PRODUCT REQUIREMENTS:
GuideLiner Catheter System

Document Approvals:

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Distribution:					

1. INTRODUCTION

1.1 Scope

This document defines the safety and performance requirements for the Vascular Solutions, Inc. GuideLiner (OTW) and rapid exchange (RX) guide catheter support system. These safety and performance features are the minimal requirements for the device to be acceptable for its intended clinical use. Applicable clinical use is for increase guide catheter back-up support.

1.2 References

- Guidelines for the Submission of Research and Marketing Applications for Interventional Cardiology Devices. May 1994
- BS EN ISO 10555 – 1:1997, Sterile Single-use Intravascular Catheters.
- Part 1: General Requirements,
- ISO 10993:2003 Biological Evaluation of Medical Devices
- European Sterilization Standard BS EN 556: 1995 Sterilization of Medical Devices – Requirements for Terminally Sterilized Devices to be Labeled Sterile
- ISO 10993-07; 1995 (E) Ethylene Oxide Sterilization Residuals
- ISO 594-1:1986 Conical Fittings with 6% Luer Taper
- ISO 594-2:1998 Conical Fittings with 6% Luer Taper
- ASTM D 4169-01; Transportation Testing (DC13 AL II)
- ASTM F 2096-02; Bubble Leak Test
- MDD 13.3: 21 CFR 801

2. SYSTEM OVERVIEW

2.1. General Description

During many coronary interventions the back-up support provided by commonly used guide catheters are inadequate to deliver guidewires and PTCA treatment catheters through tortuous anatomy or severe stenosis. Advancing a PTCA catheter against resistance causes the guide catheter to back out of the coronary ostium rather than advancing the PTCA catheter. The GuideLiner will provide a simple means

by which the operator can increase the back-up support of a guide catheter by coaxially inserting a GuideLiner into the guide catheter.

2.2. Product Philosophy

Vascular Solutions strives to introduce products which are an improvement over current technology. VSI's new products must be simple to use, meet clinicians' needs, and improve quality of life for the patient. These devices must also meet the financial needs of today's healthcare environment

2.3. User Profiles

2.3.1. Physician

- Responsible for the health and comfort of patient
- Require products to be reliable and pose minimal risk to the patient
- Under cost containment pressure and will evaluate 'value' of product
- Interventional Cardiologists and Radiologists are trained in this procedure

2.3.2. Administration/Risk Management

- Look at the full cost of treatment of a disease state including complications
- Evaluate ways to reduce risk of complications

2.4. Key Assumptions

2.4.1. During interventional cases where the physician is attempting to reach into tortuous vessels, or where the arteries are more difficult to cross, additional back-up of the guide catheter may be achieved either through improved engagement of the coronary system, or by providing additional stiffness to the guide catheter.

2.4.2. Treatment catheters have a useable length of ~135cm

2.4.3. Guide catheters have a maximum overall length of 109cm

3. REQUIREMENTS/SPECIFICATIONS

USER REQUIREMENTS	PRODUCT SPECIFICATIONS	TEST METHOD
3.1 Performance Requirements		
The catheter system must allow for advancement of the treatment catheter beyond (deeper) than using a guide catheter alone		
The catheter system must be capable of withstanding normal insertion and removal forces through commonly used guide catheters and through the arterial system.		
The catheter system must slide inside the guide catheter and through the anticipated vasculature and be able to navigate the blood vessels without kinking.		
The catheter system must provide for an atraumatic entry into and travel through the blood vessel.		

The most distal position of the catheter system must be visible using standard fluoroscopic methods.		
Catheter system must be capable of delivering standard PTCA treatment catheters.		
Catheter and dilator must be able to be flushed with liquid prior to introduction into the guide catheter.		
The catheter surfaces shall be free of extraneous matter.		
The catheter system must be sterile		
3.2 Dimensional requirements		
The catheter must be capable of being deployed over a .014" guidewire.		
The catheter must be able to be deployed through a standard coronary guide catheter used in percutaneous procedures in both diameter and length.		
The catheter must be able to be locked in position relative to the guide catheter		
The length of the catheter must not prevent or limit the treatment catheter or stent delivery system from being fully deployed.		
3.3 Chemical & Biologic Properties		
All bio-contact materials used must be compatible with the biological tissues, cells and fluids.		
EO residual levels of blood contact components must meet required medical device criteria.		
The device must not contain any Latex materials		
3.4 Infection & microbial contamination		
The catheter surfaces must be free of sharp edges.		
The device must be non-pyrogenic.		
All components entering the sterile field and intended for contact with human tissue must be sterile.		
3.5 Packaging & Labeling		

The catheter should be packaged in such a manner to protect the catheter and components.		
Catheter must have a reasonable shelf life.		
Catheter and package configuration must be designed for typical laboratory environment storage conditions.		
3.6 Ergonomic Requirements		
The catheter system should employ techniques and components that are familiar to the physician.		
The RX version of the catheter system should be capable of being used by one physician.		
3.7 Interfaces with other devices		
The catheter system connections must be able to interface with standard connectors.		
The catheter system must be able to pass a .014" guidewire.		
The 5 in 6 catheter must be able to interface with a .070" guide catheter. The 6 in 7 catheter must be able to interface with a 0.078" guide catheter The 7 in 8 catheter must be able to interface with a 0.088" guide catheter.		

4. REVISION HISTORY

Rev.	Effective Date	DCO #	Reason
01	8/24/05	4029	Pre-release