Food and Drug Administration Allows Compassionate Use for the Reverse Hip Replacement System

Compassionate Use May Provide Better Hip Replacement Option for Patients with Spinal Fusion and/or Spinal Pelvic Disorder

BOCA RATON, FL March 4, 2025 -- Hip Innovation Technology, LLC (HIT), a medical device company developing innovative orthopedic device solutions to advance the quality of life and quality of care for patients, is announcing the Food and Drug Administration (FDA) has approved the Reverse Hip Replacement System (Reverse HRS) for Compassionate Use in a patient with spinal fusion.

"I am extremely encouraged by the opportunity to offer the Reverse Hip Replacement System to an at-risk patient," said Stephen J. Zabinski, MD, Medical Director of Joint Replacement Surgery and Assistant Chairman of the Department of Surgery at Shore Medical Center. "I know myself, as well as other study investigators, have identified several patients that may be candidates for this compassionate use provision. The one patient that was approved by the FDA is scheduled for the procedure at our institution later this month."

Data Supports Compassionate Use

Currently available hip systems are not well suited for patients with previous spinal fusion. As published by Christopher G. Salib, MD, et. al. in the 2019 *Bone & Joint Journal*, these patients experience significantly increased risk of dislocation due to alteration of the spinal pelvic mechanics.[1] This alteration in biomechanics is not fully addressed by currently available conventional or dual mobility hip arthroplasty systems.[1]

Supporting evidence by Arthur L Malkani, MD, et. al. in the 2018 *Journal of Arthroplasty* reports that when compared to patients without lumbar fusion, patients with lumbar fusion demonstrated an 80% increase in dislocation at six months, 71% at one year and 60% at two years.[2] There was also a 48% increased risk of any failure leading to revision hip surgery in patients with lumbar fusion at six months, 41% at one year, and 47% of two years. [2]

"We are thankful for the FDA's compassionate use provision for our Reverse Hip Replacement System," said George Diamantoni, CEO, Hip Innovation Technology. "The data collected from these cases may help expand the existing literature, offering a potential new option for patients with spinal fusion and spinal pelvic disorders. Our hope is to provide these patients with a new option that could enable them to experience a lower risk of dislocation and improved outcomes with the Reverse HRS,"

About the Reverse HRS

The Reverse HRS is a Metal-on-Polyethylene reverse geometry hip prosthesis designed to improve stability at extended ranges of motion and reduce the risk of dislocation. Like most conventional

systems, the Reverse HRS consists of a femoral stem, an acetabular cup and a cobalt-chrome ball that articulates within a polyethylene liner. Unlike existing total hip replacement systems, the ball is placed on a trunnion within the acetabular cup instead of the femoral stem, and the polyethylene liner is attached to a femoral cup, which then attaches to the femoral stem, as opposed to the polyethylene liner being attached to the acetabular cup. This technological difference does not change the center of rotation of the Reverse HRS and it remains similar to a normal physiological hip, or a well-positioned traditional Total Hip Arthroplasty. The advanced Reverse HRS implant is designed to provide greater range of motion in all planes, enhanced hip stability, and to reduce the risk of dislocation. Importantly, the Reverse HRS also provides variability of component placement including higher abduction angles and anteversion of the acetabular cup. The femoral cup articulates around the acetabular ball and overlaps with the acetabular cup as the hip undergoes flexion-extension, abduction-adduction and internal-external rotation. This forgiving design may compensate for suboptimal component positioning which may provide benefits such as extended range of motion, hip stability and reduced likelihood of impingement. The Reverse HRS is designed to uncouple the relationship between component placement, wear and stability. This unique implant design of the Reverse HRS provides optimal surface area contact between the acetabular ball and femoral cup, which may eliminate edge loading. Elimination of edge loading may provide benefits that include reduced high-contact stresses, decreased implant wear and uniform wear, which minimizes generation of wear debris and associated concerns related to osteolysis.

About Hip Innovation Technology, LLC
Headquartered in Boca Raton, Florida, Hip Innovation Technology was formed in 2011 to provide market-leading orthopedic device solutions that advance the quality of life and quality of care for patients. In partnership with healthcare professionals worldwide, our goal is to identify unmet clinical need, then design, manufacture and ultimately market innovative orthopedic reconstructive and related surgical product solutions.

For more information, visit www.hipinnovationtechnology.com.

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1. Bone Joint J. Lumbar fusion involving the sacrum increases dislocation risk in primary total hip arthroplasty. 2019 Feb;101-B(2):198-206. doi: 10.1302/0301-620X.101B2.BJJ-2018-0754.R1.
2. J Arthroplasty. Total Hip Arthroplasty in Patients With Previous Lumbar Fusion Surgery: Are There More Dislocations and Revisions? 2018 Apr;33(4):1189-1193. doi: 10.1016/j.arth.2017.10.041. Epub 2017 Oct 31