

VUZE Medical to Showcase Next Generation Software-based Guidance System for Spine Surgery at NASS 2023 Following FDA Filing

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VUZE 2.0 designed to provide extended functionality, broader inter-operability while still requiring no tool modifications, cameras, markers or references

RA'ANANA, Israel--(BUSINESS WIRE)-- **VUZE Medical**, a privately-held company aiming to transform intra-operative guidance in minimally invasive spinal interventions, has submitted a 510(k) filing with the U.S. Food and Drug Administration (FDA) for VUZE 2.0, its second generation **VUZE System**. The new, investigational version of the VUZE System will be featured prominently at **NASS 2023**, the 38th annual meeting of the North American Spinal Society, which will be held October 18-21 in Los Angeles.

The VUZE System is a software solution installed on an off-the-shelf PC. It operates with unmodified surgical tools, requires no markers, references or cameras, and with no need for 3D imaging within the operating room (OR). Using proprietary image processing, it overlays in real time graphical representations of standard surgical tools seen in intra-operative 2D X-ray images onto axial and sagittal cross-sections that it generates from the patient's standard pre-operative 3D scan. The VUZE System previously received **U.S. FDA 510(k) clearance** in 2022 and completed a successful first-in-human **clinical trial** in early 2023. VUZE Medical has received eight related patents to date in the U.S., Europe and Asia.

Attendees of **NASS 2023** will have the opportunity to observe the investigational VUZE 2.0 in cadaveric surgery in a Surgical Stadium session titled "Navigated MISS with No Tool Modifications, References, Markers or Cameras" on October 19 from 11 a.m. to 12 p.m. PT. Hands-on experimentation will be available at a cadaveric workshop on October 19 from 1 to 4 p.m. PT. Further information will be provided at the **VUZE Medical booth #1051**. Clinical

experience will be reviewed in a Red Theater Presentation, "A New Approach to Guidance and Verification in MISS: Results of First-in-Human Trial with the VUZE System," on October 20 from 1 to 1:20 p.m. PT.

The second generation VUZE System is designed to support a broader range of surgical C-arms from multiple vendors and accommodate more sources of 3D image data, including both pre-operative CT and in-OR 3D scans. It also aims to provide expanded functionality, including the ability to perform surgical planning on a standalone laptop in addition to on the VUZE System.

"Our second generation aims to extend the operability of the VUZE System across a much larger percentage of operating rooms," said David Tolkowsky, founder and CEO of VUZE Medical. "The new features and functionality could, once cleared by FDA, make VUZE more accessible and provide surgeons with more effective guidance in situations where they previously did not have many attractive options."

Over three million surgeries for correcting spinal instability and/or deformation, collectively known as spinal stabilizations, are performed annually worldwide, with a third of those in the U.S.¹ These procedures include vertebral fixation with pedicle screws, vertebral fixation coupled with fusion, and vertebral augmentation with synthetic or biological cement. Approximately 80 percent of stabilizations treat short spinal segments ¹. Short-segment surgeries are most often performed manually and are typically assisted only by standard 2D X-ray.

About VUZE Medical

VUZE Medical is a privately-held medical technology company that aims to provide highly accurate and cost-effective surgical guidance for common spinal interventions currently aided only by standard 2D X-Ray. The company's VUZE System is a unique software-based solution that instantly merges intra-operative X-ray with pre-operative CT, providing surgeons with the cross-sectional images they need most during surgery and currently lack. The system is targeted primarily at outpatient and ambulatory settings. For more information, visit www.vuzemedical.com.

1. Orthopedic Network News: 2020 Spinal Surgery Update

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