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VIDEO/AUDIO FILE TRANSCRIPTION
GuideLiner V3 Catheter: The Engineering Story



<p style="text-align: right;">Page 2</p> <p>1 The story of Guideliner is kind of the 2 story of innovation.</p> <p>3 So back in 2009, the GuideLiner was the 4 first guide extension catheter introduced into the 5 market.</p> <p>6 The unmet clinical need was for a guide 7 catheter extension that provided backup where it was 8 needed most. We recognized that there was a need for a 9 product that really allowed physicians to deliver more 10 gear into more complex lesions through tighter vessels or 11 tortuosity and further distal into the anatomy.</p> <p>12 One of the things that the GuideLiner was 13 designed to do was to provide stability and support for 14 the guide catheter to provide additional backup and allow 15 you a solid basis of operations from which to conduct 16 your procedure.</p> <p>17 With the invention of the GuideLiner, it 18 gave us the ability to place a guide catheter distal 19 shaft into the coronary vasculature which alleviated 20 delivery issues. Once physicians got their hands on it 21 and started to see what the clinical utility was and how 22 many applications they could use this catheter for, it 23 started to become the go-to catheter.</p> <p>24 Because it gives you that confidence and 25 that stability as a basis of operation, you can continue</p>	<p style="text-align: right;">Page 4</p> <p>1 find a coating that allowed the catheter to deliver into 2 that distal anatomy, but then also provided the backup 3 support. The silicone coating provides enough lubricity 4 for movement, but it also allows the device to stay put 5 in the guide when you want it to stay put.</p> <p>6 Our bench tests show an 18 to 46 percent 7 increase in GuideLiner V3 catheter backup support, 8 compared to competitive guide catheters with fully 9 hydrophilic coated guide extensions.</p> <p>10 If you look at metal support options for 11 catheters, you're kind of left with two viable options, 12 and that's realistically a coil-reinforced design or a 13 braid reinforced design.</p> <p>14 We decided for the GuideLiner that the 15 choice was obvious to go with a coil. We came to the 16 conclusion right away that a braided design does not hold 17 its shape very well. In our bench testing, around a 7 18 and a half millimeter bend, a braided guide extension 19 catheter construction will give up 10 percent of its 20 diameter versus the coiled guide extension catheter does 21 not give up any of its diameter.</p> <p>22 Our testing also found that the stiffer 23 distal shaft of a competitive coiled guide extension 24 catheter will give up 7 percent of its diameter versus 25 the GuideLiner V3 catheter's coiled distal shaft, which</p>
<p style="text-align: right;">Page 3</p> <p>1 to focus on delivering your devices where they need to 2 go.</p> <p>3 And that really pushed us to continue to 4 innovate that design. So it went from a simple metal 5 collar design to a simple polymer collar design to what 6 is now our current GuideLiner V3 that features a 7 half-pipe that really does help with device delivery 8 interactions. It really helps align those devices and 9 get those delivered easier into the GuideLiner V3 and 10 into that distal anatomy.</p> <p>11 The half-pipe design on the GuideLiner V3 12 catheter represents our commitment to continuous 13 improvement and continuous engineering and innovation on 14 our products.</p> <p>15 The engineering process is almost always 16 the art of compromise. How feature rich do we make the 17 device versus how simple and how small, how low profile. 18 And that kind of gets back to the flexibility, 19 deliverability, pushability of the GuideLiner catheter.</p> <p>20 You can put an extremely lubricious 21 hydrophilic coating on a GuideLiner catheter, and it 22 delivers amazingly. But the problem is you have no 23 backup support. And it really comes down to laws of 24 motion and physics.</p> <p>25 And so we really had to compromise and</p>	<p style="text-align: right;">Page 5</p> <p>1 does not give up any of its diameter.</p> <p>2 In the coronary anatomy, you are 3 delivering the collar up and over the aortic arch. And 4 so we realized that if we could move that collar back to 5 a straighter section of the aorta, that you're going to 6 have better luck delivering that device.</p> <p>7 What that does is reduces the wire wrap of 8 the wire within the guide catheter into the guide 9 extension. It reduces the interactions of interventional 10 devices with the collar of the guide extension.</p> <p>11 The GuideLiner V3 catheter features a 12 17-centimeter polymer bond between the extension and the 13 push wire to minimize device separation. And we've sold 14 over a half a million GuideLiner V3 catheters, and we've 15 yet to have a collar separation in coronary PCI.</p> <p>16 When we talk about effective ID, what 17 we've really talking about is what's the smallest point 18 from the hemostasis valve all the way to the distal tip 19 of the guide catheter. And in most guide extension 20 catheters, the smallest area is in the guide catheter 21 with the pushrod.</p> <p>22 So when we were looking at the GuideLiner 23 catheter, we decided we wanted to use a 24 rectangular-shaped ribbon wire. What that gets us is 25 additional space within the guide catheter to deliver</p>


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1 interventional devices. It allows you to deliver more
 2 gear, larger gear, through your guide catheter, through
 3 the guide extension, and to the target lesion.
 4 We're 56 thousandths from the moment you
 5 enter the guide catheter to the moment you exit the
 6 distal tip. When you look at some of our competitors,
 7 they chose to do a round pushrod. They're giving up, you
 8 know, 5 to 6 thousandths in that guide catheter. The
 9 design differences can seem small. In the end, that
 10 makes a huge difference on whether or not your case is
 11 successful. 5 or 6 thousandths in effective ID, that's a
 12 big number.
 13 When you're talking about backup support,
 14 18 to 46 percent more backup support with a GuideLiner is
 15 a huge number. In the last 10 years, across the
 16 generations of GuideLiner catheters, we've sold more than
 17 a million catheters worldwide, and we've solidified our
 18 place as a market leader in guide extension.
 19 And I think in the last 10 years, we've
 20 seen a tremendous shift in the complexity of cases that
 21 are able to be treated due to the technology of
 22 GuideLiner. Whether those are, you know, longer lesions,
 23 more tortuous lesions, more calcium, you know, the
 24 GuideLiner is really a necessary tool for those.
 25 It represents the commitment to solving

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1 unmet clinical needs. That's really what we've done with
 2 the GuideLiner catheter is, is created a solution and
 3 created a market. We understand the clinical impacts and
 4 the procedural impacts of guide extension, and we've
 5 continued to improve our catheter to make sure that we
 6 address those issues.
 7 Physicians choose GuideLiner on a daily
 8 basis because they just know that when they pull a
 9 GuideLiner, it's going to work.
 10 (End of video/audio file.)
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1 REPORTER'S CERTIFICATE
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 My commission expires January 31, 2024
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