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Regulatory and Reimbursement Scenario of Robotic-Assisted Surgery

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Abstracts

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This strategic report provides a multidimensional view of the strategic evolution in the field of regulatory and reimbursement scenario of robot-assisted surgeries. The purpose of the study is to gain a holistic view of the strategic outline of regulatory and reimbursement scenario of robot-assisted surgeries in terms of various influencing factors, such as recent trends, technological advancements, reimbursement scenario, and national level initiatives across the globe. The scope of this report is centered upon conducting a detailed study of the region-specific market penetration strategies, potential impact of regulatory and reimbursement scenario, and understanding the focus of eminent stakeholders contributing in augmenting the growth of robot-assisted surgery devices and the market.

Robot-assisted surgery technologies are among the greatest technological innovations of the present century, with a potential to completely transform the way surgeries have always been performed. Since the inception of RAS, till 2018, more than 9.5 million procedures were performed using surgical robots, with 1.2 million procedures in 2018 alone. With a single company catering to the domain of RAS in 2000, the industry now functions with more than 55 companies with 25 robotic models in use, along with 25 additional robotic models in development. Also, as of 2018, more than 6,200 surgical robots have been installed across the globe.

In the recent past, there have been multiple instances of device recalls and adverse event reporting. For instance, in 2010, metal-on-metal hip-replacement procedure failed enormously, owing to the device wearing down. All of these adverse events led to the need for a standardized, legal check on product quality and their related safety

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concerns. Consequently, regulatory authorities are keeping a strict check on the quality of devices. Also, authorities ensure that regulatory guidelines are followed for those clinical procedures, which have been approved for reimbursement. Regulatory bodies across the globe generally have their own classification systems for medical devices based upon the risk they carry, and intended mode of usage, among others. Most countries have specific approval pathways based upon the classification of medical devices.

Robot-assisted surgery devices fall under class II devices under the FDA and class IIb devices under the EU guidelines. However, with the increasing advancements in robots leading to greater autonomy and higher degrees of freedom, it is highly probable that robots in the coming years will have limited surgeon control and maximum autonomy. This will lead these systems to fall under class III device category or under high-risk class of devices. The regulatory scenario has witnessed several phases of transition across the globe. For instance, Medical Device Regulation (MDR) and In-Vitro Diagnostic Regulation (IVDR) replaced the Medical Devices Directive in Europe. This led to multiple changes in the regulatory scenario of the European Union. In the U.S., there exists no standardized reimbursement pathway for robot-assisted surgery procedures. These procedures are considered for the approval of reimbursement based upon primary procedures such as laparoscopic surgeries. Current Procedural Terminology (CPT) codes were also expanded with an additional family of ICD-10-PCS codes to be used in conjunction with the primary surgeries. Furthermore, the Asia-Pacific market has witnessed certain tremendous developments, with Japan being the only country that has approved reimbursement for RAS devices for both benign as well as malignant form of tumors. In addition, China also witnessed major transitions in the CFDA regulations. Chinese regulatory authorities are ensuring stringent validations and adequate quality checks for imported products. The country follows separate bidding and procurement pathways at provincial level for imported products.

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