

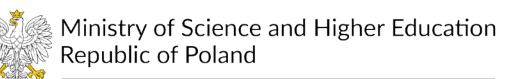
### Poland in SiliconValley Center

for Science, Innovation, and Entrepreneurship

## DEVICE FOR MEASURING FEMUR DISPLACEMENT AND METHOD OF MAKING ORTHOPEDIC MEASUREMENTS DURING A SURGICAL PROCEDURE TO CORRECT A DAMAGED HIP









#### Introduction

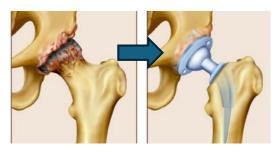
- Over 2.5 million total hip arthroplasties (THAs) are performed annually, which about 10% resulting in leg length discrepancy (LLD) greater than 10 mm. [1]
- This causes clinical complications and legal claims.[2]
- Surgeons need a precise and easy-to-use intraoperative tool to minimize clinical assessment errors and prevent postoperative LLD. [3, 4, 5]

[1] Leg Length Discrepancy After Total Hip Arthroplasty: A Review of Clinical Assessments, Imaging Diagnostics, and Medico-Legal Implications – MDPI

- [2] Total Hip Arthroplasties: A Malpractice Claims Analysis
- [3] Hip Replacement Market Size to Hit USD 11.23 Billion by 2034 Precedence Research
- [4] The United States Disposable Surgical Devices Market Size & Outlook, 2030 Grand View Research
- [5] Hip replacement Market 2025 2034

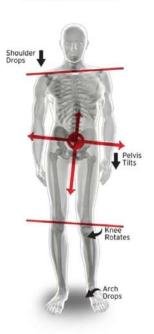


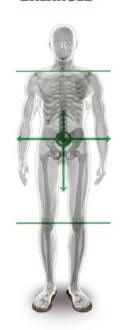






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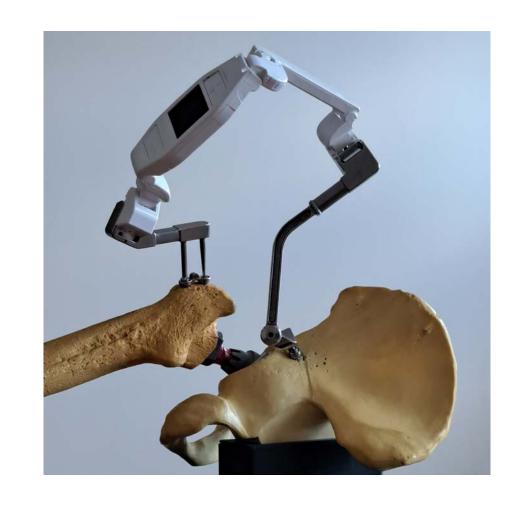




#### **Solution - NaviFast 6D**

**NaviFast 6D** is a single-use measurement arm invented by LUT and Robotic Medical Solutions Ltd. consortium. Fully validated, patent-protected, high-precision solution to one of orthopedic surgery's most persistent challenges.

This surgeon-friendly system was designed to replace classical navigation and significantly reduce LLD during hip replacement surgeries.





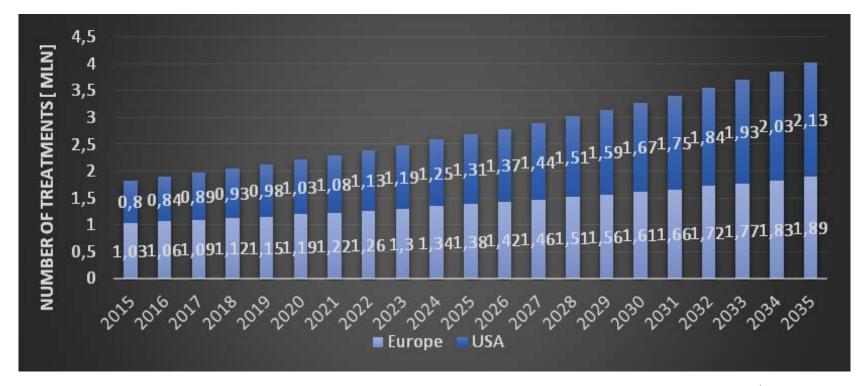






#### Goals

The project aims to commercialize the NaviFast6D device - a high-precision, surgeon-friendly system designed to replace classical navigation and significantly reduce LLD during hip replacement surgeries.











# Approach

NaviFast6D is fully developed and validated.











# Approach

- Serial production technology testing at Robotic Medical Solutions Ltd. is completed,
- Clinical trials confirmed 1.4 mm
  measurement accuracy and <6 mm
  postoperative LLD in all patients,</li>



- The measurement arm is patented in the EU, USA, and Japan,
- Remaining CE-marking certification steps are in progress,
- Training and presentation programs for surgeons and distributors will be conducted before EU launch.



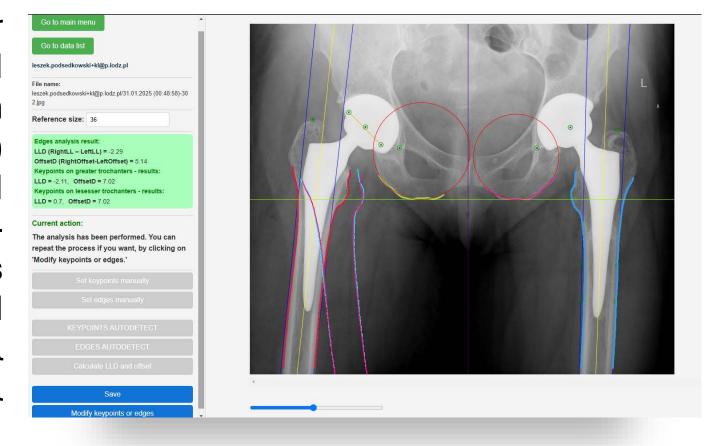






# Leg Length Discrepancy Calculator

The software used for preoperative planning and assessment of leg length discrepancy (LLD CALC) has been designed and implemented to process Xray images from various sources in a standardized manner, utilizing artificial intelligence and neural networks.











### Competitive edge

- The disposable device also provides higher confidence in sterility and user comfort. In the event of damage, the financial loss is not significant. Another advantage of a low-cost disposable device is the easier market entry.
- **Ease of Use**: Only two buttons on the device are needed to complete the full measurement cycle.
- **High Accuracy**: The accuracy of differential measurement using the measuring arm is 1.4 mm, confirmed by clinical tests.
- Short Measurement Cycle Time: The complete measurement process takes up to 6 minutes. Including the assembly of the instrumentation securing the arm to the patient's bone, the use of the device does not extend the operation by more than 15 minutes.









### Competitive edge

- Moderate Unit Price: Significantly lower than competing solutions while maintaining healthy profit margins, making it feasible for distribution in smaller hospital units with limited budgets.
- The miniature (under 30 cm) and accurate orthopedic measuring arm for intraoperative measurements is a groundbreaking system that supports orthopedic surgeons, fundamentally different from currently available solutions worldwide. Its compact size does not occupy space in the operating room, significantly facilitating the surgeons' work.





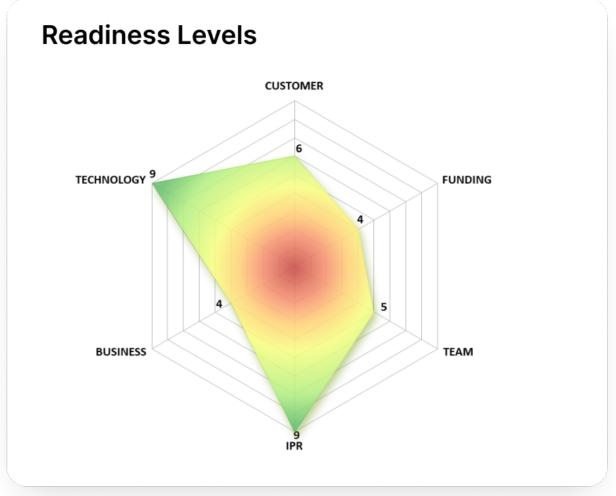






#### Readiness Levels

- CRL=6 Benefits confirmed by first customer testing.
- TRL=9 Technology complete and proven in actual operations over time.
- **BRL=4** First calculations indicate economically viable business model. First sustainability assessment of proposed business model.





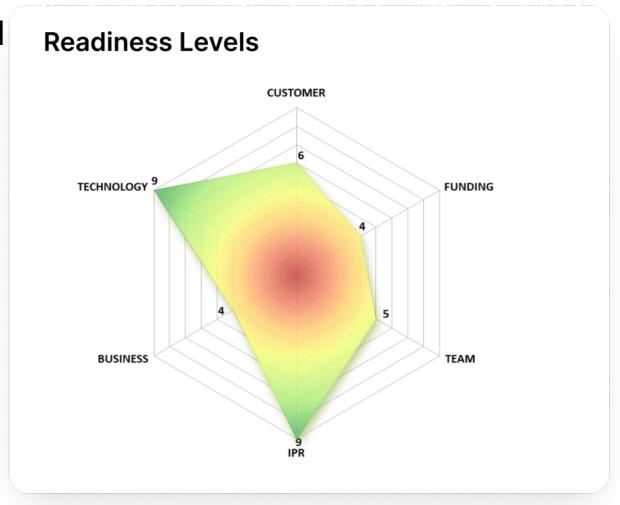






#### Readiness Levels

- IPR=9 Strong IPR support and protection for business. IPR protection granted and maintained in relevant countries.
- TMRL=5 Initial founding team with main needed competencies and capacity. Team agrees on ownership, roles, goals, and visions.
- FRL=4 Pitch/presentation in place for next-stage funding. Secured funding to initiate development.











### Expectations towards partnership terms

We are open to collaborating with business partners to achieve the following outcomes:

- Establishing partnerships with at least three U.S. medicalinnovation entities,
- Preparing marketing materials and commercialization strategies for the U.S. market,
- Securing approximately \$400,000 in funding to achieve CE certification,
- Preparing a scalable product for EU, U.S., and global deployment.









### **Impact**

- Assuming adoption in only 1% of THA procedures, NaviFast6D's projected annual market value is approximately **\$12 million**.
- We offer minority shares in Robotic Medical Solutions Ltd. to business partners who provide the expected technical and financial support. For partners who demonstrate greater commitment and offer exceptional support in the company's development, as well as a larger financial contribution, we are willing to grant a proportionately larger share package in Robotic Medical Solutions Ltd.











#### Conclusion

- NaviFast6D offers a fully validated, patent-protected (EU, USA, Japan), high-precision solution to one of orthopedic surgery's most persistent challenges.
- With development and clinical trials completed, a clear certification pathway, and strong commercial potential, the project is well-positioned to deliver significant value to surgeons, patients, and investors.
- With the LLDcalc.com software integration, the system represents a major breakthrough in orthopedic surgery - providing an accurate, affordable, and highly effective toolset for intraoperative navigation and LLD minimization.









# Risk Management

- Certification delays Most documentation is ready, prepared according to MDR, and experts confirm the project is on track.
- Perception in the medical community Many believe hip replacement is already "good enough", since 90–95% of patients are satisfied. Initially, NaviFast6D will focus on training young surgeons and delivering high-quality patient care.
- Slightly longer surgery time (about 15 minutes) Instrumentation improvements are already prepared to reduce this by 5–7 minutes; further enhancements will be implemented after obtaining CE certification.
- Additionally, operational risk is mitigated through a fully scalable production model that effectively leverages a network of subcontractors and manufacturing partners, ensuring supply stability and the ability to rapidly increase production volume.





