Minimally invasive radiology procedures require precise control and angulation to reach targets efficiently. This device ensures optimal needle alignment, adjustable support, and intuitive control, while integrating seamlessly into clinical workflows. Existing devices for image-guided interventions, such as the Patented Needle Holder for Image-Guided Intervention, offer precise angle control but lack versatility, as they are designed for specific needle gauges and insertion techniques. The Ultra-Pro II™ In-Plane Ultrasound Needle Guide is easy to use and cost-efficient, but limited to ultrasound applications and incompatible with fluoroscopy. Robotic systems like the 7-axis platform and Zerobot® enhance precision, but cost between $50,000 and $100,000 and are less accessible for many clinics. These existing solutions have limitations in terms of adaptability, cost, and compatibility across different imaging techniques, hindering their widespread use in diverse clinical settings.

The global interventional radiology market is valued at approximately $12.3 billion in 2022 and is expected to grow at a compound annual growth rate of 7.3% from 2023 to 2030 (Grand View Research, 2023). This growth is driven by the increasing demand to treat radiculopathy with minimally invasive procedures. Cervical radiculopathy affects 85 individuals per 100,000 people each year, most commonly between the ages of 50 and 54 (Cohen et al., 2016). Given a global population of about 8 billion, this translates to around 6.8 million cases each year. Currently, data suggest that over 10 million epidural steroid injections are administered annually in the US, highlighting their common use in pain management (Hopkins Medicine, 2021). The global market for minimally invasive spine surgery is expected to reach $20 billion by 2025, growing at a CAGR of 6.5% (Market Data Forecast, 2023).

The Needle Navigator is designed to improve needle stability, control, and accuracy in image-guided spine injection procedures. By integrating ergonomic design, it minimizes needle bending, enhances angulation control, and optimizes procedural efficiency for radiologists. Compatible with 22- and 25-gauge spinal needles, it is a single-use, disposable device that is compact and lightweight to minimize hand fatigue. Novel features of the device include a spring mechanism to keep the device naturally in compression and a malleable interface with the needle to reduce torque during use. Its production cost is currently under two dollars per device. The Needle Navigator offers a flexible, cost-effective, and ergonomic solution, supporting a broader range of needle gauges and imaging techniques, enhancing clinician comfort and procedural accuracy.

Ergonomic validation of the Needle Navigator will be done by conducting surveys of radiologists to assess comfort and ergonomic usability compared to a standard needle holder. An electromyography can also be used to measure muscle strain in the hand and wrist while using the device. Operational performance can be measured using a time-to-target study and calculating needle deviation with metrics of tip deviation (mm), angular deviation (°), and needle deflection (mm) under high-resolution imaging. Because of the product's increased safety risk to the patient and radiologist, a risk assessment matrix should be created to identify and quantify hazards and detail mitigation.

Upon successful completion of testing, the Needle Navigator team can advance toward commercialization. The first priority will be securing patent protection for its novel features. Subsequent steps include conducting further validation studies with radiologists to refine usability and accuracy, followed by pursuing FDA 510(k) clearance for medical device classification. Additionally, the team will explore large-scale production methods to optimize cost efficiency while maintaining quality and seek partnerships with healthcare institutions and device manufacturers for pilot implementations.