

GORE TAG Thoracic Endoprosthesis

Clinical Summary

The original Investigational Device Exemption (IDE) for the Gore TAG Thoracic Endoprosthesis, TAG device, was submitted in November 1997. The proposed TAG device indication is "treatment of aneurysms in the descending thoracic aorta". Three clinical studies were conducted to study this population: a Feasibility Study (██████████), a Pivotal Study (██████████) and a Confirmatory Study (██████████).

After the Feasibility Study (██████████) (n=28) was conducted to evaluate safety and probable benefit, the TAG device was tested in a multicenter Pivotal Study (██████████), assessing the safety and efficacy in 140 TAG device group subjects (endovascular treatment) and 94 Surgical Control group subjects (open surgical repair).

The primary safety endpoint of this study was the proportion of subjects who experienced ≥ 1 major adverse event (MAE) through 1 year post-treatment in the TAG device and Surgical Control groups. The proportion of subjects who experienced ≥ 1 MAE through 1 year post-treatment was significantly lower ($p < 0.001$) in the TAG device (42%) group vs. the Surgical Control (77%) group. Thus, the primary safety endpoint of the ██████████ study was achieved.

The primary efficacy endpoint of ██████████ was the proportion of TAG device subjects free from a major device-related event through the 12-month follow-up visit. The alternate hypothesis was that the proportion of TAG device subjects free from a major device-related event was ≥ 0.80 . The efficacy estimate was 0.94 with a lower-bound 95% confidence interval of 0.90. Thus, the null hypothesis was rejected ($p < 0.0001$) and the primary efficacy endpoint of the study was achieved.

During the follow-up period of the initial IDE studies, a higher than anticipated number of fractures occurred in the wire frame (stent) of the endoprosthesis. To date, minimal clinical sequelae have been reported as a result of these fractures. Gore suspended commercial distribution of the TAG device in order to investigate the cause and potential effects of breaks in the wire frame. The failure mode was replicated in newly developed in vitro tests. The TAG device was subsequently modified to address this failure mode.

The modified TAG device was then evaluated in a Confirmatory Study (██████████) to confirm that the design modifications did not adversely affect clinical performance. The Confirmatory Study enrolled 51 TAG device group subjects. The primary analysis compared the TAG ██████████ device group to the TAG ██████████ Surgical Control group for evaluation of the primary safety endpoint of the proportion of subjects experiencing ≥ 1 MAE through 30 days post-treatment. A secondary efficacy analysis was performed to compare the TAG ██████████ device group to the TAG ██████████ device group. This analysis was prospectively defined as the proportion of subjects with ≥ 1 major device-related events through the 30-day follow-up visit.

The proportion of subjects who experienced ≥ 1 MAE through the 30-day follow up visit was significantly less ($p < 0.001$) in the TAG ██████████ device group (12%) compared to the TAG ██████████ Surgical Control group (70%). One hundred percent efficacy was reported through the 30-day follow-up visit in the TAG ██████████ device



group compared to 96 % efficacy in the [REDACTED] device group. Thus, both the safety and efficacy endpoints were achieved in the Confirmatory study.

The successful outcomes of these IDE studies [REDACTED] and [REDACTED] indicate that endovascular repair of aneurysms in the descending thoracic aorta with the GORE TAG Thoracic Endoprosthesis is a safe and effective alternative to open surgical repair in appropriate patients.

