1.0 Purpose

This protocol describes extreme use testing a Guidewire Exchange Catheter, which is designed to facilitate the placement of a balloon guidewire distal to the primary coronary ostium. The testing described herein includes the simulation of worst-case conditions in the vicinity of the ostium and will therefore help predict device performance and reliability when misused in a clinical setting.

2.0 Scope

The data produced through execution of this protocol will be integral to determining the suitability of the Guidewire Exchange Catheter assembly for clinical trials. Extreme use testing of the remaining system components is covered under separate protocol and is beyond the scope of this document.

3.0 Documents

Table 1. Required documentation. Each document must be reviewed and redlined (if applicable).

Document	Revision	Title	Signature
-	-	Assembly	-
-	-	Catheter Liner	-
-	-	Outer Exchange Tube	-

4.0 Materials

Table 2. Consumables and test equipment. Record tool number where applicable.

Component	Description	Quantity	Device Code
-	Balloon Guidewire	13	1
-	Guidewire Exchange Catheter	13	2
-	AVE GT1 Floppy Guidewire	1	3
-	AVE Microstent II Stent Catheter	1	4
-	ACS RX Multilink Stent Catheter	1	5
-	Scimed Niron Ranger Stent Catheter	1	6
-	Scimed Magic Wallstent Stent Catheter	1	7

5.0 Mechanical Simulation

The introduction of a foreign body to the vascular system results in complications that are related to shear forces, normal forces (blunt trauma and pressure necrosis), and abrasive action caused by the invading device. Studies to predict the long-term effect of such invasion are difficult and expensive to conduct when live patients or animals are involved and often yield inconclusive results. As an alternative, mechanically simulating the insult to a tissue analog is a relatively inexpensive, easily repeatable, and logical first step to perform before resorting to animal studies or clinical trials.

The tests described in this protocol involve testing individual devices on synthetic coronary ostium tissue under worst case (extreme angle of attack) conditions. Test results will help to predict the actual tissue damage that might occur if these same devices were misused in a clinical setting.

6.0 Fixture Setup

6.1 Cut a 2 inch square section off of a lint-free wipe. Wet the center of the section with a few drops of water (don't wet the edges), then tape the section to a flat surface. This will provide a high-friction surface for the Arterial Tissue Disc (ATD - Figure 1).

Figure 1. Arterial Tissue Disc. This multilayer tissue disc includes synthetic muscle, fascia, fat, and arterial intima.

6.2 Set up the Holding Fixture as shown in Figure 2. Insert a 9F guide into the fixture so that the tip extends approximately 2 mm beyond the distal end of the tube.

6.3 Adjust the rotational position knob on the stand so that the angle of attack is approximately 80 – 85 degrees. The angle of attack is measured between the normal vector of the ATD surface plane and the primary axis of the catheter.

6.4 Place one ATD on the center of the lint-free wipe and position the Holding Fixture so that the tip of the guide catheter is centered over the disc.

6.5 See Figure 3. Adjust the vertical position knob on the fixture so that the tip of the guide catheter is approximately 1 – 2 mm from the surface of the ATD.

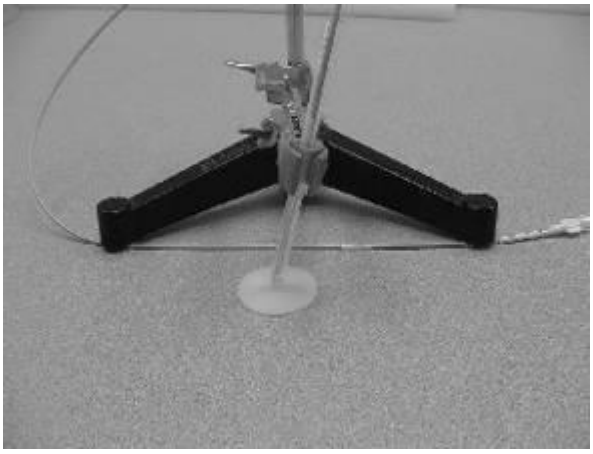

Figure 2. Holding Fixture.

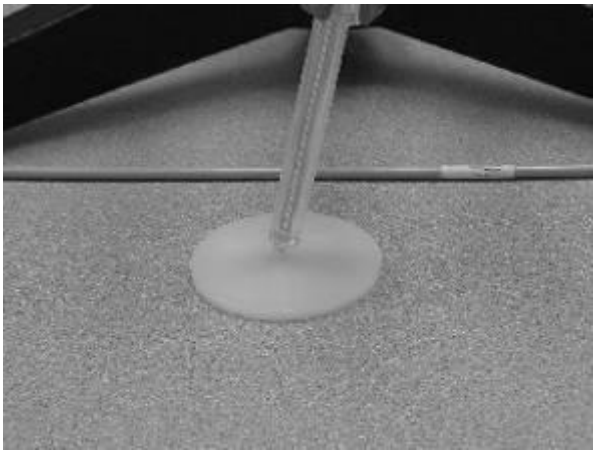

Figure 3. Disc placement.

7.0 Test Method

7.1 Fill a 20cc syringe with water and attach to the Y-branch on the guide. Close the Hemostasis valve and flood the guide so that the excess water is ejected onto the ATD. The disc needs to remain completely hydrated during the experiment, so each time it is replaced the guide must be flushed again.

7.2 Each one of the devices listed in Table 2 will be placed through the guide so that they impact the surface of the ATD. No more than 8 inches of each device will be passed out of the distal end of the guide and only one pass will be performed.

7.3 After completion of each test the ATD will be removed for examination and graded subjectively following the scorecard described in Table 3. Store each sample in a ziplock bag with a few cc of water.

7.4 Blot water off of the ATD prior to inspection so that the surface may be better visualized.

7.5 Inspect each ATD and record results in Table 4.
7.6 Compute score statistics and report in Table 4. Devices 3 – 7 were not repeated so no statistics are available.

Table 3. Description of grading scale.

Grade	Comments
0	No visible damage
1	Visible mark on surface
2	Compression marks or skipping grooves
3	Deep compression or grooving
4	Tissue model perforation or tear

Table 4. Test results.

Sample	Score	Sample	Score	Sample	Score
1-1	1.0	**2-1**	1.0	**3**	0.5
1-2	0.5	**2-2**	1.0	**4**	2.5
1-3	0.0	**2-3**	2.0	**5**	1.0
1-4	0.5	**2-4**	1.5	**6**	1.5
1-5	1.0	**2-5**	1.5	**7**	1.0
1-6	0.0	**2-6**	1.5		
1-7	1.0	**2-7**	1.0		
1-8	0.5	**2-8**	0.5		
1-9	1.0	**2-9**	2.0		
1-10	0.0	**2-10**	1.0		
1-11	0.5	**2-11**	2.5		
1-12	0.0	**2-12**	1.0		
1-13	0.5	**2-13**	1.5		

Table 5. Performance results for all tests.

Code	Device	μ	σ
1	Balloon Guidewire	0.43	0.44
2	Guidewire Exchange Catheter	1.38	0.54
3	AVE GT1 Floppy Guidewire	0.5	-
4	AVE Microstent II Stent Catheter	2.5	-
5	ACS RX Multilink Stent Catheter	1.0	-
6	Scimed Niron Ranger Stent Catheter	1.5	-
7	Scimed Magic Wallstent Stent Catheter	1.0	-

8.0 Discussion

The test plan included 13 Balloon Guidewires, 13 Guidewire Exchange Catheters, 1 standard coronary guidewire, and 4 stent catheters. The stent catheters and coronary guidewire are available commercially in the U.S, while the Balloon Guidewire has been approved for clinical trials in Europe. The relative performance of the Guidewire Exchange Catheter is the focus of this protocol. The results described above were derived from 7 devices tested under otherwise identical conditions. In each instance the same test fixture, angle of attack, and tip gap was employed. The ATD samples (Figure 1) were provided by SynDaver™ Labs (Tampa, FL) and were essentially identical. All testing was performed in a single session by one operator. It is reasonable, therefore to attribute differences between the devices to the devices themselves.

The effect of each device type on the ATD is shown in Figure 4. The guidewire (top) had minimal effect, leaving an impression (surface remained unbroken) approximately 0.15 mm in width. The stent catheter (AVE Microstent II – middle) penetrated the surface and left a much wider 0.70 mm groove in the model. The Guidewire Exchange Catheter (bottom) skipped along the surface of the model and created impressions that were as wide as 0.75 mm in some places.

Referring to Table 5 it may be seen that the mean score (n=13) of the Balloon Guidewire damage was less than 0.5, which corresponds to the creation of very minor, transient impressions in the model. The score range was 0.0 – 1.0.

The mean score attributed to the GWEC was less than 1.5, which corresponds to easily visible impressions, which may or may not result from penetration of the surface. Closer inspection of the individual data points reveals that the surface was actually compromised (range was 0.5 – 2.5) in less than a third of the specimens.

The scores attributed to the stent catheters range from 1.0 to 2.5, with a median of 2.0. The worst damage caused by one of the stent catheters was a score of 2.5 achieved by the AVE Microstent II, which was equaled in only one instance by the GWEC in 13 repetitions.

In addition, the scores achieved by the GWEC were lower than the median stent catheter value in 10 of the 13 trials. This supports the argument that the GWEC is no more likely to cause injury than other devices the FDA has previously cleared for sale, and we therefore conclude that the GWEC is suitable for clinical use.

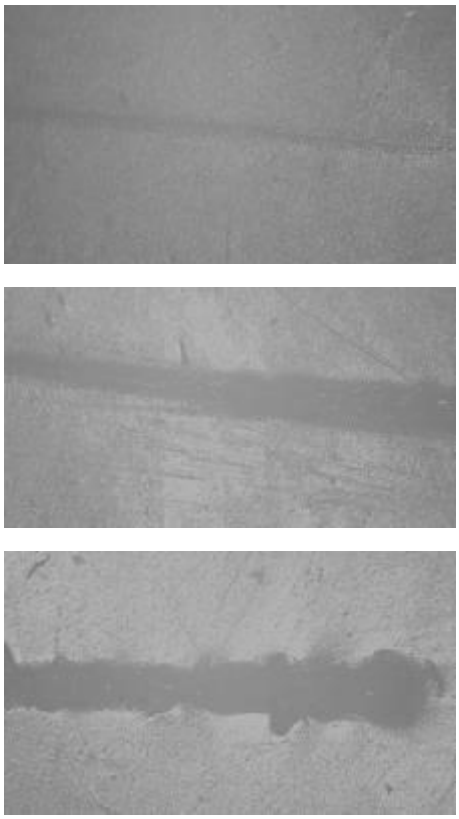

Figure 4. Photographs of device impact.