Lazarus 3D Pre-Sure

September 2024

Device Overview

The Lazarus 3D Pre-Sure (PRE-operative SUrgical REhearsal) software system is designed to help physicians utilize patient imaging for surgical planning and to create physical models. These 3D soft synthetic polymer models can serve as supplementary tools alongside other diagnostic resources, enabling physicians to rehearse surgical techniques. According to Lazarus 3D, these physical models can be used to practice the surgical procedure specific to the patient anatomy. [1] The process includes a patient computed tomography (CT) and magnetic resonance imaging (MRI) scan uploaded via a secure server that is used to print a 3D model within 24-48 hours. [1] Additionally, teaching models are available to support medical education and skills training for lumpectomies, robotics, urology, gynecology, and a variety of gastrointestinal (GI) procedures. [1]

Actions for Consideration

PARTNER

ENGAGE SUBJECT MATTER EXPERTS
Discuss capabilities of system with interested physicians to understand potential benefit and impact on surgical and patient outcomes.

CONSIDER GUIDELINES FOR USE
Develop specific guidelines to manage and plan for utilization and teaching opportunities.

SUPPLIER ENGAGEMENT
Partner with supplier to validate security related to patient privacy concerns.

CONNECT

TEACHING POTENTIAL
Review medical education model portfolio to assess need.

FINANCIAL IMPACT
Work to determine cost impact for adoption of technology and assess utilization for pre-surgical and teaching opportunities. Understand its impact on workflow.

DETERMINE POPULATION
Work with key stakeholders to identify patient populations, procedures, and specialties that may benefit from this type of planning and rehearsal prior to surgery.

COMMUNICATE

EDUCATE AND TRAIN
Partner with supplier to determine roles and responsibilities related to education and training. Communicate education & training and encourage hands on practice.

PLAN AHEAD
Create and share plan to continue ongoing education about product, use, & outcomes.

FOLLOW-UP FOR FEEDBACK
Create on-going feedback loop for challenges, ideas, recognition of wins, & further opportunities for success

Clinical Evidence

The evidence in this category does not pertain exclusively to this specific product. Rather, the review is focused on the general use of 3D printed models for training and surgery planning. A selection of the relevant evidence is presented.

A 2022 cross-sectional multispecialty review by Meyer-Szary et al. examined the use of 3D models/replicas from their beginning through their use in the current medical landscape and across multiple specialties. The review examines the use of 3D models in procedure planning and simulation of complex surgeries, in addition to medical education and training. The authors state that 3D modeling allows for "gaining better insight into patient-specific anatomy, better pre-operative planning, mock simulated surgeries, simulation-based training and education, development of surgical guides and other tools, patient-specific implants, bioprinted organs or structures, and counseling of patients." [2] The authors feel that 3D printing of models adds another teaching tool that would be applicable to the medical community. However, they do note that multicenter randomized controlled trials (RCTs), would be beneficial to validate the use of this technology.[2]

A 2023 study by Hermans et al. evaluated the use of 3D printed model of a renal tumor to train in robot-assisted partial nephrectomy. Thirty-six participants were divided into 3 groups based on surgical experience. Surgical experience robot-assisted techniques for partial nephrectomy (RAPN) varied between participants from >20 partial nephrectomies, 1–20 partial nephrectomies, and no experience at all. "The operative performance was significantly better in the expert group as compared to the beginner group." [3] Performance was assessed through a combination of factors, including surgical margins, excision time, total preserved parenchyma, tumor injury, and the Global Evaluative Assessment of Robotic Skills score (evaluated by two blinded experts) to ensure construct validity. Participants reported that the 3D models were realistic and beneficial for training and for evaluation. However, further research is recommended to validate overall benefits.[3]

A 2024 systematic review by Catasta et al. reviewed the use of 3D printed models for education and training in vascular surgery in 22 studies. The review showed that adding training on 3D models provides advantages over current practices of cadaveric dissection or simulators due to anatomical variability and limited availability. The studies showed this type of education and training has potential, allowing surgeons the ability to replicate real anatomical procedural challenges. The authors conclude "establishing standardized methodologies for generating and validating 3D-printed models in terms of the accuracy and effectiveness is necessary for their integration as a clinical standard."[4]

See Reference section for complete listing of research sources.

Member Insights: HealthTrust Member Network

Members of the HealthTrust member network provided insights and feedback on the use of this product. [5]

Member Insight

Advantages:

- Allows surgical teams to plan and rehearse complex procedures, leading to more precise and successful surgeries.
- Creates opportunities for residents and medical students to practice on realistic, patient-specific models, improving skills and confidence before performing actual surgeries.
- Offers tailored surgical planning by simulating patient-specific anatomy, which is particularly beneficial for teaching hospitals where diverse cases are common.
- Provides potential for reduced procedure times, potential reduced risk of complications, and better outcomes.

Disadvantages:

- Creates cost concerns, as the technology and models can be expensive.
- Introduces questions as to the ability to duplicate all potential variables that occur during surgery.
- Adds additional and potentially disruptive step, as patient-specific models takes time, which could delay surgeries in fast-paced environments.
- Requires specialized equipment and training for staff, which could be challenging to implement on a large scale.
- Places potential risk for over-reliance on model replicas, leaving a surgeon unprepared or less experienced in adapting to additional variables.

FDA Approval

The Lazarus 3D Pre-Sure Software System is intended for use as a software interface and image segmentation system for the transfer of Digital Imaging and Communications in Medicine (DICOM) imaging information from a medical scanner to an output file. It is also intended as pre-operative software for surgical planning. For this purpose, the output file may be used to produce a physical replica. The physical replica is intended for adjunctive use along with other diagnostic tools and expert clinical judgment for diagnosis, patient management, and/or treatment selection of genitourinary, cardiovascular, neurological, respiratory, musculoskeletal, gastrointestinal, craniofacial, and pediatric applications. (FDA Database Listing; FDA 510(k) No. K230044).[6]

Summary

1. 3D printed replicas allow for education and training, along with planning and rehearsal of complex procedures.
2. Most commonly identified disadvantages for this type of technology are cost, time and specialized resources and training.
3. Additional reviews including RCTs would be beneficial for validation and adoption of this technology.

HealthTrust Clinical Resources

Allow us to connect you with the resources you need. Examples for this category include resources on value analysis and product trials.

ASK A QUESTION | PROVIDE YOUR FEEDBACK | SHARE YOUR VOICE | NETWORK WITH PEERS

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www.hpginsights.com

PEER NETWORKING

www.huddle.healthtrustpg.com
App store: "HealthTrust Huddle"

References

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3. Hermans T, Snoeks JM, Vom Dorp F, Wiesner C, Steiner T, von Rundstedt FC. Validation of a 3D-printed robot-assisted partial nephrectomy training model. *BJUI Compass*. 2023;5(1):90-100. doi: 10.1002/bco2.269.
4. Catasta A, Martini C, Mersanne A, Foresti R, Bianchini Massoni C, Freyrie A, Perini P. Systematic Review on the Use of 3D-Printed Models for Planning, Training and Simulation in Vascular Surgery. *Diagnostics*. 2024; 14(15):1658. https://doi.org/10.3390/diagnostics14151658
5. 2024 Huddle Network Innovation Survey. Lazarus 3D Pre-Sure. Collected July 2024.
6. U.S. Food and Drug Administration. 510k Premarket Notification. https://www.accessdata.fda.gov/cdrh_docs/pdf23/K230044.pdf. Accessed June, 18, 2024.