

Documents

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Vascular Solutions, Inc. Document Number: PS1068
 Product Requirements Document Rev: 01
 GuideLiner Catheter System Page 1 of 4

**PRODUCT REQUIREMENTS:
 GuideLiner Catheter System**

Document Approvals

Reviewer	J. Kauphusman	8/24/05
Documentation	J. Kujawa	8/24/05

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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 10993-2:2003 Biological Evaluation of Medical Devices
- European Sterilization Standard BS EN 550-1:1992 Sterilization of Medical Devices - Requirements for Terminally Sterilized Devices to be Labeled Sterile
- ISO 10993-4:1995 (E) Cellular Toxic Sterilization Residuals
- ISO 594-1:1986 Conical Filings with 0% Laser Taper
- ISO 594-2:1988 Conical Filings with 0% Laser Taper
- ASTM D-4169-01; Transpiration Testing (DK13.A1.H)
- 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

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