



# Conway Chair Conversation

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FROM INNOVATION TO DISSEMINATION

- Information about the new CNH Biodesign Program.
- Overview of what happens after creating an innovation with special emphasis on disseminating results including publication and other forms of dissemination.



# The Biodesign Program

## Sheikh Zayed Institute for Pediatric Surgical Innovation



### **Kolaleh Eskandanian, Ph.D., MBA, PMP**

Vice President and Chief Innovation Officer Children's National Hospital  
Managing Director Children's National Innovation Ventures  
Principal Investigator National Capital Consortium for Pediatric Device Innovation  
Executive Director Sheikh Zayed Institute for Pediatric Surgical Innovation

### **Jules Sherman, M.F.A.**

Director Biodesign  
Program Innovation Ventures  
Children's National Hospital

### **Julia C. Finkel M.D.**

Clinical Liaison  
Director of Pain Medicine Research and Development  
The Sheikh Zayed Institute for Pediatric Surgical Innovation  
Children's National Hospital  
Professor of Anesthesiology Pediatrics and Critical Care Medicine The George Washington University

# The Biodesign Program

Funded by Innovation Venture, SZI & FDA Grant



## **Aims:**

1. Educate clinicians about innovation methods and collect clinical problems that need attention.
2. Share CNH clinical needs with UMD bioengineering students and leverage promising capstone projects for further development in our Biodesign Program.
3. Develop novel and needed medical products intended for commercialization.

# What is dissemination?

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Dissemination is **the targeted distribution of information and intervention materials to a specific public health or clinical practice audience**. The intent is to spread knowledge and the associated evidence-based interventions. Dissemination occurs through a variety of channels, social contexts, and settings.



Dissemination  
through the lens of  
a designer/  
entrepreneur...

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# What is marketing?

Marketing is **the activity, and processes for creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large.**



2016 Stanford Byers Center for Biodesign



Salon.com



<b>R&amp;D/Manufacturing</b>	<b>FDA/Regulatory/IP</b>	<b>Clinical Studies/Early Customer Adoption</b>	<b>Commercial Launch</b>
Iterative Prototyping	Biocompatibility/ Sterility	Product Evaluations	Free Samples
Engineering Drawings	Regulatory Report	Multi-Center Trials	Trade Shows
Patterns	Verification and Validation (V&V)	Value Analysis Assessments	Publishing in Trade Journals
Molds/Tooling	Intellectual Property Filing (Patent)	Publishing Studies in Journals/Poster Presentations	Sales/Licensing/ Acquisition



R&D/Manufacturing	FDA/Regulatory/IP	Clinical Studies/Early Customer Adoption	Commercial Launch
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Dissemination  
means...

*sharing the story.*

Dissemination  
means...  
*sharing the story.*

What?

(the problem)

Dissemination  
means...  
*sharing the story.*

What?

(the problem)

Now What?

(new innovation)

Dissemination  
means...  
*sharing the story.*

What?

(the problem)

Now What?

(new innovation)

So What?

(making meaning from data)



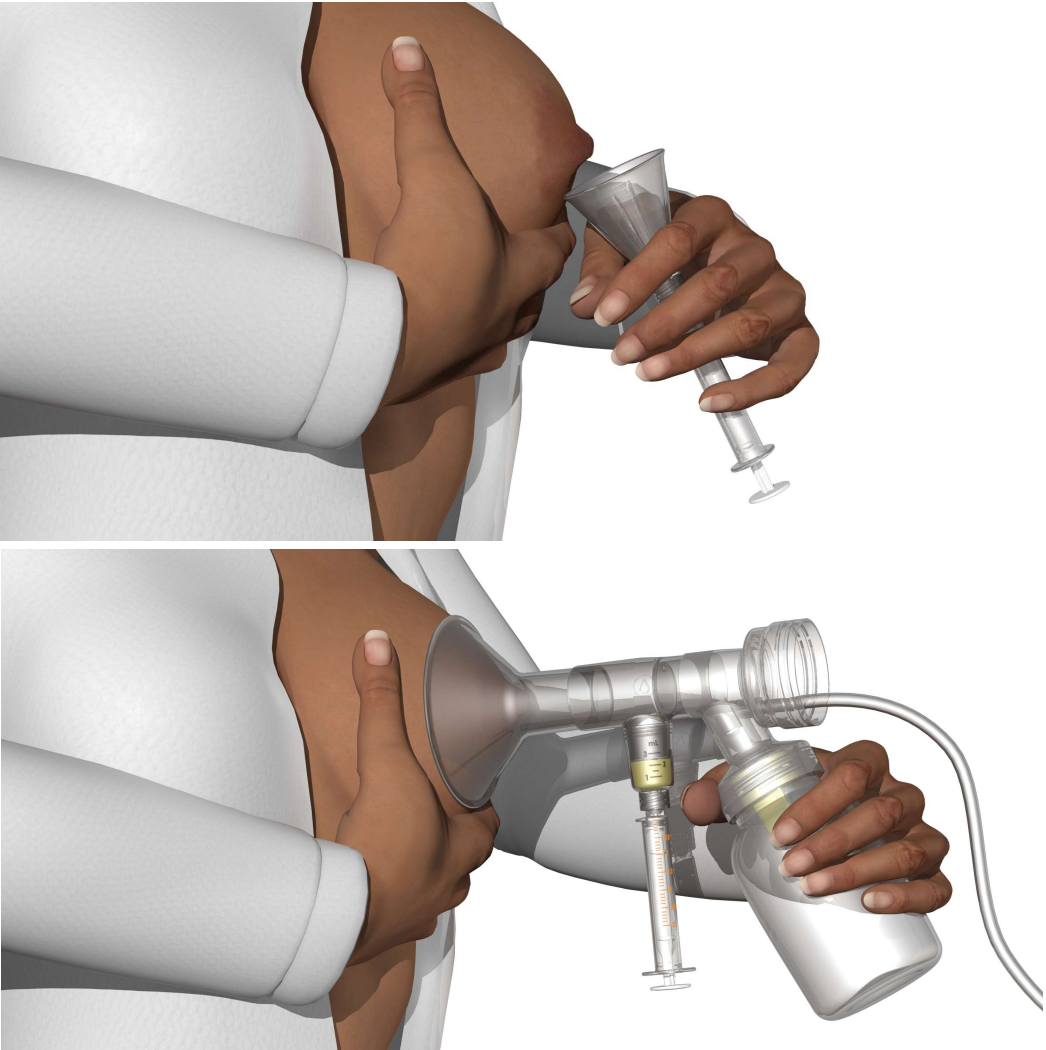
For me, meaning is created when we can translate knowledge into something tangible to help people live healthier lives.

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Kangarobe

# Primo-Lacto: A closed system for colostrum collection





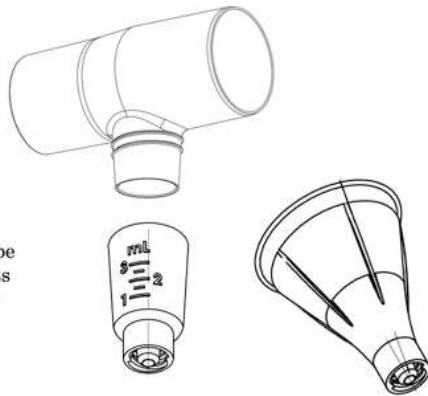
## Clinical Need

Photos from Stanford School Of Medicine.  
*Early Hand-Expression Increases Later Milk Production*, by Dr. Jane Morton MD.

**There is a need to effectively collect colostrum in the first days of lactation and safely administer a mother's "liquid gold" to the neonate.**

We have recently completed a clinical pilot study at three different hospitals:

Sharp Mary Birch in San Diego, CA, John Muir Hospital in Walnut Creek, CA, and Indiana Memorial Hospital in South Bend, IN. The most important critique from mothers, LCs and nurses has been that the connection between both the hand expression funnel and adapter cup must be more secure, as there were a few incidents where the cup detached from the adapter during a pumping session. **Therefore I** have added a threaded connection to ensure there is a tight fit.



### RESEARCH ARTICLE

## A prospective clinical study of Primo-Lacto: A closed system for colostrum collection

Alexandria I. Kristensen-Cabrera<sup>1</sup>, Jules P. Sherman<sup>1,2\*</sup>, Henry C. Lee<sup>1</sup>

**1** Department of Pediatrics, Division of Neonatology, Stanford University School of Medicine, Palo Alto, CA, United States of America, **2** Hasso Plattner Institute of Design, Stanford University, Palo Alto, CA, United States of America

\* [julessherman@alumni.stanford.edu](mailto:julessherman@alumni.stanford.edu)

### Abstract

#### Background

Colostrum is the first nutritional liquid that comes out of the breast during lactation. Colostrum collection can be challenging due to the small volume produced, and because breast pumps are not designed for colostrum collection. Besides pumping colostrum, the generally accepted practice is to use any available container to hand-express colostrum. Transfer between containers may lead to contamination, higher chance of infection and loss of colostrum. Our aim was to understand if a dedicated colostrum collection system (Primo-Lacto, Maternal Life, LLC, Palo Alto, CA) is more effective than standard hospital practice.

#### Methods

Mothers who delivered preterm infants < 34 weeks gestation and mothers with non-latching infants were approached within 24 hours of delivery. Surveys were distributed to participating patients (n = 67), and nurses or lactation consultants (n = 89). Mothers compared ease of use, their confidence level and satisfaction with the amount collected during standard practice vs. the colostrum collection system. Nurses or lactation consultants compared ease of use, differences in colostrum loss and time invested collecting. Quantitative data were analyzed using the Wilcoxon signed rank test and qualitative data were analyzed with grounded theory methods.

### OPEN ACCESS

**Citation:** Kristensen-Cabrera AI, Sherman JP, Lee HC (2018) A prospective clinical study of Primo-Lacto: A closed system for colostrum collection. PLoS ONE 13(11): e0206854. <https://doi.org/10.1371/journal.pone.0206854>

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**Lansinoh**  
Primo-Lacto®  
Colostrum Collection System

Designed to increase the volume of usable colostrum for neonates

The first closed system kit for colostrum collection & feeding. Designed to improve the experience for both healthcare professionals and patients.

- Connects directly to an oral feeding syringe
- Eliminates the need for multiple containers
- Multi-functional system for hand or pump expression
- Available for Medela® and Ameda® breast pump kits

**Clinician Perspective Analysis**  
In a study of 67 mothers with preterm infants ranging from 25 to 38 weeks gestational age, 87 clinician observations recorded the following results:

**Reduce wasted colostrum\***  
Healthcare providers estimated that a 41% decrease in the amount of colostrum wasted when using the Primo-Lacto® for hand expression and a 30% decrease in the amount of colostrum wasted when using the Primo-Lacto® for pump expression.

**Improved ease of use for professionals**  
Designed to promote safer practice and consistency, minimize set-up time, and aid transition from colostrum collection to oral feeding of infant. Healthcare professionals reported a significant improvement in ease of use with the Primo-Lacto® collection system.

**Increased patient satisfaction levels**  
Primo-Lacto® has a unique interface designed to ensure optimal colostrum collection for improved patient confidence & comfort. Patients reported a significant increase in satisfaction when using the Primo-Lacto®.

For more information, please contact Jamie Palla: [jpalla@lansinoh.com](mailto:jpalla@lansinoh.com) or 443-822-3698

National Association of Neonatal Nurses  
35<sup>TH</sup> ANNUAL CONFERENCE  
SAVANNAH • 2019

## Learning Center Schedule

**Wednesday, October 9**  
5:20 – 5:50 pm  
Guardian™ Human Milk Warmer Improves Growth in Premature Infants  
Sponsored by: Medela LLC  
Presented by: Susan Bedwell DNP, APRN, CCNS-N

**Thursday, October 10**  
11:10 – 11:40 am  
Lansinoh's Primo-Lacto® Colostrum Collection System  
Sponsored by: Lansinoh  
Presented by: Jamie Palla & Jules Sherman

11:50 am – 12:20 pm  
Advances in Neonatal Care Writers Workshop  
Presented by: Debra Brandon, CCNS, FAAN, PhD, RN

12:30 – 1 pm  
Determinants of Gastrointestinal Inflammation in Very Low Birth Weight (VLBW) Infants\*  
Presented by: Katelyn M. Desorcy, RN, BSN

2:40 – 3:10 pm  
Searching for Evidence: A Short and Sweet Synopsis  
Presented by: Tiffany A. Moore, PhD, RN

Friday, Oct 11

**Lansinoh.**  
**Primo-Lacto**  
Colostrum Collection System

Improve colostrum collection and feeding for neonates



**CONNECT**



**EXPRESS**



**RELEASE**

# The Empathy Project

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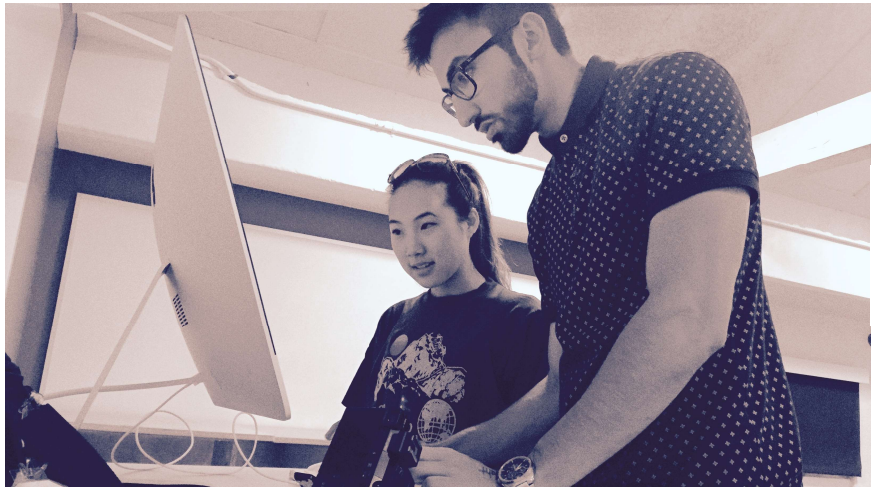


HASSO PLATTNER  
Institute of Design at Stanford

## Gaining Patient Perspectives On Disease Through Storytelling



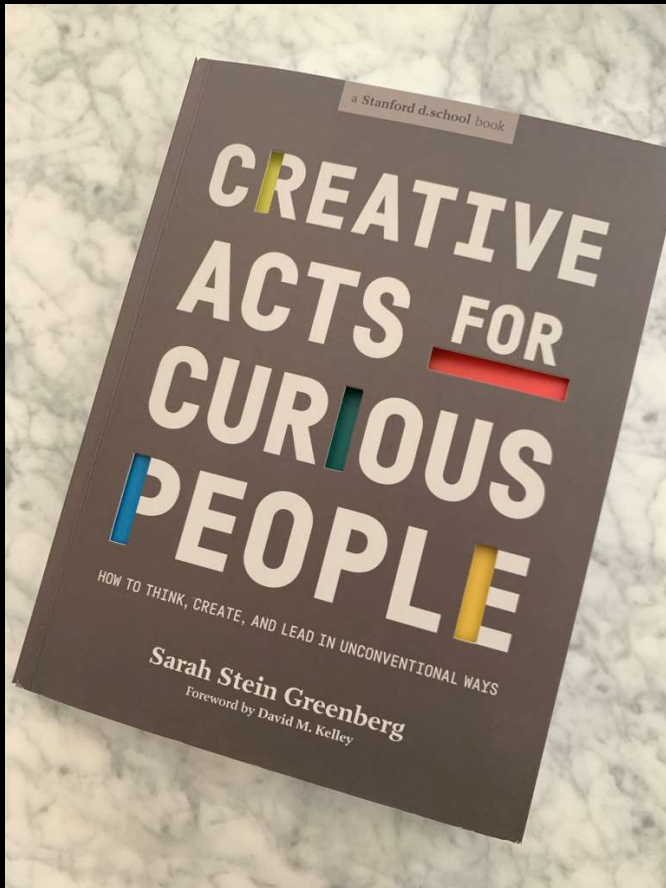
Come be a part of a new pilot class! A maximum of 10 students will be selected. You will learn practical ethnography and video media skills while experiencing a “day in the life” of a patient. Your final group project will be a video that tells the story of a patient you have the opportunity to interview and shadow.















### Problem:

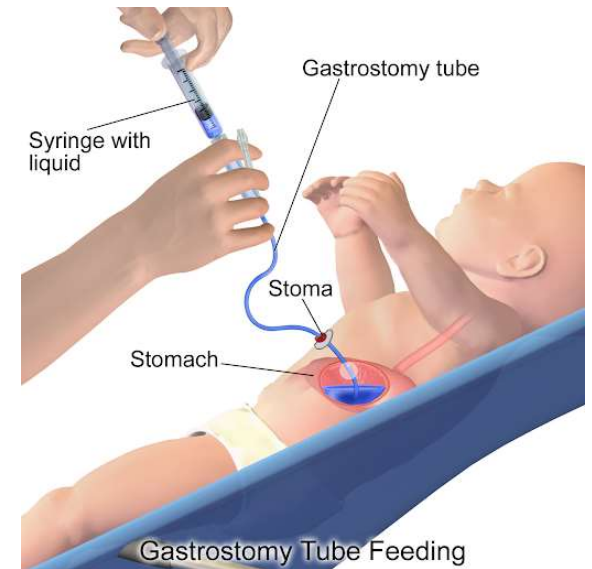
Disconnection of tubes/lines/drains may go unnoticed in pediatric or adult patients which can exacerbate their health condition and leading to longer hospital stays.

### Negative Outcomes:

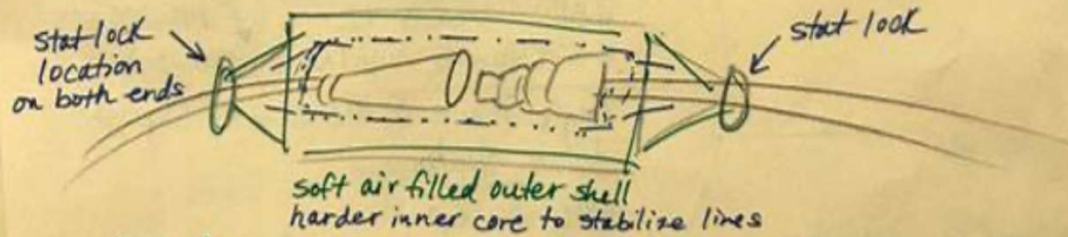
- Bloodstream infections
- Inaccurate I/O
- Inaccurate drain
- Leaked IV fluids
- Leaked IV medications

### Need Statement:

A way to secure and prevent disconnections between a patient and life-saving fluids, nutrition, and antibiotics in order to reduce infections, and hospital stay.



- Offer different sizes - Central lines connections/drainage tubes
- Hard inner core to protect tube connections
- Surrounded by an air filled outer shell, soft
- Back side would have the ability to be adhered to patient  
 - Duoderm-like adhesive allowing skin to breathe... OR...
- Possibly use a grip lock/stat lock-like device on either end of the tube.

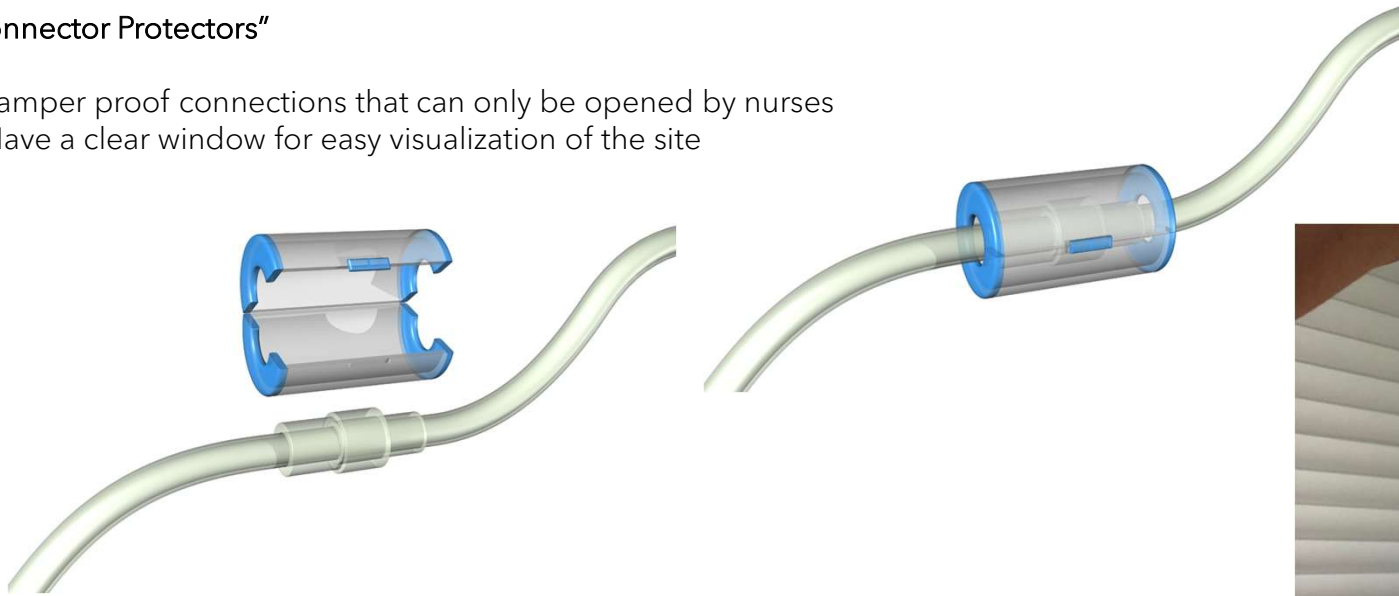


- Duoderm

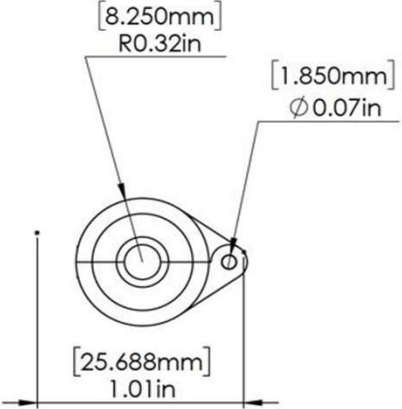
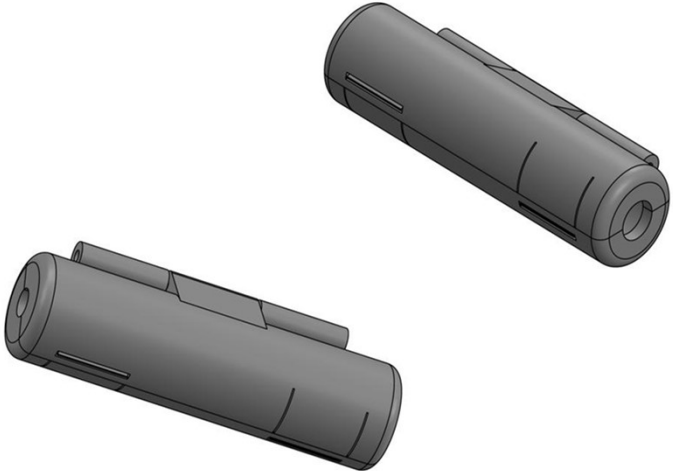
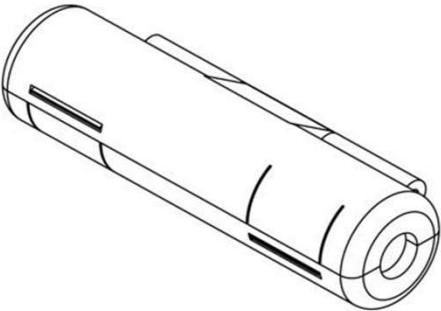
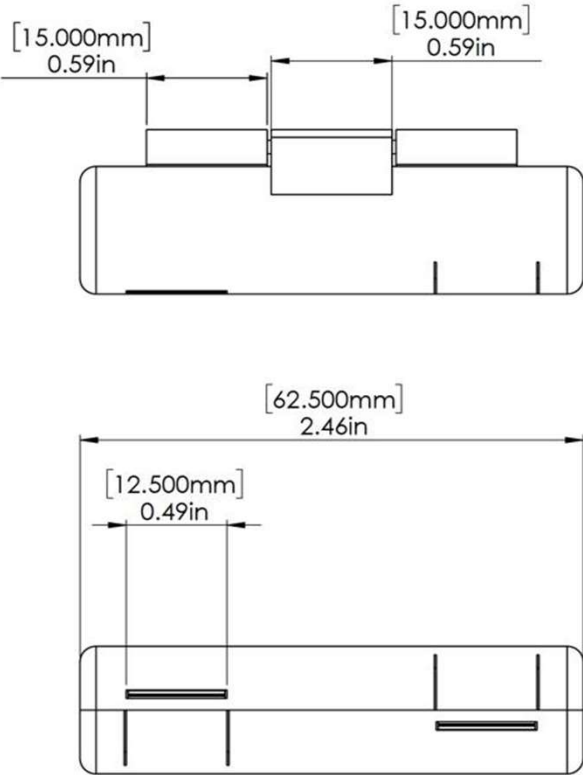
Connector Protector initial concept sketch by, Lori Irvin, BSN, RN, CPN

## "Connector Protectors"

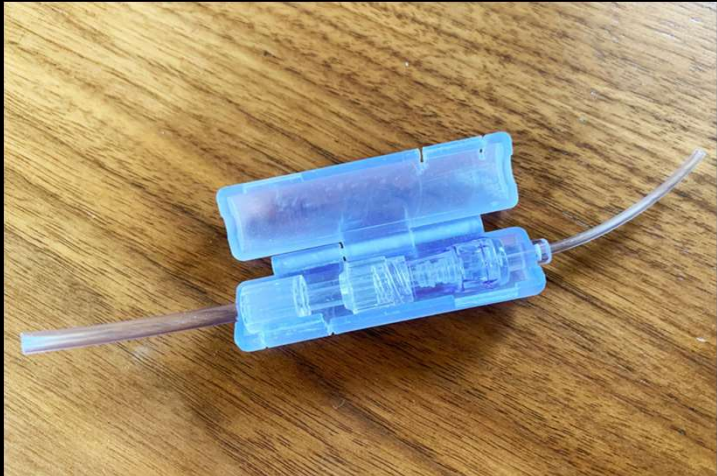
1. Tamper proof connections that can only be opened by nurses
2. Have a clear window for easy visualization of the site



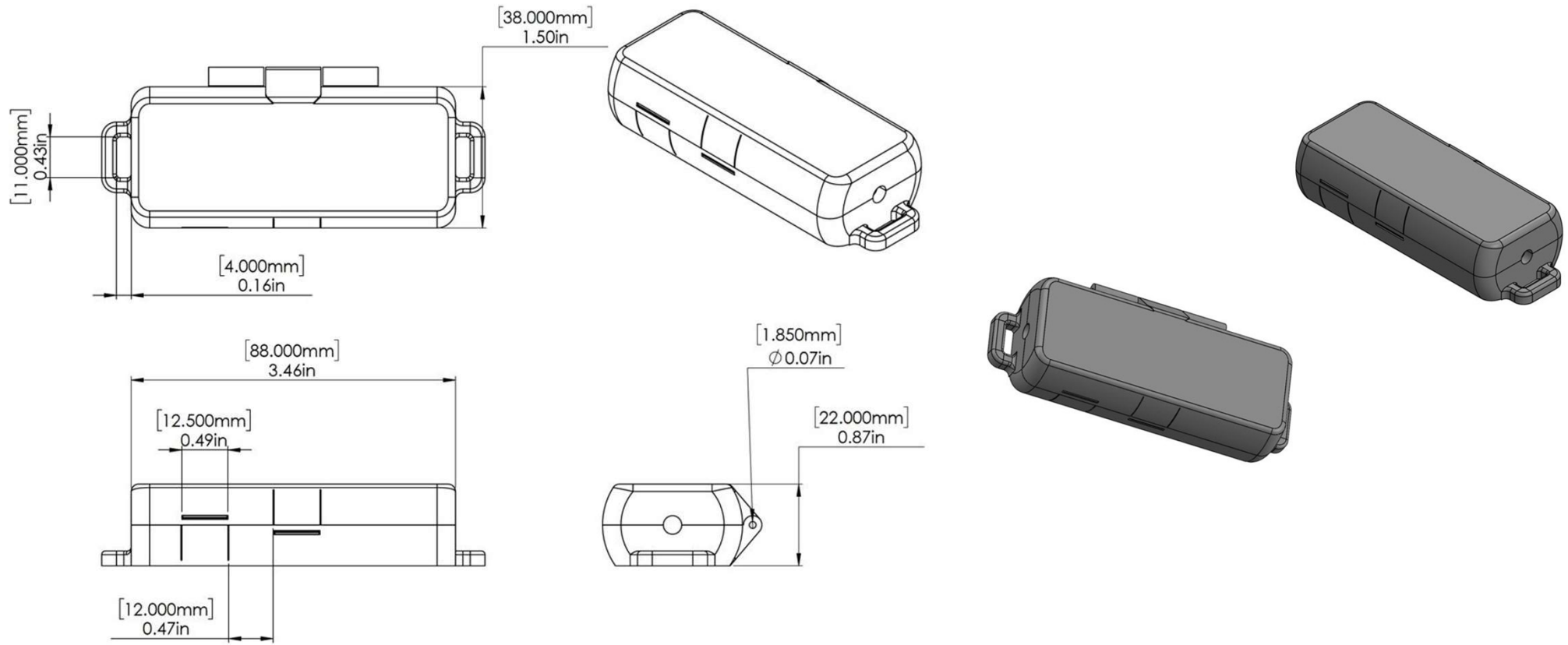
IV Line Connector Protector Prototype-Iteration 4



IV Line Connector Protector Prototype-Iteration 4

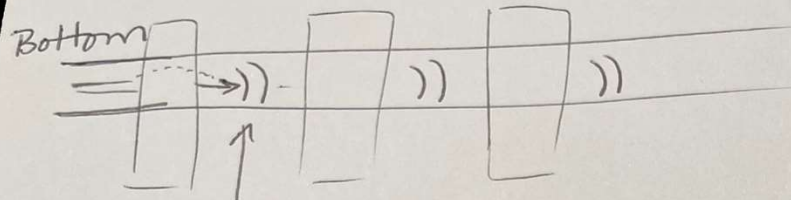


# G-Tube Line Connector Protector Prototype-Iteration 4

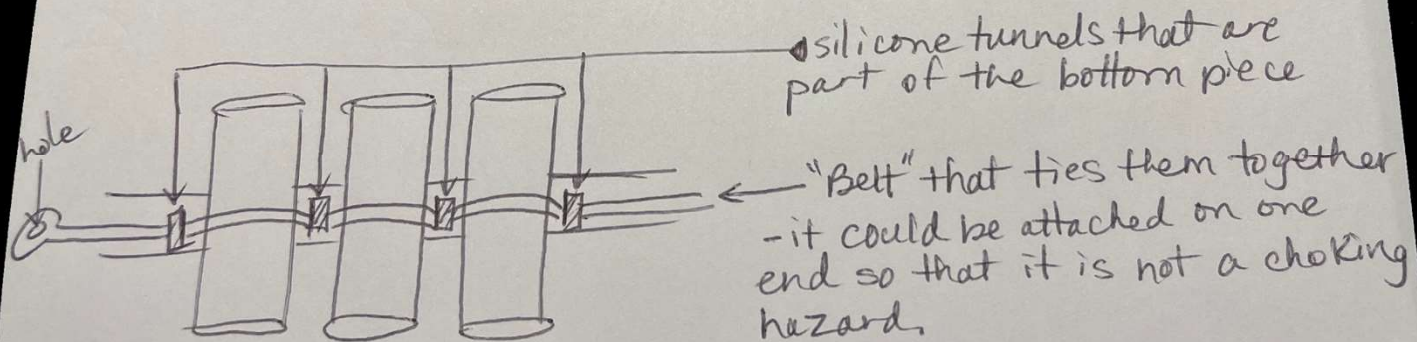
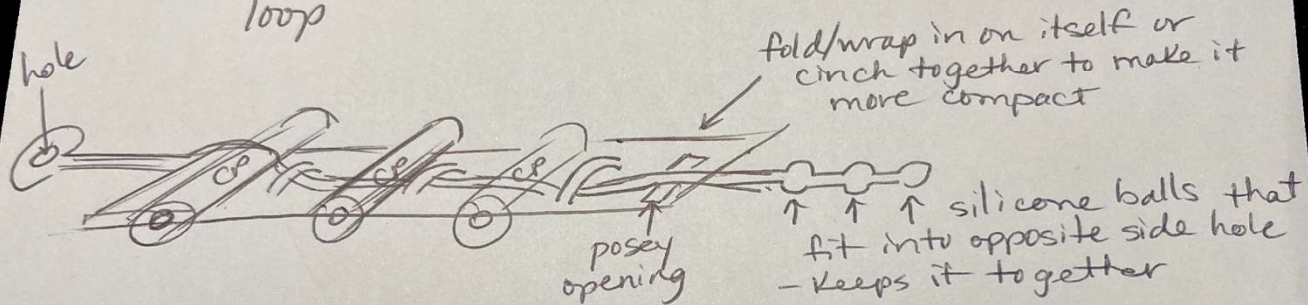


G-Tube Line Connector Protector Prototype-Iteration 4





under  
small  
loop





Triple IV Line Connector Protector Holder Concept

