September 30, 2015

RE: Product Name: Precision Plus™ Implantable Pulse Generator (IPG)

This letter is in response to your recent inquiry regarding the use of a hyperbaric chamber for patients who have been implanted with a Boston Scientific Precision Plus™ Spinal Cord Stimulator.

Boston Scientific does not support the use of a hyperbaric chamber for patients who have been implanted with a Boston Scientific Precision Plus™ Spinal Cord Stimulator. Functional testing of the device was performed after the device was stored at 2 atm (30 psia). However, we have not performed any tests with the device inside a human body and cannot guarantee that the device will operate correctly or that there will be no harm to a patient during or after use of a hyperbaric chamber.

If further research is conducted to test the compatibility of the device implanted in a patient within a hyperbaric chamber, we would be happy to inform you of our research findings upon completion. At this time, no further testing is being conducted.

If you have any questions regarding the information provided, please do not hesitate to contact our Patient Care department at (866) 360-4747.

Sincerely,

Boston Scientific Neuromodulation