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BEST PRACTICES

AWARDS

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2020 BEST PRACTICES AWARD

KUKA

2020 GLOBAL
MEDICAL ROBOTICS
COMPANY OF THE YEAR AWARD

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Background and Company Performance

Industry Challenges

Current clinical guidelines recommend image-guided interventions for high-risk procedures such as arterial embolization, percutaneous tumor ablation, and high-intensity focused ultrasound. Image-guided surgery or surgical navigation, in particular, has emerged as one of the most transformative technologies of the last 20 years, decisively moving surgical interventions into safer, less invasive procedures. For example, interventional oncology continues to grow and evolve, combining image guidance with therapeutic modalities in real-time to provide a significant leap forward for medical treatment. Overall, converging developments in multi-modality integration and image fusion are playing an increasing role in spurring technical progress, simplifying complex procedures, and unlocking synergies for novel advanced non-invasive and minimally-invasive treatment options.

Underpinning image-guided interventions and other innovative modalities are the use of medical robotics. As capabilities become increasingly sophisticated, medical robotics can address multiple applications—i.e., biopsy procedures, rehabilitation, suturing, and surgery—requiring fine dissection and manipulation procedures. Robots excel in precise control of movement trajectory, depth, and speed as well as limiting force exertion. Unlike humans, robots can also engage in repetitive movements without fatigue, or remain stationary for long periods. As a result, robots can perform tasks that traditional surgical methodologies and tools cannot. Hence, medical robotics allows for next-generation surgery to help patients remain physically intact and functional by facilitating minimally-invasive and efficient therapies. For example, medical robotics can control and position ablation devices accurately, thereby minimizing damage to surrounding healthy tissues.

Furthermore, robotics can help alleviate the impact of the labor shortage in healthcare as physicians retire or leave the profession. Surgical robots enable less experienced surgeons to perform at higher levels, increasing throughput. Additionally, robots can help diminish the effects of hand tremors, thus constraining unintended or accidental movements. Futuristic applications include robots performing mundane secondary tasks such as suction, irrigation, and tissue retraction, typically done by an assisting surgeon resident and a second surgeon. Automation can further ease labor requirements while eliminating the underutilization of surgeons' expertise, thus increasing the potential number of patients treated.

Advancing established clinical guidelines and demonstrating clinical and operational benefits to new customers are key market challenges that medical robotics vendors must overcome. Cost is another primary consideration due to the significant capital investment medical robotics require. However, Frost & Sullivan notes the strategic procurement of medical robotics can generate a substantial return on investment (ROI) as procedure costs come down. Advanced medical robotics that demonstrates ROI and state-of-the-art capabilities will withstand the price pressure typical of the market. Furthermore, inflexible conventional robotics limits use cases and applications expansion. Vendors who can provide intuitive and versatile technologies that do not require time-consuming re-calibration will enjoy a competitive edge.

Visionary Innovation & Performance and Customer Impact of Kuka

Founded in 1898 and headquartered in Augsburg, Germany, KUKA is a leading supplier of intelligent automation solutions worldwide. It operates in over 40 countries worldwide, employs 14,000 employees globally, and has two decades of experience in medical applications with over 1,500 systems integrated.

With almost 50 years' experience in industrial robotics, the company leverages its proven expertise to address the complex field of medical robotics. Medical applications KUKA addresses include x-ray imagery, radiation therapy, patient positioning, laser cutting, hair transplants, and intraoperative radiation therapy as well as custom projects and development.

Frost & Sullivan research reveals that the company dedicates over fifty German engineers to the medical robotics side of the business. With continued engagement in robust research and development, the medical robotics team can meet the emerging requirements of the healthcare sector, allowing the robotic components to integrate with existing medical devices readily.

KUKA is a leader in human-robot collaboration (HRC) standards with an extensive knowledge base. Its experienced medical robotics team supports clients throughout the product's life cycle, including offering a robotics feasibility study, clinical tests, regulatory approval, and product launch. A dedicated team sets the product apart on the support and service side as well. KUKA partners with universities, technology providers, system integrators, research institutes, and end-users to develop innovative robotic solutions for various application domains. For example, the company is currently collaborating with a research team from the Universities of Leeds, Vanderbilt and Turin who develop a concept for robotic magnetic flexible endoscope for painless colorectal cancer screening, surveillance and intervention. This team won the KUKA Innovation Award 2019 . KUKA's close ties with academic and research institutions, as well as with technology and medical device providers, help the company keep a competitive edge and allows for future developments to the benefit of healthcare stakeholders.

KUKA addresses mid-size as well as large clients such as Siemens Healthineers and Accuray. Regional market focus includes Europe, the United States (US), China, and Japan. Frost & Sullivan notes that KUKA's sterling reputation in the industrial sector provides powerful brand equity for its medical robotics division. Customers take comfort in knowing the company's industrial robots and the robust underlying technology is proven in the field, with the ability to work 24/7 at maximum speed with a full payload.

KUKA's unique selling points are myriad:

- Firstly, it has gained a deep understanding of the medical robotics business by leveraging its prowess and proven expertise in the industrial sector. KUKA's partner network helps ensure its medical robotic components support cutting-edge innovations such as multi-directional imaging that does not require patient repositioning.
- Secondly, the company can develop, produce, deliver, and service complex certified components on a worldwide scale. KUKA's production line for the LBR Med is ISO 13485 certified, which is a medical device manufacturing standard; the company meets industrial standards as well.
- KUKA offers a certified off-the-shelf standardized medical robotic component: the LBR Med which is a key market differentiator. The company develops all robotics per relevant medical device standards, thus accelerating regulatory approval.
- KUKA Medical Robotics received the IERA Award in 2018 for the LBR Med. The IERA Award is considered one of the most important international awards in robotics and is presented by the International Federation of Robotics (IFR) and the Robotics and Automation Society of the international engineering association IEEE. In the field of robotics and automation, the IERA Award stands for the outstanding performance of companies and inventors who turn their ideas into world-class products.
- Unlike other collaborative robot manufacturers, KUKA offers a full line of industrial robots with payloads from 3 kilograms (kg) to over 1,000 kg. Many industrial robots can be adapted for HRC and are thus used in medical devices which require simpler levels of HRC, but payloads higher than 14 kg. This allows KUKA to address the full range of medical applications including patient positioning (Mevion, Optivus, Accuray), imaging (Siemens), and cancer treatment (Accuray).

The company offers exceptional client support via a 24-hour, year-round hotline that provides access to specialized medical robotics expertise. Overall, as a proven, reliable offering that can adapt to the medical environment, KUKA delivers a compelling value proposition.

Revolutionizing Healthcare through Innovation: Introducing the LBR Med Robot

In 2017, KUKA launched the LBR Med—a state-of-the-art robotic innovation for the medical sector. It leverages its leading industrial LBR iiwa technology, which has proven itself in Industry 4.0 environments and serves as the company’s foray into workplace HRC.

KUKA’s LBR Med



LBR Med Demonstration



Source: KUKA

Unlike the industrial version, the LBR Med is certified to meet robust medical device standards, e.g., mounting areas are not exposed to prevent fluid, and bacteria, accumulation; sealed electrical connections, and overload testing requirements. LBR Med also includes strong haptic capabilities, collision prevention, and the ability to perceive external inputs.

LBR Med is a lightweight robot available in two variants—the LBR Med 7 R800 with a 7 kilogram (kg) payload and the LBR Med 14 R820 with a 14 kg payload and extended reach—that can readily adapt as a component of an innovative medical solution due to industry-leading sensor, control, and safety systems. The LBR Med provides precise positioning as well as exceptional sensitivity, responsiveness, and safety from diagnostics to treatment and surgical interventions. A special surface coating suits the LBR Med to the hygiene requirements in hospitals. The LBR Med also facilitates the development and incorporation of robotic products by medical device manufacturers. Certification per the internationally-recognized Certified Body Scheme simplifies the approval of the final medical product with the integrated LBR Med component.

Frost & Sullivan notes that while there are many simple collaborative robots in the market, they typically do not offer flexibility—grossly limiting medical applications. LBR Med, on the other hand, is uniquely configurable and versatile. For example, the robot can facilitate intraoperative radiation therapy in a given use case and operate as a rehabilitation application for another. With a variety of preconfigured interfaces, LBR Med is a versatile robot system for various applications in medical technology.

The LBR Med is the first robotic component specially designed for integration into a medical device and complies with medical device standards. LBR Med complies with IEC 60601 and 62304, which makes it the first robot worldwide certified for integration into a medical product. This certification significantly reduces the global approval process complexity for manufacturers of medical products that incorporate the LBR Med. Capable of superior HRC, the robot technology tailors to the specific requirements of the healthcare sector, e.g., tasks in therapeutic and clinical operating room applications and can support a high payload capacity and precision requirements.

Other key features include:

- On account of its flexible media flange, the LBR Med can readily integrate into various medical products. For customized medical instruments, a range of connections is available, e.g., for EtherNet or the power supply. It is a seven-axis robot with integrated torque sensors in each joint to provide enhanced sensitivity and collision avoidance.
- The LBR Med requires no additional devices for calibration or high-precision work. Integrated mastering sensors allow completely autonomous calibration and outstanding repeatability.
- The LBR Med has an extensive and redundant safety structure and alerting system with relevant signals monitored by both hardware and software. Safety equipment includes force/torque sensor systems, configurable safety events, and single fault safety—thereby meeting the Robotics Industries Association safety standards for HRC systems.
- Frost & Sullivan notes that a significant development area for KUKA’s medical robotics team is trocar kinematics, which allows for a port to operate as the pivot point (necessary for minimally-invasive procedures). The company, recognizing the need to maneuver all the surgical instruments around this pivot point, is developing software to offer automated robot motion that enables users to set a trocar pivot point. Currently, the LBR Med provides hand-guided trocar kinematics itself - an industry-leading functionality.

Frost & Sullivan notes that automation and assisted robotics can improve the procedure throughput, consistency, and speed while enabling complex therapies impossible without robotic assistance. Hence, LBR Med makes it easier for surgeons to perform their job successfully, as well as implement new procedures. KUKA has successfully incorporated its exceptional medical robotics technology in complex applications. Select case studies include:

Accuray’s CyberKnife leverages the larger KUKA Quantec robot to offer precise, non-surgical treatment for tumors and lesions anywhere in the body as well as automatic, real-time tumor tracking and motion management. As the patient lies on the operating table, KUKA’s high-payload Quantec robot guides a high-energy X-ray beam around him so that the radiology concentrates the dose precisely in the tumor. The CyberKnife system

provides high-precision tumor treatment at leading radiation therapy centers globally, offering an alternative to patients diagnosed with previously inoperable tumors.

Accuray's Robocouch. The RoboCouch patient positioning system uses KUKA's technology to allow greater precision during robotic radiosurgery by positioning the patient to the planned treatment position. The RoboCouch integrates with Accuray's CyberKnife radiosurgery system to enable specialized robotic kinematics.

The **ARTAS® iX hair restoration system**, developed by Restoration Robotics, uses a KUKA LBR Med robot to not only harvest hair follicles from the back of a patient's head but to implant newly harvested follicular units into targeted areas of the scalp. Integrated force-sensing ensures the robot maintains desired force when making contact with the patient during harvesting and implantation. Restoration Robotics was acquired by Venus Concept end of 2019.

The CARLO® system, developed for craniomaxillofacial surgery by AOT AG, uses an LBR Med-guided laser bone-cutting device to precise ablation locations. The CARLO® system can cut the jaw bone in a three-dimensional, interlocking pattern—thus allowing clinicians to hold the jaw in place with minimal hardware.

The Sculptura™ system, developed by Sensus Healthcare, uses the LBR Med for intraoperative radiotherapy during surgical removal of cancerous tumors. KUKA's technology ensures a high radiation dose delivered precisely to the targeted area with minimal exposure to surrounding healthy tissues.

Siemens ARTIS pheno. The ARTIS pheno employs KUKA's Quantec robot technology for operating rooms globally for patient imaging, interventional radiology (thus reducing the risk of human exposure to radiation, both for patients and healthcare professionals), and cardiology as it enables quick and precise X-ray investigations of blood vessels. The system can image a particular body region from all directions without patient relocation. If an examination is interrupted, a memory function within the system allows recreating the position precisely at a later point. Consequently, it allows checking results even during an ongoing intervention.

Conclusion

As healthcare continues shifting towards minimally-invasive, image-guided procedures that can enhance treatment success, technological innovation is necessary. KUKA leverages its leadership in the field of industrial robotics to inform its best-in-class LBR Med medical robot—thus lowering procedure-related morbidity, improving patient outcomes, and decreasing treatment costs. With a uniquely configurable programming platform and robust - certifications, the LBR Med is one of the most advanced off-the-shelf robots in the market. As the first robotic component certified for medical product integration worldwide, the LBR Med strategically positions KUKA to resolve the industry's most difficult modern medical challenges. For its unparalleled expertise, thought leadership, and commitment to quality, service, and value, KUKA earns Frost & Sullivan's 2020 Global Company of the Year Award in the medical robotics market.

Significance of Company of the Year

To receive the Company of the Year Award (i.e., to be recognized as a leader not only in your industry, but among your non-industry peers as well) requires a company to demonstrate excellence in growth, innovation, and leadership. This kind of excellence typically translates into superior performance in three key areas: demand generation, brand development, and competitive positioning. These areas serve as the foundation of a company's future success and prepare it to deliver on the two criteria that define the Company of the Year Award (Visionary Innovation & Performance and Customer Impact).



Understanding Company of the Year

As discussed above, driving demand, brand strength, and competitive differentiation all play a critical role in delivering unique value to customers. This three-fold focus, however, must ideally be complemented by an equally rigorous focus on Visionary Innovation & Performance to enhance Customer Impact.

Key Benchmarking Criteria

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated two key factors—Visionary Innovation & Performance and Customer Impact—according to the criteria identified below.

Visionary Innovation & Performance

- Criterion 1: Addressing Unmet Needs
- Criterion 2: Visionary Scenarios through Mega Trends
- Criterion 3: Implementation Best Practices
- Criterion 4: Blue Ocean Strategy
- Criterion 5: Financial Performance

Customer Impact

- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity

Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

| STEP | OBJECTIVE | KEY ACTIVITIES | OUTPUT |
|---|--|---|---|
| 1 Monitor, target, and screen | Identify Award recipient candidates from around the globe | <ul style="list-style-type: none"> • Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies | Pipeline of candidates who potentially meet all best-practice criteria |
| 2 Perform 360-degree research | Perform comprehensive, 360-degree research on all candidates in the pipeline | <ul style="list-style-type: none"> • Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice criteria • Rank all candidates | Matrix positioning of all candidates' performance relative to one another |
| 3 Invite thought leadership in best practices | Perform in-depth examination of all candidates | <ul style="list-style-type: none"> • Confirm best-practice criteria • Examine eligibility of all candidates • Identify any information gaps | Detailed profiles of all ranked candidates |

| STEP | OBJECTIVE | KEY ACTIVITIES | OUTPUT |
|--|--|--|--|
| 4 Initiate research director review | Conduct an unbiased evaluation of all candidate profiles | <ul style="list-style-type: none"> Brainstorm ranking options Invite multiple perspectives on candidates' performance Update candidate profiles | Final prioritization of all eligible candidates and companion best-practice positioning paper |
| 5 Assemble panel of industry experts | Present findings to an expert panel of industry thought leaders | <ul style="list-style-type: none"> Share findings Strengthen cases for candidate eligibility Prioritize candidates | Refined list of prioritized Award candidates |
| 6 Conduct global industry review | Build consensus on Award candidates' eligibility | <ul style="list-style-type: none"> Hold global team meeting to review all candidates Pressure-test fit with criteria Confirm inclusion of all eligible candidates | Final list of eligible Award candidates, representing success stories worldwide |
| 7 Perform quality check | Develop official Award consideration materials | <ul style="list-style-type: none"> Perform final performance benchmarking activities Write nominations Perform quality review | High-quality, accurate, and creative presentation of nominees' successes |
| 8 Reconnect with panel of industry experts | Finalize the selection of the best-practice Award recipient | <ul style="list-style-type: none"> Review analysis with panel Build consensus Select winner | Decision on which company performs best against all best-practice criteria |
| 9 Communicate recognition | Inform Award recipient of Award recognition | <ul style="list-style-type: none"> Inspire the organization for continued success Celebrate the recipient's performance | Announcement of Award and plan for how recipient can use the Award to enhance the brand |
| 10 Take strategic action | Upon licensing, company able to share Award news with stakeholders and customers | <ul style="list-style-type: none"> Coordinate media outreach Design a marketing plan Assess Award's role in future strategic planning | Widespread awareness of recipient's Award status among investors, media personnel, and employees |

The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS



About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best-in-class positions in growth, innovation, and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation, and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.