Force Gauge for the Removal of Epidural Catheters

BIOMEDICAL ENGINEERING
UNIVERSITY OF MICHIGAN

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Epicath

Introduction

Epidural Catheters

- Epidural catheters are used for administering anesthesia or other drugs into the epidural space of the spinal cord
- Used by nurse anesthetists and anesthesiologists
- Gold-standard catheter made of polyurethane shell with stainless steel coil

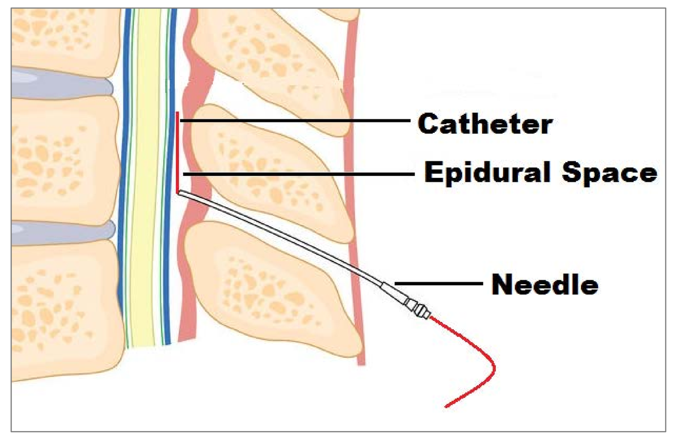

Figure 1: Epidural catheter inserted into human body
https://www.123rf.com/photo_46938395_stock-vector-cross-section-of-the-spine-showing-the-spinal-cord-and-the-epidural-space-with-a-catheter-in-situ.html

Problem Definition

- During removal, catheter can fragment inside patient's epidural space
- Causes: excessive pulling force, kinking of catheter, shearing of catheter by needle
- Unretrieved catheter fragments may cause complications and even death
- Instructions for use says 1/3rd pound is minimum force necessary to remove

Market Size

- 9.0% of catheter reports in MAUDE are because of unretrieved catheter fragments
- Hospitals not required to report catheter breakages
- 1.45 billion catheters sold in 2014[1]
- $222.6 million revenue from anesthetic department[2]

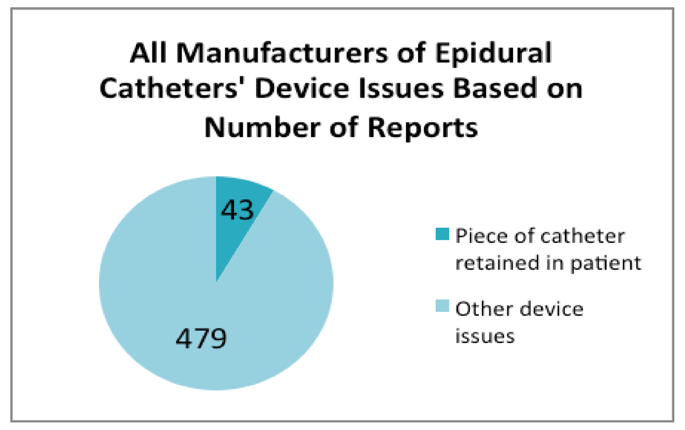

Figure 2: MAUDE data for reported catheter adverse events

Goal & Scope

Goal

- Determine the mechanical properties of the gold-standard catheter at U of M
- Design a device that alerts the user when this catheter is nearing failure

Scope

- Must be an add-on device to the gold-standard catheter
- Cannot modify the catheter itself
- The alert system cannot be audible, preferably visual
- Cannot mechanically prevent the user from removing the catheter
- Focus on failure caused by excessive pulling force by user

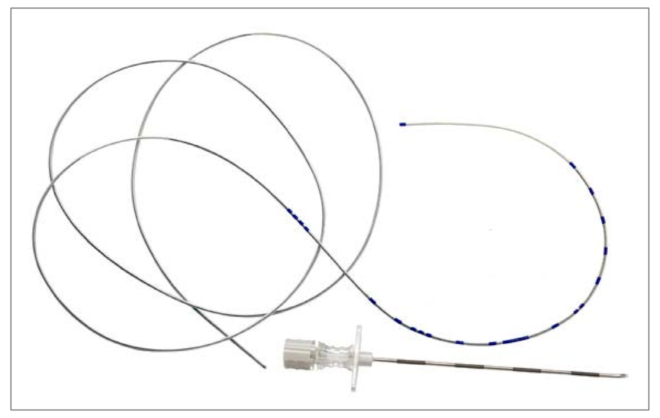
Figure 3: Generic epidural catheter and needle
https://www.123rf.com/photo_46938395_stock-vector-cross-section-of-the-spine-showing-the-spinal-cord-and-the-epidural-space-with-a-catheter-in-situ.html

Design Requirements

Requirement	Specification
Detects force applied by user on catheter	0 lb to 3.5 lb
Alerts user when catheter is nearing ultimate tensile strength	1.25 lb
Real time force measurement	< 300 ms time delay
Biocompatible with skin	Biocompatible materials
Accurate force measurement	≤ 0.05 lb
Attachable to catheter	Outer diameter of 1.016 mm
Disposable	Intended for 1 procedure
Low cost	< $5
Attachable with low workflow interference	< 10 seconds
Time to train user fits in workflow	< 5 minutes
Small in size	< 89 mm
Lightweight	< 500 g

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Detailed Design

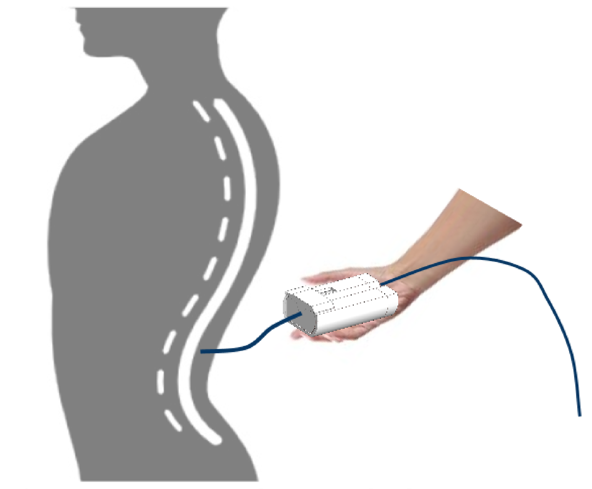
Figure 4: Device with patient body

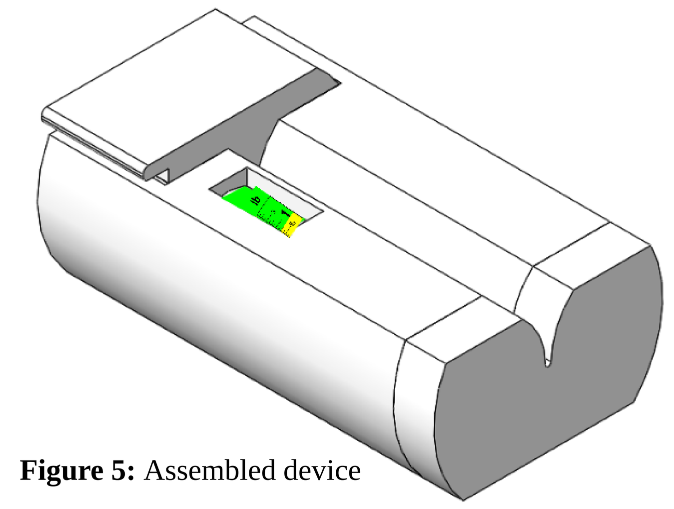
Figure 5: Assembled device

- 3D printed using Cube® 2
- Casing made of polylactic acid (PLA)
- Springs are made of 304 stainless steel

Components

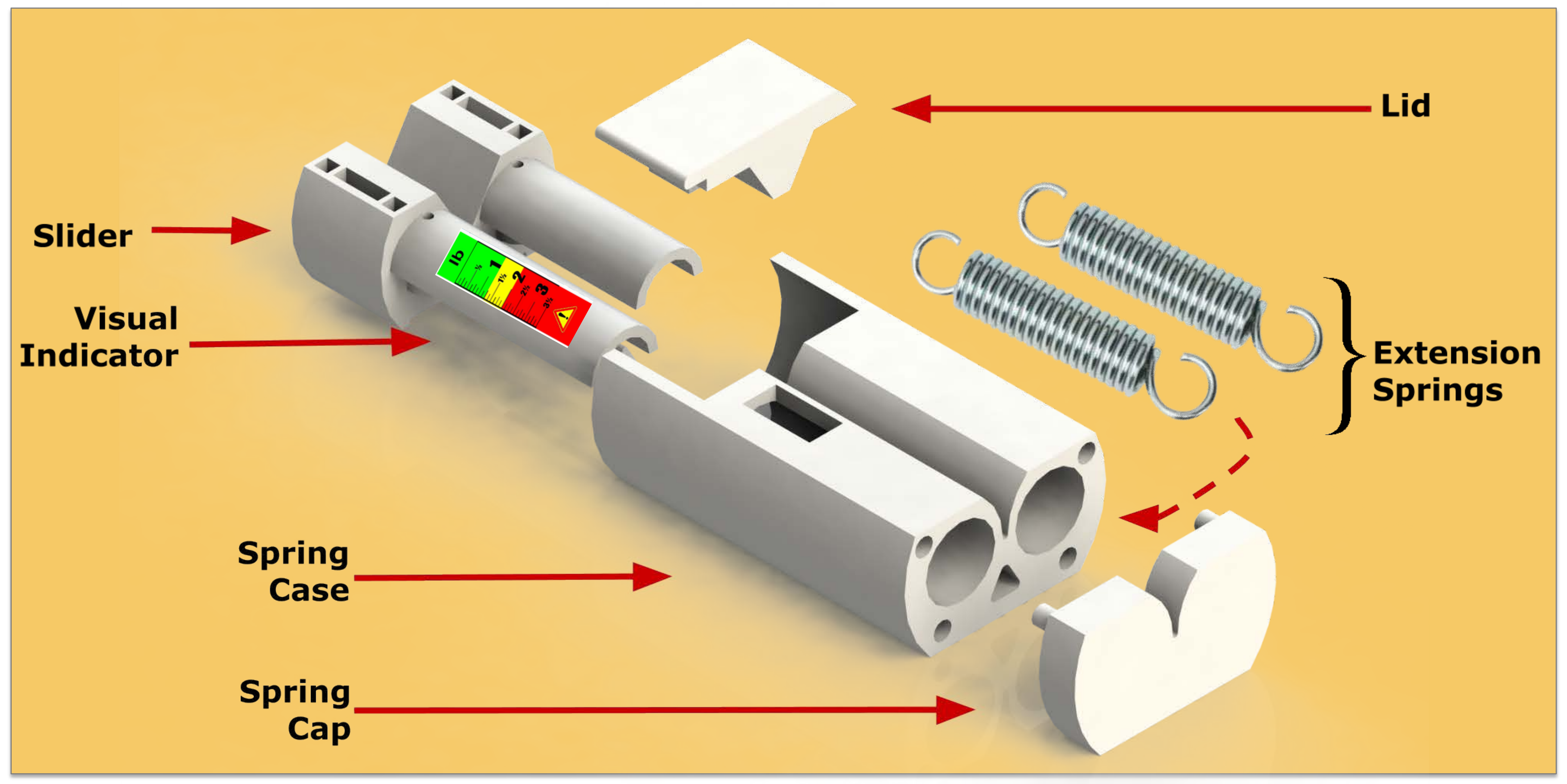

Figure 6: Exploded view of the EpiCath force gauge and its components

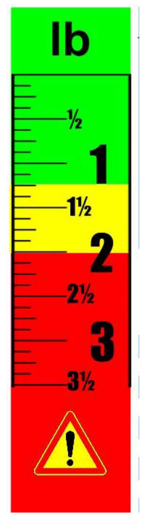

Figure 7: Visual indicator of force

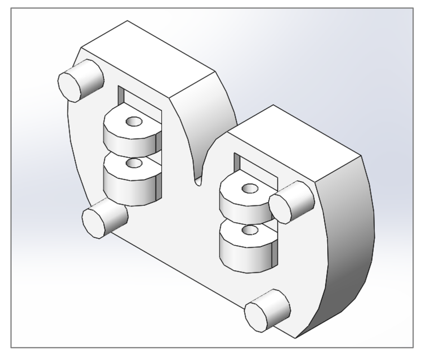
Figure 8: Spring cap for assembly of the springs

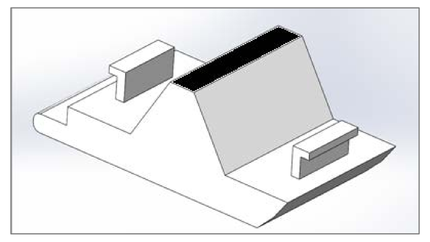
Figure 9: Lid for securing catheter with pad shown in black

Name	Features
Slider	Holds visual indicator, mates with lid, loops for securing springs
Visual Indicator	Attached to slider, force scale (lb), color severity
Spring case	Encases springs, mates with slider and spring cap, viewing window for visual indicator
Spring cap	Mates with spring case, loops for securing springs
Extension Springs	Two extension springs with hooks on ends
Lid	Hinge, two snap locks, handle to open, pad for gripping catheter

Operation

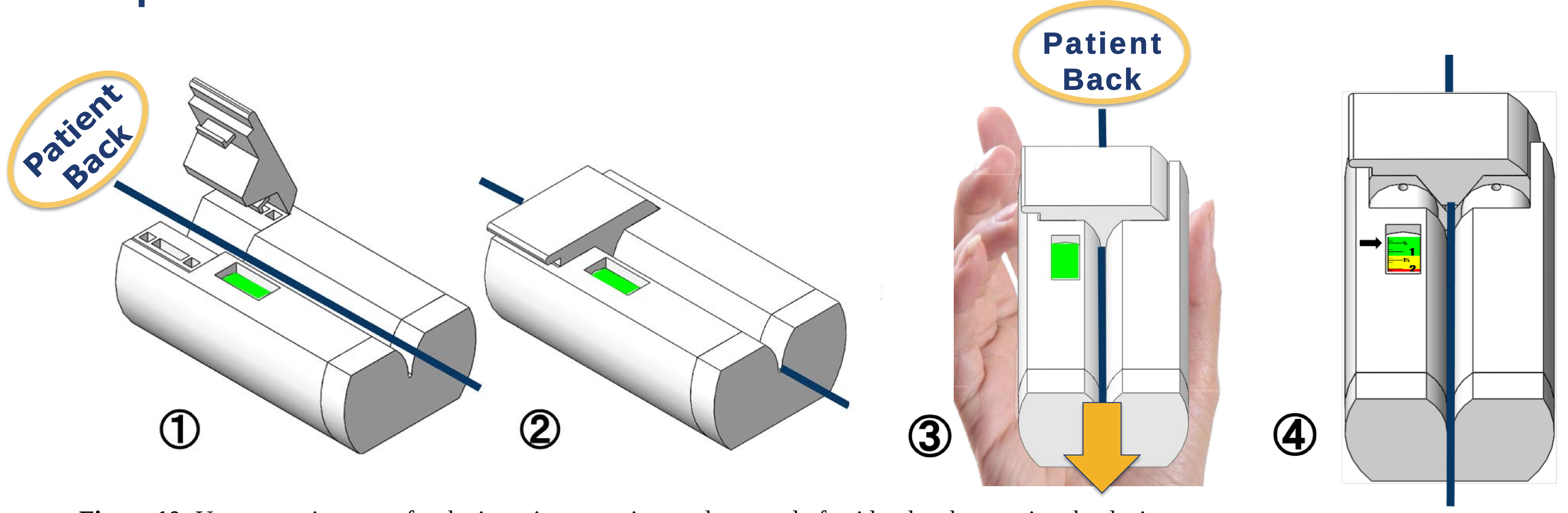

Figure 10: User operation steps for the insertion, securing, and removal of epidural catheter using the device

Step	Instruction
1	Position the device next to patient's back. Open the lid and place the catheter in the trough
2	Close the lid until there is an audible snap
3	Hold the spring case, and begin pulling away from the patient's body
4	Watch the viewing window to monitor the current force being applied on the catheter

- **Green zone:** proceed pulling normally
- **Yellow zone:** use discretion when pulling, and proceed with caution
- **Red zone:** reduce the pulling force and slow down

Validation

Type of Test	Description of Test	Specification	Result	Pass / Fail
Secure interface – tensile strength test	Increased force at constant rate until slippage occurred	Grips catheter from 0 to 3.5 lb	Grips catheter from 0 to 1.10 ± 0.25 lb	✗
Force measurement accuracy – creep test	Held force constant to determine spring displacement	0.05 lb	0.022 lb	✓
Mass test	Used electronic scale	< 500 g	75.6 g	✓
Key dimensions size test	Used caliper to measure	Length: < 89 mm Width: < 57 mm	Length: 78 mm Width: 45 mm	✓

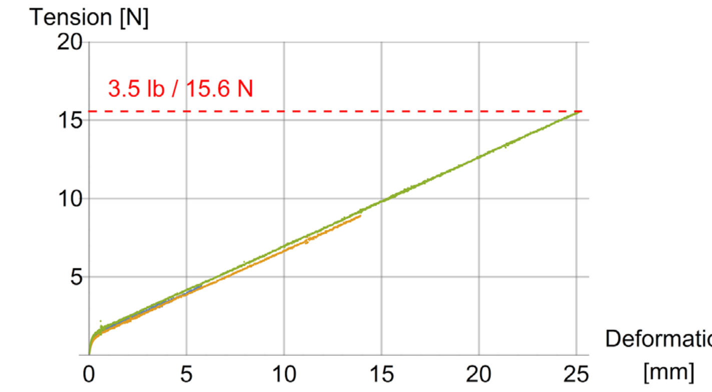

Figure 11: Graph of force measurement accuracy creep test showing linear relationship between deformation and force

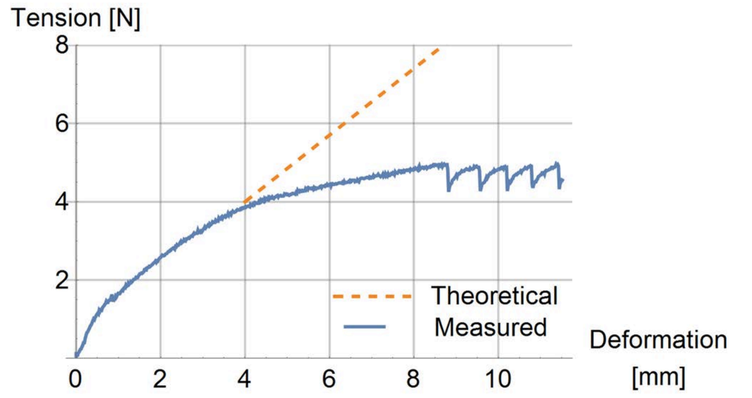

Figure 12: Representative graph of catheter slippage when deviates from linear deformation versus force relationship

Usability Testing Procedure

- Used fellow BME students for testing
- Simulated procedure by holding catheter in hand
- Asked students to use the device to remove the catheter before and after reading instructions
- Used questionnaire to qualify their experience

Usability Testing Results

- 100% of students inserted the catheter in the device in the correct orientation before reading instructions
- 17% of students held device correctly before reading instructions
- 67% of students held device correctly after reading instructions
- 100% of students found the device easy to handle
- No students found the viewing window large enough

Future Plans

Design Modifications

- Distinguish between lid/slider and rest of device by using two colors
- Add markings to indicate orientation and pulling direction
- Use polyethylene terephthalate (PET) for pad material to grip catheter and decrease slippage
- Adjust visual indicator to account for initial spring tension
- Increase size of viewing window

Long-Term Milestones

- Increase usability testing sample size for higher accuracy in user response
- File an Institutional Review Board (IRB) application to U of M to have attending anesthesiologists use device
- Use polypropylene (PP) as material for mass production via injection molding
- Incorporate a living hinge using PP

Acknowledgements

Epicath would like to thank clinical safety specialist Mr. Salim Kai of the University of Michigan Health Systems for his direction and support on this project. We would also like to thank Dr. Rachel Schmedlen, Dr. Christian Casper, and Dr. Hengky Chandrahalim of the University of Michigan Biomedical Engineering Department for their assistance and guidance. Finally, we would like to thank Michael Deininger in the Design Science PhD program for his expertise in prototyping.

References

1. "Kalorama The World Market of Catheters." Kalorama Information. 17 June 2015. http://www.prnewswire.com/news-releases/report-over-14-billion-catheters-sold-globally-300094433.html
2. "Teleflex 2014 Annual Report: Focusing on the Future." http://www.annualreports.com/Company/teleflex-inc

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