuideLiner είναι ένας καθετήρας μονού αυλού ταχείας εναλλαγής, ο οποίος προσφέρεται σε μεγέθη συμβατά με καθετήρες-οδηγούς 6F, 7F και 8F και μπορεί να τοποθετηθεί μέσω μήκους εναλλαγής ή σύρματος-οδηγού 180 cm. Τα μεγαλύτερα μεγέθη του καθετήρα GuideLiner προορίζονται για χρήση εντός των εγγύτερων τμημάτων του στεφανιαίου αγγειακού συστήματος για να υποβοηθήσουν ή/και να διευκολύνουν τη χρήση πολλαπλών επεμβατικών συσκευών. Η συσκευή των 150 cm διαθέτει άξονα από ανοξείδωτο χάλυβα με μονό αυλό 25 cm, με επίστρωση σιλικόνης.

Ο καθετήρας GuideLiner διαθέτει δύο ακτινοσκιερούς δακτυλίους από πλατίνα-ιρίδιο, οι οποίοι επιτρέπουν την απεικόνιση κατά τη χρήση τυπικών ακτινοσκοπικών μεθόδων. Ο περιφερικός ακτινοσκιερός δακτύλιος βρίσκεται σε απόσταση 2.16 mm / 0,078" από το περιφερικό άκρο. Ο εγγύς ακτινοσκιερός δακτύλιος βρίσκεται σε απόσταση 1cm από το κολάρο. Η συσκευή διαθέτει δύο δείκτες τοποθέτησης που βρίσκονται στα 95 cm (μονός δείκτης) και στα 105 cm (διπλός δείκτης) από το περιφερικό άκρο, αντίστοιχα.

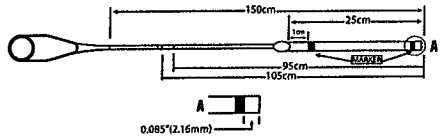
Ο καθετήρας GuideLiner προωθείται μέσω ενός καθετήρα-οδηγού και καταλήγει με εσωτερική διάμετρο περίπου 1 French μικρότερη από του καθετήρα-οδηγού. Ο καθετήρας GuideLiner διαθέτει μια εγγύς προεξοχή που επισημαίνει τη συμβατότητα με τους καθετήρες-οδηγούς και την προκύπτουσα εσωτερική διάμετρο του καθετήρα GuideLiner.

Ο καθετήρας GuideLiner έχει αποστειρωθεί με οξείδιο του αιθυλενίου.

STERILE EO

ΠΡΟΔΙΑΓΡΑΦΕΣ

Μοντέλο	Συμβατός καθετήρας-οδηγός	Ελάχ. εσωτ. διάμ. GuideLiner	Εξωτ. διάμ. άκρου GuideLiner
5570 5,5F	≥ 6F (≥ 1,68 mm / 0,066" εσωτ. διάμ.)	0,051" / 1,30 mm	0,063" / 1,60 mm
5571 6F	≥ 6F (≥ 1,78 mm / 0,070" εσωτ. διάμ.)	1,42 mm / 0,056"	1,70 mm / 0,067"
5572 7F	≥ 7F (≥ 1,98 mm / 0,078" εσωτ. διάμ.)	1,57 mm / 0,062"	1,90 mm / 0,075"
5573 8F	≥ 8F (≥ 2,24 mm / 0,088" εσωτ. διάμ.)	1,80 mm / 0,071"	2,16 mm / 0,085"



ΕΝΔΕΙΞΕΙΣ

Οι καθετήρες GuideLiner προορίζονται για χρήση σε συνδυασμό με καθετήρες-οδηγούς, προκειμένου να είναι δυνατή η πρόσβαση σε διακριτές περιοχές του στεφανιαίου ή/και περιφερειακού αγγειακού συστήματος και να διευκολυνθεί η τοποθέτηση και εναλλαγή συρμάτων-οδηγών και άλλων επεμβατικών συσκευών.

ΑΝΤΕΝΔΕΙΞΕΙΣ

Η χρήση των καθετήρων GuideLiner αντενδείκνυται σε αγγεία διαμέτρου μικρότερης των 2,5 mm και σε αγγεία στο νευραγγειακό σύστημα και στο φλεβικό σύστημα.

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ

Ο καθετήρας GuideLiner παρέχεται αποστειρωμένος για μία και μόνο χρήση. Η επαναχρησιμοποίηση συσκευής μίας χρήσης δημιουργεί πιθανό κίνδυνο λοιμώξεων στον ασθενή ή στον χρήστη. Μόλυνση της συσκευής μπορεί να οδηγήσει σε ασθένεια ή σε σοβαρό τραυματισμό του ασθενούς.

Ποτέ μην προωθείτε τον καθετήρα GuideLiner μέσα σε αγγείο χωρίς να προηγηθεί σύρμα-οδηγός ή χωρίς να επιβεβαιώνετε τη θέση του με ακτινοσκοπική καθοδήγηση. Μπορεί να προκύψει ανατομή ή διάτρηση αγγείου.

Ποτέ μην προωθείτε τον καθετήρα GuideLiner μέσα σε αγγείο με ωφέλιμη διάμετρο μικρότερη από 2,5 mm. Μπορεί να προκύψει τραυματισμός του αγγείου, ισχαιμία ή/και απόφραξη. Αν η πίεση σε ένα αγγείο πέσει μετά την εισαγωγή του καθετήρα GuideLiner, αποσύρετε τον καθετήρα GuideLiner μέχρι η πίεση να επανέλθει στην κανονική της τιμή.

Λόγω του μεγέθους και του ειδικού στρογγυλεμένου άκρου του καθετήρα GuideLiner, συνιστάται ιδιαίτερη προσοχή για να αποφευχθεί αγγειακή απόφραξη και τραυματισμός στα τοιχώματα των αγγείων από τα οποία περνά ο καθετήρας.

Ποτέ μην προωθείτε ή αποσύρετε μία ενδαγγειακή συσκευή σε περίπτωση που συναντήσετε αντίσταση, προτού προσδιορίσετε την αιτία της αντίστασης με ακτινοσκόπηση. Η μετακίνηση του καθετήρα ή του σύρματος οδηγού ενώ υπάρχει αντίσταση, ενδέχεται να προκαλέσει διαχωρισμό του άκρου του καθετήρα ή του σύρματος οδηγού, ζημιά στον καθετήρα ή διάτρηση αγγείου.

ΠΡΟΦΥΛΑΞΕΙΣ

Μην χρησιμοποιήσετε τον καθετήρα GuideLiner, εάν η συσκευασία έχει υποστεί ζημιά.

Πριν τη χρήση, επιθεωρήστε τον καθετήρα GuideLiner για οποιαδήποτε κάμψη ή στρέβλωση. Μην χρησιμοποιείτε έναν καθετήρα αν έχει υποστεί ζημιά. Ενδέχεται να προκληθεί αγγειακός τραυματισμός ή/και αδυναμία προώθησης ή απόσυρσης του καθετήρα.

Ο αυλός του καθετήρα πρέπει να εκπλυθεί διεξοδικά με ηπαρινισμένο αλατούχο διάλυμα πριν τη χρήση, για να αποφύγετε τον σχηματισμό θρόμβων.

Η διαδικασία εγκατάστασης του καθετήρα GuideLiner θα πρέπει να εκτελείται από ιατρούς απολύτως εκπαιδευμένους στις διαδερμικές ενδοαγγειακές τεχνικές και επεμβάσεις.

Πρέπει να λαμβάνονται προφυλάξεις για την πρόληψη ή τη μείωση της πήξης, όταν χρησιμοποιείται οποιοσδήποτε καθετήρας στο αγγειακό σύστημα. Θα πρέπει να εξετάζεται το ενδεχόμενο χρήσης συστηματικού ηπαρινισμού και αποστειρωμένου ηπαρινισμένου αλατούχου διαλύματος.

Να είστε προσεκτικοί κατά το χειρισμό του καθετήρα κατά τη διάρκεια μιας διαδικασίας, για να μειωθεί η πιθανότητα τυχαίας θραύσης, κάμψης ή στρέβλωσης.

Όταν ο καθετήρας βρίσκεται εντός του σώματος του ασθενούς, οι χειρισμοί θα πρέπει να πραγματοποιούνται μόνο υπό ακτινοσκόπηση. Μην αποπειραθείτε να κινήσετε τον καθετήρα χωρίς να παρατηρείτε την επακόλουθη απόκριση του άκρου του.

Ποτέ μην προωθείτε τον καθετήρα GuideLiner περισσότερο από 15cm πέρα από το άκρο του καθετήρα οδηγού, γιατί ο καθετήρας GuideLiner μπορεί να σφηνώσει μέσα στον καθετήρα-οδηγό και να είναι δύσκολη η αφαίρεσή του.

ΕΠΙΠΛΟΚΕΣ

Γενικά σχετίζονται οι παρακάτω επιπλοκές με διαδικασίες καθετηριασμού και μπορεί να προκύψουν κατά τη χρήση του καθετήρα GuideLiner:

- τοπική ή συστημική μόλυνση
- εμβολή αέρα
- διατάραξη του έσω χιτώνα
- αρτηριακή ανατομή
- διάτρηση αγγειακού τοιχώματος
- αγγειακή απόφραξη
- αρτηριακή θρόμβωση
- έμφραγμα του μυοκαρδίου
- αρτηριακός σπασμός

ΚΛΙΝΙΚΗ ΔΙΑΔΙΚΑΣΙΑ

Ο καθετήρας GuideLiner πρέπει να χρησιμοποιείται από ιατρούς καταρτισμένους στις διαδικασίες, για τις οποίες προορίζεται η συσκευή. Οι τεχνικές και οι διαδικασίες που περιγράφονται δεν αντιπροσωπεύουν ΟΛΑ τα ιατρικώς αποδεκτά πρωτόκολλα, ούτε υποκαθιστούν την εμπειρία και την κρίση του ιατρού σε σχέση με την αγωγή οποιουδήποτε συγκεκριμένου ασθενούς. Πριν ληφθεί απόφαση για ένα συγκεκριμένο πρόγραμμα θεραπείας, πρέπει να εκτιμηθούν όλα τα διαθέσιμα δεδομένα, συμπεριλαμβανομένων των ενδείξεων και των συμπτωμάτων του ασθενούς και άλλων αποτελεσμάτων διαγνωστικών εξετάσεων.

Η συσκευασία περιέχει:

- Αναλώσιμος καθετήρας μίας χρήσης GuideLiner

Άλλα υλικά που απαιτούνται αλλά δεν συμπεριλαμβάνονται:

- Καθετήρας-οδηγός με εσωτερική διάμετρο αρκετά μεγάλη ώστε να χωρά το συγκεκριμένο μοντέλο καθετήρα GuideLiner που χρησιμοποιείται
- Προσαρμογέας σχήματος Y με αιμοστατική βαλβίδα (τύπου Tuohy-Borst)
- Σύρμα-οδηγός με διάμετρο ≤ 0,36 mm / 0,014"
- Αποστειρωμένη σύριγγα (για την έκπλυση του συστήματος)
- Αποστειρωμένο ηπαρινισμένο αλατούχο διάλυμα (για την έκπλυση του συστήματος)

ΠΡΟΕΤΟΙΜΑΣΙΑ ΓΙΑ ΧΡΗΣΗ

1. Πριν τη χρήση, επιθεωρήστε τη συσκευασία και τα εξαρτήματα του καθετήρα GuideLiner για τυχόν ζημιά.

2. Εφαρμόζοντας αποστειρωμένη τεχνική, μεταφέρετε τη σπείρα παροχής με τον καθετήρα GuideLiner σε αποστειρωμένο πεδίο.
3. Κάντε διεξοδική έκπλυση του αυλού του καθετήρα GuideLiner από το περιφερικό άκρο με ηπαρινισμένο αλατούχο διάλυμα.

ΔΙΑΔΙΚΑΣΙΑ ΕΚΠΤΥΞΗΣ

Εκπτύξτε τον καθετήρα GuideLiner ως εξής:

1. Στερεώστε το εκ των προτέρων εισηγμένο σύρμα-οδηγό και τοποθετήστε ανάδρομα το περιφερικό άκρο του καθετήρα GuideLiner στο σύρμα-οδηγό και προωθήστε τον καθετήρα, μέχρι ο καθετήρας να βρεθεί ακριβώς εγγύς της αιμοστατικής βαλβίδας.
2. Ανοίξτε την αιμοστατική βαλβίδα και προωθήστε τον καθετήρα GuideLiner διαμέσου της αιμοστατικής βαλβίδας και εντός του καθετήρα-οδηγού.
3. Υπό ακτινοσκόπηση, προωθήστε τον καθετήρα GuideLiner το πολύ έως 15 cm πέρα από το περιφερικό άκρο του καθετήρα-οδηγού και στο επιθυμητό σημείο εντός του αγγείου.

   Προσοχή: Ποτέ μην προωθείτε τον καθετήρα GuideLiner μέσα σε αγγείο με ωφέλιμη διάμετρο μικρότερη από 2,5 mm. Μπορεί να προκύψει τραυματισμός του αγγείου, ισχαιμία ή/και απόφραξη. Αν η πίεση σε ένα αγγείο πέσει μετά την εισαγωγή του καθετήρα GuideLiner, αποσύρετε τον καθετήρα GuideLiner μέχρι η πίεση να επανέλθει στην κανονική της τιμή.

   Προσοχή: Λόγω του μεγέθους και του ειδικού στρογγυλεμένου άκρου του καθετήρα GuideLiner, συνιστάται ιδιαίτερη προσοχή για να αποφευχθεί αγγειακή απόφραξη και τραυματισμός στα τοιχώματα των αγγείων από τα οποία περνά ο καθετήρας.
4. Χρησιμοποιήστε ακτινοσκόπηση για να επιβεβαιώσετε την επιθυμητή θέση του καθετήρα GuideLiner εντός του αγγείου.
5. Αν εκτελείτε μια παρεμβατική διαδικασία, τοποθετήστε ανάδρομα την παρεμβατική συσκευή επάνω από το τοποθετημένο σύρμα-οδηγό και προωθήστε τη συσκευή διαμέσου του καθετήρα-οδηγού και του καθετήρα GuideLiner, εντός του επιθυμητού αγγειακού χώρου.
6. Σφίξτε καλά την αιμοστατική βαλβίδα με προσαρμογέα σχήματος Y στον εγγύς άξονα του καθετήρα GuideLiner, για να αποτρέψετε την ανάδρομη αιμορραγία.
7. Εκτελέστε τη διαδικασία καθετηριασμού. Αφού ολοκληρώσετε τη διαδικασία, αφαιρέστε τον καθετήρα GuideLiner πριν αφαιρέσετε τον καθετήρα-οδηγό από το αγγείο.

ΠΕΡΙΟΡΙΣΜΕΝΗ ΕΓΓΥΗΣΗ

Η Vascular Solutions, Inc. εγγυάται ότι ο καθετήρας GuideLiner δεν φέρει ελαττώματα σχετικά με τα υλικά και την κατασκευή πριν από την αναγραφόμενη ημερομηνία λήξης. Η ευθύνη στα πλαίσια της εγγύησης αυτής περιορίζεται στην επιστροφή του καταβαλλόμενου ποσού ή την αντικατάσταση οποιουδήποτε προϊόντος που έχει βρεθεί ελαττωματικό από τη Vascular Solutions, Inc. όσον αφορά την κατασκευή ή τα υλικά. Η Vascular Solutions, Inc. δεν φέρει ευθύνη για οποιεσδήποτε συμπτωματικές, ειδικές ή παρεπόμενες ζημιές που τυχόν προκύψουν από τη χρήση του καθετήρα GuideLiner. Η ζημιά που θα προκληθεί στο προϊόν λόγω κακής χρήσης, μετατροπής, ακατάλληλης φύλαξης ή ακατάλληλου χειρισμού θα καταστήσει άκυρη την παρούσα περιορισμένη εγγύηση.

Κανένας υπάλληλος, αντιπρόσωπος ή διανομέας της Vascular Solutions, Inc. δεν έχει το δικαίωμα να αλλάξει ή να τροποποιήσει αυτήν την περιορισμένη εγγύηση κατά κανένα τρόπο. Καμία μεταβολή ή τροποποίηση δεν θα έχει ισχύ κατά της Vascular Solutions, Inc.

Η ΠΑΡΟΥΣΑ ΕΓΓΥΗΣΗ ΑΝΤΙΚΑΘΙΣΤΑ ΟΛΕΣ ΤΙΣ ΑΛΛΕΣ ΕΓΓΥΗΣΕΙΣ, ΡΗΤΕΣ Ή ΕΜΜΕΣΕΣ, ΣΥΜΠΕΡΙΛΑΜΒΑΝΟΜΕΝΗΣ ΚΑΙ ΚΑΘΕ ΕΓΓΥΗΣΗΣ ΕΜΠΟΡΕΥΣΙΜΟΤΗΤΑΣ Ή ΚΑΤΑΛΛΗΛΟΤΗΤΑΣ ΓΙΑ ΕΝΑΝ ΣΥΓΚΕΚΡΙΜΕΝΟ ΣΚΟΠΟ Ή ΟΠΟΙΑΣΔΗΠΟΤΕ ΑΛΛΗΣ ΥΠΟΧΡΕΩΣΗΣ ΤΗΣ VASCULAR SOLUTIONS, INC.

ΔΙΠΛΩΜΑΤΑ ΕΥΡΕΣΙΤΕΧΝΙΑΣ ΚΑΙ ΕΜΠΟΡΙΚΑ ΣΗΜΑΤΑ

Το GuideLiner® είναι εμπορικό σήμα κατατεθέν της Vascular Solutions, Inc.

Catéter GuideLiner® Instrucciones de uso

PRECAUCIÓN PARA EE. UU.

La ley federal limita la venta de este dispositivo a médicos o por solicitud de un médico.

DESCRIPCIÓN DEL DISPOSITIVO

El GuideLiner es un catéter de una sola luz, de intercambio rápido, disponible en tamaños compatibles con catéteres guía de 6 F, 7 F y 8 F y se puede colocar sobre una longitud de intercambio o un alambre guía de 180 cm. Los tamaños más grandes de los catéteres GuideLiner están previstos para usarse con las partes proximales de la vasculatura coronaria para dar apoyo y/o facilitar el uso de múltiples dispositivos de intervención. El dispositivo de 150 cm posee un eje proximal de acero inoxidable con una sola luz recubierto con silicona.

El catéter GuideLiner incluye dos bandas marcadoras de platino-iridio que permiten la visibilidad mediante procedimientos fluoroscópicos estándar. La banda marcadora distal está situada a 2.16 mm de la punta distal. La banda marcadora proximal está situada a 1 cm del cuello. El dispositivo dispone de dos marcas de posicionamiento situadas a 95 cm (marca única) y 105 cm (marca doble) de la punta distal, respectivamente.

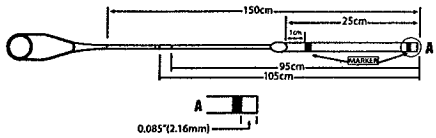
El catéter GuideLiner se introduce a través de un catéter guía, de modo que el diámetro interno es aproximadamente 1 French menor que el catéter guía. El catéter GuideLiner incluye una lengüeta proximal que indica la compatibilidad con el catéter guía y el diámetro interno resultante del catéter GuideLiner.

El catéter GuideLiner ha sido esterilizado con óxido de etileno.

STERILE EO

ESPECIFICACIONES

Modelo	Catéter guía compatible	D.I. mínimo del GuideLiner	D.E. de la punta del GuideLiner
5570 5,5 F	≥ 6 F (≥ 0,066" / 1,68 mm D.I.)	0,051" / 1,30 mm	0,063" / 1,60 mm
5571 6 F	≥ 6 F (≥ 0,070" / 1,78 mm D.I.)	0,056" / 1,42 mm	0,067" / 1,70 mm
5572 7F	≥ 7 F (≥ 0,078" / 1,98 mm D.I.)	0,062" / 1,57 mm	0,075" / 1,90 mm
5573 8 F	≥ 8 F (≥ 0,088" / 2,4 mm D.I.)	0,071" / 1,80 mm	0,085" / 2,16 mm



INDICACIONES

Los catéteres GuideLiner se deben utilizar conjuntamente con catéteres guía para acceder a regiones discretas de la vasculatura coronaria y/o periférica y para facilitar la colocación y el intercambio de alambres guía y otros dispositivos de intervención.

CONTRAINDICACIONES

Los catéteres GuideLiner están contraindicados en vasos con un diámetro inferior a 2,5 mm y en vasos que se encuentren en la neurovasculatura y en el sistema venoso.

ADVERTENCIAS

El catéter GuideLiner se proporciona esterilizado y es de un solo uso. La reutilización de dispositivos indicados para un solo uso crea un riesgo potencial de infección para el paciente o el usuario. La contaminación del dispositivo puede causar enfermedades o lesiones graves al paciente.

Nunca haga avanzar el catéter GuideLiner por un vaso sin un alambre guía o sin confirmar la ubicación mediante una guía fluoroscópica. De lo contrario, se puede producir la disección o perforación del vaso.

Nunca haga avanzar el catéter GuideLiner por un vaso cuyo diámetro efectivo sea inferior a 2,5 mm. De lo contrario, se pueden producir lesiones, isquemia y/o oclusión del vaso. Si se produce un descenso de presión en un vaso tras introducir un catéter GuideLiner, retírelo hasta que la presión vuelva a la normalidad.

Debido al tamaño de la punta del GuideLiner y a que no está ahusada, hay que tener mucho cuidado para evitar la oclusión del vaso y no dañar la pared de los vasos por donde pasa este catéter.

Nunca haga avanzar ni retire un dispositivo intravascular cuando encuentre resistencia, hasta que determine la causa de la misma mediante fluoroscopia. El movimiento del catéter o del alambre guía en condiciones de resistencia puede causar la separación de la punta del catéter o del alambre guía, daños al catéter o perforación de los vasos.

PRECAUCIONES

No utilice el catéter GuideLiner si el envase está dañado.

Inspeccione el catéter GuideLiner antes de utilizarlo para descartar dobladuras o torsiones. No utilice un catéter dañado. Si lo hace, puede ocasionar daño a los vasos o incapacidad para hacer avanzar o retirar el catéter.

Antes del uso, la luz del catéter debe estar completamente irrigada con una solución salina heparinizada para evitar la formación de coágulos.

El procedimiento de implementación del catéter GuideLiner debe ser efectuado por médicos rigurosamente entrenados en técnicas y procedimientos percutáneos e intravasculares.

Deben tomarse las precauciones necesarias para prevenir o reducir la coagulación cuando se utiliza algún catéter en el sistema vascular. Debe tenerse en cuenta el uso de una solución estéril heparinizada y de heparinización sistémica.

Tenga cuidado al manipular el catéter durante un procedimiento para reducir la posibilidad de rotura, doblamiento o torsión accidental.

Cuando el catéter está en el cuerpo, sólo se debe manipular bajo fluoroscopia. No intente mover el catéter sin observar la respuesta resultante de la punta.

Nunca haga avanzar el catéter GuideLiner más de 15 cm por delante de la punta del catéter guía, ya que el catéter GuideLiner puede quedar alojado dentro del catéter guía, lo que haría difícil su extracción.COMPLICACIONES

Las siguientes complicaciones suelen estar asociadas a procedimientos de cateterización y pueden ocurrir al utilizar el catéter GuideLiner:

- infección local o sistémica
- embolia gaseosa
- rotura de la íntima
- disección arterial
- perforación de la pared del vaso
- oclusión vascular
- trombosis arterial
- infarto de miocardio
- espasmo arterial

PROCEDIMIENTO CLÍNICO

El catéter GuideLiner debe ser utilizado por médicos capacitados en procedimientos para los cuales esté destinado el dispositivo. Las técnicas y los procedimientos descritos no representan TODOS los protocolos médicamente aceptables, ni tampoco pretenden sustituir la experiencia y el criterio clínico del médico en el tratamiento de pacientes específicos. Toda la información disponible, incluso los signos y los síntomas del paciente y otros resultados de análisis, debe tenerse en cuenta antes de determinar un plan de tratamiento específico.

El envase contiene:

- Catéter GuideLiner desechable para un solo uso

No incluye los demás elementos requeridos:

- Catéter guía con un diámetro interno lo suficientemente grande para acomodar el modelo específico del catéter GuideLiner que se use
- Adaptador en Y con válvula hemostática (tipo Tuohy-Borst)
- Alambre guía con un diámetro ≤ 0,36 mm
- Jeringa estéril (para irrigación del sistema)
- Solución salina heparinizada estéril (para irrigación del sistema)

PREPARACIONES PARA EL USO

1. Antes de utilizarlo, inspeccione cuidadosamente el envase del catéter GuideLiner y los componentes para ver si están dañados.

2. Utilizando una técnica estéril, transfiera la bobina dispensadora con el catéter GuideLiner al campo estéril.
3. Enjuague bien la luz del catéter GuideLiner desde la punta distal con solución salina heparinizada.

PROCEDIMIENTO DE DESPLIEGUE

Siga los siguientes pasos a la hora de utilizar el catéter GuideLiner:

1. Fije el alambre guía previamente insertado, cargue por detrás la punta distal del catéter GuideLiner en el alambre guía y hágalo avanzar hasta que quede próximo a la válvula hemostática.
2. Abra la válvula hemostática, haga avanzar el catéter GuideLiner a través de la misma hacia el interior del catéter guía.
3. Bajo fluoroscopia, haga avanzar el catéter GuideLiner de 15 cm máximo afuera del catéter guía hasta alcanzar la ubicación deseada en el vaso.

   Advertencia: Nunca haga avanzar el catéter GuideLiner en un vaso cuyo diámetro real sea inferior a 2,5 mm. De lo contrario, se pueden producir lesiones, isquemia y/o oclusión del vaso. Si la presión del vaso disminuye tras la introducción del catéter GuideLiner, retírelo hasta que la presión vuelva a la normalidad.

   Advertencia: Debido al tamaño de la punta del GuideLiner y a que no está ahusada, hay que tener mucho cuidado para evitar la oclusión del vaso y no dañar la pared de los vasos por donde pasa este catéter.
4. Mediante fluoroscopia, confirme la posición deseada del catéter GuideLiner en el vaso.
5. Si realiza un procedimiento intervencionista, cargue por detrás el dispositivo sobre el alambre guía ya colocado y hágalo avanzar a través del catéter guía y el catéter GuideLiner hacia el interior del espacio vascular deseado.
6. Apriete bien la válvula hemostática con adaptador en Y en el eje proximal del catéter GuideLiner para evitar el sangrado retrógrado.
7. Lleve a cabo el procedimiento de cateterización. Una vez finalizado, retire el catéter GuideLiner antes de extraer el catéter guía del vaso.

GARANTÍA LIMITADA

Vascular Solutions, Inc. garantiza que el catéter GuideLiner no tiene defectos de fabricación y materiales antes de la fecha de vencimiento establecida. La responsabilidad de esta garantía se limita al reembolso o a la sustitución de cualquier producto en el que Vascular Solutions, Inc. encuentre defectos de fabricación o de materiales. Vascular Solutions, Inc. no se responsabiliza de ningún daño incidental, especial o consecuente ocasionado por el uso del catéter GuideLiner. La garantía quedará anulada por los daños que tengan su causa en el uso indebido, la alteración, el almacenamiento inadecuado o la manipulación indebida del producto.

Ningún empleado, agente o distribuidor de Vascular Solutions, Inc. tiene autoridad para alterar o enmendar esta garantía limitada en ningún sentido. Cualquier supuesta alteración o enmienda no podrá aplicarse contra Vascular Solutions, Inc.

ESTA GARANTÍA SE OTORGA EXPRESAMENTE EN LUGAR DE TODA OTRA GARANTÍA EXPRESADA O IMPLÍCITA, INCLUYENDO TODA GARANTÍA DE COMERCIABILIDAD O ADECUACIÓN A UN FIN PARTICULAR O CUALQUIER OTRA OBLIGACIÓN DE VASCULAR SOLUTIONS, INC.

PATENTES Y MARCAS COMERCIALES

GuideLiner® es una marca registrada de Vascular Solutions, Inc.

GuideLiner®-katetri Käyttöohjeet

USA: TA KOSKEVA HUOMAUTUS

Yhdysvaltain liittovaltion laki rajoittaa laitteen myynnin tapahtuvaksi ainoastaan lääkärin toimesta tai määräyksestä.

LAITTEEN KUVAUS

GuideLiner-katetri on yksiluumeninen nopeasti vaihdettava katetri, joka on saatavana yhteensopivana 6F:n, 7F:n ja 8F:n kokoisille ohjainkatetreille ja joka voidaan asettaa vaihto-osan tai 180 cm pituisen ohjainvaljerin päälle. GuideLiner-katetrin suuremmat koot on tarkoitettu käytettäväksi sepelvaltimoiden proksimaalisissa osissa tukemaan ja/tai helpottamaan useiden interventiolaitteiden käyttöä. Tämän 150 cm pitkän laitteen varsi on ruostumatonta terästä. Varsi on varustettu yhdellä 25 cm pitkällä luumenilla, joka on käsitelty silikonilla.

GuideLiner-katetrissa on kaksi platina-iridium-merkkiviivaa, jotka näkyvät normaaleja läpivalaisumenetelmiä käytettäessä. Distaalinen merkkiviiva on 2.16 mm etäisyydellä distaalikärjestä. Proksimaalinen merkkiviiva on 1 cm etäisyydellä holkista katsottuna. Laitteessa on kaksi paikannusmerkkiä 95 cm (yksi merkki) ja 105 cm (kaksoismerkki) päässä distaalikärjestä, tässä järjestyksessä.

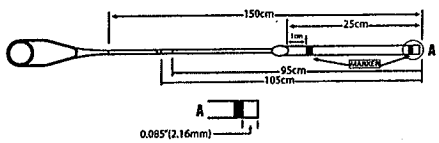
GuideLiner-katetri pujotetaan ohjainkatetrin lävitse, minkä seurauksena GuideLiner-katetrin sisähalkaisija on noin 1 French-kokoa pienempi kuin ohjainkatetri. GuideLiner-katetrin proksimaalisessa päässä on merkkilappu, josta ilmenee ohjauskatetrin yhteensopivuus ja tämän käytöstä johtuva GuideLiner-katetrin sisähalkaisija.

GuideLiner-katetri on steriloitu etyleenioksidilla.

STERILE EO

TEKNISET TIEDOT

Malli	Yhteensopiva ohjainkatetri	GuideLinerin väh.sisäh alkaisija	GuideLiner in kärjen ulkohalk.
5570 5,5F	≥ 6F (sisähalk. ≥ 0,066"/ 1,68 mm)	0,051"/ 1,30 mm	0,063"/ 1.60 mm
5571 6F	≥ 6F (sisähalk. (≥ 0.070"/ 1,78 mm)	0,056"/ 1,42 mm	0,067"/ 1,70 mm
5572 7F	≥ 7F (sisähalk. (≥ 0.078"/ 1,98 mm)	0,062"/ 1,57 mm	0,075"/ 1,90 mm
5573 8F	≥ 8F (sisähalk. (≥ 0,088"/ 2,24 mm)	0,071"/ 1,80 mm	0,085"/ 1,80 mm



KÄYTTÖAIHEET

GuideLiner-katetrit on tarkoitettu käytettäväksi ohjainkatetrien käytön yhteydessä yksittäisiin koronaarisen ja/tai perifeerisen verisuoniston alueisiin käsiksi pääsemiseksi sekä ohjainvaijereiden tai muiden toimenpidelaitteiden paikalleen asetuksen tai vaihtamisen edesauttamiseksi.

VASTA-AIHEET

GuideLiner-katetrien käyttö on vasta-aiheinen verisuonissa, joiden sisähalkaisija on alle 2,5 mm, neurovaskulaarisen kudoksen verisuonissa ja laskimoissa.

VAROITUKSET

GuideLiner-katetri toimitetaan steriilinä vain kertakäyttöä varten. Kertakäyttöisen laitteen uudelleenkäyttö aiheuttaa mahdollisen potilas- tai käyttäjäinfektioiden riskin. Laitteen kontaminaatio voi johtaa sairastumiseen tai vakavaan potilasvammaan.

Älä koskaan työnnä GuideLiner-katetria verisuoneen ilman johtavaa ohjainvaijeria tai ilman sijainnin varmistamista läpivalaisulla. Tämä saattaa aiheuttaa verisuonen dissekoituman tai perforaation.

Älä koskaan työnnä GuideLiner-katetria verisuoneen, jonka todellinen läpihalkaisija on alle 2,5 mm. Tämä saattaa aiheuttaa verisuonen vahingoittumisen, iskemian tai tukkeutumisen. Mikäli verisuonen paine laskee GuideLiner-katetrin paikalleen asettamisen jälkeen, vedä GuideLiner-katetria ulos kunnes paine palautuu normaaliksi.

GuideLiner-katetrin koon ja tylpän kärjen vuoksi tulee noudattaa äärimmäistä varovaisuutta, jotta vältettäisiin suonen tukkiutuminen tai sen seinämien vahingoittuminen katetrin kulkiessa suonen lävitse.

Älä koskaan kuljeta suonensisäistä välinettä eteenpäin tai vedä sitä taaksepäin vastusta vastaan, ennen kuin vastuksen syy on määritetty läpivalaisulla. Katetrin tai johtimen liikuttaminen vastusta vastaan saattaa aiheuttaa katetrin tai johtimen kärjen irtoamisen, katetrin vaurioitumisen tai suonen perforaation.

VAROTOIMET

Älä käytä GuideLiner-katetria, jos pakkaus on vahingoittunut.

Tarkasta GuideLiner-katetri ennen käyttöä kiertymien tai taittumien varalta. Vaurioitunutta katetria ei saa käyttää. Seurauksena voi olla suonen vaurioituminen ja/tai katetrin eteenpäin kuljettamisen tai taaksepäin vetämisen epäonnistuminen.

Katetrin luumenin tulee olla kauttaaltaan huuhdeltu heparinoidulla keittosuolaliuoksella ennen sen käyttöä hyytymien muodostumisen estämiseksi.

GuideLiner-katetrin sisäänviennin saavat toimittaa vain lääkärit, jotka on koulutettu perkutaanisten intravaskulaaristen tekniikoiden käyttöön ja näihin liittyviin toimenpiteisiin.

Kun katetria käytetään verisuonistossa, on aina suoritettava tarvittavat varotoimenpiteet hyytymisen estämiseksi tai vähentämiseksi. Systeemisen heparinisaation ja heparinoidun steriilin liuoksen käyttöä tulee harkita.

Noudata varovaisuutta käsitellessäsi katetria toimenpiteen aikana välttääksesi vahingossa tapahtuvan katkeamisen, taipumisen tai kiertymisen.

Kun katetri on potilaan verisuonistossa, sen manipulointi pitää suorittaa aina läpivalaisukontrollissa. Älä yritä liikuttaa katetria tarkkailematta katetrin pään vastetta.

Älä koskaan työnnä GuideLiner-katetria 15 cm ohjainkatetrin kärkeä pidemmälle, sillä GuideLiner-katetri saattaa juuttua ohjainkatetrin sisälle, jolloin se on vaikea poistaa.

KOMPLIKAATIOT

Seuraavia katetrointitoimenpiteisiin yleisesti liittyviä komplikaatioita voi ilmaantua GuideLiner-katetria käytettäessä:

- paikallinen tai systeeminen infektio
- ilmaembolia
- intimarepeämä
- valtimon dissekoituma
- perforaatio ja suonen repeäminen
- verisuonen tukkeutuminen
- valtimotromboosi
- sydänlihaksen infarkti
- valtimospasmi

TOIMENPITEETN SUORITTAMINEN

GuideLiner-katetrin käyttö on sallittu sellaisille lääkäreille, jotka on koulutettu laitteen käyttötarkoituksen mukaisiin toimenpiteisiin. Kuvatut tekniikat ja toimenpiteet eivät edusta KAIKKIA lääketieteellisesti hyväksyttyjä protokollia, eikä niiden ole myöskään tarkoitus korvata lääkärin kokemusta ja harkintaa minkään tietyn potilaan hoidossa. Kaikki saatavilla olevat tiedot, mukaan lukien potilaan tilan merkit ja oireet sekä muut diagnostiset koetulokset, tulee ottaa huomioon ennen erityisen hoitosuunnitelman määrittämistä.

Pakkauksen sisältö:

- Kertakäyttöinen GuideLiner-katetri

Muut tarvittavat materiaalit, joita ei toimiteta pakkauksessa:

- Ohjainkatetri, jonka sisähalkaisija on tarpeeksi suuri käytössä olevaa erityistä GuideLiner-katetria varten.
- Hemostaasiventtiilillä varustettu Y-liitin (Tuohy-Borst-tyyppinen)
- Ohjainvaijeri, jonka halkaisija ≤ 0,36 mm
- Steriili ruisku (järjestelmän huuhteluun)
- Steriilillä heparinoitua keittosuolaliuosta (järjestelmän huuhteluun)

KÄYTÖN VALMISTELU

1. Tarkasta GuideLiner-katetrin pakkaus ja komponentit huolellisesti vaurioiden varalta ennen käyttöä.
2. Vie annostelulaite ja GuideLiner-katetri steriilisti steriilille alueelle.
3. Huuhtele GuideLiner-katetrin luumen distaalikärjestä käsin kauttaaltaan heparinoidulla keittosuolaliuoksella.

SISÄÄNVIENTI

Aseta GuideLiner-katetri paikalleen noudattaen seuraavia vaiheita:

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1. Varmista jo etukäteen paikalleen asetettu ohjainvaijeri ja lataa GuideLiner-katetrin distaalikärki ohjainvaijeriin. Työnnä sitten katetria vain, kunnes sen sijainti on proksimaalinen hemostaasiventtiiliin nähden.
2. Avaa hemostaasiventtiili ja työnnä GuideLiner-katetri hemostaasiventtiilin läpi ohjainkatetriin.
3. Työnnä GuideLiner-katetri enintään 15 cm ohjainkatetrin distaalikärjen ohitse läpivalaisun ohjaamana ja sitten haluttuun suonensisäiseen paikkaan.

   Varoitus: Älä koskaan työnnä GuideLiner-katetria verisuoneen, jonka todellinen läpihalkaisija on alle 2,5 mm. Tästä saattaa aiheuttaa verisuonen vahingoittumisen, iskemian tai tukkeutumisen. Mikäli verisuonen paine laskee GuideLiner-katetrin paikalleen asettamisen jälkeen, vedä GuideLiner-katetria ulos kunnes paine palautuu normaaliksi.

   Varoitus: GuideLiner-katetrin koon ja tylpän kärjen vuoksi tulee noudattaa äärimmäistä varovaisuutta, jotta vältettäisiin suonen tukkiutuminen tai sen seinämien vahingoittuminen katetrin kulkiessa suonen lävitse.
4. Vahvista GuideLiner-katetrin haluttu sijainti verisuonessa läpivalaisun avulla.
5. Interventiota suorittaessa lataa toimenpidelaite paikalleen asetetun ohjainvaijerin päälle ja työnnä laite ohjainkatetrin ja GuideLiner-katetrin lävitse haluttuun suonensisäiseen paikkaan.
6. Kiristä Y-liittimen hemostaasiventtiili kunnolla GuideLiner-katetrin proksimaaliseen varteen veren takaisinvuodon estämiseksi.
7. Suorita katetrisointi. Poista GuideLiner-katetri ennen ohjainkatetrin poistamista verisuonesta toimenpiteen tultua valmiiksi.

RAJOITETTU TAKUU

Vascular Solutions, Inc. takaa, että GuideLiner-katetri on vapaa valmistus- ja materiaalivioista annettua viimeistä käyttöpäivää edeltävänä aikana. Tämän takuun sisältämä vastuu rajoittuu vain sellaisten tuotteiden hinnan palauttamiseen tai tuotteiden vaihtoon, joissa Vascular Solutions, Inc. on todennut olevan raaka-aine- tai valmistusvikoja. Vascular Solutions, Inc. ei ole vastuussa mistään satunnaisesta, erityisestä tai epäsuorasta vahingosta, joka syntyy GuideLiner-katetrin käytöstä. Tuotteen väärinkäytön, muuntelun, väärän säilytystavan tai väärän käsittelyn aiheuttama vaurio mitätöi tämän rajoitetun takuun.

Vascular Solutions, Inc. työntekijöillä, edustajilla tai jälleenmyyjillä ei ole valtuuksia muuttaa tai laajentaa tätä takuuta millään tavalla. Vascular Solutions, Inc. ei ole vastuussa mistään oletetuista muutoksista tai lisäyksistä.

TÄMÄ TAKUU KORVAA KAIKKIMUUT ILMAISTUT TAI KONKLUDENTTISET TAKUUT, MUKAAN LUKIEN KAUPATTAVUUTTA JA TIETTYÄ KÄYTTÖTARKOITUSTA KOSKEVAT TAKUUT, SEKÄ KAIKKI MUUT VASCULAR SOLUTIONS, INC:N VASTUUT JA VELVOLLISUUDET.

PATENTIT JA TAVARAMERKIT

GuideLiner® on Vascular Solutions, Inc. -yhtiön rekisteröity tavaramerkki.

Cathéter GuideLiner®
Mode d'emploi

MISE EN GARDE APPLICABLE AUX ÉTATS-UNIS

La législation fédérale restreint la vente de ce dispositif aux médecins ou sur prescription médicale.

DESCRIPTION DU DISPOSITIF

Le cathéter GuideLiner est un cathéter de remplacement rapide à lumière unique disponible dans des tailles compatibles avec les cathéters-guides 6F, 7F et 8F. Il peut être placé sur une longueur de rechange ou sur un fil-guide de 180 cm. Les tailles supérieures des cathéters GuideLiner permettent une utilisation au sein des portions proximales du système vasculaire coronarien pour apporter un soutien et/ou faciliter l'utilisation de plusieurs appareils d'intervention. Le dispositif de 150 cm possède une tige en acier inoxydable avec une lumière unique de 25 cm revêtue de silicone.

Le cathéter GuideLiner possède deux bandes-repères en platine et en iridium qui permet de le visualiser lors de l'utilisation de méthodes radioscopiques standard. La bande-repère distale est située à 2.16 mm de l'embout distal. La bande-repère proximale est située à 1 cm de la bague. Le cathéter possède deux repères de positionnement situés à 95 cm (repère simple) et 105 cm (repère double) de son embout distal, respectivement.

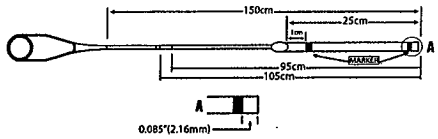
Le cathéter GuideLiner est introduit à travers un cathéter-guide qui permet d'obtenir un diamètre interne d'environ 1 French plus petit que celui du cathéter-guide. Le cathéter GuideLiner possède une languette proximale qui indique la compatibilité avec les cathéters-guides et le diamètre interne final du cathéter GuideLiner.

Le cathéter GuideLiner a été stérilisé à l'oxyde d'éthylène.

STERILE EO

CARACTÉRISTIQUES TECHNIQUES

Modèle	Cathéter-guide compatible	D.I. minimal GuideLiner	D.E. de l'extrémité du GuideLiner
5570 5.5F	≥ 6F (≥ D.I. 0,066 po/ 1,68 mm)	0,051 po/ 1,30 mm	0,063 po/ 1,60 mm
5571 6F	≥ 6F (≥ D.I. 0,070 po/ 1,78 mm)	0,056 po/ 1,42 mm	0,067 po/ 1,70 mm
5572 7F	≥ 7F (≥ D.I. 0,078 po/ 1,98 mm)	0,062 po/ 1,57 mm	0,075 po/ 1,90 mm
5573 8F	≥ 8F (≥ D.I. 0,088po/ 2,24 mm)	0,071 po/ 1,80 mm	0,085 po/ 2,16 mm



INDICATIONS

Les cathéters GuideLiner sont conçus pour être utilisés conjointement avec des cathéters-guides pour accéder à des régions discrètes de l'appareil vasculaire coronarien et/ou périphérique et faciliter la mise en place et le remplacement de fils-guides et d'autres dispositifs utilisés en cours d'intervention.

CONTRE-INDICATIONS

Les cathéters GuideLiner sont contre-indiqués sur les vaisseaux de moins de 2,5 mm de diamètre, les vaisseaux de l'appareil neurovasculaire et le système veineux.

MISES EN GARDE

Le cathéter GuideLiner est fourni stérile et exclusivement pour un usage unique. La réutilisation d'un dispositif à usage unique engendre un risque potentiel d'infection pour le patient ou l'utilisateur. La contamination du dispositif peut être à l'origine d'une maladie ou d'une blessure grave du patient.

Ne jamais faire progresser le cathéter GuideLiner dans un vaisseau sans un fil-guide en tête ou sans avoir vérifié l'emplacement sous contrôle radioscopique. Cela pourrait entraîner la dissection ou la perforation du vaisseau.

Ne jamais faire progresser le cathéter GuideLiner dans un vaisseau dont le diamètre effectif est inférieur à 2,5 mm. Cela pourrait léser le vaisseau, entraîner une ischémie et/ou une occlusion. Si l'introduction du cathéter GuideLiner dans un vaisseau entraîne une baisse de la tension, le retirer immédiatement jusqu'au retour d'une pression normale.

La taille et l'embout non effilé du GuideLiner exigent de prendre d'infimes précautions pour éviter toute occlusion des vaisseaux et tout endommagement des parois des vaisseaux à travers lesquels passe le cathéter.

Ne jamais insérer ni retirer un dispositif intravasculaire rencontrant une résistance tant que la cause de la résistance n'aura pas été déterminée par radioscopie. Tout mouvement du cathéter ou du fil-guide rencontrant une résistance peut entraîner la séparation de l'embout du cathéter ou du fil-guide, une détérioration du cathéter ou une perforation de vaisseau.

PRÉCAUTIONS

Ne pas utiliser le cathéter GuideLiner si l'emballage a été endommagé.

Avant utilisation, vérifier que le cathéter GuideLiner n'est pas plié ou déformé. Ne pas utiliser un cathéter abîmé. Une détérioration vasculaire et/ou l'impossibilité d'insérer ou de retirer le cathéter peuvent survenir.

La lumière du cathéter doit être soigneusement rincée avec une solution saline héparinisée avant emploi de manière à prévenir la formation de caillots.

La procédure de déploiement du cathéter GuideLiner doit être effectuée par des médecins correctement formés aux procédures et aux techniques percutanées et intravasculaires.

Des précautions doivent être prises pour éviter ou réduire le risque de formation de caillots de sang lorsqu'un cathéter est utilisé dans le système vasculaire. L'héparinisation systémique et l'utilisation d'une solution stérile héparinisée doivent être envisagées.

Manipuler le cathéter avec soin pendant l'intervention afin d'éviter de le rompre, le courber ou le plier par inadvertance.

Une fois le cathéter à l'intérieur du corps, il doit être manipulé exclusivement sous radioscopie. Ne pas tenter de déplacer le cathéter sans observer la réaction résultante de l'embout.

Ne jamais faire progresser le cathéter GuideLiner plus de 15 cm au-delà de l'extrémité du cathéter-guide car il risquerait de se loger dans le cathéter-guide, ce qui rendrait son extraction difficile.

COMPLICATIONS

Les complications suivantes sont généralement associées aux procédures de cathétérisation et peuvent se manifester lors de l'utilisation du cathéter GuideLiner :

- Infection locale ou généralisée
- Embolie gazeuse
- Rupture intimale
- Dissection artérielle
- Perforation de la paroi vasculaire
- Occlusion vasculaire
- Thrombose artérielle
- Infarctus du myocarde
- Spasme artériel

INTERVENTION CLINIQUE

Le cathéter GuideLiner doit être utilisé par des médecins dûment formés aux procédures indiquées pour le dispositif. Les techniques et modalités décrites ne représentent pas TOUS les protocoles médicalement acceptables, et ne sont pas conçues pour se substituer à l'expérience et au jugement du médecin pour traiter un patient en particulier. Toutes les données fournies, y compris les signes et symptômes du patient ainsi que d'autres résultats de tests diagnostiques, doivent être examinées avant de déterminer un plan de traitement spécifique.

L'emballage contient :

- Un cathéter GuideLiner jetable à usage unique

Autres éléments requis mais non fournis :

- Un guide-cathéter avec un diamètre interne suffisamment important pour s'adapter au modèle spécifique du cathéter GuideLiner utilisé
- Un adaptateur en Y avec interrupteur de flux (de type Tuohy-Borst)
- Un fil-guide d'un diamètre de ≤ 0,36 mm
- Une seringue stérile (pour le rinçage du système)
- Une solution saline héparinée stérile (pour le rinçage du système)

PRÉPARATIFS AVANT UTILISATION

1. Avant utilisation, inspecter minutieusement l'emballage et les composants du cathéter GuideLiner pour vérifier l'absence de dommages.
2. En utilisant une technique stérile, transférer la spirale de distribution avec le cathéter GuideLiner dans le champ stérile.
3. Rincer soigneusement la lumière du cathéter GuideLiner à partir de l'extrémité distale avec la solution saline héparinée.

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PROCÉDURE DE MISE EN PLACE

Déployer le cathéter GuideLiner en suivant les étapes suivantes :

1. Fixer le fil-guide précédemment introduit et charger par l'arrière l'extrémité distale du cathéter GuideLiner sur le fil-guide et la faire progresser jusqu'à ce qu'elle se trouve en position immédiatement proximale de l'interrupteur de flux.
2. Ouvrir l'interrupteur de flux et faire progresser le cathéter GuideLiner à travers celui-ci jusque dans le cathéter-guide.
3. Sous contrôle radioscopique, faire progresser le cathéter GuideLiner jusqu'à 15 cm au maximum au-delà de l'extrémité distale du cathéter-guide et jusqu'à l'emplacement souhaité dans le vaisseau.

   Avertissement : Ne jamais faire progresser le cathéter GuideLiner dans un vaisseau dont le diamètre effectif est inférieur à 2,5 mm. Cela pourrait léser le vaisseau, entraîner une ischémie et/ou une occlusion. Si l'introduction du cathéter GuideLiner dans un vaisseau entraîne une baisse de la tension, le retirer immédiatement jusqu'au retour d'une pression normale.

   Avertissement : La taille et l'embout non effilé du GuideLiner exigent de prendre d'infimes précautions pour éviter toute occlusion des vaisseaux et tout endommagement des parois des vaisseaux à travers lesquels passe le cathéter.
4. Sous contrôle radioscopique, vérifier la position souhaitée pour le cathéter GuideLiner dans le vaisseau.
5. Pour une insertion dans le cadre d'une intervention, charger le dispositif d'intervention par derrière au-dessus du fil-guide en place et le faire avancer dans le cathéter-guide et le cathéter GuideLiner pour le placer dans l'espace vasculaire souhaité.
6. Bien serrer l'interrupteur de flux de l'adaptateur en Y sur la tige proximale du cathéter GuideLiner pour empêcher un saignement rétrograde.
7. Effectuer la procédure de cathétérisme. Une fois l'intervention terminée, retirer le cathéter GuideLiner avant de retirer le cathéter-guide du vaisseau.

GARANTIE LIMITÉE

Vascular Solutions, Inc. garantit que le cathéter GuideLiner est exempt de défauts d'exécution et de matériaux avant la date de péremption indiquée. La responsabilité aux termes de cette garantie se limite au remboursement ou au remplacement de tout produit dont Vascular Solutions, Inc. a mis en évidence qu'il présente des défauts matériels ou de fabrication. Vascular Solutions, Inc. décline toute responsabilité pour tout dommage accidentel, particulier ou consécutif, résultant de l'utilisation du cathéter GuideLiner. Un endommagement du produit dû à une mauvaise utilisation, à une transformation, à un stockage non conforme ou à une manipulation inappropriée, annulerait cette garantie limitée.

Aucun salarié, mandataire ou distributeur de Vascular Solutions, Inc. n'a d'autorité quelconque pour transformer ou modifier cette garantie à quelque égard que ce soit. Tout amendement ou changement prétendu ne sera pas opposable à Vascular Solutions, Inc.

LA PRÉSENTE GARANTIE REMPLACE EXPRESSÉMENT TOUTES LES AUTRES GARANTIES, EXPLICITES OU IMPLICITES, Y COMPRIS TOUTE GARANTIE DE CARACTÈRE ADÉQUAT POUR LA COMMERCIALISATION OU D'APTITUDE À UN USAGE PARTICULIER OU TOUTE AUTRE OBLIGATION DE VASCULAR SOLUTIONS, INC.

BREVETS ET MARQUES COMMERCIALES

GuideLiner® est une marque déposée de Vascular Solutions, Inc.

GuideLiner® katéter Használati utasítás

USA FIGYELMEZTETÉS

A szövetségi (USA) törvények értelmében ez az eszköz csak orvos által vagy orvosi rendelvényre árusítható.

AZ ESZKÖZ LEÍRÁSA

A GuideLiner katéter egy 1 lumenű gyorscserés katéter, amely 6F, 7F, és 8F vezetőkatéterrel kompatibilis méretekben érhető el, és amely cserére alkalmas vagy 180 cm hosszú vezetődróttal használható. A nagyméretű GuideLiner katétereket a koszorúér proximális szakaszain belül használatra tervezték, hogy alátámasztást nyújtson és vagy megkönnyítse a több műtéti eszköz használatát. A 150 cm-es készülék egy rozsdamentes acélból készült, 25 cm-es, szilikonkezelt lumennel ellátott tengellyel rendelkezik.

A GuideLiner katéter két platina-iridium markervonallal rendelkezik, amelyek lehetővé teszik a láthatóságot a szabványos fluoroszkópiás eljárások során. A disztális markervonal a disztális végtől 2.16 mm távolságra található. A proximális markervonal a peremtől 1 cm távolságra található. A készüléken két pozícionáló jelölés található, amelyek a disztális végtől 95 cm (egy jelölés) és 105 cm (két jelölés) távolságra helyezkednek el.

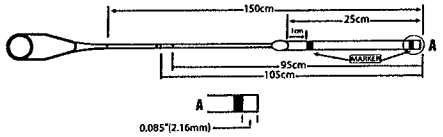
The GuideLiner katéter átvezetése egy vezetőkatéteren keresztül történik, így a belső átmérő körülbelül 1 french kisebb, mint a vezetőkatéter átmérője. A GuideLiner katéter egy proximális füllel rendelkezik, amely a vezetőkatéterekkel való kompatibilitást és a GuideLiner katéter belső átmérőjét mutatja.

A GuideLiner katéter sterilizálása etilén-oxiddal történt.

STERILE EO

MŰSZAKI LEÍRÁS

Modell	Kompatibilis vezetőkatéter	GuideLiner Min. belső átmérő	GuideLiner végének külső átmérője
5570 5,5F	≥ 6F (≥ 0,066" / 1,68 mm belső átmérő)	0,051" / 1,30 mm	0,063" / 1,60 mm
5571 6F	≥ 6F (≥ 0,070" / 1,78 mm belső átmérő)	0,056" / 1,42 mm	0,067" / 1,70 mm
5572 7F	≥ 7F (≥ 0,078" / 1,98 mm belső átmérő)	0,062" / 1,57 mm	0,075" / 1,90 mm
5573 8F	≥ 8F (≥ 0,088" / 2,24 mm belső átmérő)	0,071" / 1,80 mm	0,085" / 2,16 mm



JAVALLATOK

GuideLiner katéterek a vezetőkatérekkel együtt használandók a koszorúerek és/vagy perifériás erek nehezen megközelíthető részeinek elérésére, valamint a vezetődrótok vagy egyéb műtéti eszközök elhelyezésének és cserélésének a megkönnyítésére.

ELLENJAVALLATOK

The GuideLiner katéter használata ellenjavallott a 2.5 mm átmérőnél kisebb véredények, valamint a neurovaszkuláris és vénás rendszerek esetében.

FIGYELMEZTETÉSEK

A GuideLiner katéter egyszer használatos steril eszköz. Az egyszer használatos eszköz ismételt felhasználása a beteg vagy a felhasználó fertőzésének potenciális kockázatát eredményezi. Az eszköz kontaminációja betegséghez vagy a beteg súlyos sérüléséhez vezethet.

A GuideLiner katétert soha ne vezesse a véredényekbe vezetődrót nélkül, vagy anélkül, hogy a helyzetét folyamatosan fluoroszkópiás eljárással figyelné. Fennáll a véredény falának szétválásának vagy kilyukadásának veszélye.

A GuideLiner katétert soha ne vezesse be 2,5 mm-nél kisebb átmérőjű véredénybe. Ez véredénysérülést, vértelenséget, és/vagy elzáródást okozhat. Ha a véredényben levő nyomás a GuideLiner katéter bevezetése után csökken, húzza ki a GuideLiner katétert, amíg a nyomás visszaáll normális értékre.

A GuideLiner mérete és nem elkeskenyedő vége miatt különös gondossággal kell eljárni a véredény elzáródásának és azon véredények falának megsértésének elkerülése érdekében, amelyen áthatol a katéterHa ellenállásba ütközik, soha ne toljon előre vagy húzzon ki egy intravaszkuláris eszközt, amíg fluoroszkópiával meg nem határozta az ellenállás okát. Ha ellenállás észlelése esetén mozgatja a katétert vagy a vezetődrótot, az a katéter vagy a vezetődrót végének a leválását, a katéter sérülését, illetve a véredény átlyukasztását okozhatja.

ÓVINTÉZKEDÉSEK

Ne használja a GuideLiner katétert, ha a csomagolás sérült.

Használat előtt ellenőrizze a katétert meghajlások vagy megtörések után kutatva. Ne használjon sérült katétert. Ellenkező esetben megsértheti a véredényeket és/vagy lehetetlenné válhat a katéter előre tolása vagy visszahúzása.

Az alvadék kialakulásának elkerülése érdekében használat előtt mossa át alaposan a katéter lumenét heparinos sóoldattal.

A GuideLiner katéter beültetését percután és intravaszkuláris technikák és eljárások területén megfelelően képzett orvos végezze.

Bármilyen katéter érrendszerben történő használatakor tegye meg a szükséges óvintézkedéseket a véralvadás megelőzése érdekében. Alkalmazzon szisztémás heparinizációt és heparinos steril oldatot.

A véletlenszerű szakadás, meghajlás vagy megtörés lehetőségének csökkentése érdekében járjon el elővigyázatosan a katéter használata során.

Amikor a katéter a testben van, kezelése kizárólag fluoroszkópia alkalmazásával engedélyezett. Ne próbálja meg elmozdítani a katétert anélkül, hogy ne figyelné meg a vég mozgását.

A GuideLiner katétert ne mozgassa előre több mint 15 cm-rel a vezetőkatétertől, mivel a GuideLiner katéter megakadhat a vezetőkatéterben, ami megnehezíti az eltávolítást.

KOMPLIKÁCIÓK

A katéterezés során általában az alábbi komplikációk léphetnek fel, és ezek a GuideLiner katéter használatakor is jelentkezhetnek:

- helyi vagy szisztémás fertőzés
- légembólia
- az érfalak belső rétegének szakadása
- az artériák falának szétválása
- az érfalak kilyukadása
- érelzáródás
- artériás trombózis
- miokardiális infarktus
- artériás görcsök

KLINIKAI ELJÁRÁS

A GuideLiner katétert olyan orvosok használhatják, akik megfelelő képzésben részesültek az eszköz rendeltetését képező eljárásokat illetően. Az itt leírt technikák és eljárások nem tükrözik az ÖSSZES orvosilag elfogadható protokollt, és nem céljuk az orvos tapasztalatának és ítélőképességének helyettesítése egyetlen konkrét beteg kezelése során sem. Minden elérhető adatot, így a beteg jeleit és tüneteit és más diagnosztikai teszteredményeket figyelembe kell venni a konkrét kezelési terv meghatározása előtt.

A csomag tartalma:

- Egyszer használatos eldobható GuideLiner katéter

Egyéb szükséges, de a csomag részét nem képező elemek:

- A használatban levő GuideLiner katéter modell befogadására alkalmas, megfelelő nagyságú belső átmérővel rendelkező vezetőkatéter.
- Hemosztázis szeleppel ellátott Y-adapter (Tuohy-Borst típus)
- 0,36 mm átmérőjű vagy annál vékonyabb vezetődrót
- Steril fecskendő (a rendszer átmosásához)
- Steril heparinos sóoldat (a rendszer átmosásához)

AZ ALKALMAZÁSRA VALÓ FELKÉSZÜLÉS

1. Használat előtt vizsgálja meg alaposan, hogy a GuideLiner katéter csomagolása és alkotóelemei ne legyenek megsérülve.
2. Steril eljárást alkalmazva helyezze a dobot a GuideLiner katéterrel steril területre.
3. A GuideLiner katéter disztális végének lumenét alaposan mossa át heparinos sóoldattal.

A BEÜLTETÉS MENETE

A GuideLiner katéter beültetését az alábbiak szerint végezze:

1. Biztosítsa az előzőleg bevezetett vezetődrótot, majd helyezze be a GuideLiner katéter disztális végét a vezetődrótba, és mozgassa előre addig, amíg a katéter a hemosztázis szelep mellett található.
2. Nyissa meg a hemosztázis szelepeket, és vezesse át a GuideLiner katétert a hemosztázis szelepen át a vezetőkatéterbe.
3. Fluoroszkópia alkalmazása közben tolja előre a GuideLiner katétert a vezető katéter disztális végétől maximum 15 cm távolságra, a véredényen belül a kívánt pozícióba.

   Figyelem: A GuideLiner katétert soha ne vezesse be 2,5 mm-nél kisebb átmérőjű véredénybe. Ez véredénysérülést, vértelenséget, és/vagy elzáródást okozhat. Ha a véredényben levő nyomás a GuideLiner katéter bevezetése után csökken, húzza ki a GuideLiner katétert, amíg a nyomás visszaáll normális értékre.

   Figyelem: A GuideLiner mérete és nem elkeskenyedő vége miatt különös gondossággal kell eljárni a véredény elzáródásának és azon véredények falának megsértésének elkerülése érdekében, amelyen áthatol a katéter.
4. Fluoroszkópia alkalmazásával bizonyosodjon meg arról, hogy a GuideLiner katéter elérte a véredényben a kívánt pozíciót.
5. Beavatkozás során csúsztassa át az intervenciós eszközt az elhelyezett vezetődrót segítségével, majd mozdítsa előre a készüléket a vezetőkatéteren és a GuideLiner katéteren át a kívánt vaszkuláris részbe.
6. Szorítsa meg az Y-adapter hemosztázis szelepét a GuideLiner katéter proximális szárán a vérzés megelőzése végett.
7. Végezze el a katéterezési eljárást. Az eljárás befejezését követően a vezetőkatéter véredényből történő eltávolítását megelőzően távolítsa el a GuideLiner katétert.

KORLÁTOZOTT JÓTÁLLÁS

A Vascular Solutions, Inc. vállalat garantálja, hogy a GuideLiner katéter gyártási és anyaghibáktól mentes a feltüntetett szavatossági idő lejárta előtt. A jótállás által biztosított felelősség a Vascular Solutions, Inc. által gyártási és anyagi hibásnak minősített termék árának megtérítésére vagy cseréjére korlátozódik. A Vascular Solutions, Inc vállalat nem felel a GuideLiner katéter használatából eredő véletlen, különleges vagy következményes kárért. A termék nem megfelelő használatából, módosításából, helytelen tárolásából vagy helytelen kezeléséből eredő kár érvényteleníti ezt a korlátozott jótállást.

A Vascular Solutions, Inc. egyetlen alkalmazottja, ügynöke vagy viszonteladója sem rendelkezik felhatalmazással arra, hogy bármilyen tekintetben módosítsa vagy kiegészítse ezt a korlátozott jótállást. Semmilyen feltételezett módosítás vagy kiegészítés nem érvényesíthető a Vascular Solutions, Inc. céggel szemben.

EZ A GARANCIA KIFEJEZETTEN HELYETTESÍT MINDEN MÁS KIFEJEZETT VAGY VÉLELMEZETT GARANCIÁT, IDE ÉRTVE AZ ELADHATÓSÁGOT, AZ ADOTT CÉLRA VALÓ ALKALMASSÁGOT VAGY A VASCULAR SOLUTIONS, INC. BÁRMILYEN EGYÉB KÖTELEZETTSÉGÉT.

SZABADALMAK ÉS VÉDJEGYEK

A GuideLiner® a Vascular Solutions, Inc. bejegyzett védjegye.

Catetere GuideLiner®
Istruzioni per l'uso

AVVERTENZE PER IL MERCATO U.S.A.

La legge federale degli Stati Uniti stabilisce che il dispositivo debba essere venduto a personale medicoo dietro prescrizione medica.

DESCRIZIONE DEL DISPOSITIVO

Il catetere GuideLiner è un catetere rapido a lume singolo proposto in dimensioni compatibili con i cateteri guida 6F, 7F e 8F; può inoltre essere collocato sopra a un filo guida o di scambio di 180 cm. L'impiego di cateteri di dimensioni maggiori si intende per le parti prossimali della vascolatura coronarica allo sopo di fornire un opportuno sostegno e/o facilitare l'utilizzo dei vari dispositivi di procedure interventistiche. Il dispositivo di 150 cm è dotato di un corpo di acciaio inossidabile con un lume singolo di 25 cm rivestito in silicone.

Il catetere GuideLiner è dotato di due fasce di marcatura in platino-iridio, che permettono la visibilità con l'uso di metodi fluoroscopici standard. La fascia della tacca distale si trova a 2.16 mm dalla punta distale. La fascia della tacca prossimale è situata a 1 cm dal collare. Sul dispositivo sono riportate due tacche di posizionamento situate rispettivamente a 95 cm (tacca singola) e a 105 cm (tacca doppia) dalla punta distale.

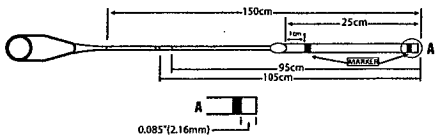
Il catetere GuideLiner viene inserito attraverso un catetere guida, per un diametro interno risultante di circa 1 French più piccolo del catetere guida. Il catetere GuideLiner è dotato di una linguetta prossimale che indica la compatibilità del catetere guida e il risultante diametro interno del catetere GuideLiner.

Il catetere GuideLiner è stato sterilizzato con ossido di etilene.

STERILE EO

SPECIFICHE

Modello	Catetere guida compatibile	Diam. int. min. GuideLiner	Diam. esterno punta GuideLiner
5570 5,5 F	≥ 6 F (diam. int. ≥ / 1,68 mm / 0,066 pollici)	1,30 mm / 0,051 pollici	1,60 mm / 0,063 pollici
5571 6 F	≥ 6 F (diam. int. ≥ / 1,78 mm / 0,070 pollici)	1,42 mm / 0,056 pollici	1,70 mm / 0,067 pollici
5572 7 F	≥ 7 F (diam. int. ≥ / 1,98 mm / 0,078 pollici)	1,57 mm / 0,062 pollici	1,90 mm / 0,075 pollici
5573 8 F	≥ 8 F (diam. int. ≥ / 2,24 mm / 0,088 pollici)	1,80 mm / 0,071 pollici	2,16 mm / 0,085 pollici



INDICAZIONI

La messa a punto dei cateteri GuideLiner prevede l'utilizzoin combinazione con cateteri guida al fine di accedere alle regioni discrete delle coronarie e/o dei vasi periferici e facilitare la collocazione o lo scambio di fili guida e di altri dispositivi di procedure interventistiche.

CONTROINDICAZIONI

I cateteri GuideLiner sono controindicati nei vasi con diametro inferiore ai 2,5 mm, nei vasi presenti nella neuromuscolatura e nel sistema venoso.

AVVERTENZE

Il catetere GuideLiner viene fornito sterile ed è solo monouso. Il riutilizzo di un dispositivo monouso crea un potenziale rischio di infezione per il paziente e l'operatore. La contaminazione del dispositivo può causare malattie o lesioni gravi al paziente.

Non inserire il catetere GuideLiner in un vaso senza un filo guida introduttivo o in mancanza di una guida fluoroscopia che ne confermi la posizione. Ne può conseguire una dissezione o una perforazione dei vasi.

Non inserire il catetere GuideLiner in un vaso con un diametro effettivo inferiore ai 2,5 mm. Ne possono conseguire lesioni, ischemia e/o occlusione. Se la pressione di un vaso si riduce dopo l'inserimento del catetere GuideLiner, rimuovere il catetere GuideLiner fino a quando la pressione non si sia ripristinata su valori normali.

A causa delle dimensioni e dela punta non rastremata di GuideLiner, si raccomanda di prestare la massima attenzione al fine di evitare l'occlusione di un vaso e danni alla parete dei vasi attraverso cui il catetere viene inserito e fatto avanzare.

Se si avverte della resistenza, non far avanzare o rimuovere un dispositivo intravascolare fino a quando non sia stata determinata la causa di tale resistenza mediante fluoroscopia. Il movimento del catetere o del filo guida, nel caso in cui incontri resistenza, può provocare la separazione della punta del catetere o del filo guida, danni al catetere o la perforazione dei vasi.

PRECAUZIONI

Non utilizzare il catetere GuideLiner se la confezione risulta danneggiata.

Prima di ogni utilizzo, controllare che il catetere GuideLiner non presenti pieghe o attorcigliamenti. Non utilizzare un catetere danneggiato. È possibile che si verifichino danni ai vasi e/o che non sia più possibile inserire o estrarre il catetere.

Lavare in modo accurato il lume del catetere con soluzione salina eparinizzata prima dell'uso,al fine di evitare la formazione di coaguli.

La procedura di applicazione del catetere GuideLiner deve essere eseguita da un medico che abbiaricevuto una preparazione adeguata in tecniche e procedure percutanee e intravascolari.

Quando un catetere viene utilizzato nel sistema vascolare, occorre adottare le opportune precauzioni onde prevenire o ridurre la formazione di coaguli. Si raccomanda il ricorso all'eparinizzazione sistemica e alla soluzione sterile eparinizzata.

Per ridurre il rischio di rottura, piegamento o attorcigliamento accidentali, maneggiare il catetere con estrema cura durante la procedura.

Quando il catetere è inserito nel corpo, manipolarlo esclusivamente con l'ausilio della fluoroscopia. Non muovere il catetere senza avere prima osservato la risposta ottenuta dalla punta.

Non inserire mai un catetere GuideLiner più di 15 cm oltre la punta del catetere guida: il catetere GuideLiner potrebbe bloccarsi nel catetere guida e renderne difficile la rimozione.

COMPLICAZIONI

Di seguito sono riportate le complicazioni generalmente associate alle procedure di cateterismo e che possono verificarsi con l'applicazione del catetere GuideLiner:

- infezione locale o sistemica
- embolia gassosa
- rottura della tonaca intima
- dissezione arteriosa
- perforazione delle pareti vascolari
- occlusione vascolare
- trombosi arteriosa
- infarto del miocardio
- spasmo arterioso

PROCEDURA CLINICA

Il catetere GuideLiner deve essere utilizzato da medici preparati nell'esecuzione delle procedure per cui è stato creato il dispositivo. Le tecniche e le procedure descritte non rappresentano TUTTI i protocolli accettabili dal punto di vista medico e non intendono sostituire l'esperienza e il giudizio del medico nel trattamento di un paziente specifico. È opportuno tenere conto di tutti i dati disponibili, compresi i segnali e i sintomi dei pazienti e gli altri esiti dei test diagnostici, prima di determinare la terapia specifica.

La confezione contiene:

- Catetere GuideLiner monouso

Altri articoli richiesti ma non forniti:

- Catetere guida con un diametro interno abbastanza grande da accogliere il modello specifico di catetere GuideLiner utilizzato

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- Adattatore a Y con valvola emostatica (tipo Tuohy-Borst)
- Filo guida con diametro ≤ 0,36 mm
- Siringa sterile (per il lavaggio del sistema)
- Soluzioni salina sterile eparinizzata (per il lavaggio del sistema)

PROCEDURA DI PREPARAZIONE PER L'USO

1. Prima dell'uso, ispezionare con attenzione l'imballaggio e i componenti del catetere GuideLiner per verificare la presenza di eventuali danni.
2. Adottando una tecnica sterile, trasferire l'erogatore a spirale con il catetere GuideLiner nel campo sterile.
3. Sciacquare abbondantemente il lume del catetere GuideLiner dalla punta distale con soluzione salina eparinizzata.

PROCEDURA DI APPLICAZIONE

Applicare il catetere GuideLiner attenendosi alle indicazioni riportate di seguito.

1. Fissare il filo guida precedentemente introdotto e caricare a ritrosola punta distale del catetere GuideLiner nel filo guida, quindi farlo avanzare fino a quando il catetere è nei pressi della valvola emostatica.
2. Aprire la valvola emostatica e fare avanzare il catetere GuideLiner attraverso la valvola, fin nel catetere guida.
3. Alla fluoroscopia, fare avanzare il catetere GuideLiner fino a un massimo di 15 cm oltre la punta distale del catetere guida, fin nella posizione desiderata all'interno del vaso.

   Avvertenza: Non inserire il catetere GuideLiner in un vaso con un diametro effettivo inferiore ai 2,5 mm. Ne possono conseguire lesioni, ischemia e/o occlusione. Se la pressione di un vaso si riduce dopo l'inserimento del catetere GuideLiner, rimuovere il catetere GuideLiner fino a quando la pressione non si sia ripristinata su valori normali.

   Avvertenza: A causa delle dimensioni e della punta non rastremata di GuideLiner, si raccomanda la massima attenzione al fine di evitare l'occlusione di un vaso e danni alla parete del vasi attraverso cui il catetere viene inserito e fatto avanzare.
4. Alla fluoroscopia, confermare la posizione desiderata del catetere GuideLiner nel vaso.
5. Durante l'esecuzione di una procedura interventistica,, caricare a ritroso il dispositivo sul filo guida in situ facendolo avanzare attraverso il catetere guida e il catetere GuideLiner fino a raggiungere lo spazio vascolare desiderato.
6. Serrare saldamente la valvola emostatica dell'adattatore a Y sul corpo prossimale del catetere GuideLiner per impedire il ritorno del sangue.
7. Eseguire la procedura di cateterizzazione. Al termine della procedura, rimuovere il catetere GuideLiner prima di rimuovere il catetere guida dal vaso.

GARANZIA LIMITATA

Vascular Solutions, Inc. garantisce che il catetere GuideLiner non presenterà difetti nella lavorazione e nei materiali prima della data di scadenza riportata sulla confezione. La responsabilità prevista dalla presente garanzia è limitata al rimborso del costo o alla sostituzione di qualsiasi prodotto che Vascular Solutions, Inc. abbia appurato presentare difetti nella lavorazione o nei materiali. Vascular Solutions, Inc. non sarà responsabile di danni indiretti, speciali o consequenziali derivanti dall'uso del catetere GuideLiner. I danni causati al dispositivo da utilizzi impropri, alterazioni, modalità di conservazione non idonee o errata manipolazione annulleranno la presente garanzia limitata.

I dipendenti, gli agenti o i distributori di Vascular Solutions, Inc. non sono autorizzati a modificare o a correggere in nessun modo la presente garanzia limitata. Eventuali modifiche o correzioni presunte non potranno essere considerate applicabili ai danni di Vascular Solutions, Inc.

QUESTA GARANZIA SOSTITUISCE ESPLICITAMENTE QUALSIASI ALTRA GARANZIA, ESPRESSA O IMPLICITA, INCLUSA QUALSIASI GARANZIA DI COMMERCIABILITÀ, IDONEITÀ AD UN USO PARTICOLARE O OGNI ALTRA RESPONSABILITÀ DI VASCULAR SOLUTIONS, INC.

BREVETTI E MARCHI

GuideLiner® è un marchio registrato di Vascular Solutions, Inc.

GuideLiner® Katheter Gebruiksaanwijzing

VS OPGELET

Volgens de federale wetgeving in de VS mag dit product uitsluitend worden verkocht door of op voorschrift van een arts.

BESCHRIJVING VAN HET INSTRUMENT

De GuideLiner katheter is een katheter met één lumen voor snelle uitwisseling die wordt aangeboden in maten die combineerbaar zijn met 6F, 7F en 8F geleidekatheters en die via 180 cm voerdraad verwisseld kunnen worden. De grotere maten GuideLiner katheters zijn bedoeld voor gebruik binnen de proximale gedeelten van de coronaire vasculatuur om ondersteuning te bieden en/of het gebruik van meerdere interventionele hulpmiddelen te vergemakkelijken. Het 150 cm lange hulpmiddel heeft een roestvrij stalen schacht met een 25 cm lange lumen die is ingesmeerd met siliconen.

De GuideLiner katheter heeft twee markeringsbanden van platina-iridium die door het gebruik van standaard fluoroscopische methoden zichtbaar zijn. De distale markeringsband bevindt zich op 2.16 mm vanaf het distale eind. De proximale markeringsband bevindt zich op 1 cm vanaf de kraag. Het hulpmiddel heeft twee witte positioneringsmarkeringen op respectievelijk 95 cm (enkele markering) en 105 cm (dubbele markering) van het distale uiteinde.

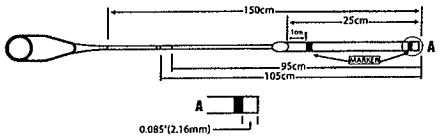
De GuideLiner katheter wordt op zijn plaats gebracht door een geleidekatheter waardoor een binnendiameter ontstaat die ongeveer 1 French kleiner is dan de geleidekatheter. De GuideLiner katheter heeft een proximaal klepje dat de combineerbaarheid met de geleidekatheter en de resulterende binnendiameter van de GuideLiner katheter aanduidt.

De GuideLiner katheter is gesteriliseerd met ethyleenoxide.

STERILE EO

SPECIFICATIES

Model	Combineerbare geleidekatheter	GuideLiner min. Binnendiameter	GuideLiner tip buitendiameter
5570 5,5F	≥ 6F (≥ 0,066" / 1,68mm binnendiameter)	0,051" / 1,30 mm	0,063" / 1,60 mm
5571 6F	≥ 6F (≥ 0,070" / 1,78 mm binnendiameter)	0,056" / 1,42 mm	0,067" / 1,70 mm
5572 7F	≥ 7F (≥ 0,078" / 1,98 mm binnendiameter)	0,062" / 1,57 mm	0,075" / 1,90 mm
5573 8F	≥ 8F (≥ 0,088" / 2,24 mm binnendiameter)	0,071" / 1,80 mm	0,085" / 2,16 mm



INDICATIES

De GuideLiner katheters zijn bestemd voor gebruik in combinatie met geleidekatheters voor toegang tot moeilijk toegankelijke delen van de coronaire en/of de perifere vasculatuur, en om het plaatsen en uitwisselen van voerdraden en andere interventionele hulpmiddelen te vergemakkelijken.

CONTRA-INDICATIES

De GuideLiner katheters zijn gecontra-indiceerd bij bloedvaten van minder dan 2,5 mm in diameter, vaten in de neurovasculatuur en in aderen.

WAARSCHUWINGEN

De GuideLiner katheter wordt steriel geleverd en is uitsluitend bedoeld voor eenmalig gebruik. Bij hergebruik van een instrument voor eenmalig gebruik bestaat er een kans op infecties bij de patiënt of gebruiker. Contaminatie van het instrument kan leiden tot ziekte of ernstig letsel bij de patiënt.

Voer de GuideLiner katheter nooit zonder voerdraad door een bloedvat of zonder de plaatsing met behulp van fluoroscopische hulp te bevestigen. Dit kan scheuren of perforatie van het bloedvat tot gevolg hebben.

Voer de GuideLiner katheter nooit door een bloedvat met een kleinere effectieve diameter dan 2,5 mm. Dit kan bloedvatletsel, ischemie, en/of occlusie tot gevolg hebben. Als na het invoeren van de GuideLiner katheter de druk in een bloedvat afneemt moet de GuideLiner katheter worden teruggetrokken totdat de druk weer naar normale waarden terugkeert.

Vanwege het formaat en het niet taps toelopende uiteinde van de GuideLiner katheter, moet bijzonder voorzichtig te werk worden gegaan om vaatocclusie en schade aan de wand van de vaten waardoor deze katheter wordt geleid te vermijden.

Voer een intravasculair instrument nooit door en trek het nooit terug tegen weerstand in tot de oorzaak van de weerstand via fluoroscopie is bepaald. Beweging van de katheter of de voerdraad tegen weerstand in kan leiden tot loslating van de katheter of het uiteinde van de voerdraad, beschadiging van de katheter of perforatie van een vat.

VOORZORGSMAATREGELEN

Gebruik de GuideLiner katheter niet als de verpakking beschadigd is.

Inspecteer de GuideLiner katheter vóór gebruik op eventuele bochten en knikken. Gebruik een beschadigde katheter niet. Vaatbeschadigingen en/of niet kunnen doorvoeren of terugtrekken van de katheter kunnen voorkomen.

Het katheter lumen moet voorafgaand aan het gebruik grondig met gehepariniseerde zoutoplossing worden gespoeld om het vormen van bloedstolsels te voorkomen.

Het gebruiken van GuideLiner katheters moet worden gedaan door artsen die grondig zijn opgeleid voor percutane, intravasculaire technieken en methoden.

Telkens wanneer een katheter in het vaatstelsel wordt gebruikt, moeten er voorzorgsmaatregelen worden genomen om stolselvorming te voorkomen of te verminderen. Overweeg systemische heparinisatie en het gebruik van een gehepariniseerde steriele oplossing.

Wees voorzichtig bij het hanteren van de katheter tijdens een ingreep om de mogelijkheid van onopzettelijk breken, buigen of knikken te verminderen.

Als de katheter in het lichaam zit, mag deze uitsluitend onder fluoroscopie worden bewogen. Probeer niet de katheter te bewegen zonder te letten op de reactie van het uiteinde op die beweging.

Voer de GuideLiner katheter nooit verder dan 15 cm voorbij het uiteinde van de geleidekatheter omdat de GuideLiner katheter dan in de geleidekatheter vast kan komen te zitten, waardoor deze moeilijk te verwijderen is.

COMPLICATIES

Zoals tijdens alle katherisatie procedures, kunnen er ook bij gebruik van de GuideLiner katheter complicaties optreden. De volgende complicaties zijn onder meer mogelijk:

- lokale of systemische infectie
- luchtembolie
- intimale verstoring
- arteriële dissectie
- perforatie van de vaatwand
- vaat-occlusie
- arteriële trombose
- myocardinfarct
- arterieel spasme

KLINISCHE PROCEDURE

De GuideLiner katheter mag alleen worden gebruikt door artsen die zijn opgeleid voor de procedures waarvoor het instrument is bedoeld. De beschreven technieken en procedures representeren niet ALLE medisch aanvaardbare protocollen, noch zijn zij bedoeld ter vervanging van de ervaring en het oordeel van een arts tijdens de behandeling van specifieke patiënten. Er dient rekening gehouden te worden met alle beschikbare gegevens, inclusief de tekenen en symptomen van de patiënt en andere diagnostische onderzoeksresultaten, voordat er een specifiek behandelingsplan wordt opgesteld.

De verpakking bevat:

- Disposable GuideLiner katheter voor eenmalig gebruik

Andere materialen die nodig zijn, maar niet zijn bijgeleverd:

- Geleidekatheter met een binnendiameter die groot genoeg is voor het model GuideLiner katheter dat gebruikt wordt.
- Y-adapter met hemostaseklep (Tuohy-Borst type)
- Voerdraad met een diameter ≤ 0,36 mm
- Steriele spuit (voor doorspoelen van het systeem)
- Steriele gehepariniseerde zoutoplossing (voor het flushen van het systeem)

VOORBEREIDINGEN VOOR GEBRUIK

1. Controleer voor gebruik de verpakking en onderdelen van de GuideLiner katheter zorgvuldig op beschadiging.
2. Breng met gebruikmaking van steriele techniek de dispenserspoel met de GuideLiner katheter in het steriele veld.
3. Spoel de lumen van de GuideLiner katheter vanaf het distale uiteinde goed door met gehepariniseerde zoutoplossing.

GEBRUIKSPROCEDURE

Plaats de GuideLiner katheter aan de hand van de volgende stappen:

1. Zet de vooraf ingebrachte voerdraad vast en plaats het distale uiteinde van de GuideLiner katheter op de voerdraad en schuif de katheter op tot net voor de hemostaseklep.
2. Open de hemostaseklep en voer de GuideLiner katheter door de hemostaseklep en in de geleidekatheter.
3. Voer de GuideLiner katheter onder geleide van fluoroscopie tot maximaal 15 cm voorbij het distale uiteinde van de geleidekatheter en naar de gewenste locatie binnen het bloedvat.

   Waarschuwing: Voer de GuideLiner katheter nooit door een bloedvat met een kleinere effectieve diameter dan 2,5 mm. Dit kan bloedvatletsel, ischemie, en/of occlusie tot gevolg hebben. Als na het invoeren van de GuideLiner katheter de druk in een bloedvat afneemt moet de GuideLiner katheter worden teruggetrokken totdat de druk weer naar normale waarden terugkeert.

   Waarschuwing: Vanwege het formaat en het niet taps toelopende uiteinde van de GuideLiner katheter, moet bijzonder voorzichtig te werk worden gegaan om vaatocclusie en schade aan de wand van de vaten waardoor deze katheter wordt geleid te vermijden.
4. Bevestig door middel van fluoroscopie dat de GuideLiner katheter op de juiste plaats in het bloedvat zit.
5. Bij het uitvoeren van een interventionele procedure, plaats het interventionele hulpmiddel over de voerdraad en schuif het hulpmiddel door de geleidekatheter en de GuideLiner katheter in het gewenste bloedvat.
6. Bevestig de Y-adapter hemeostaseklep goed op de proximale schacht van de GuideLiner katheter om terugvloeiing te voorkomen.
7. Voer de katheterisatie procedure uit. Nadat het voltooien van de procedure verwijdert u de GuideLiner katheter alvorens de geleidekatheter uit het bloedvat te halen.

BEPERKTE GARANTIE

Vascular Solutions, Inc. garandeert dat de GuideLiner katheter voorafgaand aan de vermelde vervaldatum vrij is van materiaal- en fabricagefouten. De aansprakelijkheid onder deze garantie is beperkt tot de vergoeding of de vervanging van ieder product waarvan Vascular Solutions, Inc. heeft vastgesteld dat het materiaal- en fabricagefouten vertoont. Vascular Solutions, Inc. is niet aansprakelijk voor incidentele, speciale of gevolgschade die voortvloeit uit het gebruik van de GuideLiner katheter. Schade aan het product door onjuist gebruik, verandering, onjuiste opslag of onjuiste hantering maken deze beperkte garantie ongeldig.

Geen enkele medewerker, agent of distributeur van Vascular Solutions, Inc. is bevoegd om deze beperkte garantie op enigerlei wijze te wijzigen of amenderen. Enige beoogde verandering of aanpassing kan niet worden opgelegd aan Vascular Solutions, Inc.

DEZE GARANTIE IS UITDRUKKELIJK IN PLAATS VAN ALLE ANDERE GARANTIES, STILZWIJGEND OF UITDRUKKELIJK, INCLUSIEF GARANTIES VAN VERKOOPBAARHEID OF GESCHIKTHEID VOOR EEN BEPAALD DOEL OF ENIGE ANDERE VERPLICHTING VAN VASCULAR SOLUTIONS, INC.

PATENTEN EN HANDELSMERKEN

GuideLiner® is een geregistreerd handelsmerk van Vascular Solutions, Inc.

GuideLiner® kateter Bruksanvisning

USA OBS

Føderal lovgivning i USA begrenser salg av dette produktet til fra lege eller etter leges anvisning.

GuideLiner-kateteret med rask utveksling for ett lumen tilbys i størrelser som er kompatible med 6F, 7F, og 8F ledekatetre, og kan plasseres over en utvekslingslengde eller en 180 cm lang ledesonde. De største GuideLiner-kateterne skal brukes innenfor de proksimale delene av den koronare vaskulaturen for å støtte og/eller muliggjøre innføringen av flere instrumenter.150 cm-instrumentet har et rustfritt skaft med et 25 cm langt enkelt lumen innsmurt med silikon.

GuideLiner-kateteret har to markørbånd i platina-iridium, som gjør det mulig å se når du bruker vanlige gjennomlysingsmetoder. Det distale markørbåndet ligger 2.16 mm fra distalspissen. Det proksimale markørbåndet ligger 1 cm fra mansjetten. Kateteret har to posisjoneringsmerker plassert 95 cm (enkeltmerke) og 105 cm (dobbeltmerke) fra distalspissen.

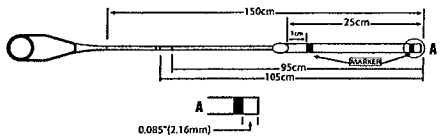
GuideLiner-kateteret innføres gjennom et ledekateter som gir en indre diameter som er omtrent 1 french mindre enn ledekateteret. GuideLiner kateteret har en proksimal tunge som indikerer ledekateterkompatibilitet og den resulterende indre diameteren i GuideLiner-kateteret.

GuideLiner-kateteret er sterilisert med etylenoksid.

STERILE EO

SPESIFIKASJONER

Modell	Kompatibelt ledekateter	GuideLiner Min. I.D.	GuideLiner-tupp OD
5570 5,5F	≥ 6F (≥ 1,68 mm ID)	0.051" / 1,30 mm	0.063" / 1,60 mm
5571 6F	≥ 6F (≥ 1,78 mm I.D.)	1,42 mm	1,70 mm
5572 7F	≥ 7F (≥ 1,98 mm I.D.)	1,57 mm	1,90 mm
5573 8F	≥ 8F (≥ 2,24 mm I.D.)	1,80 mm	2,16 mm



INDIKASJONER

GuideLiner-katetre er laget for bruk i forbindelse med ledekatetre for å få tilgang til atskilte områder av koronare og/eller perifere blodkar, og for å legge til rette for plassering og utveksling av ledesonder og andre intervensjonsinstrumenter.

KONTRAINDIKASJONER

GuideLiner-kateteret er kontraindisert i blodkar som er mindre enn 2,5 mm i diameter, kar i det nevrovaskulære og venøse systemet.

ADVARSLER

GuideLiner-kateteret leveres sterilt og er kun til engangsbruk. Gjenbruk av et engangsanordninger utgjør en potensiell fare for infeksjoner hos pasient og bruker. Kontaminering av instrumentet kan føre til sykdommer eller alvorlig pasientskade.

Sett aldri GuideLiner-kateteret inn i et blodkar uten ledesonde eller uten å bekrefte posisjonen ved hjelp fluoroskopisk veiledning. Kardisseksjon eller perforering kan være resultatet.

Før aldri GuideLiner-kateteret inn i et blodkar med en effektiv diameter på under 2,5 mm. Karskade, iskemi, og/eller okklusjon kan være resultatet. Dersom trykket i et kar synker etter innlegging av GuideLiner-kateteret, trekkes kateteret ut til trykket tilbake til det normale.

Før aldri GuideLiner-kateteret mer enn 15 cm lengre enn spissen på ledekateteret, siden GuideLiner-kateteret kan sette seg fast i ledekateteret og bli vanskelig å fjerne.

Et intravaskulært instrument må aldri føres frem eller trekkes tilbake mot motstand før årsaken til motstanden er avdekket med gjennomlysning. En bevegelse av kateteret eller ledesonden mot motstand kan føre til at kateter- eller ledesondespissen separeres, skade på kateteret eller perforering av blodkaret.

På grunn av størrelsen og tuppen på GuideLiner, må det utøves ekstrem forsiktighet for å unngå blodkarokklusjon og skade på blodkarveggene som kateteret føres igjennom.

FORHOLDSREGLER

Ikke bruk GuideLiner-kateteret hvis emballasjen er skadet.

Inspiser GuideLiner-kateteret før bruk for enhver form for knekk. Ikke bruk et skadet kateter. Dette kan føre til skade på blodkar og/eller til at kateteret ikke kan føres frem eller trekkes tilbake.

Kateterlumenet bør skylles grundig med heparinisert saltløsning før bruk for å hindre dannelse av blodpropp.

Prosedyren for anbringing av GuideLiner-kateteret må utføres av leger med grundig opplæring i perkutane, intravaskulære teknikker og prosedyrer.

Det må tas forholdsregler for å hindre eller redusere koagulering når kateteret brukes i vaskulaturen. Man bør vurdere bruk av systemisk heparinisering og heparinisert steril løsning.

Vær forsiktig ved håndtering av kateteret under inngrepet for å redusere faren for utilsiktet brudd, bøying eller knekking.

Når kateteret er i kroppen, må det manipuleres bare under gjennomlysning. Ikke forsøk å bevege kateteret uten å observere den resulterende spissresponsen.

Før aldri GuideLiner-kateteret mer enn 15 cm lengre enn spissen på ledekateteret, siden GuideLiner-kateteret kan sette seg fast i ledekateteret og bli vanskelig å fjerne

KOMPLIKASJONER

Følgende komplikasjoner er generelt forbundet med innføring av kateter, og kan forekomme ved bruk av GuideLiner-kateteret:

- lokal eller systemisk infeksjon
- luftemboli
- sprengt blodkar
- arteriedisseksjon
- perforering av karveggen
- vaskulær okklusjon
- arterietrombose
- myokardinfarkt
- arteriespasmer

KLINISK PROSEDYRE

GuideLiner-kateteret må brukes av leger med opplæring i prosedyrene som instrumentet er beregnet på. Teknikkene og prosedyrene som beskrives utgjør ikke ALLE medisinsk akseptable protokoller, de er heller ikke ment å erstatte legens erfaring og vurdering ved behandling av spesifikke pasienter. Alle tilgjengelige data, inkludert pasientens vitale tegn, symptomer og andre diagnostiske testresultater, må vurderes før en bestemt behandlingsplan besluttes.

Pakken inneholder:

- GuideLiner-kateter til engangsbruk

Annet utstyr som kreves, men som ikke følger med:

- Ledekateter med en indre diameter stor nok til å romme den modellen av GuideLiner-kateteret som er i bruk
- Y-adapter med hemostaseventil (Tuohy-Borst-type)
- Ledesonde med diameter ≤ 0,36 mm
- Steril sprøyte (for systemskylling)
- Steril, heparinisert løsning (for systemskylling)

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KLARGJØRING FOR BRUK

1. Før bruk må man inspisere emballasjen og komponentene i GuideLiner-kateteret.
2. Bruk steril teknikk, plasser dispenserspiralen med GuideLiner-kateteret i det sterile feltet.
3. Skyll lumen av GuideLiner-kateteret fra distalspissen med heparinisert saltløsning.

PROSEDYRE FOR ANLEGGELSE

Anlegg GuideLiner-kateteret i henhold til følgende trinn:

1. Fest tidligere innsatte ledesonder og sett distalspissen av GuideLiner-kateter på ledesonden. Før den inn til kateteret er akkurat proksimal i forhold til hemostaseventilen.
2. Åpne hemostaseventilen og før GuideLiner-kateteret gjennom hemostaseventilen og inn i ledekateteret.
3. Under gjennomlysning føres GuideLiner-kateteret opp til maksimalt 15 cm fra distaltuppen på ledekateteret og inn til ønsket plassering i karet.

   Advarsel: Før aldri GuideLiner-kateteret inn i et blodkar med en effektiv diameter på under 2,5 mm. Karskade, iskemi, og/eller okklusjon kan være resultatet. Dersom trykket i et kar synker etter innlegging av GuideLiner-kateteret, trekkes kateteret ut til trykket tilbake til det normale.

   Advarsel: På grunn av størrelsen og tuppen på GuideLiner, må det utøves ekstrem forsiktighet for å unngå blodkarokklusjon og skade på blodkarveggene som kateteret føres igjennom.
4. Ved hjelp av gjennomlysning bekreftes den ønskede posisjonen til GuideLiner-kateteret i blodkaret.
5. Hvis du utfører et intervensjonsinngrep, plasserer du intervensjonsinstrumentet over ledesonden som er på plass, og fører instrumentet gjennom ledekateteret og GuideLiner-kateteret til ønsket vaskulær posisjon.
6. Stram til Y-adapter-hemostaseventilen på proksimalskaftet på GuideLiner-kateteret for å unngå tilbakeblødning.
7. Utfør kateteriseringsinngrepet. Etter å ha fullført inngrepet, må du fjerne GuideLiner-kateteret før du fjerner ledekateteret fra karet.

BEGRENSET GARANTI

Vascular Solutions, Inc. garanterer at GuideLiner-kateteret er fritt for defekter i materialer og utførelse frem til den oppgitte utløpsdatoen. Ansvaret under denne garantien begrenser seg til refusjon eller erstatning av produkter som Vascular Solutions, Inc. finner å ha defekter i materialer eller utførelse. Vascular Solutions, Inc. har ikke noe ansvar for tilfeldige tap, spesielle tap eller følgeskader som oppstår ved bruk av GuideLiner-katetere. Skade på produktet som skyldes feilaktig bruk, endringer, feilaktig oppbevaring eller ukorrekt håndtering vil gjøre denne garantien virkningsløs.

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DENNE GARANTIEN ERSTATER UTTRYKKELIG ALLE ANDRE GARANTIER, UTTRYKTE ELLER IMPLISERTE, INKLUDERT ENHVER GARANTI OM SALGBARHET, EGNETHET TIL ET BESTEMT FORMÅL ELLER ENHVER ANNEN FORPLIKTELSE FOR VASCULAR SOLUTIONS, INC.

PATENTER OG VAREMERKER

GuideLiner® er et registrert varemerke som tilhører Vascular Solutions, Inc.

GuideLiner® - cewnik
Instrukcja obsługi

PRZESTROGA DOT. USA

Prawo federalne (USA) dopuszcza sprzedaż tego narzędzia wyłącznie lekarzowi lub na zalecenie lekarza.

OPIS NARZĘDZIA

GuideLiner jest szybkowymienialnym cewnikiem o jednym lumenie, dostępnym w rozmiarach zgodnych z prowadnikami w rozmiarach 6F, 7F i 8F, który można nakładać na prowadnik niezmiennej długości lub o długości 180 cm. Zamysłem wykorzystywania większych rozmiarów jest stosowane cewnika GuideLiner w proksymalnych odcinkach naczyń wieńcowych, by podpierać i/lub ułatwiać manipulację różnorodnymi narzędziami interwencyjnymi. Narzędzie o długości 150 cm ma trzpień ze stali nierdzewnej o lumenie 25 cm, wyłożonym silikonem.

Cewnik GuideLiner ma dwie opaski markerów platynowo-irydowych, umożliwiających widoczność podczas stosowania standardowych metod fluoroskopii. Dystalna opaska markera znajduje się 2.16 mm od końcówki dystalnej cewnika. Proksymalna opaska markera znajduje się 1 cm od kołnierza. Cewnik ma dwa znaczniki pozycjonujące, znajdujące się, odpowiednio, 95 cm (znacznik pojedynczy) i 105 cm (znacznik podwójny) od końcówki dystalnej.

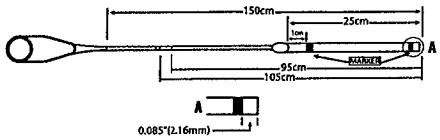
Cewnik GuideLiner jest wprowadzany przez cewnik prowadzący, w wyniku czego jego średnica wewnętrzna zmniejsza się o około 1F w stosunku do średnicy cewnika prowadzącego. Cewnik GuideLiner ma w proksymalnej części oznaczenie, wskazujące kompatybilność cewnika prowadzącego i ostateczną średnicę wewnętrzną cewnika GuideLiner.

Cewnik GuideLiner został wysterylizowany tlenkiem etylenu.

STERILE EO

SPECYFIKACJE

Model	Kompatybilny cewnik prowadzący	Min. średn. wewn. GuideLiner	Średn. zewn. końcówki cewnika GuideLiner
5570 5.5F	≥ 6F (średn. wewn. ≥ 0,066"/ 1,68 mm)	0,051"/ 1,30 mm	0,63"/ 1,60 mm
5571 6F	≥ 6F (średn. wewn. ≥ 0,070"/ 1,78 mm)	0,056"/ 1,42 mm	0,067"/ 1,70 mm
5572 7F	≥ 7F (średn. wewn. ≥ 0,078"/ 1,98 mm)	0,062"/ 1,57 mm	0,075"/ 1,90 mm
5573 8F	≥ 8F (średn. wewn. ≥ 0,088"/ 2,24 mm)	0,071"/ 1,80 mm	0,085"/ 2,16 mm



ZALECENIA

Cewniki GuideLiner są przeznaczone do stosowania z cewnikami prowadzącymi w celu uzyskiwania dostępu do dyskretnych regionów naczyń wieńcowych i/lub obwodowych oraz aby ułatwić rozmieszczenie i wymianę prowadników i innych urządzeń interwencyjnych.

PRZECIWWSKAZANIA

Cewniki GuideLiner są przeciwwskazane do wprowadzania do naczyń o średnicy mniejszej niż 2,5 mm, do układu nerwowo-naczyniowego i układu żylnego.

OSTRZEŻENIA

Cewnik GuideLiner jest przeznaczony wyłącznie do jednorazowego użytku. Ponowne zastosowanie sprzętu jednorazowego użytku stanowi potencjalne ryzyko zakażenia pacjenta lub użytkownika. Zanieczyszczenie narzędzia może prowadzić do choroby lub poważnego uszkodzenia ciała pacjenta.

Nigdy nie wolno wsuwać cewnika GuideLiner do naczynia bez prowadnicy wiodącej ani bez potwierdzenia lokalizacji przy użyciu fluoroskopii. Może to spowodować rozwarstwienie lub perforację naczyń.

Nigdy nie wolno wprowadzać cewnika GuideLiner do naczynia z rzeczywistą średnicą mniejszą niż 2,5 mm. Może to spowodować uszkodzenie naczynia, niedokrwienie i/lub jego okluzję. Jeżeli ciśnienie w naczyniu spada po wsunięciu cewnika GuideLiner, wycofać cewnik GuideLiner aż powróci normalne ciśnienie.

Z uwagi na rozmiary oraz niezwężającą się końcówkę cewnika GuideLiner należy zachować szczególną ostrożność, by uniknąć zamknięcia się naczynia i uniknąć uszkodzeń ścian naczyń krwionośnych, przez które przechodzi cewnik.

Nigdy nie należy wprowadzać lub wycofywać narzędzia wewnątrznaczyniowego przy wyczuwalnym oporze, dopóki przyczyna oporu nie zostanie stwierdzona w warunkach fluoroskopii. Ruch cewnika lub prowadnicy mimo oporu może spowodować oddzielenie końcówki cewnika lub prowadnicy, uszkodzenie cewnika lub perforację naczynia.

ŚRODKI OSTROŻNOŚCI

Nie używać cewnika GuideLiner, jeśli opakowanie zostało uszkodzone.

Przed użyciem cewnika GuideLiner sprawdzić, czy nie ma zgięć ani skręceń. Nie korzystać z uszkodzonego cewnika. Może to spowodować uszkodzenie naczynia i/lub niezdolność do wprowadzenia lub wycofania cewnika.

Lumen cewnika należy dokładnie przepłukać sterylnym heparynizowanym roztworem soli fizjologicznej, aby zapobiegać powstawaniu skrzepów.

Cewnik GuideLiner powinni wprowadzać wyłącznie lekarze, odpowiednio przeszkoleni w zakresie przezskórnych technik i zabiegów wewnątrznaczyniowych.

Podczas każdego stosowania cewnika w układzie naczyniowym należy stosować środki mające na celu zapobieganie lub zmniejszanie krzepnięcia krwi. Należy rozważyć zastosowanie heparynizacji układowej i heparynizowanego sterylnego roztworu.

Używając cewnika podczas procedury należy zachować ostrożność, aby zmniejszyć ewentualność przypadkowego uszkodzenia, zgięcia lub skręcenia.

Gdy cewnik znajduje się w organizmie pacjenta, należy nim manipulować wyłącznie w warunkach fluoroskopii. Nie podejmować próby poruszania cewnikiem przy braku reakcji końcówki.

Nigdy nie wolno wsuwać cewnika GuideLiner więcej niż 15 cm poza końcówkę cewnika prowadzącego, ponieważ cewnik GuideLiner może utknąć w cewniku prowadzącym, co utrudni jego wysunięcie.

POWIKŁANIA

Poniżej opisano powikłania związane z procedurami cewnikowania, które mogą wystąpić podczas stosowania cewnika GuideLiner:

- infekcja miejscowa lub systemowa
- zator powietrzny
- przerwanie błony wewnętrznej
- rozwarstwienie tętnic
- perforacja ściany naczynia
- okluzja naczyniowa
- zakrzepica tętnicza
- zawał mięśnia sercowego
- skurcz tętniczy

PROCEDURA KLINICZNA

Cewnika GuideLiner powinni używać lekarze przeszkoleni w stosowaniu procedur, do których to narzędzie jest przeznaczone. Techniki i procedury opisane poniżej nie odzwierciedlają WSZYSTKICH dopuszczalnych medycznie protokołów, nie mają też pełnić funkcji substytutu doświadczenia lekarza ani jego możliwości oceny podczas leczenia jakiegokolwiek pacjenta. Przed ustaleniem konkretnego planu leczenia należy rozważyć wszystkie dostępne dane, w tym objawy przedmiotowe i podmiotowe występujące u pacjenta oraz wyniki badań diagnostycznych.

Opakowanie zawiera:

- Cewnik jednorazowego GuideLiner

Inne niezbędne elementy, ale niedołączone do zestawu:

- Cewnik prowadzący o średnicy wewnętrznej wystarczająco dużej, aby pomieścić dany model używanego cewnika GuideLiner
- Adapter Y wyposażonej w zawór hemostatyczny (typu Tuohy-Borst),
- Prowadnica o średnicy ≤ 0,36 mm
- Sterylna strzykawka (do przepłukiwania układu)
- Heparynizowany roztwór soli fizjologicznej (do przepłukiwania układu)

PRZYGOTOWANIE DO UŻYCIA

1. Przed użyciem cewnika GuideLiner dokładnie zbadać jego opakowanie i komponenty w poszukiwaniu uszkodzeń.
2. Przy użyciu sterylnej techniki przenieść cewkę dozującą wraz z cewnikiem GuideLiner do sterylnej strefy.

3. Dokładnie przepłukać lumen cewnika GuideLiner, od końcówki dystalnej, używając heparynizowanego roztworu soli fizjologicznej.

PROCEDURA UMIEJSCAWIANIA

Wprowadzić cewnik GuideLiner zgodnie z następującymi krokami:

1. Zamocować wcześniej wsuniętą prowadnicę i umieścić na końcówce dystalnej cewnika GuideLiner na prowadnicy i wsuwać, aż cewnik znajdzie się w pobliżu zaworu hemostatycznego.
2. Otworzyć zawór hemostatyczny i wsunąć cewnik GuideLiner zawór hemostatyczny oraz do cewnika prowadzącego.
3. W warunkach fluoroskopii przesuwać cewnik GuideLiner maksymalnie do 15 cm poza końcówkę dystalną cewnika prowadzącego i do żądanej lokalizacji w naczyniu.

   Ostrzeżenie: Nigdy nie wsuwać cewnika GuideLiner do naczynia z efektywną średnicą mniejszą niż 2,5 mm. Może to spowodować uszkodzenie naczynia, niedokrwienie i/lub jego okluzję. Jeżeli ciśnienie w naczyniu spada po wsunięciu cewnika GuideLiner, wycofać cewnik GuideLiner aż powróci normalne ciśnienie.

   Ostrzeżenie: Z uwagi na rozmiary oraz niezwężającą się końcówkę cewnika GuideLiner należy zachować szczególną ostrożność, by uniknąć zamknięcia się naczynia i uniknąć uszkodzeń ścian naczyń krwionośnych, przez które przechodzi cewnik.
4. W warunkach fluoroskopii potwierdzić żądaną pozycję cewnika GuideLiner w naczyniu.
5. Podczas procedur zabiegowych, umieścić narzędzie na wprowadzonej prowadnicy i wsuwać narzędzie przez cewnik prowadzący i cewnik GuideLiner do pożądanego miejsca w naczyniu.
6. Dokręcić zawór hemostatyczny adaptera Y na trzpieniu proksymalnym cewnika GuideLiner, aby zapobiec krwawieniu wstecznemu.
7. Wykonać procedurę cewnikowania. Po zakończeniu procedury, usunąć cewnik GuideLiner, przed wyjęciem cewnika prowadzącego z naczynia.

OGRANICZONA GWARANCJA

Vascular Solutions, Inc. gwarantuje, że przed upływem daty ważności cewnik GuideLiner nie ma wad produkcyjnych i materiałowych. Odpowiedzialność w ramach niniejszej gwarancji ogranicza się do zwrotu kosztów lub wymiany produktu, który według firmy Vascular Solutions, Inc. ma wady produkcyjne lub materiałowe. Firma Vascular Solutions, Inc. nie ponosi odpowiedzialności za żadne uboczne, specjalne ani wtórne szkody wynikające z użytkowania cewnika GuideLiner. Uszkodzenia produktu wynikające z niewłaściwego użycia, przeróbek, niewłaściwego przechowywania lub niewłaściwego posługiwania się spowodują unieważnienie niniejszej ograniczonej gwarancji.

Żaden pracownik, przedstawiciel czy dystrybutor firmy Vascular Solutions, Inc. nie jest upoważniony do wprowadzania zmian lub poprawek do niniejszej ograniczonej gwarancji w żadnym zakresie. Wszelkie domniemane zmiany lub poprawki nie są skuteczne w stosunku do Vascular Solutions, Inc.

NINIEJSZA KLAUZULA GWARANCYJNA W SPOSÓB WYRAŹNY WYŁĄCZA STOSOWANIE WSZELKICH INNYCH WARUNKÓW USTANAWIAJĄCYCH ODPOWIEDZIALNOŚĆ Z TYTUŁU GWARANCJI JAKOŚCI LUB RĘKOJMI WYRAŹNEJ LUB DOROZUMIANEJ, WŁĄCZAJĄC W TO JAKĄKOLWIEK ODPOWIEDZIALNOŚĆ VASCULAR SOLUTIONS, INC. ZA PRZYDATNOŚĆ DO CELÓW ZWYKŁYCH ALBO TEŻ DO CELÓW SZCZEGÓLNYCH LUB INDYWIDUALNYCH.

PATENTY I ZNAKI TOWAROWE

GuideLiner® jest zastrzeżonym znakiem towarowym Vascular Solutions, Inc.

Cateter GuideLiner®
Instruções de uso

AVISO PARA OS EUA

A lei federal restringe a venda deste dispositivo por um médico ou mediante requisição de um médico.

DESCRIÇÃO DO EQUIPAMENTO

O cateter GuideLiner é um cateter de troca rápida com lúmen simples oferecido em tamanhos compatíveis com os cateteres guia 6F, 7F e 8F e pode ser colocado sobre um comprimento de troca ou fio-guia de 180 cm. Os diâmetros maiores dos cateteres GuideLiner permitem a utilização no interior das porções próximas aos vasos coronarianos de modo a oferecer apoio e facilitar o uso de múltiplos dispositivos de intervenção. O dispositivo de 150 cm tem um eixo de aço inoxidável com um lúmen simples de 25 cm esfregado com silicone.

O cateter GuideLiner tem duas faixas de marcador de platina-irídio, que permite visibilidade durante a utilização de métodos fluoroscópicos padrão. A faixa de marcador distal está localizada a 2.16 mm da ponta distal. A faixa de marcador proximal está localizada a 1 cm do anel. O dispositivo tem duas marcas de posicionamento localizadas a 95 cm (marca única) e 105 cm (marca dupla) da ponta distal, respectivamente.

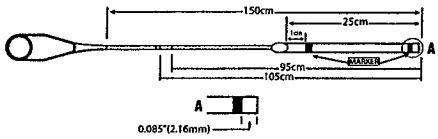
O cateter GuideLiner é aplicado através de um cateter guia resultando em um diâmetro interno que é aproximadamente 1 "french" menor do que o cateter guia. O cateter GuideLiner tem uma aba proximal que indica a compatibilidade com o cateter guia e o diâmetro interno do cateter GuideLiner resultante.

O cateter GuideLiner foi esterilizado com óxido de etileno.

STERILE EO

ESPECIFICAÇÕES

Modelo	Cateter guia compatível	Diâ. int. mín. do GuideLiner	Diâ. ext. da ponta do GuideLiner
5570 5,5F	≥ 6F (diâ. int. ≥ 0,066"/ 1,68 mm)	0,051"/ 1,30 mm	0,063"/ 1,60 mm
5571 6F	≥ 6F (diâ. int. ≥ 0,070"/ 1,78 mm)	0,056"/ 1,42 mm	0,067"/ 1,70 mm
5572 7F	≥ 7F (diâ. int. ≥ 0,078"/ 1,98 mm)	0,062"/ 1,57 mm	0,075"/ 1,90 mm
5573 8F	≥ 8F (diâ. int. ≥ 0,086"/ 2,24 mm)	0,071"/ 1,80 mm	0,085"/ 2,16 mm



INDICAÇÕES

Os cateteres GuideLiner é projetado para ser usado em conjunto com cateteres guia para acessar regiões distintas da vasculatura coronariana e/ou periférica.

CONTRA-INDICAÇÕES

Os cateteres GuideLiner são contra-indicados em vasos com menos de 2,5 mm de diâmetro, vasos na neurovasculatura e no sistema venoso.

ADVERTÊNCIAS

O cateter GuideLiner apresenta-se estéril e descartável. A reutilização de um dispositivo descartável cria um risco potencial de infecções para o paciente ou usuário. A contaminação do dispositivo pode provocar uma doença ou lesão grave no paciente

Nunca avance o cateter GuideLiner em um vaso sem um fio-guia condutor ou sem confirmar a localização usando orientação fluoroscópica. Pode ocorrer dissecação ou perfuração do vaso.

Nunca avance o cateter GuideLiner em um vaso com um diâmetro efetivo menor do que 2,5 mm. Pode ocorrer lesão, isquemia e/ou oclusão do vaso. Se a pressão em um vaso cair após inserir o GuideLiner, retire o cateter GuideLiner até que a pressão retorne ao normal.

Devido ao diâmetro e à ponta não afilada do GuideLiner, deve-se ter extremo cuidado para evitar oclusão do vaso e lesões às paredes dos vasos pelos quais este cateter passa.

Nunca avance ou retire um equipamento intravascular contra resistência, antes de determinar a causa da mesma por fluoroscopia. O movimento do cateter ou fio-guia contra resistência pode resultar em separação da ponta desses instrumentos, em um dano ao cateter ou na perfuração do vaso.

PRECAUÇÕES

Não use o cateter GuideLiner se a embalagem estiver danificada.

Verifique se há dobras ou torções no cateter GuideLiner antes da sua utilização. Não use um cateter danificado. O dano ao vaso e/ou a incapacidade de avançar ou retirar o cateter podem ocorrer.

O lúmen do cateter deve ser cuidadosamente lavado com solução salina heparinizada para evitar formação de coágulo antes da utilização.

O procedimento de aplicação do cateter GuideLiner deve ser realizado por médicos totalmente treinados em técnicas e procedimentos percutâneos e intravasculares.

Devem ser tomadas precauções para evitar ou diminuir a coagulação quando qualquer cateter for usado no sistema vascular. Deve ser considerado o uso de heparinização sistêmica ou de solução estéril heparinizada.

Cuidado ao manipular o cateter durante um procedimento, para reduzir a possibilidade de quebra, dobra ou torção acidental.

Quando o cateter está no corpo, deve ser manipulado somente sob fluoroscopia. Não tente mover o cateter sem observar a resposta resultante na ponta.

Nunca avance o cateter GuideLiner mais do que 15 cm além da ponta do cateter guia visto que o cateter GuideLiner pode ficar preso no cateter guia, tornando difícil a remoção dele.

COMPLICAÇÕES

As seguintes complicações estão geralmente associadas aos procedimentos de cateterismo e podem ocorrer durante o uso do cateter GuideLiner:

- infecção local ou sistêmica
- embolia gasosa
- ruptura da íntima
- dissecação arterial
- perfuração da parede do vaso
- oclusão vascular
- trombose arterial
- infarto de miocárdio
- espasmo arterial

PROCEDIMENTO CLÍNICO

O cateter GuideLiner deve ser usado por médicos experientes nos procedimentos aos quais o dispositivo está destinado. As técnicas e os procedimentos descritos não representam TODOS os protocolos médicos aceitáveis, tampouco têm o propósito de substituírem a experiência e a avaliação do médico no tratamento de qualquer paciente específico. Todos os dados disponíveis, inclusive os sinais e sintomas do paciente e outros resultados de teste de diagnóstico, devem ser considerados antes de determinar um plano de tratamento específico.

A embalagem contém:

- Cateter GuideLiner descartável

Outros itens necessários, mas não fornecidos:

- O cateter guia com um diâmetro interno grande o bastante para acomodar o modelo específico do cateter GuideLiner em uso
- Adaptador em Y com válvula hemostática (do tipo Tuohy-Borst)
- Fio-guia com diâmetro ≤ 0,36 mm
- Seringa estéril (para irrigação do sistema)
- Solução salina estéril heparinizada (para irrigação do sistema)

PREPARAÇÕES PARA O USO

1. Antes do uso, inspecione cuidadosamente a embalagem do cateter GuideLiner e dos componentes para verificar se há falhas.
2. Usando a técnica estéril, transfira a bobina do dispensador com o cateter GuideLiner para o campo estéril.
3. Irrigue cuidadosamente o lúmen do cateter GuideLiner a partir da ponta distal com a solução salina estéril heparinizada.

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PROCEDIMENTO DE IMPLANTAÇÃO

Aplique o cateter GuideLiner seguindo os seguintes passos:

1. Segure o fio-guia inserido previamente e retrocarregue a ponta distal do cateter GuideLiner no fio-guia e avance até o cateter estar exatamente proximal à válvula hemostática.
2. Abra a válvula hemostática e avance o cateter GuideLiner através da válvula hemostática e no cateter guia.
3. Sob fluoroscopia, avance o cateter GuideLiner até um máximo de 15 cm além da ponta distal do cateter guia e para o local desejado no vaso.

   Advertência: Nunca avance o cateter GuideLiner em um vaso com um diâmetro efetivo menor do que 2,5 mm. Pode ocorrer lesão, isquemia e/ou oclusão do vaso. Caso a pressão em um vaso cair após inserir o GuideLiner, retire o cateter GuideLiner até que a pressão retorne ao normal.

   Advertência: Devido ao diâmetro e à ponta não afilada do GuideLiner, deve-se ter extremo cuidado para evitar oclusão do vaso e lesões às paredes dos vasos pelos quais este cateter passa.
4. Usando fluoroscopia, confirme a posição desejada do cateter GuideLiner no vaso.
5. Caso esteja executando um procedimento de intervenção, retrocarregue o dispositivo de intervenção sobre o fio-guia no local e avance o dispositivo sobre o cateter guia e o cateter GuideLiner no espaço vascular desejado.
6. Aperte a válvula hemostática do adaptador em Y com firmeza no eixo proximal do cateter para prevenir retorno de sangue.
7. Execute o procedimento de cateterismo. Após completar o procedimento, remova o cateter GuideLiner antes de remover o cateter guia do vaso.

GARANTIA LIMITADA

A Vascular Solutions, Inc. garante que o cateter GuideLiner permanece isento de defeitos de fabricação e materiais até a data de validade indicada. A esponsabilidade estabelecida por meio desta garantia está limitada ao reembolso ou substituição de qualquer produto que a Vascular Solutions, Inc. venha identificar como defeituoso devido a fabricação ou material. A Vascular Solutions Inc. não será responsável por quaisquer danos incidentais, especiais ou consequentes derivados do uso do cateter GuideLiner. Danos ao produto devido ao uso incorreto, a alterações, ao armazenamento incorreto ou ao manuseio inadequado invalidarão esta garantia limitada.

Nenhum funcionário, agente ou distribuidor da Vascular Solutions, Inc. tem autoridade para alterar ou corrigir esta garantia limitada, sob nenhum aspecto. Qualquer alteração ou emenda pretendida não será executável contra a Vascular Solutions, Inc.

ESTA GARANTIA SUBSTITUI EXPRESSAMENTE TODAS AS OUTRAS GARANTIAS, EXPRESSAS OU IMPLÍCITAS, INCLUINDO QUALQUER GARANTIA DE COMERCIABILIDADE OU ADEQUAÇÃO PARA UM OBJETIVO EM PARTICULAR, OU QUALQUER OUTRA OBRIGAÇÃO POR PARTE DA VASCULAR SOLUTIONS, INC.

PATENTES E MARCAS REGISTRADAS

GuideLiner® é uma marca comercial registrada da Vascular Solutions, Inc.

GuideLiner® kateter Bruksanvisning

FÖRSIKTIGHETSÅTGÄRDER USA

Enligt amerikansk federal lag får detta instrument endast säljas av läkare eller enligt läkares ordination.

BESKRIVNING AV ENHETEN

GuideLiner-katetern är en snabbyteskateter med enkellumen, som erbjuds i storlekar som är kompatibla med 6F, 7F och 8F ledarkatetrar och kan placeras över en byteslängd eller en 180 cm ledare. De större storlekarna av GuideLiner-katetrarna är avsedda för användning inom de proximala delarna av koronar vaskulatur för att ge stöd och/eller underlätta användning av olika interventionella enheter. Den 150 cm långa enheten har ett skaft i rostfritt stål med ett 25 cm enkellumen, belagt med silikon.

GuideLiner-katetern har två markeringsband i platina-iridium, som gör den synlig vid användning av standardfluoroskopi. Det distala markeringsbandet är placerat 2.16 mm från den distala spetsen. Det proximala markeringsbandet är placerat 1 cm från kragen. Enheten har två positionsmarkeringar placerade 95 cm (enkelmarkering), respektive 105 cm (dubbelmarkering) från den distala spetsen.

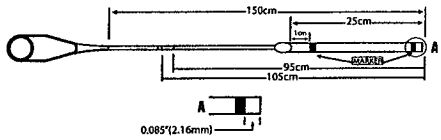
GuideLiner-katetern levereras via en ledarkateter, vilket resulterar i en innerdiameter som är ca 1 F mindre än ledarkatetern. GuideLiner-katetern har en proximal flik som anger ledarkateterns kompatibilitet och den resulterande innerdiametern på GuideLiner-katetern.

GuideLiner-katetern har steriliserats med etylenoxid.

STERILE EO

SPECIFIKATIONER

Modell	Kompatibla ledarkatetrar	GuideLiner min. innerdiameter	GuideLiner-kateters petsens yttre diameter
5570 5,5F	≥ 6F (≥ 0,066 tum/1,68 mm innerdiameter)	0,051 tum/ 1,30 mm	0,063 tum/ 1,60 mm
5571 6F	≥ 6F (≥ 0,070 tum/1,78 mm innerdiameter)	0,056 tum/1,42 mm	0,067 tum/1,70 mm
5572 7F	≥ 7F (≥ 0,078 tum/1,98 mm innerdiameter)	0,062 tum/1,57 mm	0,075 tum/1,90 mm
5573 8F	≥ 8F (≥ 0,088 tum/2,24 mm innerdiameter)	0,071 tum/1,80 mm	0,085 tum/2,16 mm



INDIKATIONER

GuideLiner-katetrar är avsedda att användas tillsammans med ledarkatetrar för att få åtkomst till skilda regioner av kranskärl och/eller perifer vaskulatur, och för att underlätta placering och byte av ledare och andra interventionella enheter.

KONTRAINDIKATIONER

GuideLiner-katetrar är kontraindicerade i kärl som är mindre än 2,5 mm i diameter, kärl i neurovaskulaturen och i vensystemet.

VARNINGAR

GuideLiner-katetern levereras steril för engångsbruk. Återanvändning av en engångsartikel innebär potentiell fara för infektioner hos patienten och användaren. Kontaminering av enheten kan leda till sjukdom eller allvarlig patientskada

För aldrig fram GuideLiner-katetern i ett kärl utan en ledare eller utan att bekräfta platsen genom fluroskopisk vägledning. Detta kan resultera i kärldissektion eller perforering.

För aldrig fram GuideLiner-katetern i ett kärl med en effektiv diameter på mindre än 2,5 mm. Blodkärlsskador, ischemi och/eller ocklusion kan uppstå. Om trycket inne i ett kärl sjunker efter införandet av GuideLiner-katetern, ska du dra ut GuideLiner-katetern tills trycket återgår till det normala.

Med tanke på storleken och GuideLiner-kateterns trubbiga spets måste man vara extremt försiktig för att undvika kärlocklusion samt skador på kärlväggarna genom vilka katetern passerar.

För aldrig fram eller dra tillbaka en intravaskulär enhet mot motstånd förrän orsaken till motståndet fastställts genom fluoroskopi. Om katetern eller ledaren förflyttas trots ett motstånd kan detta leda till att katetern eller ledarensptesen avskiljs, katetern skadas eller kärlperforation.

FÖRSIKTIGHETSÅTGÄRDER

Använd inte GuideLiner-katetern om förpackningen skadats.

Inspektera GuideLiner-katetern före användning för att kontrollera att den inte har bockats eller snott sig. Använd inte en skadad kateter. Detta kan leda till blodkärlsskador och/eller att det inte går att föra fram eller dra tillbaka katetern.

Kateterlumen ska spolas igenom ordentligt med hepariniserad koksaltlösning före användning för att förhindra koagelbildning.

GuideLiner-kateterns placeringsprocedur ska utföras av läkare som har fullgod utbildning i perkutana, intravaskulära tekniker och procedurer.

Försiktighetsåtgärder för att förhindra eller minska koagulering ska vidtas när katetrar används i kärlsystemet. Överväg eventuellt att använda systemisk heparinisering och hepariniserad steril lösning.

Var försiktig vid hantering av katetern under en procedur för att förhindra risken för att katetern oavsiktligt bryts, böjs eller snor sig.

När katetern befinner sig i kroppen får den endast manipuleras genom fluoroskopi. Försök inte flytta katetern utan att observera resulterande spetsrespons.

För aldrig fram GuideLiner-katetern mer än 15 cm bortom ledarkateterns spets, eftersom GuideLiner-katetern kan fastna i ledarkatetern och bli svår att avlägsna.

KOMPLIKATIONER

Följande komplikationer kan inträffa under alla kateteriseringsingrepp och kan även inträffa vid användning av GuideLiner-katetern:

- lokal eller systemisk infektion
- luftemboli
- intimaruptur
- artärdissektion
- perforering av kärlväggen
- vaskulär ocklusion
- artärtrombos
- hjärtinfarkt
- artärspasm

KLINISK PROCEDUR

GuideLiner-katetern ska användas av läkare som har utbildats i användning av utrustningen. De tekniker och förfaranden som beskrivs representerar inte ALLA medicinskt acceptabla rutiner och är inte heller avsedda att ersätta läkarens erfarenhet och omdöme vid behandling av en viss patient. Alla tillgängliga data, inklusive patientens tecken och symptom samt andra diagnostiska testresultat, bör övervägas innan en specifik behandlingsplan bestäms.

Följande ingår i förpackningen:

- GuideLiner-kateter för engångsbruk

Övrigt material som behövs men inte ingår:

- Ledarkateter med en innerdiameter som tillräckligt stor för att rymma den specifika modellen av den GuideLiner-kateter som används
- Y-adaptor med hemostasventil (Tuohy-Borst-typ)
- Ledare med diameter ≤ 0,36 mm
- Steril spruta (för systemspolning)
- Steril hepariniserad koksaltlösning (för systemspolning)

FÖRBEREDELSER INFÖR ANVÄNDNING

1. Undersök förpackningen med GuideLiner-katetern och de medföljande komponenterna noga för eventuella skador före användning.
2. Använd steril teknik för att flytta dispensercylindern med GuideLiner-katetern till det sterila fältet.
3. Spola GuideLiner-kateterns lumen noggrant från den distala änden med hepariniserad koksaltlösning.

PLACERINGSFÖRFARANDE

Placera GuideLiner-katetern enligt följande steg:

1. Säkra den tidigare införda ledaren och backladda GuideLiner-kateterns distala spets på ledaren och för fram tills katetern är precis proximal om hemostasventilen.
2. Öppna hemostasventilen och för fram GuideLiner-katetern genom hemostasventilen och in i ledarkatetern.

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3. För fram GuideLiner-katetern under fluoroskopi, upp till högst 15 cm bortom ledarkateterns distala spets och in i den önskade platsen i kärlet.

   Varning: För aldrig fram GuideLiner-katetern i ett kärl med en effektiv diameter på mindre än 2,5 mm. Blodkärlsskador, ischemi och/eller ocklusion kan uppstå. Om trycket inne i ett kärl sjunker efter införandet av GuideLiner-katetern, ska du dra ut GuideLiner-katetern tills trycket återgår till det normala.

   Varning: Med tanke på storleken och GuideLiner-kateterns trubbiga spets måste man vara extremt försiktig för att undvika kärlocklusion samt skador på kärlväggarna genom vilka katetern passerar.

4. Bekräfta GuideLiner-kateterns position i kärlet genom fluoroskopi.
5. Om interventionell procedur utförs, ska du backladda den interventionella enheten över ledaren som är på plats och föra fram enheten genom ledarkatetern och GuideLiner-katetern till den önskade platsen i kärlet.
6. Dra åt Y-adaptorns hemostasventil ordentligt på GuideLiner-kateterns proximala skaft, för att förhindra återblödning.
7. Utför katetriseringsproceduren. Efter procedurens avslutning ska GuideLiner-katetern avlägsnas innan ledarkatetern avlägsnas från kärlet.

BEGRÄNSAD GARANTI

Vascular Solutions, Inc. garanterar att GuideLiner-katetern är fri från defekter i utförande och material fram till angivet utgångsdatum. Det ansvar som omfattas av denna garanti begränsas till återbetalning för, eller utbyte av, en produkt som Vascular Solutions, Inc. finner vara defekt med avseende på utförande eller material. Vascular Solutions, Inc. ansvarar inte för några tillfälliga eller speciella skador eller följdskador som uppkommer i samband med användning GuideLiner-katetern. Denna begränsade garanti gäller ej då skador på produkten uppkommer på grund av felaktig användning, modifiering, felaktig förvaring eller felaktig hantering.

Ingen anställd, agent eller distributör för Vascular Solutions, Inc. har rätt att på något sätt ändra eller modifiera denna begränsade garanti. Vascular Solutions, Inc. ansvarar inte för eventuella korrigeringar eller ändringar.

DEN HÄR GARANTIN ERSÄTTERALLA ANDRA GARANTIER, UTTRYCKLIGA ELLER ANTYDDA, INKLUSIVE GARANTIER FÖR SÄLJBARHET ELLER LÄMPLIGHET FÖR ETT VISST ÄNDAMÅL ELLER ANDRA FÖRPLIKTELSER SOM TILLFALLER VASCULAR SOLUTIONS, INC.

PATENT OCH VARUMÄRKEN

GuideLiner® är ett registrerat varumärke som tillhör Vascular Solutions, Inc.

GuideLiner® Kateter Kullanım Talimatları

ABD ile İLGİLİ UYARI

Federal (ABD) yasalar bu cihazın bir doktor tarafından veya doktorun siparişi üzerine satılmasını zorunlu kılmaktadır.

CİHAZ TANIMI

GuideLiner tekli lumen hızlı değişim kateteri olup 6F, 7F ve 8F kılavuz kateterler ile uyumlu boyutlarda sunulmaktadır ve değişim uzunluğu için veya 180cm kılavuz olarak da kullanılabilmektedir. Büyük boyutlardaki GuideLiner kateterler birden çok girişimsel cihazı desteklemek ve/veya onların kullanılmasını sağlamak için koroner vaskülatürün proksimal kısımlarında kullanılmak üzere tasarlanmıştır. 150 cm uzunluğunda olan aygıt paslanmaz çelik şaft ve 25 cm uzunluğunda silikonla silinmiş tekli lümene sahiptir.

GuideLiner kateter standart floroskopik yöntem kullanıldığında görüntüyü sağlayan iki adet platinyum-iridyum işaretleyici banda sahiptir. Distal işaretleyici bandı distal uçtan 2.16 mm içeride yer almaktadır. Proksimal işaretleyici bantı yakadan 1 cm içeride yer almaktadır. Aygıt üzerinde distal uçtan sırasıyla 95 cm (tek işaret) ve 105 cm (çift işaret) uzaklıkta bulunan iki adet pozisyonlama işareti bulunmaktadır.

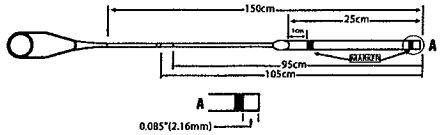
GuideLiner kateter kılavuz bir kateter üzerinden gönderilmekte ve iç çapı kılavuz kateter çapından 1 French daha küçük olmaktadır. GuideLiner kateterin proksimal sekmesi bulunmaktadır ve bu kılavuz kateter uyumluluğunu ve GuideLiner kateter iç çapını göstermektedir.

GuideLiner kateter etilen oksitle sterilize edilmiştir.

STERILE EO

ÖZELLİKLER

Model	Uygun Kılavuz Kateteri	GuideLiner Min. I.D.	GuideLiner Ucu O.D.
5570 5.5F	≥ 6F (≥ 0.066" / 1.68 mm I.D.)	0,051" / 1,30 mm	0.063" / 1,60 mm
5571 6F	≥ 6F (≥ 0,070" / 1,78 mm I.D.)	0,056" / 1,42 mm	0,067" / 1,70 mm
5572 7F	≥ 7F (≥ 0.078"/ 1.98 mm I.D.)	0,062" / 1,57 mm	0,075" / 1,90 mm
5573 8F	≥ 8F (≥ 0.088" / 2.24 mm I.D.)	0,071" / 1,80 mm	0,085" / 2,16 mm



ENDİKASYONLAR

GuideLiner kateterleri koronerin daha zor ulaşılabilir yerlerine erişim için kullanılan kılavuz kateterlerle birlikte kullanılmak üzere düşünülmüştür ve/veya periferik vaskülatürün farklı bölgelerine erişmek için yönlendirilebilir kılavuz tellerinin veya diğer müdahale aygıtlarının yerine kullanılır.

KONTRA ENDİKASYONLAR

GuideLiner kateterler 2.5 mm den daha küçük olan damarlarda, nerovasküler damarlarda ve toplardamar sistemlerinde kontraendikedir.

UYARILAR

GuideLiner kateteri steril olarak sadece tek kullanım için sağlanır. Tek kullanımlık bir cihazın yeniden kullanılması hasta veya kullanıcının enfeksiyon kapmasına neden olabilir. Aygıtın kirli olması durumunda, hastanın enfeksiyona maruz kalmasına veya ciddi şekilde yaralanmasına yol açabilir.

GuideLiner kateteri öncü kılavuz kateter olmaksızın veya floroskopik kılavuz kullanarak yerini doğrulamadan damar içine asla uygulamayın. Damar diseksiyonu veya perforasyonuna yol açabilir.

GuideLiner kateteri asla etkin çapı 2.5 mm2den daha küçük çapa sahip damar içine sokmayın. Damar yaralanmasına, iskemi ve/veya oklüzyona neden olabilir. Guideliner kateterin uygulanmasından sonra damar içi basıncının düşmesi durumunda GuideLine kateteri yerinden basınç normale dönene kadar yerinden çıkarın.

GuideLiner'ın boyutuna ve sivriltilmemiş ucuna bağlı olarak, bu kateterin geçtiği damarlarda damar oklüzyonundan ve damarların duvarında hasardan kaçınmak için aşırı dikkat gösterilmelidir.

Direnç nedeni fluroskopi ile belirleninceye kadar bir intravasküler cihazı asla dirence karşı itmeyin veya çekmeyin. Kateter veya kılavuz telinin dirence karşı hareket ettirilmesi kateter veya kılavuz tel ucunun ayrılmasına, kateterin zarar görmesine veya damar perforasyonuna yol açabilir.

ÖNLEMLER

Paketi hasarlıysa GuideLiner'ı kullanmayın.

GuideLiner kateteri kullanmadan önce eğilme veya kıvrılmalara karşı inceleyin. Hasarlı kateteri kullanmayın. Damar hasarı meydana gelebilir ve/veya kateteri itilemez veya çekilemez.

Pıhtı oluşumunu önlemek için kateter lümenini kullanmadan önce heparinize salin ile iyice yıkayın.

GuideLiner kateter yerleştirme işlemi, perkütan, intravasküler teknikler ve prosedürler konusunda kapsamlı eğitim görmüş doktorlar tarafından yapılmalıdır.

Vasküler sistemde herhangi bir kateter kullanıldığında pıhtılaşmayı önlemek ya da azaltmak için alınacak önlemler. Sistematik hipernizasyon ve heparinize steril solüsyon kullanılması göz önünde tutulmalıdır.

İstenmeyen kırılma, kıvrılma ya da bükülme olasılığını azaltmak için kateter ile prosedür sırasında ve uygulama yaparken dikkatli olun.

Kateter vücuttayken, sadece fluoroskopi altında işleme tabi olmalıdır. Son uç tepkisini gözlemlemeden kateteri hareket ettirmeye çalışmayın.

GuideLiner kateteri hiçbir zaman kılavuz kateterin ucundan 15 cm daha öteye ilerletmeyin; böyle bir durumda GuideLine kateter kılavuz kateter içinde takılı kalarak çıkarma işleminin zorlaşmasına neden olabilir.

KOMPLİKASYONLAR

Aşağıdaki komplikasyonlar genellikle kateterizasyon prosedürleriyle ilişkilendirilmiştir ve Guideliner kateter kullanılırken ortaya çıkabilir:

- lokal veya sistemik enfeksiyon
- hava embolisi
- intimal disrüpsiyon
- arteriyel diseksiyon
- damar çeperinin perforasyonu
- vasküler oklüzyon
- arteriyel tromboz
- miyokard enfarktüs
- arteriyel spazm

KLİNİK PROSEDÜR

The GuideLiner kateteri aygıtın kullanımı ile ilgili alanda eğitim almış hekimler tarafından kullanılmalıdır. Açıklanan teknikler ve prosedürler TÜM tıbbi açıdan kabul edilebilir protokolleri temsil etmez, ayrıca herhangi bir hastayı tedavi ederken doktorun deneyiminin ve yargısının yerine geçmez. Hastanın verdiği işaretler, bulgular ve diğer tanı test sonuçları da dâhil olmak üzere mevcut tüm veriler belirli bir tedavi planı belirlemeden önce göz önünde bulundurulmalıdır.

Paket İçindekiler:

- Tek kullanımlık atılabilir GuideLiner kateter

Diğer öğeler gereklidir, fakat sağlanmaz:

- İç çapı belli bir model GuideLiner kateterinin kullanılması için yeteri kadar büyük olan Kılavuz kateter kullanımda
- T adaptörlü Hemostaz Vansı (Tuohy-Borst tip)
- ≤ 0.36 mm çapında kılavuz tel
- Steril şırınga (sistem yıkaması için)
- Steril heparinize salin (sistem yıkaması için)

KULLANIM HAZIRLIKLARI

1. Kullanmadan önce, GuideLiner kateter paketini ve parçalarını hasara karşı dikkatlice kontrol edin.
2. Steril teknik kullanarak, GuideLiner kateter ile birlikte dağıtma serpantinini steril alana aktarın.
3. GuideLiner kateter lümenini distal uçtan itibaren heparinize saline solüsyon ile tamamen yıkayın.

YERLEŞTİRME PROSEDÜRÜ

GuideLine kateteri aşağıda yer alan adımlara göre yerleştirin:

1. Daha önceden yerleştirilmiş kılavuz teli emniyete alın ve GuideLiner kateter distal ucunu kılavuz teli üzerine yerleştirin ve kateter hemostaz vanasına yakınan gelene kadar ilerleyin.
2. Hemostaz vanasını açın ve GuideLiner kateteri hemostaz vanası içinden kılavuz katetere ilerletin.
3. Floroskopi altında, GuideLiner kateterini kılavuz kateterin distal ucundan en fazla 15 cm ötesine ilerleterek damar içinde istenilen yere ulaşın.

   Uyarı: GuideLiner kateteri asla etkin çapı 2.5 mm'den daha küçük çapa sahip damar içinde ilerletmeyin. Damar yaralanmasına, iskemi ve/veya oklüzyona neden olabilir. Guideliner kateterin uygulanmasından sonra damar içi basıncının düşmesi durumunda GuideLine kateteri yerinden basınç normale dönene kadar yerinden çıkarın..

   Uyarı: GuideLiner'ın boyutuna ve sivriltilmemiş ucuna bağlı olarak, bu kateterin geçtiği damarlarda damar oklüzyonundan ve damarların duvarında hasardan kaçınmak için aşırı dikkat gösterilmelidir.

4. Floroskopi kullanımı GuideLiner'in damar içinde istenen yerde olduğunu teyit eder.

5. Girişimsel bir prosedürün uygulanması durumunda, girişimsel aygıtı, yerleştirilmiş kılavuz teli üzerinden aygıtı kılavuz kateter ve GuideLiner kateter vasıtası ile istenen vasküler alana ilerletin.
6. GuideLiner kateter proksimal şaftı üzerinde Y-adaptörü hemostaz vanasını güvenli bir şekilde sıkarak geri kanamayı durdurun.
7. Kateterizasyon prosedürünü uygulayın. Prosedürü tamamladıktan sonra damar içinden GuideLiner kateterini kılavuz kateteri çekmeden önce çekin.

SINIRLI GARANTİ

Vascular Solutions, Inc., GuideLiner kateterler belirtilen son kullanma tarihinden önce işçilik ve malzeme kusurları bulunmayacağını garanti eder. Bu garanti kapsamında sorumluluk, Vascular Solutions, Inc.'nin işçilik veya malzeme açısından kusurlu bulduğu herhangi bir ürünün parasının geri ödenmesi veya değiştirilmesiyle sınırlıdır. Vascular Solutions, Inc. GuideLiner kateterin kullanımından kaynaklanan tesadüfi, özel veya izleyen hasarlardan sorumlu tutulamaz. Hatalı kullanım, üzerinde değişiklik yapma, yanlış depolama veya yanlış taşıma gibi yollarla ürüne verilen hasarlar bu sınırlı garantiyi geçersiz kılacaktır.

Hiçbir Vascular Solutions, Inc. çalışanı, temsilcisi veya dağıtıcısının bu sınırlı garantiyi herhangi bir şekilde değiştirme yetkisi yoktur. Sözde değişiklik veya düzeltme Vascular Solutions, Inc.'e karşı uygulanabilir değildir.

İŞBU GARANTİ HERHANGİ BİR TİCARİ GARANTİ VEYA BELİRLİ BİR AMAÇ İÇİN UYGUNLUK YA DA VASCULAR SOLUTIONS, INC.'IN DİĞER YÜKÜMLÜLÜĞÜ DAHİL OLMAK ÜZERE, SARİH VEYA ZIMNİ TÜM DİĞER GARANTİ VE YASAL HAKLARIN YERİNE GEÇER.

PATENTLER VETİCARİ MARKALAR

GuideLiner® Vascular Solutions, Inc. firmasının tescilli ticari markasıdır.

International Symbols Glossary

	MARKER	GCID Guide catheter inner diameter	GLID GuideLiner inner diameter
International Symbols Glossary	Radiopaque Marker	Guide catheter inner diameter	GuideLiner inner diameter
Slovník mezinárodních symbolů	Značkovač nepropustný pro záření	Vnitřní průměr zaváděcího katétru	Vnitřní průměr katetru GuideLiner
Ordliste med internationale symboler	Radiopak markør	Indvendig diameter på guidekatetret	Indvendig diameter, GuideLiner
Legende der Internationalen Symbole	Strahlenundurchlässiger Marker	Innendurchmesser Führungskatheter	GuideLiner Innendurchmesser
Επεξήγηση διεθνών συμβόλων	Ακτινοσκιερός δείκτης	Εσωτερική διάμετρος οδηγού καθετήρα	Εσωτερική διάμετρος GuideLiner
Glosario de Símbolos Internacionales	Marcador radiopaco	Diámetro interno del catéter guía	Diámetro interno del GuideLiner
Kansainvälisten merkkien hakemisto	Varjoaine markkeri	Ohjainkatetrin sisäläpimitta	GuideLiner-sisähalkaisija
Glossaire des symboles internationaux	Marqueur radio-opaque	Diamètre intérieur du cathéter guide	Diamètre interne du GuideLiner
Nemzetközi jelszótár	Sugárfogó jelző	Vezetőkatéter belső átmérője	GuideLiner vezetőbetétes katéter belső átmérője
Glossario internazionale dei simboli	Marcatore radiopaco	Diametro interno del catetere guida	Diametro interno del GuideLiner
Lijst met internationale symbolen	Radiopake markering	Inwendige diameter geleide-katheter	Binnendiameter GuideLiner
Ordliste med internasjonale symboler	Røntgentett markør	Indre diameter på ledekateter	GuideLiner indre diameter
Słowniczek symboli międzynarodowych	Znacznik cieniodajny	Wewnętrzna średnica cewnika prowadzącego	Wewnętrzna średnica GuideLiner
Glossário de símbolos internacionais	Marcador radiopaco	Diâmetro interno do cateter guia	Diâmetro interior do dispositivo Guide Liner
Förklaring av internationella symboler	Röntgenmarkör	Guidekatetrets inre diameter	Inre diameter för Guide Liner
Uluslararası Sembol Sözlüğü	Radyopak Markör	Kılavuz kateter iç çapı	Guide Liner İç Çapı

Content Glossary

	
Content Glossary	GuideLiner Catheter
Obsah Glosář	Katétr GuideLiner
Indhold ordliste	GuideLiner -kateter
Inhalt Glossar	GuideLiner Katheter
Περιγραφή περιεχόμενων ειδών	Καθετήρας GuideLiner
Glosario de Contenidos	Catéter GuideLiner
Sisällön sanasto	GuideLiner-katetri
Glossaire du contenu	Cathéter GuideLiner
Tartalmi szótár	GuideLiner Katéter
Glossario del contenuto	Catetere GuideLiner
Overzicht van de inhoud	GuideLiner-Katheter
Innholdsordliste	GuideLiner kateter
Słowniczek zawartości	GuideLiner -cewnik
Glossário do Conteúdo	Cateter GuideLiner
Ordlista	GuideLiner kateter
İçerik Sözlüğü	GuideLiner Kateter

Exhibit 27

Certificate of Registration

This Certificate issued under the seal of the Copyright Office in accordance with title 17, *United States Code*, attests that registration has been made for the work identified below. The information on this certificate has been made a part of the Copyright Office records.

Register of Copyrights, United States of America

Registration Number
TX 7-679-167

Effective date of registration:
May 15, 2013

Title

Title of Work: GuideLiner V2 Catheter
Previous or Alternative Title: GuideLiner Catheter Instructions for Use

Completion/Publication

Year of Completion: 2013
Date of 1st Publication: April 22, 2013 **Nation of 1st Publication:** United States

Author

- **Author:** Vascular Solutions, Inc.

Author Created: text, editing, artwork

Work made for hire: Yes
Citizen of: United States **Domiciled in:** United States

Copyright claimant

Copyright Claimant: Vascular Solutions, Inc.
6464 Sycamore Court, Minneapolis, MN, 55369, United States

Limitation of copyright claim

Material excluded from this claim: text, artwork
New material included in claim: text, editing, artwork

Rights and Permissions

Organization Name: Vascular Solutions, Inc.
Address: 6464 Sycamore Court
Minneapolis, MN 55369 United States

Certification

Name: Jeffrey R. Cadwell
Date: May 15, 2013
Applicant's Tracking Number: M239283


0000TX0007679167020 1

Certificate of Registration

This Certificate issued under the seal of the Copyright Office in accordance with title 17, *United States Code*, attests that registration has been made for the work identified below. The information on this certificate has been made a part of the Copyright Office records.

Register of Copyrights, United States of America

Registration Number
TX 7-679-165

Effective date of registration:
May 15, 2013

Title

Title of Work: GuideLiner Catheter
Previous or Alternative Title: GuideLiner Catheter Instructions for Use

Completion/Publication

Year of Completion: 2009
Date of 1st Publication: September 30, 2009 **Nation of 1st Publication:** England

Author

- **Author:** Vascular Solutions, Inc.

Author Created: text, editing

Work made for hire: Yes
Citizen of: United States **Domiciled in:** United States

Copyright claimant

Copyright Claimant: Vascular Solutions, Inc.
6464 Sycamore Court, Minneapolis, MN, 55369, United States

Rights and Permissions

Organization Name: Vascular Solutions, Inc.
Address: 6464 Sycamore Court
Minneapolis, MN 55369 United States

Certification

Name: Jeffrey R. Cadwell
Date: May 15, 2013
Applicant's Tracking Number: M239282

Registration #: TX0007679165

Service Request #: 1-935914601

Dorsey & Whitney LLP
Jeffrey R. Cadwell
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402 United States

Exhibit 28

Boston Scientific
Advancing science for life™

New Product Evaluation Form

Hospital: City: State:	Date:
Physician:	Phone / Email:

BSC Representative:

What percentage of your cases do you use a GuideLiner™ Catheter? ____%

What GuideLiner Catheter sizes do you use? (Check all that apply)
☐ 5.5F ☐ 6F ☐ 7F ☐ 8F

What percentage of your GuideLiner Catheter cases do you use 6F? ____%

What percentage of your GuideLiner Catheter cases do you use 8F? (Use "N/A" if you do not use 8F) ____%

If you can share, how much is a GuideLiner Catheter sold for in your lab? ____

Equipment Used:

Access Site:	☒ Radial ☐ Femoral
Where was the GUIDEZILLA Catheter used?	☒ RCA ☐ LAD ☐ Circ
Guide catheter(s):	Size: 6F Curve: MP SH Brand: Boston Size: Curve: Brand: Size: Curve: Brand:
What interventional device(s) was used following GUIDEZILLA Catheter delivery?	☒ Balloon Size: 2.5 x 15 Brand: Boston Energe ☐ Stent Size: Brand: ☐ Balloon Size: Brand ☐ Stent Size: Brand:

IMPORTANT: Please fax this form as soon as possible upon completion to the Marketing Department at 763.494.12

Lesion Type:

Vessel tortuosity (1= No tortuosity, 10 = Extremely Tortuous)	1	2	3	4	5	6	7	8	9	10

GUIDEZILLA™ Catheter vs. GuideLiner™ Catheter Evaluation:

(Please provide a reason for any "Unacceptable" responses in the comments section below)

	1	2	3	4	5
Pushability Performance	Unacceptable	Slightly Worse	Same	Slightly Better	Significantly Better
Insertion of interventional device	Unacceptable	Slightly Worse	Same	Slightly Better	Significantly Better
Withdrawal of interventional device	Unacceptable	Slightly Worse	Same	Slightly Better	Significantly Better
Back-up support Performance	Unacceptable	Slightly Worse	Same	Slightly Better	Significantly Better
Overall Deliverability of Guidezilla	Unacceptable	Slightly Worse	Same	Slightly Better	Significantly Better

Quality

Please note that any response received on this form that alleges dissatisfaction or deficiencies related to the identity, design, quality, durability, reliability, safety, effectiveness or performance of a Boston Scientific Corporation (BSC) product could be a complaint. Upon learning of product complaints, BSC Sales representatives are responsible for completing a Complaint Notification Form and reporting the Complaint.

What clinical need caused you to pull this device? (tortuosity, location, lesion type, etc...)

Did you use any special techniques to deliver the GUIDEZILLA Catheter?

Was using the GUIDEZILLA Catheter proactive (you planned to use prior to beginning the case) or responsive (chose to use once in the anatomy)? Why?

Will the GUIDEZILLA Catheter's one size (5-in-6F) influence your purchasing decision?

☐ No ☐ Yes

Comments:

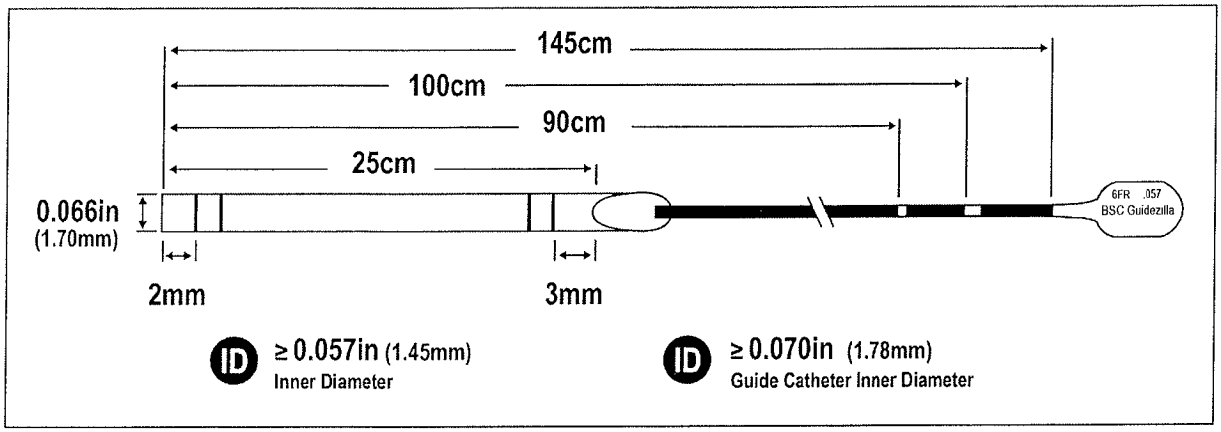
IMPORTANT: Please fax this form as soon as possible upon completion to the Marketing Department at 763-494-1210

Exhibit 29

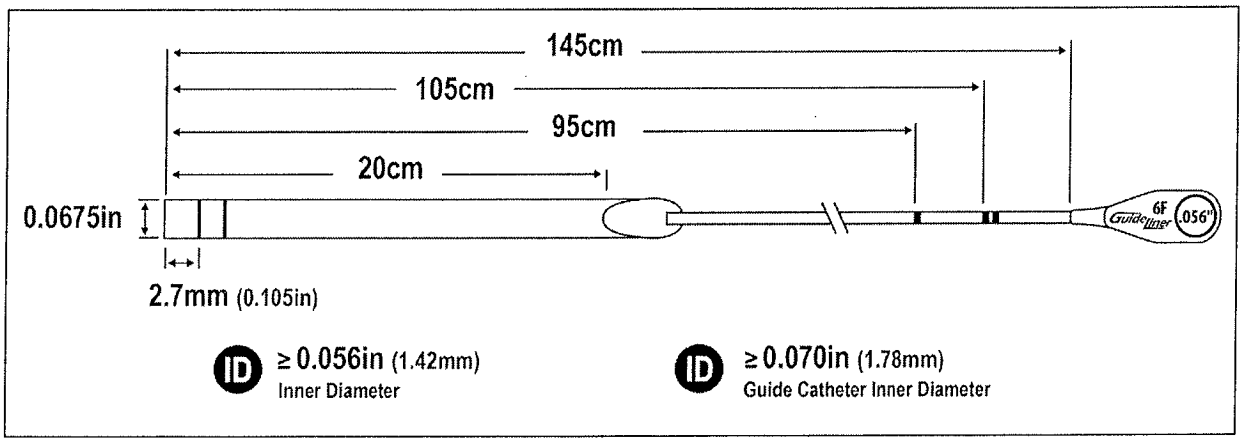
Product Comparison Drawings

1. Complete Dimensions

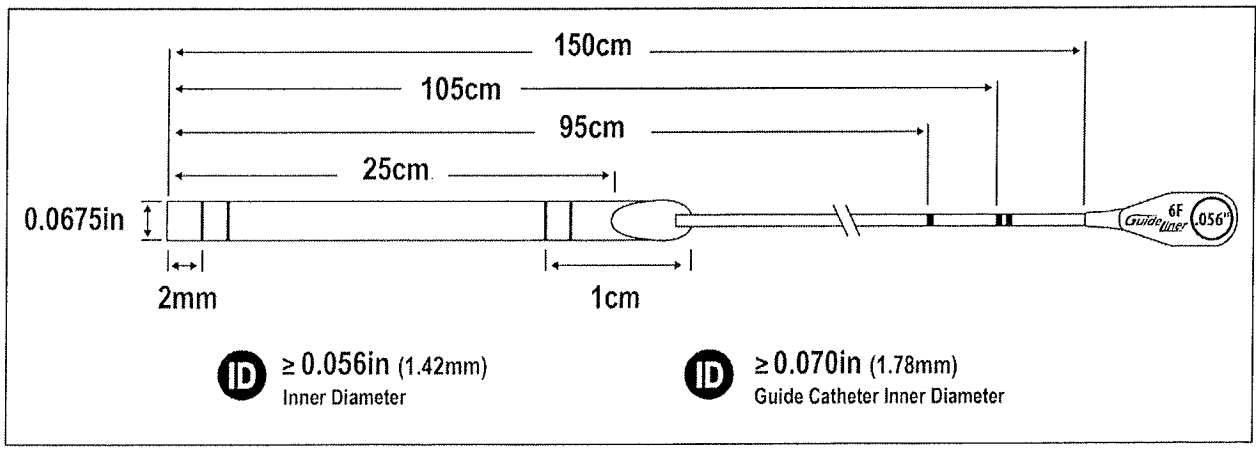
Guidezilla



GuideLiner V1

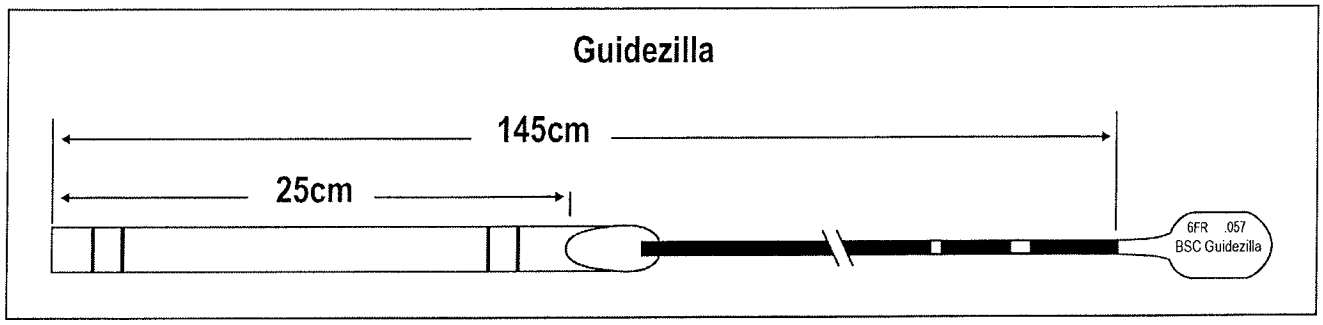


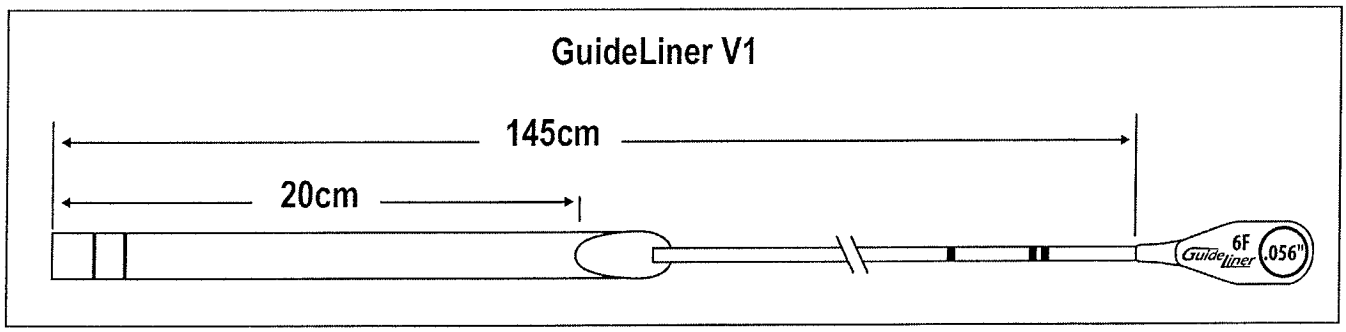
GuideLiner V2

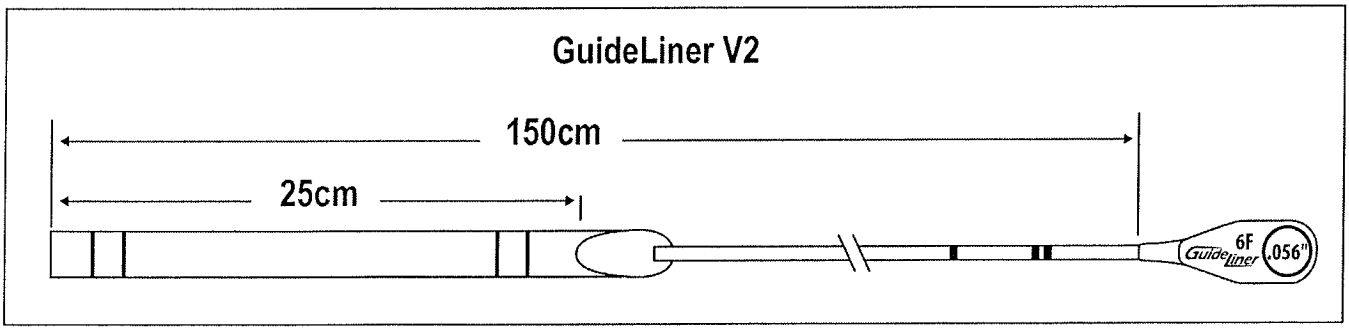


Product Comparison Drawings

2. Simplified Dimensions





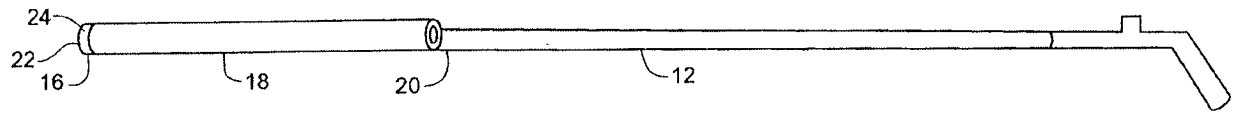


Patent Comparison Drawings

1. Overall Catheter

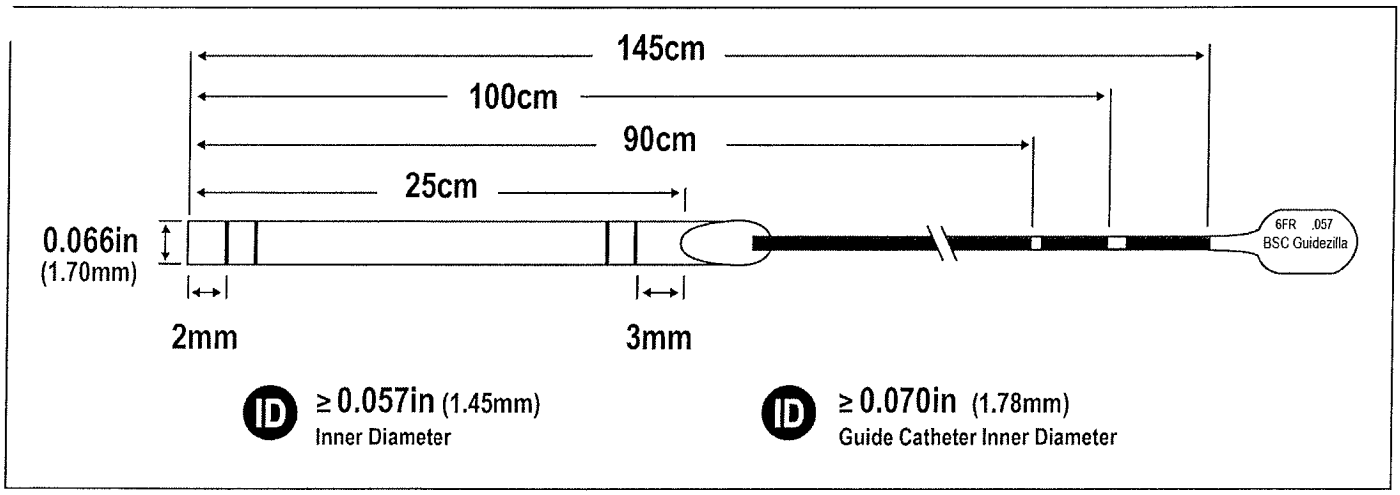
U.S. Patent Nov. 1, 2011 Sheet 1 of 13 US 8,048,032 B2

Fig. 1



(Image is reverse orientation from what was in the patent for comparison purposes.)

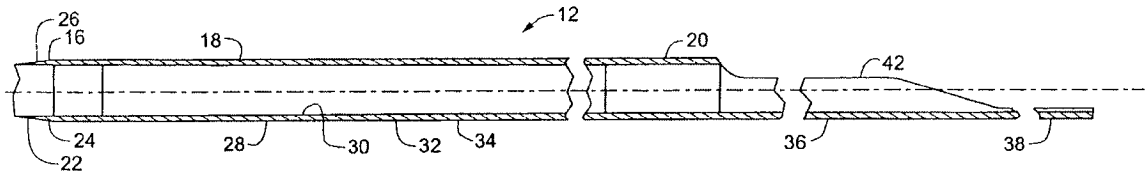
Guidezilla



Patent Comparison Drawings

2. Collar Transition

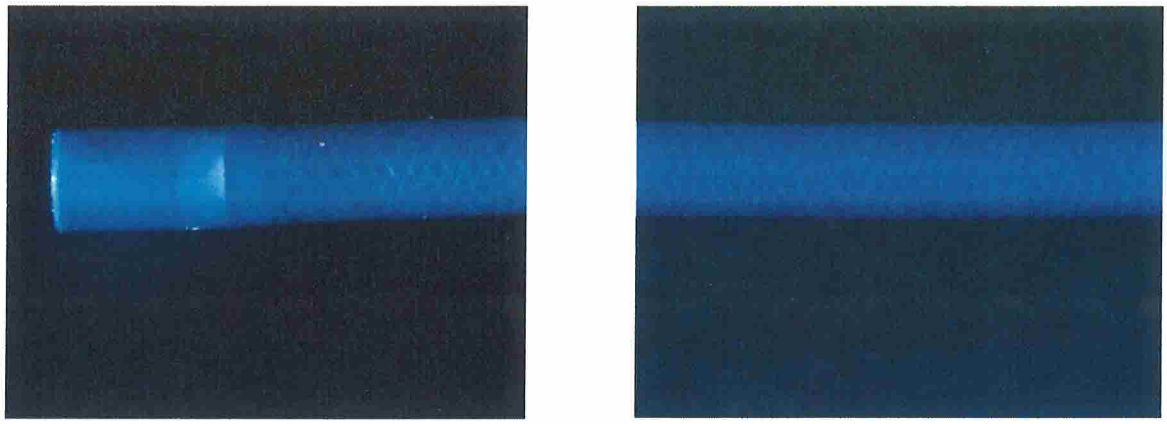
Fig. 4



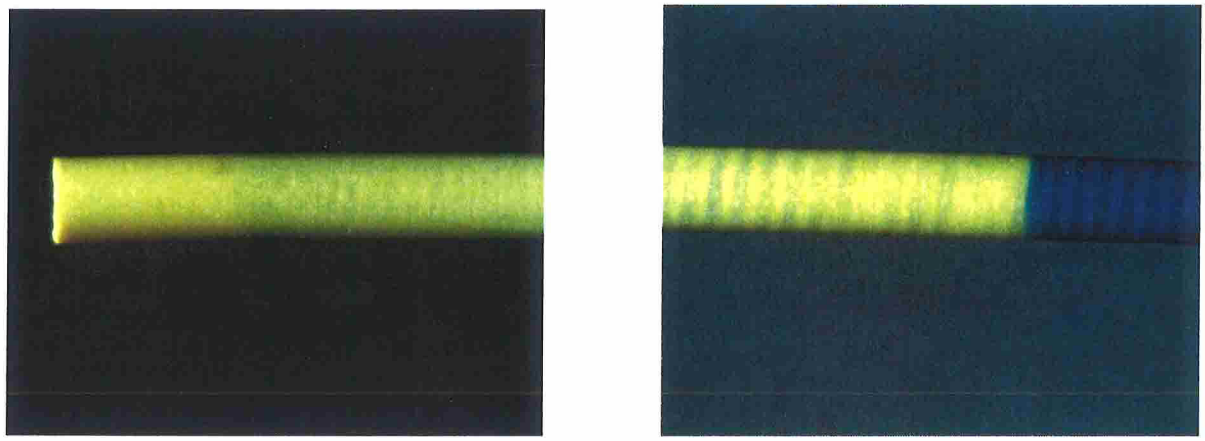
Guidezilla

Exhibit 30

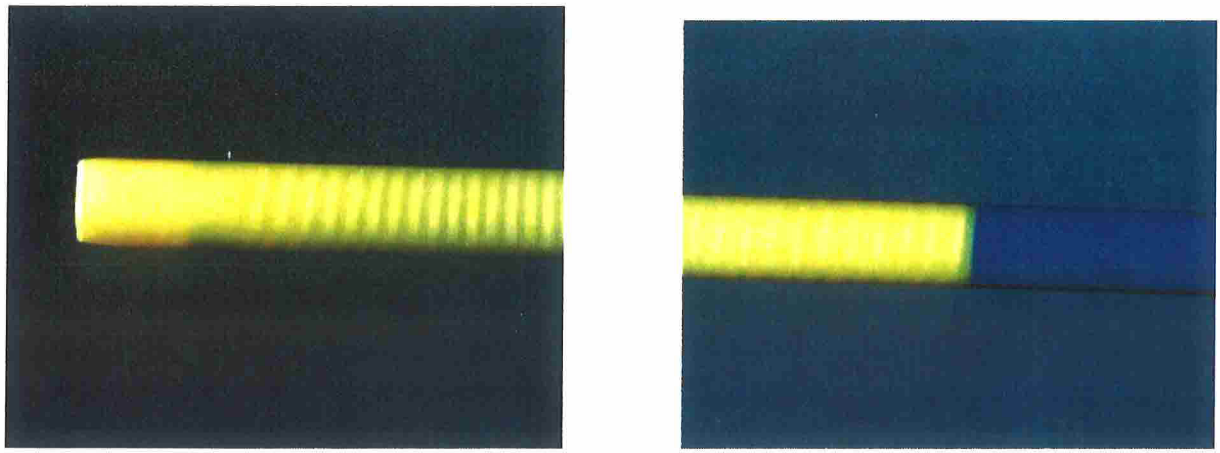
Guidezilla vs. GuideLiner V1 & V2 Photo Comparison
Distal Lumen Comparison



Guidezilla

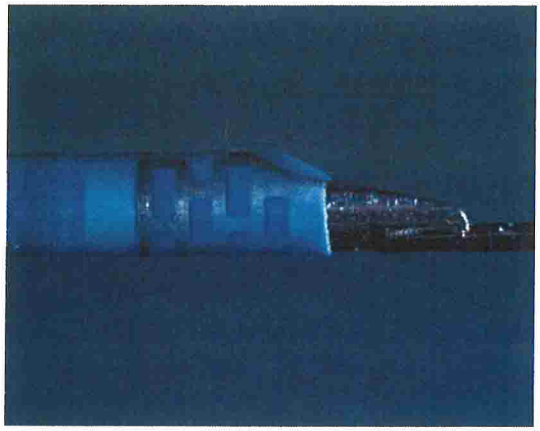


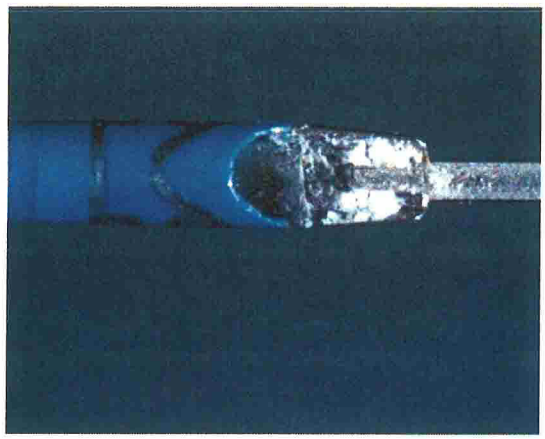
GuideLiner V1



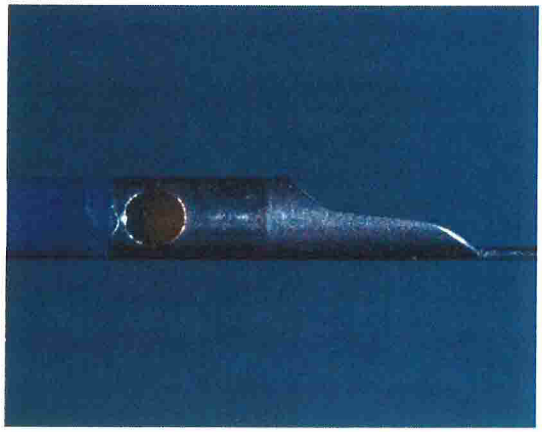
GuideLiner V2

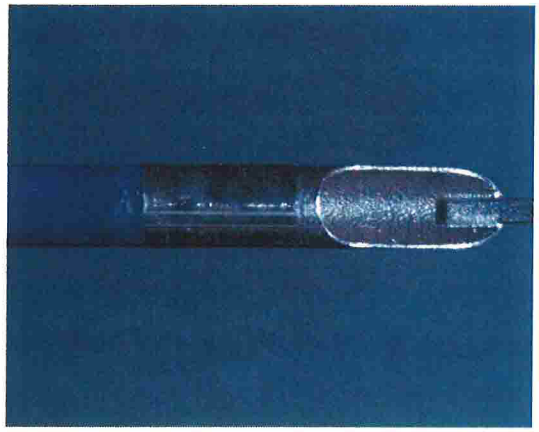
Collar Transition Comparison



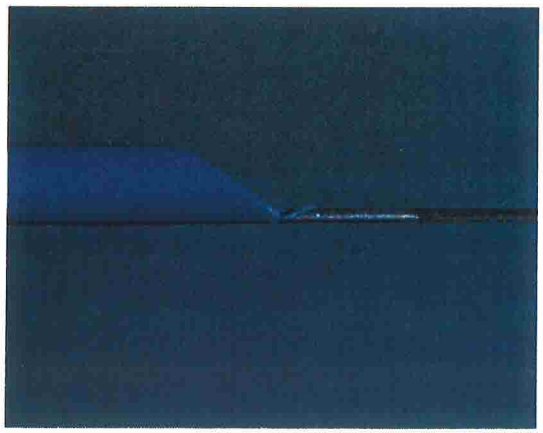


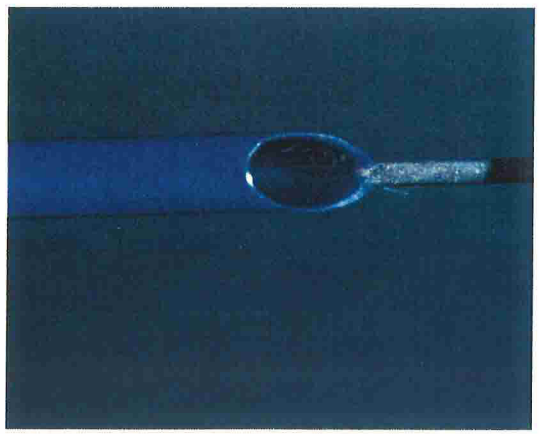
Guidezilla





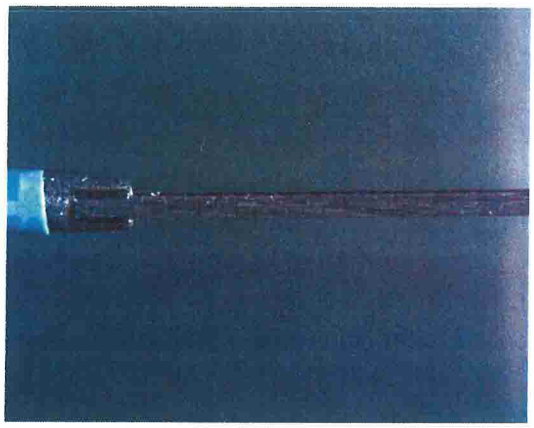
GuideLiner V1

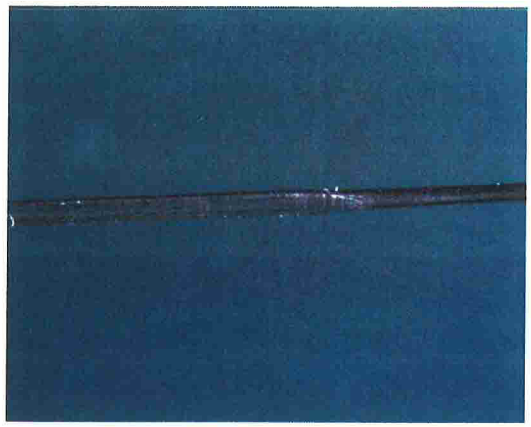




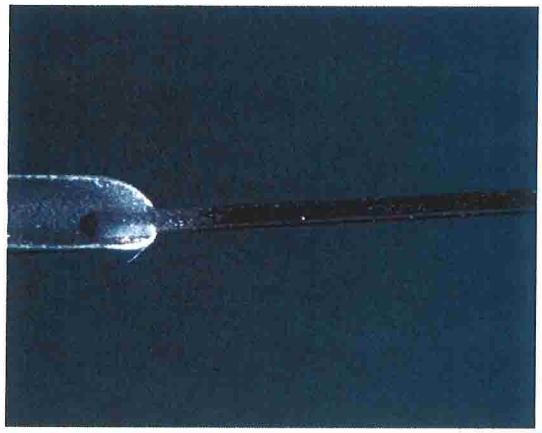
GuideLiner V2

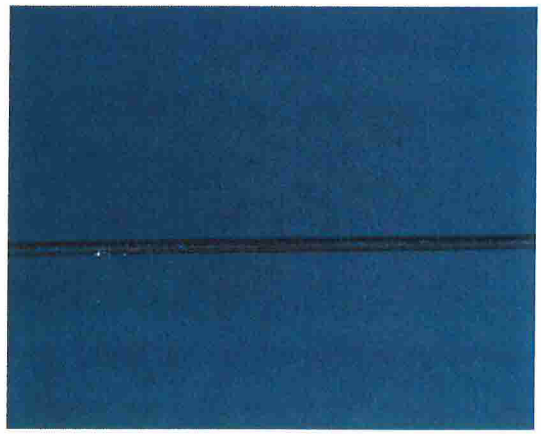
Push Rod Comparison



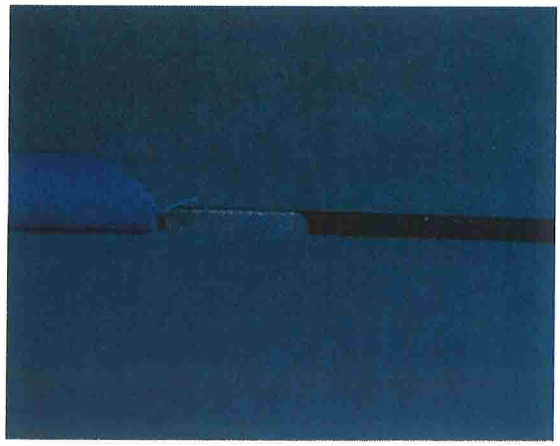


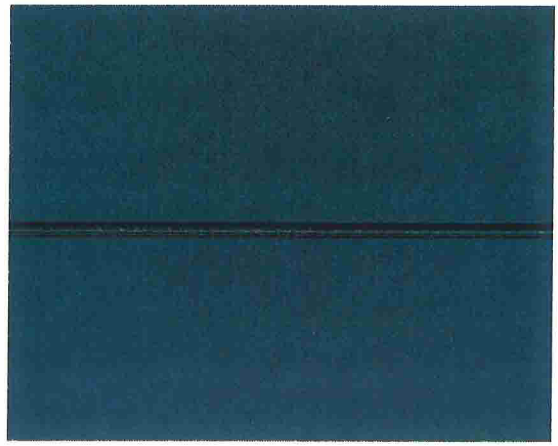
Guidezilla





GuideLiner V1

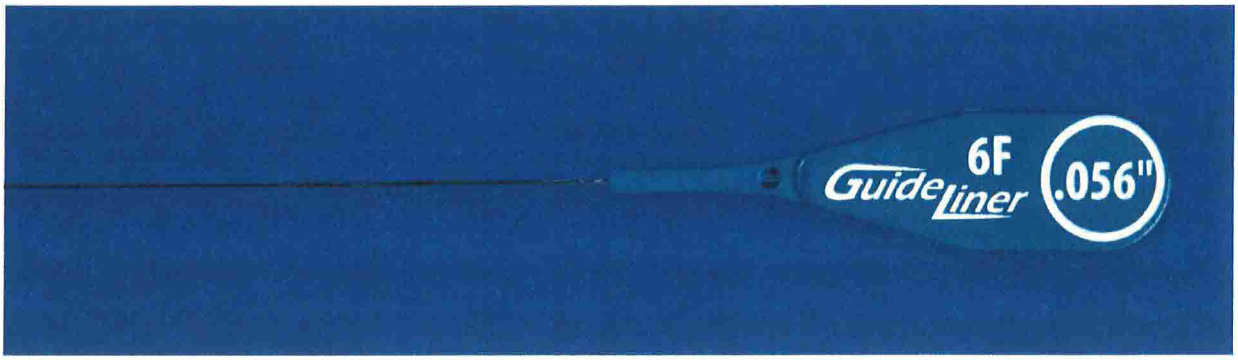




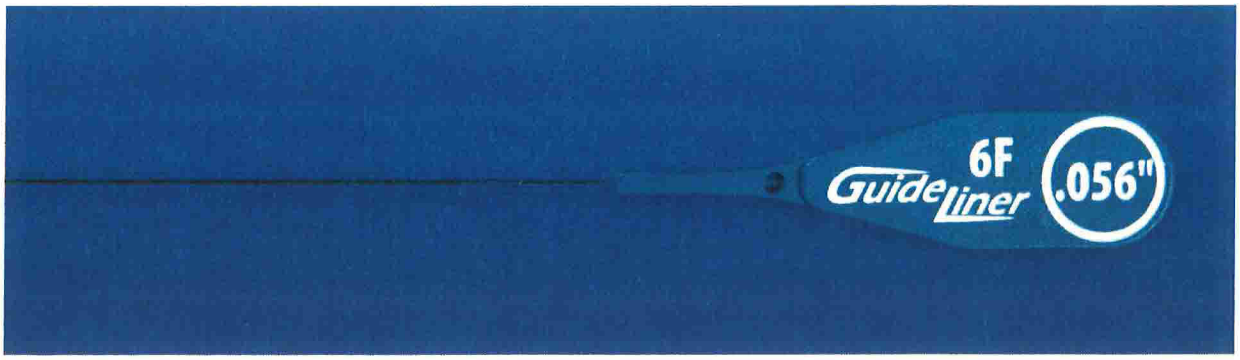
GuideLiner V2

Proximal Tab Comparison

Guidezilla



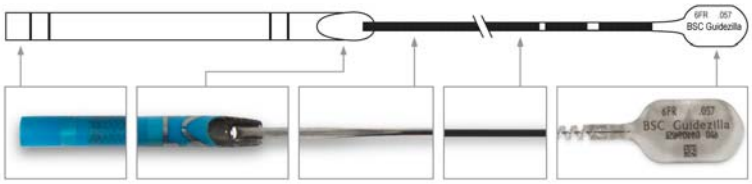
GuideLiner V1

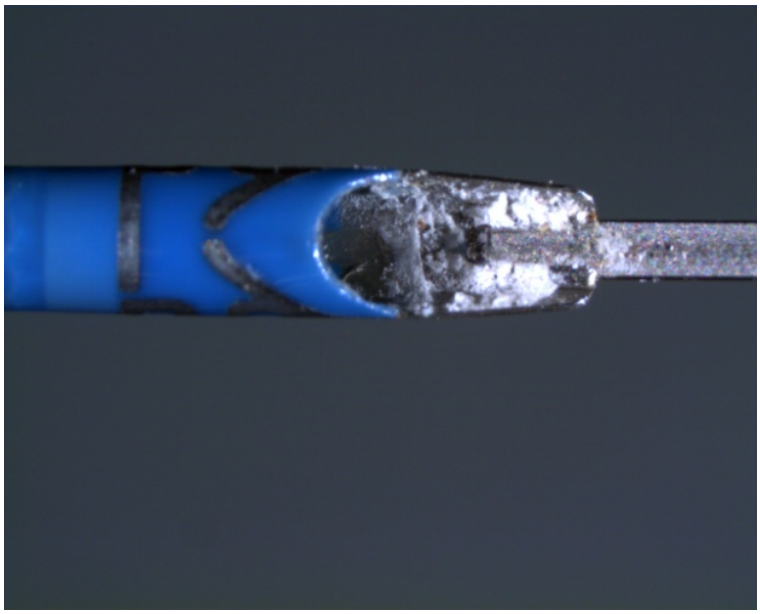


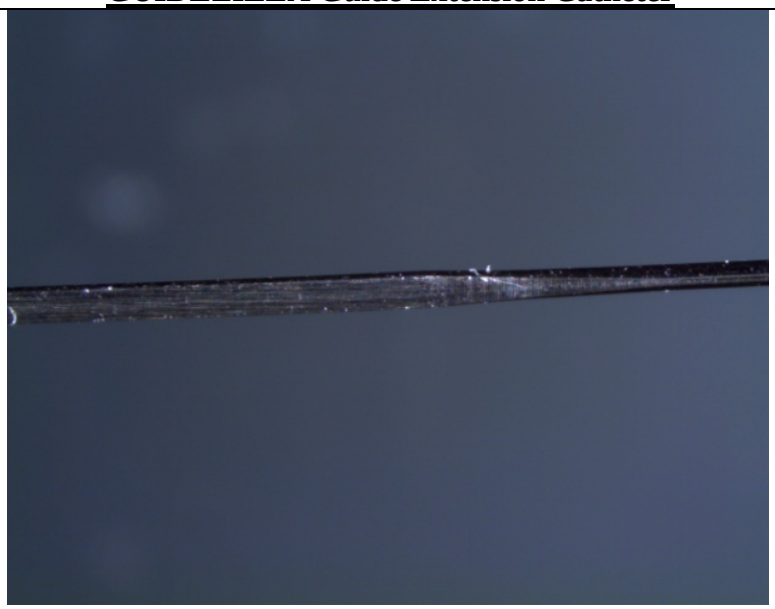
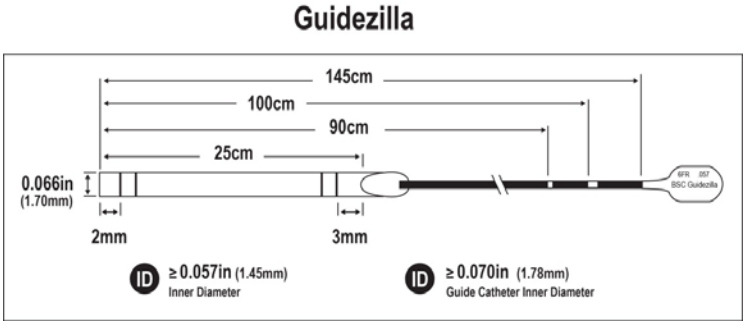
GuideLiner V2

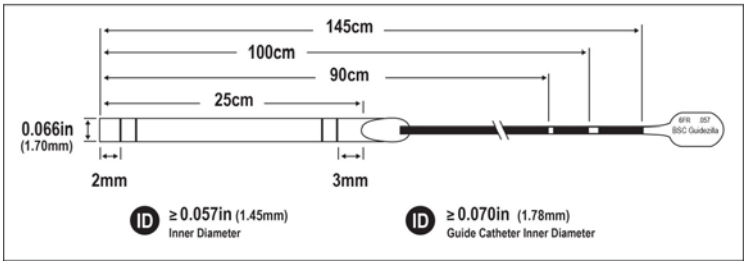
Exhibit 31

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
'032 patent, claim 1. 1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	This is preamble language, which I understand may not necessarily limit the scope of the claim. Notwithstanding, Boston Scientific's Guidezilla is for use with a standard guide catheter. "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Summary (Ex. 21); see also Guidezilla Directions for Use at 2 (Ex. 25). A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and that has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The Guidezilla has a flexible tip portion that defines a tubular structure with a circular cross-section, which is the blue, tubular structure in the following photographs, and the tubular structure in the following drawing:

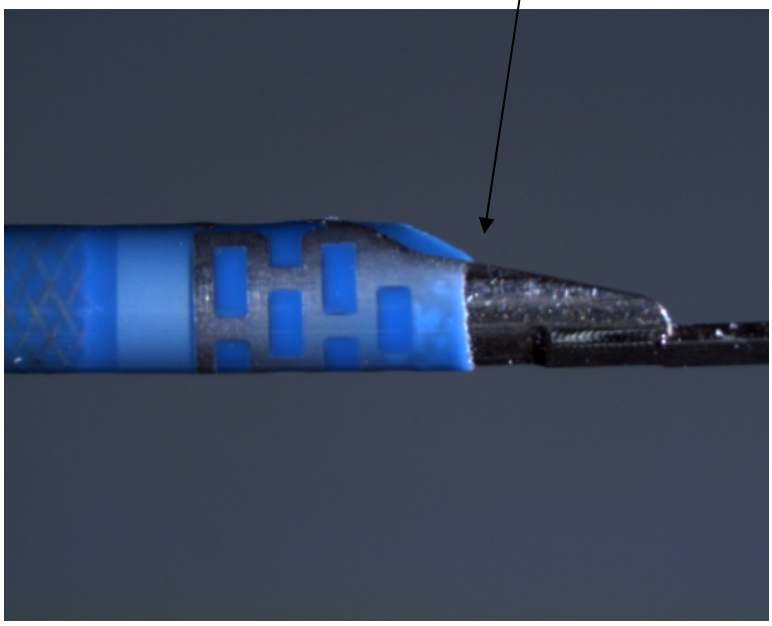
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	  Guidezilla has "a single lumen distal guide segment." Guidezilla Directions for Use at 2 (Ex. 25). "GUIDEZILLA consists of . . . a distal guide catheter segment through which interventional devices may be delivered." Boston Scientific's 510(k) Summary (Ex. 21). The flexible tip portion's length of 25cm is shorter than the 100cm length of the continuous lumen of a standard guide catheter. The tubular structure has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter, and it defines a coaxial lumen with a cross-sectional inner diameter through which interventional

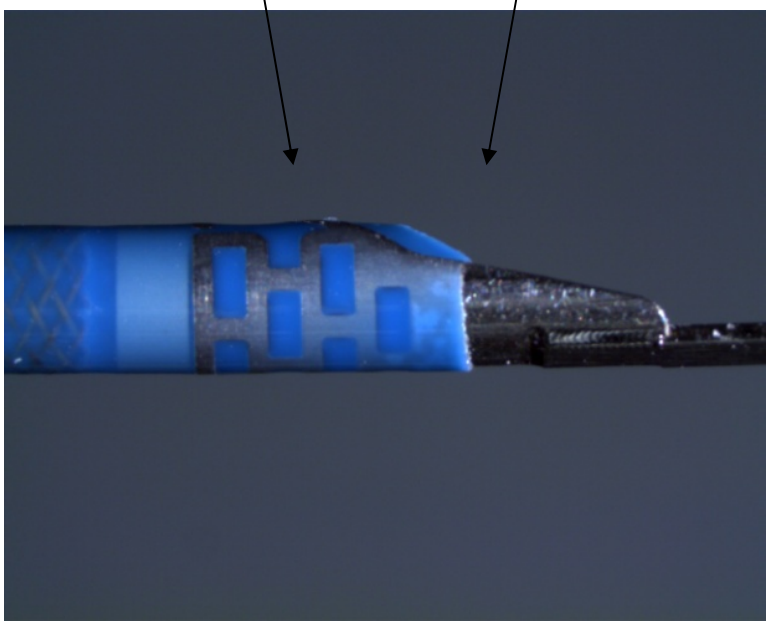
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,	cardiology devices are insertable. "The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." with "a stainless steel proximal shaft with a 25cm single lumen distal guide segment . . . ." Guidezilla Directions for Use at 2 (Ex. 25). As the attached photographs depict, Guidezilla's "stainless steel proximal shaft" is substantially rigid, proximal of and operably connected to, and more rigid than the flexible tip portion, and it is a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion. That the Guidezilla's substantially rigid portion does not have a lumen is discussed in more detail in my declaration, at ¶¶ 89-103. 

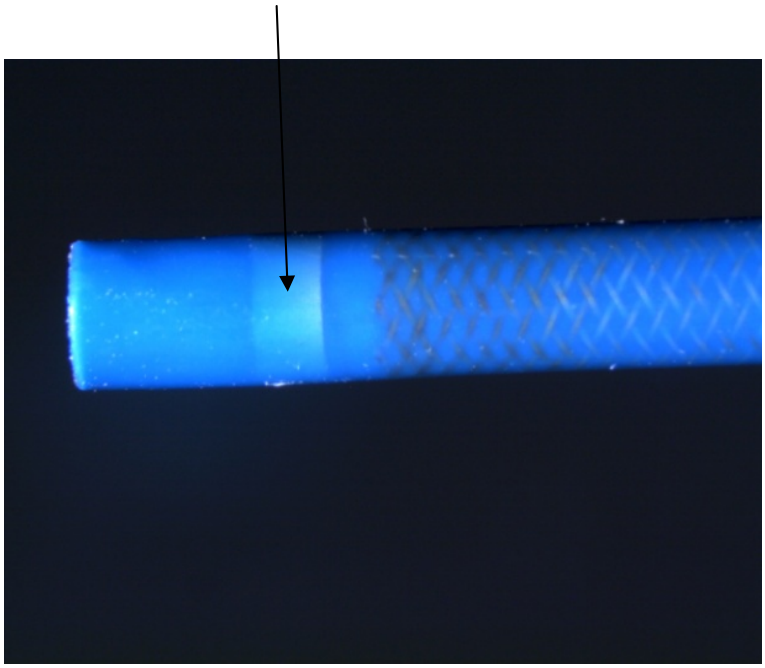
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	 The rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is longer than the length of the continuous lumen of the guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a length of 145cm. A standard 6F guide catheter is 100cm long. 
such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion	When the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve. "The Boston Scientific GUIDEZILLA™ Guide Extension

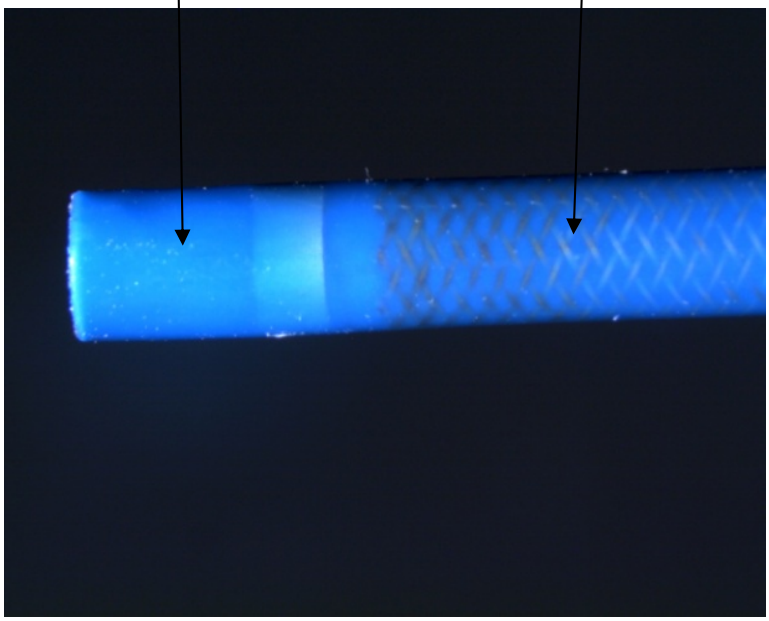
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary (Ex. 21). The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3 (Ex. 25). "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). At the same time, the proximal end of the Guidezilla extends from the proximal end of the guide catheter, through a hemostasis device. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3 (Ex. 25).
'032 patent, claim 2. 2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	The Guidezilla's the tubular structure has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a tubular structure that is 25cm in length: **Guidezilla**  That the tubular structure has a distal portion that is adapted to be extended beyond the distal end of the guide

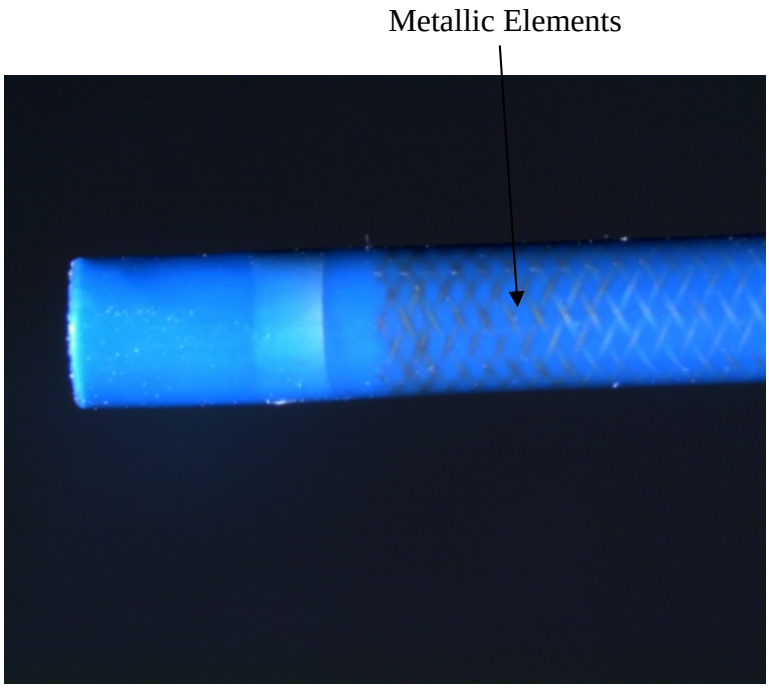
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	catheter while a proximal portion remains within the lumen of the guide catheter can be seen in that the length of the tubular structure is 25cm, but not more than 15cm of the tubular structure is advanced past the distal tip of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3 (Ex. 25). "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). See also above, in the discussion regarding claim 1. The Guidezilla device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen, where those forces would otherwise tend to dislodge the guide catheter from the branch artery.
'032 patent, claim 3. 3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	The proximal portion of the Guidezilla's tubular structure includes a proximal side opening that extends for a distance along the device's longitudinal axis and is accessible from a longitudinal side that is transverse to the longitudinal axis, so that the opening can receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter. This opening is shown in the following photograph of the Guidezilla device:

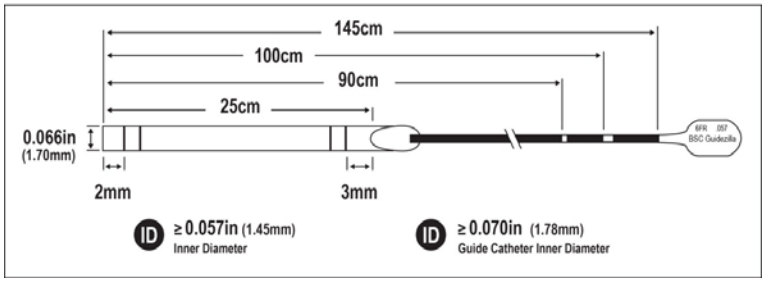
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	Proximal Side Opening 
'032 patent, claim 4. 4. The device of claim 3 wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.	The Guidezilla device's proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion, as can be seen in the photograph below of the Guidezilla device:

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
'032 patent, claim 5. 5. The device of claim 2 wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.	Guidezilla has two radiopaque markers located in the tubular structure. "The guide catheter segment incorporates two radiopaque marker bands to aid in positioning the device during the procedure." Boston Scientific's 510(k) Summary (Ex. 21). "The Guidezilla device has two platinum-iridium marker bands, which enable visibility while using standard fluoroscopic methods. The distal marker band is located 2 mm from the distal tip. The proximal marker band is located 3 mm distal to the opening of the guide segment." Guidezilla Directions for Use at 2 (Ex. 25). One of Guidezilla's radiopaque markers is positioned in the device's flexible cylindrical distal tip portion, proximate a distal tip. The distal marker can be seen in the following photograph of the Guidezilla device: Radiopaque Marker 

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
'032 patent, claim 6. 6. The device of claim 1 wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.	The Guidezilla device's tubular structure has a flexible cylindrical distal tip portion, and a flexible cylindrical reinforced portion that is proximal to the flexible distal tip portion, as can be seen in the following photograph: Flexible Cylindrical Distal Tip Portion Flexible Cylindrical Reinforced Portion 
'032 patent, claim 7. 7. The device of claim 6 wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.	The Guidezilla device's flexible cylindrical reinforced portion is reinforced with metallic elements in a braided pattern, as can be seen in the following photograph:

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	
'032 patent, claim 8. 8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The cross-sectional inner diameter of the Guidezilla's coaxial lumen of the tubular structure is one French smaller than the cross-sectional inner diameter of the standard 6F guide catheter. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary (Ex. 21). "Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2 (Ex. 25).
'032 patent, claim 11. 11. A device for use with a	See above, in the discussion of claim 1.

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	
an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:	Guidezilla has an elongate structure with an overall length that is longer than the lumen of the guide catheter. Guidezilla is 145cm in length, as the following Boston Scientific drawing shows. A standard 6F guide catheter is 100cm long. Guidezilla  "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary (Ex. 21). In use, the proximal end of the Guidezilla extends through the hemostatis valve. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3 (Ex. 25).

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	The distal end of the Guidezilla extends beyond the distal end of the guide catheter. "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3 (Ex. 25).
a flexible tip portion defining a tubular structure having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;	See above, in the discussion of claim 1.
a reinforced portion proximal to the flexible tip portion; and	See above, in the discussion of claim 6.
a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension	See above in the discussion of this claim 11, and above in the discussion of claim 1.

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	See above in the discussion of this claim 11, and above in the discussion of claim 1. When a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve. "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary (Ex. 21). The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3 (Ex. 25). "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). At the same time, the proximal end of the Guidezilla extends from the proximal end of the guide catheter, through a hemostasis device. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3 (Ex. 25).
'032 patent, claim 12. 12. The device of claim 11 wherein, when the distal portion of the flexible tip portion is insertable	See above, in the discussion of claim 2.

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through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter, the device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	
'032 patent, claim 13. 13. The device of claim 11 wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.	See above, in the discussion of claims 3 and 4.
'032 patent, claim 14. 14. The device of claim 11 wherein, after the device is inserted into the continuous lumen of the guide catheter, the device extends an overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing	See above, in the discussion of claims 1, 2, and 11.

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.	
'032 patent, claim 15. 15. The device of claim 11, further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.	See above, in the discussion of claim 5.
'032 patent, claim 16. 16. The device of claim 11, wherein the reinforced portion is reinforced with metallic elements in a braided or coiled pattern.	See above, in the discussion of claim 7.
'032 patent, claim 17. 17. The device of claim 11 wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	See above, in the discussion of claim 8.
'032 patent, claim 19. 19. The device of claim 11 wherein the elongate structure includes, starting at the distal portion of the flexible distal portion, at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural	The Guidezilla device is an elongate structure that includes, starting at the distal portion of the flexible distal portion, at least four different portions, as shown in the photographs below, having increasing levels of stiffness. Claim 19 requires only three, so any three of the four portions shown below establish infringement of this claim.