Product Design Specifications

Project Title: Needle Navigator: support and control device for image-guided minimally invasive procedures

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Function

The device is designed to enhance the stability and precision of the needle during minimally invasive radiology procedures. These procedures require precise control and optimal angulation to reach the target without unnecessary movements. In constrained or awkward positions, maintaining control becomes challenging, increasing the risk of procedural errors. The device aims to provide adjustable support, reduce needle bending, and facilitate smooth angulation adjustments, improving both accuracy and usability. Intended for radiologists and healthcare professionals, it integrates seamlessly into workflows, offering ergonomic and practical benefits in clinical settings.

Client requirements

Purpose & Functionality

- Designed to replace the current clamp used in minimally invasive radiology procedures, such as image-guided needle insertions.
- Improves ergonomics for easier handling compared to the existing technique.
- Functions as an assistive tool, providing stability and control without directly aiming the needle.

Key Features

- Incorporates a sliding mechanism that enables the users to slide and adjust the needle with one hand for improved maneuverability.
- Enables precise angulation for enhanced procedural accuracy.
- Designed to accommodate 22-gauge and 25-gauge needles.
- A lightweight, comfortable, and intuitive-to-use design to minimize hand fatigue and integrate seamlessly into procedures.
- Disposable and sterile to ensure patient safety.

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements**

Following client requirements, the device must securely support, stabilize, and precisely manipulate needles in the range of 2 to 6 inches in length while focusing on improving control for cervical spine injections specifically. It should facilitate single-handed operation, and allow for precise control over the needle's position while allowing for fine adjustments to its angle in real time. Needle trajectory alignment must be rapid and precise but not allow for movement or bending. The device should be compatible with needles of multiple sizes, ranging from 22 gauge to 25 gauge, and efficiently work with X-ray and fluoroscopic imaging.

b. Safety

The device must be designed to reduce medical complications related to cervical spine injections where the abundance of blood vessels near the brain increases the risk of a stroke if one of them is punctured [1]. After alignment is completed, the device must have a locking mechanism to prevent any unintended shifts. The support structure should enable the operator to anchor their hand to the procedure table to allow for more stability and precision. Additionally, the device should be made of medical grade, non-toxic, and disposable material that complies with the regulatory standards of sterile surgical tools {see section j: Materials}. It should be rigid enough to avoid needle bending but flexible enough to perform controlled and precise adjustments during the procedure. The needle should be firmly held without crushing or limiting movement.

c. Accuracy and Reliability

The device must prevent unintended needle deviations that may lead to inaccurate procedures by ensuring that, once aligned, the needle stays on its intended path without requiring any external manual corrections. In addition, it should maintain a stable hold while allowing for fine angle adjustment to fit various anatomical structures. It should work under fluoroscopic imaging and, therefore, keep the needle positioning clear and without any view blockages. It should provide a smooth and predictable sliding mechanism, and motion should be quick but controlled when and where it is required. Also, it should withstand the forces exerted by the operator's hand without loss of precision or significant deformation.

d. Life in Service

This is a disposable medical device that is expected to be limited to a single procedure, which usually ranges from 15 to 45 minutes [2]. Since the device will be used in minimally invasive radiology procedures that require precise needle control, it should be designed for reliable operation over the course of one procedure and discarded according to OSHA's initial measures for discarding regulated medical-waste items [3]. Maintaining safety and effectiveness is critical to equipment use and structure integrity, and sterility should be maintained for the duration of use.

e. Shelf Life

The needle navigator system must remain sterile and effective upon storage under proper conditions. As stated by manufacturers of similar disposable medical devices such as Teqler's Mayo-Hegar, these medical devices typically have a shelf life of 3 years [4]. Our client has requested that the device be made of plastic and due to availability and fabrication constraints, polycarbonate would be the only feasible option for this project. The shelf life of polycarbonate ranges from 10 to 20 years if stored properly in a cool, dry place [5]. In order to determine the exact shelf life of this particular device, a further analysis of the material stability retention, degradation, and packaging integrity must be performed.

f. Operating Environment

The device will be used in clinical and hospital settings, specifically in radiology and interventional procedure rooms. The temperature range for operation is expected to be 15°C to 30°C, with the ability to withstand short-term storage at temperatures between 0°C and 50°C in accordance with ISO 11608-1:2022 [6, p. 1]. Additionally, the device must function in 40% to 70% relative humidity without experiencing material degradation or performance issues. As it will be used in controlled hospital environments, the material must withstand normal atmospheric pressure.

The device must be pre-sterilized and packaged for single use, preventing cross-contamination. Materials must be resistant to disinfectants, bodily fluids, and saline solutions to avoid degradation and maintain durability throughout their intended use. The device must also be mechanically resilient, and capable of withstanding minor handling impacts, such as drops from a standard table height (~1.14m) and vibrations during transport [7]. Additionally, it should operate silently to avoid any disturbances in medical settings.

g. Ergonomics

The device must be designed for one-handed operation and be ambidextrous, ensuring comfortable use for both left- and right-handed radiologists. It should allow unobstructed access to the needle without requiring unnatural wrist movements or excessive reach. The ergonomic grip design must accommodate various hand sizes, incorporating anti-slip materials or textured surfaces to prevent unintended movement. To enhance stability, the design should minimize wrist strain, and maintain a neutral wrist position during use. The overall weight should be light (<170g) to ensure comfort without compromising stability.

h. Size

The device must be compact and lightweight, fitting within the operator’s hand span (~75-100mm width, ~150mm length) to ensure ease of handling and precision [8]. The device must be small enough for easy transport and sterile packaging, with dimensions that do not obstruct the operator’s field of view or interfere with imaging equipment. As a

single-use, disposable device, it requires no maintenance and must be easily discarded in standard medical waste containers (~150mm x 200mm opening) without excessive bulk.

i. Weight

The device must have weight constrictions to accommodate for one-handed, ambidextrous operation. The weight of the device will impact the control and comfort of the operator. Lighter needle holders provide precision for intricate procedures and minimizes fatigue, while heavier needle holders handle heavy-duty procedures or tasks [9]. The device will be designed for a cervical injection procedure. This procedure is categorized as an intricate procedure by the client because it requires accurate needle placement, therefore the device should be reasonably light. The current needle holder the client is using is Mayo-Hegar needle holder which weighs approximately 170g [10]. To maintain consistency with existing equipment used by radiologists, the proposed device should have a similar weight to 170g.

j. Materials

The client specified to use plastics in our design. Plastic is generally durable, cost effective, and lightweight [11]. Plastics work well within the operating environment {see Section f: Operating Environment}, since they have a relatively low density (compared to other commonly used medical materials) ranging from 0.9 to 1.4 grams per cubic centimeter (g/cm^3) [12]. Plastics' low density accounts for their radiolucent appearance through x-rays [13]. Three types of plastic are commonly used for medical/surgical equipment: polycarbonate, polyethylene, and polyvinyl chloride. Polycarbonate has high-impact and temperature-resistant properties. Polyethylene is especially durable and resistant to steam sterilization. Polyvinyl chloride (PVC) is used for its high tensile strength [14]. On the other hand, PVC has been noted to be environmentally unfavorable due to its degradation and disposal methods [15].

The device will be 3D-printed due to its complex geometry (to accommodate hand shape) and high specifications (since the needle holder will need to perfectly hold a needle). Polycarbonate is the only available plastic offered by the Makerspace that is suitable for medical purposes and a Class 2 medical device {See Section 3a: Standards and Specifications}. Polycarbonate is five cents per gram (¢/g), a low cost based on the following calculations in Section 2b: Target Production Cost [16].

Polycarbonate has an ultimate tensile strength of 70 megapascals (MPa) [17]. This will be adequate to resist deformation under an average grip strength of 55 kilograms (kg) [18]. There is also a regression equation that can be used to calculate the grip strength using BMI, age, sex, and height.

Side	Adjusted R^2	Regression Equation
R	0.762	$y = 21.57 - 16.14 \times \text{Female} - 3.13 \times 10^{-5} \times \text{Age}^3 + 3.15 \times 10^{-6} \times \text{Height}^3 + 0.74 \times \text{BMI} - 2.32 \times 10^{-4} \times \text{BMI}^3$
L	0.752	$y = 13.90 - 16.36 \times \text{Female} + 1.26 \times \text{Age} - 2.32 \times 10^{-2} \times \text{Age}^2 + 1.01 \times 10^{-4} \times \text{Age}^3 + 2.35 \times 10^{-6} \times \text{Height}^3 + 0.16 \times \text{BMI}$

y, predicted grip strength; R^2, amount of variance accounted for by the model; Age (years); Height (cm); Female = 0 for male patient; Female = 1 for female patient.

Table 1: Grip Strength Regression Equations from "Grip Strength in Healthy Caucasian Adults"[19]

Certain materials, namely metals, should be avoided in the CT field because of metal artifacts and beam hardening [20]. Metal is radiopaque since they have a material composition that absorbs and scatters radiation [21] If metal becomes required for the Needle Holder device design, then there are techniques such as iterative reconstruction and metal deletion methods [20]. Metal should be avoided so that yielding distortions/artifacts do not appear on imaging scans [22].

k. Aesthetics, Appearance, and Finish

The device surface finish must not shine (which may block the medical provider's field of vision) and the color of the device is arbitrary. The device should also be smooth to touch so the operator can seamlessly maneuver in hand [23].

2. Production Characteristics

a. Quantity

The client requested that this device be disposable per a single procedure. Section 2b: Target Production Cost outlines an approximate total number of iterations, specifically 35 copies, of the device design that can be manufactured. A rough estimate for the number of prototype iterations is 5, with 30 copies allocated for testing. Pilot testing can be done with a sample size of 30, which is considered the minimum to calculate statistical significance [24].

At the client's request, one finished/ adequately tested unit is the semester goal, however the final design must be replicated easily for a higher volume production.

b. Target Production Cost

The client's proposed budget is $300 to make a prototype and conduct testing. Additional expenditure is available, however the Needle Navigator team and client think this budget is appropriate.

The material of choice, Polycarbonate {See Section j: Materials}, is five cents per gram. Polycarbonate is priced at $0.05 per gram. If a maximum of 170 grams is used, the cost per prototype iteration would be $8.50. This allows for approximately 35 prototype iterations within the given budget.

3. Miscellaneous

a. Standards and Specifications

According to the FDA, this needle navigation device would be classified as a Class 2 medical device, which thereby increases its regulatory control by the FDA [25]. If in the future this device is to be sold commercially on the market, a Premarket Notification 510(k) form must be submitted to the FDA for approval prior to market release according to **21 CFR Part 807 Part E** [26]. After 510k is approved by the FDA, the device will be subject to Medical Device Reporting, Quality System Regulation, Labeling Requirements, and Good Manufacturing Practices by the manufacturer. This device must also be compliant with ISO 11608 which outlines the regulations for the use of needle-based injection systems [24].

b. Customer

The client has requested that the device contain a feature that incorporates some form of sliding mechanism which allows for the needle to comfortably slide into the needle navigator during use to allow for accuracy. The client also requests that this device be compatible with X-Ray guidance to ensure minimal changes to current needle insertion procedures as well as accurate needle placement. The device should be designed for use with only one hand and should also be designed so that the user is able to hold the shaft of the needle during use. Additionally, the needle navigator device must be compatible with different diameter needles including a 22 and 25 gauge surgical needle. The device must also be disposable after each use. The client also wants the device to be user-friendly and efficient to ensure the procedure duration remains as originally intended.

c. Patient-related concerns

This needle navigation device itself will be disposable, however the needle that is being used must be sterilized before use with the device. The device must ensure proper handling of the needle, avoiding contamination during insertion or removal of the needle. This device must also be stable to use, as any movement can lead to needle misplacement which can cause potential harm to the patient. Needle angle and needle placement accuracy is imperative to reduce the risk of complications in the patient during the procedure. This is especially important for device use in

cervical spine applications, as there are a lot of blood vessels close to the brain, and if the vessels are punctured, the patient can suffer from a stroke.

d. Competition

There is currently a patent for a needle holder for image guided intervention procedures that would provide competition with this device. This device includes a clip for holding the needle and a guide arrangement for supporting the needle and directing the needle at a desired angle relative to the patient's body [25]. This patented device also includes a resealable connection such that the needle can be disengaged from the guide arrangement by moving the clip laterally. Another product that is currently on the market is the Ultra-Pro II™ In-Plane Ultrasound Needle Guides-Multi-Angle, which can provide competition to the device. The Ultra-Pro device by Civco Medical utilizes a two-part system containing a custom reusable bracket and a disposable snap needle guide [26]. The Ultra-Pro device provides competition to the design however the intended use of the Ultra-Pro device is to be used with an ultrasound machine, which is not applicable to this project.

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