

Urgent Product Advisory Vercise Genus[™] Deep Brain Stimulation

08 August 2024

Dear Patient:

We recently sent information to the physician who manages your rechargeable Vercise Genus[™] Deep Brain Stimulation (DBS) device that describes the possibility for header wire break(s) to occur due to compression on your device, if it is implanted under your chest muscle. A very small number of device failures have been reported and not every device implanted in this manner is expected to be affected. However, if this event occurs, you may observe a sudden loss of therapy, undesired sensation, return of pre-implant symptoms and/or Bluetooth connectivity challenges.

Device header wire break(s) can prevent successful delivery of stimulation therapy, and a device replacement may be required.

What should you do?

We recommend that you discuss this letter with your doctor and continue to follow their instructions. If you have any additional questions after contacting your doctor, please contact Boston Scientific Neuromodulation Support via email: <u>bsndbspatientcare@bsci.com</u>.

Sincerely,

Scott Heim

Scott Heineman Vice President, Quality Assurance Boston Scientific