ROSA One 3.1 Brain Application Field Action Notification

Zimmer Biomet has recently identified a rare anomaly that can occur in the brain software application deployed on ROSA One 3.1 robots. Specifically, when a particular sequence workflow in the brain software application is utilized, an unplanned calibration of the mounted tool occurs that can result in inaccuracy of the tool trajectory. Since the installation of the impacted software beginning in December 2019, there have been three global complaints related to the software anomaly out of approximately 3,600 surgeries performed. No patient injuries were reported.

Importantly, the ROSA Spine, Total Knee, Partial Knee and Hip application systems are **not** affected by this software anomaly, as the software and surgical workflow included in this action are specific to the ROSA One 3.1 brain application system.

Zimmer Biomet has notified users of the ROSA One 3.1 brain application of a software upgrade to address the anomaly. Until the unit upgrade is completed, users have been provided instructions to follow in order to address the anomaly. Therefore, while the software upgrade is being implemented, Zimmer Biomet will work with surgeon users to ensure that there is no disruption to their ability to safely perform procedures on their patients. The Company has also self-reported the need for the software upgrade to the FDA. The letter provided to users, along with the additional instructions being applied to the units, are provided at the link below.

Zimmer Biomet is dedicated to patient safety, and quality excellence is an integral aspect of our commitment to the patients and surgeons who rely on our products every day. We stand behind our products and will deploy upgraded brain software for ROSA One 3.1 units that are on the market today in a comprehensive and timely manner to ensure quality, safety and efficacy.

View User Letter
View Unit Instructions

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