

Multispecialty hospital Shalby announces strategic clinical trial agreement with Monogram Technologies

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Clinical trial agreement preludes planned international launch for the mBôs TKA System



Shalby Limited, a leading multispecialty hospital in India, has announced a strategic partnership with US-based startup Monogram Technologies Inc., an artificial intelligence (AI)-driven robotics company specialising in orthopedic surgery. This collaboration will focus on conducting a multicenter clinical trial in India to demonstrate the safety and effectiveness of Monogram's mBôs TKA System, a precision robotic surgical system designed for knee replacements.

Monogram's mBôs precision robotic surgical system is designed to autonomously execute optimised paths for high-precision insertion of its FDA-cleared mPress press-fit implants. The goal is well balanced better-fitting bone sparing knee replacements. The company initially intends to produce and market robotic surgical equipment and related software, orthopedic implants, tissue ablation tools, navigation consumables, and other miscellaneous instrumentation necessary for reconstructive joint replacement procedures. Other clinical and commercial applications for the mBôs with mVision navigation are also being explored.

Under the agreement, Shalby will enroll up to patients at various sites in India for surgeons to evaluate the safety and effectiveness of the mBôs TKA System with the Consensus CKS implant, which is substantially equivalent to the Monogram mPress implants for regulatory purposes. Monogram received comments on the Clinical Investigational Plan during its February 2024 Pre submission Communications with the FDA and has incorporated feedback. Notably, the strategic Clinical

Trial Agreement contemplates the post-trial transfer of a robot to the hospital system under certain conditions following the trial as the companies contemplate further collaboration.

Monogram plans to leverage the clinical data from the US study for post-launch marketing and to support international clearance and commercialisation.