## SEMICON® VEST BUILDING A PATH FORWARD

### MANUFACTURING CONSIDERATIONS FOR WEARABLES

PRESENTED BY: RAFAEL TUDELA









#### Why Wearables?



**Capacity Strain**: 50-150% increase in mortality rates for capacity strained hospitals



#### **Hospital Staff**

- Availability  $\bullet$
- Exposure ightarrow
- Planning ullet



- Volume  $\bullet$
- Severity  $\bullet$
- Data Collection  $\bullet$

- ullet

ullet

Eriksson, C., Stoner, R. C., Eden, K., Newgard, C. D., & Guise, J. (2016). The Association Between Hospital Capacity Strain and Inpatient Outcomes in Highly Developed Countries: A Systematic Review. Journal of General Internal Medicine, 32(6), 686-696. https://doi.org/10.1007/s11606-016-3936-3









#### Throughput Symptom Monitoring **Re-admittance**



#### **Wearable Patches vs Integrated Fabrics**

- Wearable Patches are lower cost options than integrated fabric for single use
- More adaptable to wide range of patients
- Direct connection to body

nttp://www.dotmedical.com/uploads/2/5/4/0/2540174/ba dy-camtorso-webedit\_orig.jpg

https://wordpress.textileworld.com/wpcontent/uploads/2017/03/WearablesA-420x420.jpg





#### Is the Price Right?

#### **Development Stages**





Sertkaya A, DeVries R, Jessup A, Beleche T. Estimated Cost of Developing a Therapeutic Complex Medical Device in the US. JAMA Netw Open. 2022;5(9):e2231609. doi:10.1001/jamanetworkopen.2022.31609

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#### \$6M Post approval Study 81 months



#### **Development Time Mitigation: Pre-Development (3D's)**



Clearly define project scope to avoid "Scope Creep"

# Deduce

Conduct Market Research



Design for Manufacturing:

Learn more tomorrow
at Flex

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## **gn** for uring:



#### **Development Time Mitigation: Product Development**



GET A MANUFACTURING PARTNER

PRIORITIZE ESSENTIAL FEATURES

ESTABLISH QUALITY SYSTEM EARLY ON

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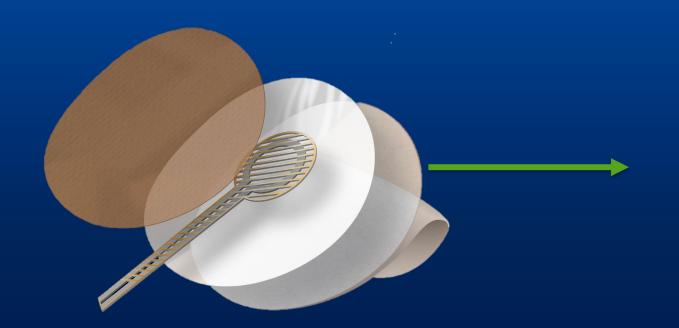
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## TAKE A PHASED APPROACH



#### **Material Considerations: Breakdown**



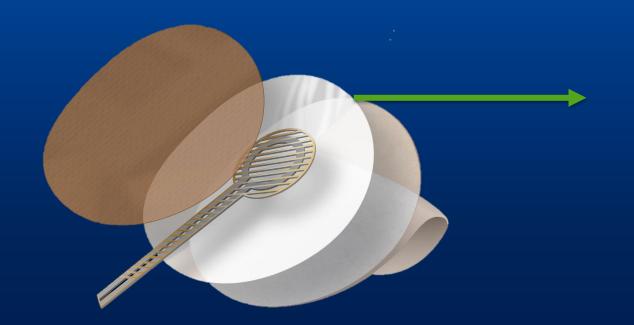
#### **Stick to Skin Adhesive:**

- Most Important Non-Device Layer  $\bullet$
- Who will be wearing this device? ullet
- How long will it be applied? ullet
- Where will the device be?  $\bullet$





#### Material Considerations: Breakdown



#### **Device Layer:**

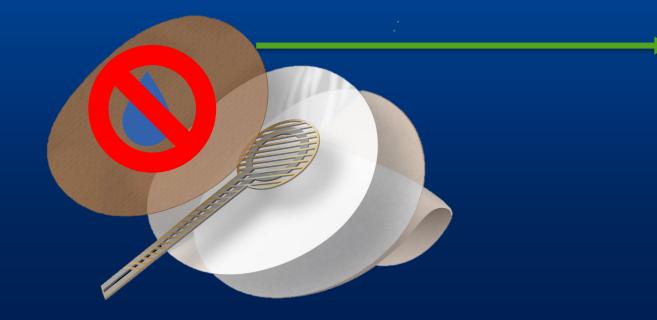
- How are components secured?
- Where and how will the device bend?
- Is the device reusable?
- How is it powered?



#### d? e bend?



#### **Material Considerations: Breakdown**



#### **Encapsulation:**

- How breathable is the device? ullet
- What fluids will the device be exposed to?  $\bullet$
- Is EMI a concern?  $\bullet$
- What information do you want to  $\bullet$ communicate?









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