



## **BRYAN® CERVICAL DISC: OUTLINE OF PROPOSED POST-APPROVAL STUDY**

As part of the Panel review of the BRYAN® Cervical Disc, the FDA has asked Medtronic to submit an outline of our post-approval study plans for the device. The goal of the BRYAN® Cervical Disc post-approval study will be to assess long-term performance of the disc in the treatment of patients with cervical degenerative disc disease. Further objectives and key points of the proposed post-approval study are as follows:

- The study will be comprised of the investigational and control patients from the original IDE clinical trial, as well as patients who received the BRYAN device as part of the continued access arm.
- The primary consideration of long-term performance of the device will be overall success. Overall success is a composite variable comprised of the following key safety and effectiveness parameters:
  - Neck Disability Index improvement from preoperative;
  - Maintenance or improvement of neurological status from preoperative;
  - No serious adverse event classified as implant- or implant/surgical procedure-associated; and
  - No second surgical procedure classified as a failure (revision, removal, or supplemental fixation at implanted level).
- The overall success rate for the BRYAN device group will be compared to that of the concurrent fusion control group. Study success will be based on showing non-inferiority of the investigational device group overall success rate at seven years following surgery.
- Data will be collected at 4, 5, and 7 years postoperative to determine the long-term safety and effectiveness of the device. Note that some patients have already had a 4-year follow-up visit under the IDE protocol. Those patients will next be examined at the 5-year follow-up time point.
- In addition to the measurements included in the overall success determination, all other endpoints from the clinical trial will also be evaluated in the post-approval study.
- All 30 original investigational sites that contributed patients to the IDE study will be requested to participate in the post-approval study.
- Postoperative data will be collected at 4, 5, and 7 year time points on a minimum of 200 eligible patients (minimum of 100 patients each from the control and investigative arms) from the original randomized cohort of IDE

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patients who agree to participate in the post-approval study. However, we will attempt to collect data on all patients, including continued access patients.

- Patients who were study failures due to device removals or second surgeries should also be asked to participate.
- At the time such information is available, reports of any explanted devices will be generated and included in the annual and final reports following the procedure of the explant protocol that was utilized in the clinical trial.
- Medtronic will submit reports of the post-approval study of the BRYAN® device at 6-month intervals for the first 2 years from the date of approval and then annually thereafter until such time as the final report is submitted.