Vascular Solutions, Inc.

Memo

From: Howard Root

To: GuideLiner DHF

Date: June 23, 2005

RE: **Market Feasibility for the GuideLiner catheters**

Background

As part of Phase I of the product development SOP 1043, a review of the market feasibility of the new product is required. The GuideLiner catheter is a new product idea of a "liner" to be delivered inside standard guide catheters to provide the ability to create a deep seating of the guide for added support in the interventional procedure. The GuideLiner catheter is designed to be used in interventional cardiology procedures. Three versions of the GuideLiner product are anticipated: a "5in6 GuideLiner", a "6in7 GuideLiner" and a "7in8 Guideliner." In addition, it is possible to make the GuideLiner in an Over-the-Wire version, a Rapid Exchange Version, or both.

Market Feasibility of GuideLiner catheters

The placement of a smaller guide catheter through a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents has been described in the literature (Takahashi, "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," Catheterization and Cardiovascular Interventions 63:452-456 (2004)). This coaxial technique has been used in order to provide a safer method of deep seating the guide catheter. The danger of deep seating a normal guide catheter is that the guide is relatively stiff with a fixed curve, which can result in dissections of the coronary artery when advanced past the ostium. Using a smaller, and therefore more flexible, guide catheter (with either no curve or a very gentle curve) and placing it through the larger standard guide catheter can reduce this risk to the vessel. By safely deep seating the guide catheter, the physician can then have the added support for pushing a wire through a chronic total occlusion or advancing a balloon or stent through a tight stenosis.

There are several problems with simply using a smaller guide catheter placed coaxially through a larger guide, to perform this technique as described in the literature. First, a new hemostasis valve must be placed on the inner guide catheter, and then the larger guide catheter can't be used for contrast injections or pressure measurements, and the overall system grows substantially in length (to the detriment of using standard tools to reach distal lesions). Second, the smaller guide catheter still must be inserted carefully into the coronary vessel since there is no tapered transition or dilator/obturator for insertion. And finally, a guide catheter used as a guide liner is not as flexible as is desired for insertion into the coronary artery.

A specifically designed guide liner product would have substantial market potential. Worldwide, there are over two million coronary interventions performed each year. Each of these procedures utilizes a guide catheter for gaining access to the coronary vessel (with a separate guide for the right and left). Because currently there is no guide liner product available, it is difficult to estimate the percentage of coronary interventions where a guide liner would be used. Estimating the incidence at just 1% would yield an annual market opportunity of over 20,000 procedures a year. Estimating a selling price of [redacted] per unit would create an annual market opportunity of [redacted], which is above the company's [redacted] annual market threshold for developing a new product.

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To meet this market opportunity, our GuideLiner product should be deliverable through the standard guide catheters (J&J, BSX, Guidant and Medtronic) currently on the market. The GuideLiner should include a tapered dilator that runs over a standard .014" coronary guide wire to allow atraumatic placement within the coronary artery (and then removal of the dilator/obturator). Also, the GuideLiner should include a hemostatic valve to connect to the guide catheter and lock the Guideliner in place. Finally, the GuideLiner should have an inner diameter that is acceptable for delivering standard coronary devices after it is placed in the vessel. In addition, a rapid exchange version of the GuideLiner product could use a short (preferably app. 20cm) rail segment, thus allowing delivery using standard rapid exchange techniques and negating the need for switching the Y-adaptor and using the GuideLiner for injections.

Three sizes of the GuideLiner product should be developed, corresponding to the 8F, 7F and 6F guide catheters that are used in interventional cardiology procedures. The minimum I.D.'s of the current guide catheters (J&J, Guidant, BSX, Medtronic) that would be used with the GuideLiner are as follows:

8F $\geq$ 0.088" I.D.
7F $\geq$ 0.078" I.D.
6F $\geq$ 0.070" I.D.

A crude evaluation of the space necessary between the O.D. of the GuideLiner and the I.D. of the guide catheter to allow acceptable movement and delivery was performed. From this evaluation, it is expected that a minimum of only 0.002" in space is necessary between the GuideLiner and the I.D. of the guide catheter to allow for delivery of the GuideLiner.

To completely satisfy user expectations, the effective I.D. of each size of our GuideLiner product should be equivalent to the next smaller guide catheter to allow the typical cardiology tools to be used. According to the published research, a 0.059" I.D. will allow all PTCA balloons and stents up to 4.0mm in size to be delivered. Thus, the desired maximum O.D. and the minimum effective I.D. of each size of the Guide Liner should be as follows:

Size	Min. I.D.	Max. O.D.
7in8 GuideLiner	$\geq$ 0.078"	$\leq$ 0.086"
6in7 GuideLiner	$\geq$ 0.068"	$\leq$ 0.076"
5in6 GuideLiner	$\geq$ 0.059"	$\leq$ 0.068"

Finally, the distal portion of the GuideLiner and the dilator should be radiopaque to indicate positioning during delivery, and a hydrophilic or other slippery coating could be applied to the distal potion of the GuideLiner to aid in delivery.

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