Section 7 - Performance Data Demonstrating Safety and Effectiveness

1. Device Integrity Testing

The following table identifies the tests which were performed to verify that the UNIPOLAR IPG GROUND CABLE, Model 5473 meets the device integrity requirements. The table includes a summary of the requirements for each test. Following the table, a summary of each test objective and method is provided.

2. Sample Size

A total sample size of thirty (30) cable assemblies were used for the Model 5473 performance testing. Twenty (20) cable assemblies were exposed to life cycle testing, providing a 90% confidence level with a minimum reliability of 89%. Ten (10) cable assemblies were exposed to autoclave sterilization testing, providing a 90% confidence level with a minimum reliability of 79%. Rotational flex testing required a sample size of eight (8) cable assemblies to gain a 90% confidence with a minimum reliability of 74%. Lower sample sizes for the sterilization and rotational flex testing were deemed adequate due to the proven history that these materials have in many other Medtronic surgical cable assemblies.

Table 4: Device Integrity Tests

Test	Test Requirement	Devices Tested	Test Results
Autoclave Sterilization	Devices shall remain within specification following flash autoclave sterilization.	10	Pass
Grounding Clip Life Cycling	Devices shall be capable of grasping and holding a minimum of 2 ounce weight in the vertical direction, and shall have acceptable contact resistance.	20	Pass
Rotational Flex	Devices shall be reusable	8	Pass

3. Device Integrity Test Objectives and Methods

A. Autoclave Sterilization

Objective

To verify the device can be sterilized without loss of function.

Test Method

The samples are subjected to an initial visual inspection, a contact resistance measurement, and a grip force measurement. The samples are subjected to one hundred (100) flash autoclave sterilization at 270° F for 10 minutes at a pressure of 21 psi. After sterilization, the samples are subjected to a visual inspection, a contact resistance measurement, and a grip force measurement.

B. Grounding Clip Life Cycling

Objective

To verify the device can be reused without loss of function.

Test Method

The samples are subjected to an initial visual inspection, a contact resistance measurement, and a grip force measurement. The samples are subjected to 250 cycles of opening and closing of the IPG grounding clip. After cycling, the samples are subjected to a visual inspection, a contact resistance measurement, and a grip force measurement.

C. Rotational Flex

Objective

To verify the device can be reused without loss of function.

Test Method

The samples are subjected to an initial visual inspection, and a contact resistance measurement. The samples are subjected to 1000 cycles of rotational flex by clamping the IPG ground clip to a rotating platform, with a one (1) ounce weight six (6) inches from the ground clip. After cycling, the samples are again subjected to visual inspection, and a contact resistance measurement.