Medtronic News

Medtronic Begins Pediatric Clinical Trial of Spinal Tether for Treatment of Scoliosis

As First Patient Is Enrolled in the Clinical Trial of Braive™ Growth Modulation System, Study Reaffirms Medtronic's Commitment to Pediatric Spine Innovation

DUBLIN, Sept. 22, 2021 /PRNewswire/ -- Medtronic plc (NYSE: MDT), the global leader in medical technology, today announced that it has enrolled its first patient and completed the first surgical procedure in its BRAIVE™ IDE study, which will evaluate the safety and effectiveness of the Braive™ growth modulation system for treatment of progressive juvenile (JIS) or adolescent (AIS) idiopathic scoliosis. The first patient was recruited by The Newcastle Upon Tyne Hospitals NHS Foundation Trust, United Kingdom. The device is Medtronic's latest innovation in the pediatric spine category, and the study's initiation reaffirms the company's commitment to continued innovation for pediatric patients.

About 4% of children globally have scoliosis, making it one of the most common pediatric orthopedic deformities.[1] It occurs when the vertebrae twist or rotate, causing the spine to curve into a "C" or "S" shape, rather than a straight line. It typically occurs in children and impacts girls more often than boys. Standard treatment options may include braces or spinal fusion surgery. According to the National Scoliosis Foundation, an estimated 30,000 children a year receive a brace to treat their condition, while 38,000 patients are treated with spinal fusion.[2] While successful in correcting the spine's curve, spinal fusion causes vertebrae to fuse together into a single bone, which stops growth in that area of the spine.

The Braive growth modulation system uses a braid secured to the spine with screws to slow growth on the curved side of the spine, while allowing growth to continue on the other side. The BRAIVE IDE study will evaluate whether the system is safe and effective in correcting the spine's curve in patients with juvenile or adolescent idiopathic scoliosis. The prospective, multi-center study will enroll patients in the United States, Canada, and the United Kingdom.

"There continues to be an unmet need for medical devices specifically tailored to pediatric patients," said Andrew Bowey, consultant orthopedic surgeon, Newcastle Hospitals, and BRAIVE IDE study principal investigator. "The Braive system is designed to correct scoliosis while allowing the spine to continue to grow, which is important for adolescents who are experiencing their most significant period of growth. I'm excited about its potential and the ability to bring this study to my patients who may benefit."

"Launching the BRAIVE IDE study is our latest step in bringing life-changing technologies to pediatric patients," said Carlton Weatherby, vice president and general manager of Spine & Biologics within the Cranial & Spinal Technologies business, which is part of the Neuroscience Portfolio at Medtronic. "As image guidance and navigation compatibilities extend further into additional spinal implant systems indicated for pediatric populations, they are coupled with a rapid cadence of transformative implant innovation. This uniquely positions us to offer the most comprehensive and integrated ecosystem of procedural solutions to pediatric spine surgeons driving meaningful improvements in clinical outcomes for young patients."

To learn more about Medtronic Spine & Biologics, visit Medtronic.com/SpineSurgery.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical

technology, services, and solutions companies – alleviating pain, restoring health, and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals, and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

References

1. Julien C, Gorman KF, et al. "Towards a comprehensive diagnostic assay for scoliosis." Per Med. 2013 Jan;10(1):97-103. doi: 10.2217/pme.12.117.
2. "Scoliosis." American Association of Neurological Surgeons. https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Scoliosis. Accessed Aug. 30, 2021.

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