

Detection of Hydrophilic Coating on Biomedical Devices via Fluorescent Nanoparticles

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Introduction

Surface properties of devices are one of the largest indicators of biocompatibility. Hydrophilic coatings on sheath introducers for intravenous catheters have been shown to reduce complications in their use

- Current detection of the coating is destructive
 - Relies on statistical sampling
 - Results in significant loss of viable product, and a loss of significant revenue and material for biomedical companies

A proposed alternative includes the addition of a fluorescent nanoparticle:

- ThermoFisher Fluoromax nanoparticles show promising optical and biocompatible properties

Figure 1 – Intravenous Catheter Sheath Introducer



These sheaths have a hydrophilic coating that helps with functionality and biocompatibility of the device.

Table 1- Goniometer Results

Sample	Left Contact Angle	Right Contact Angle	Average
Un-coated Sheath	110.5 ± 9.7°	108.4 ± 11.4°	109.5 ± 9.6°
Coated Sheath	54.7 ± 4.7°	50.4 ± 2.9°	52.6 ± 4.19°
Coated Sheath With Fluorophore	61.3 ± 4.4°	53.8 ± 6.2°	57.5 ± 5.3°

Work completed

Fluorophore additive

- Dilution ratios
 - 10% v/v chosen
- Coating process
- Goniometer testing
- Statistical analysis

Design solution research

- Toxicity evaluation
- Process incorporation

Results

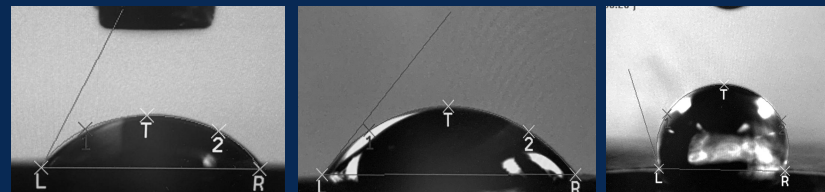
Goniometer testing on coated sheath with fluorophore

- Hydrophilic properties were conserved
- Further toxicity testing required

Statistical testing on samples

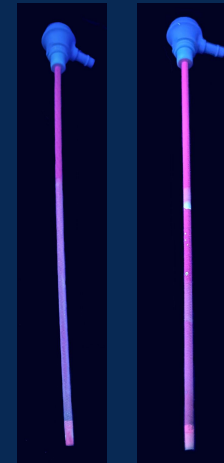
- Identification of uncoated or contaminated sheaths
- Experimental sample (n = 53) produced
 - 83% accurate identification of contaminated product
 - 13% of samples falsely identified as contaminated
 - 4% of samples falsely identified as not contaminated

Figure 2 – Goniometer Images



Coated sheath showing hydrophilic properties (left), modified coated sheath with similar hydrophilic properties (center) and uncoated sheath showing hydrophobic properties (right)

Figure 3 – Sheath Under UV Light



Modified Coating viewed under UV light. 10% concentration of fluorophore with a contaminated sheath on the right.

Future Work

Next steps of this project include:

- Second round of statistical analysis with comparison to Congo Red Dye test
- Determine biocompatibility
- Cost and repeatability analysis
- Quantification of visual inspection
- Incorporation on assembly line