

# The 506J Device List & our Next Critical Care Crisis!

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# Disclaimer



Intentions are good



Anxiety is high

# Objectives

"A  
manufacturer  
of a device  
that-

- (1) is critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery”
- What is essential
- Maybe... what don't we need?

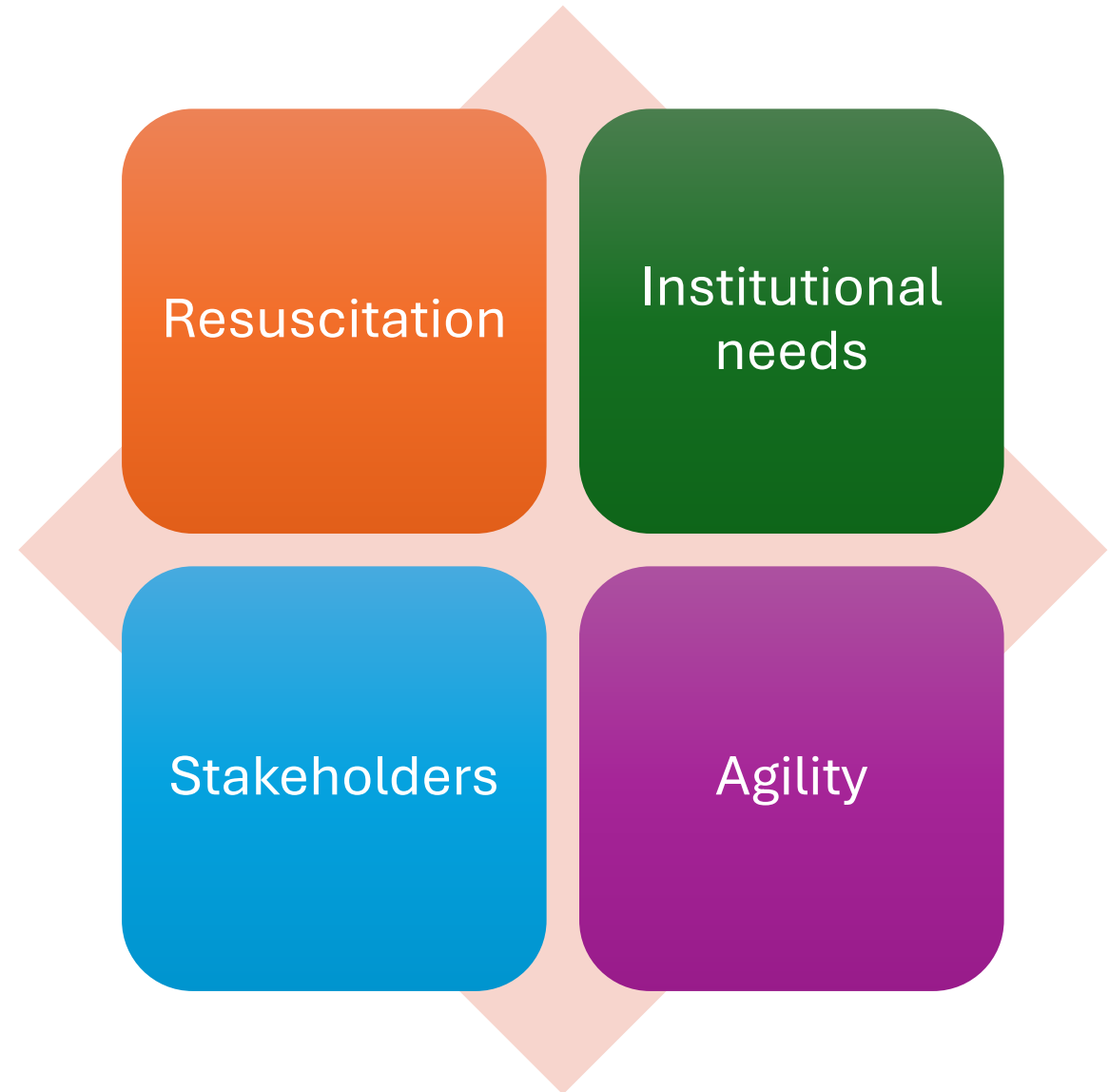
# What did we learn from COVID-19?

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- Differing perspectives are helpful, but proceed with caution
- Information overload
- Social Media
- Crisis leads to positive change
- Perspectives on oxygenation and managing respiratory failure
- Reaction versus Anticipation
- Ethical considerations



# Overview

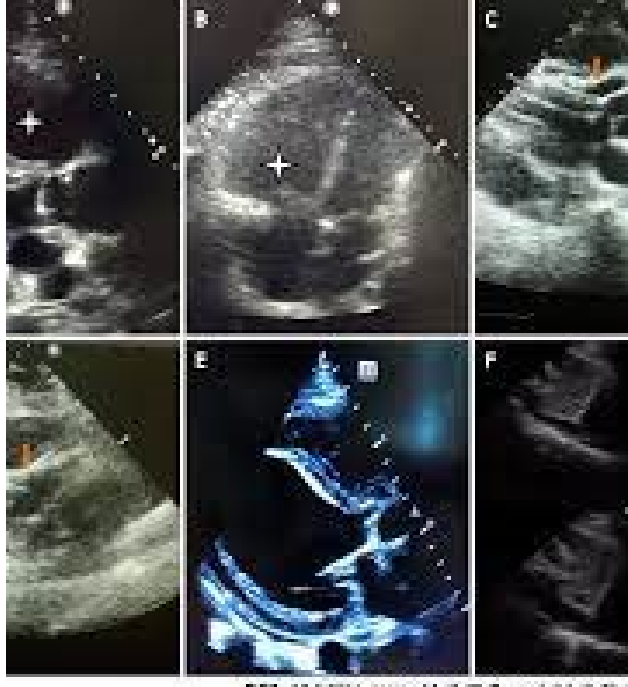
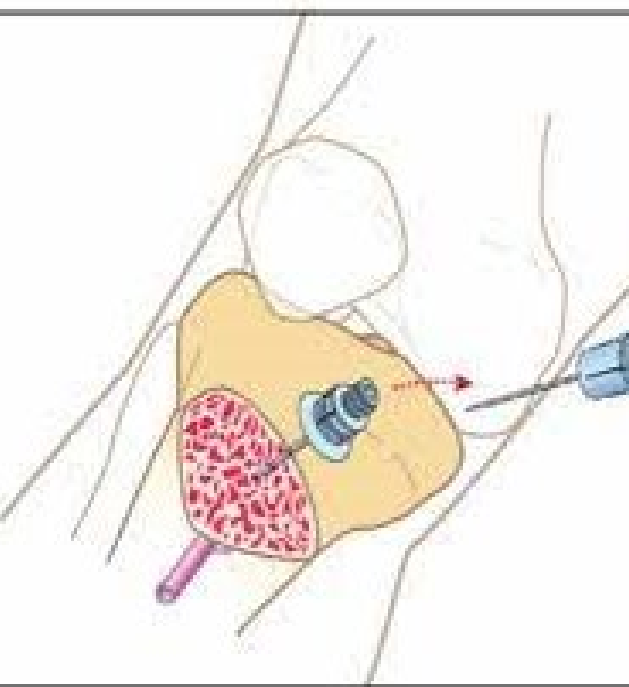


# Resuscitation Must haves!

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- Resuscitation equipment
  - Airway
  - Vascular access
  - Hemostasis/ hemorrhage control





DOI: 10.5402/2016/1214278 Copyright © The

# Resuscitation

- Point-of-care Ultrasound
- Iv flushes (sterile)
- Intraosseous access kits



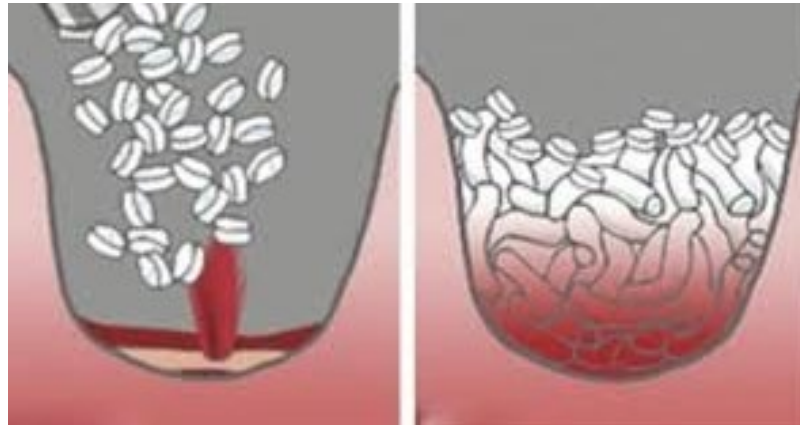


## Airway

- Diagnostic laryngoscopy
  - Glidescope (video)
  - Different ETT sizes
    - Bougie
- Disposable bronchoscopy







## SINGLE-HANDED APPLICATION



1. Pull the free end of the tourniquet to make it as tight as possible and secure the free end.



2. Spinning the windless (rod) until bleeding stops.



3. Secure the windless (rod) to keep the tourniquet tight.



4. Record the time the tourniquet was applied.



## Silver Nitrate ( $\text{AgNO}_3$ ) Sticks

Cautery Agent – Silver Nitrate

How and when to



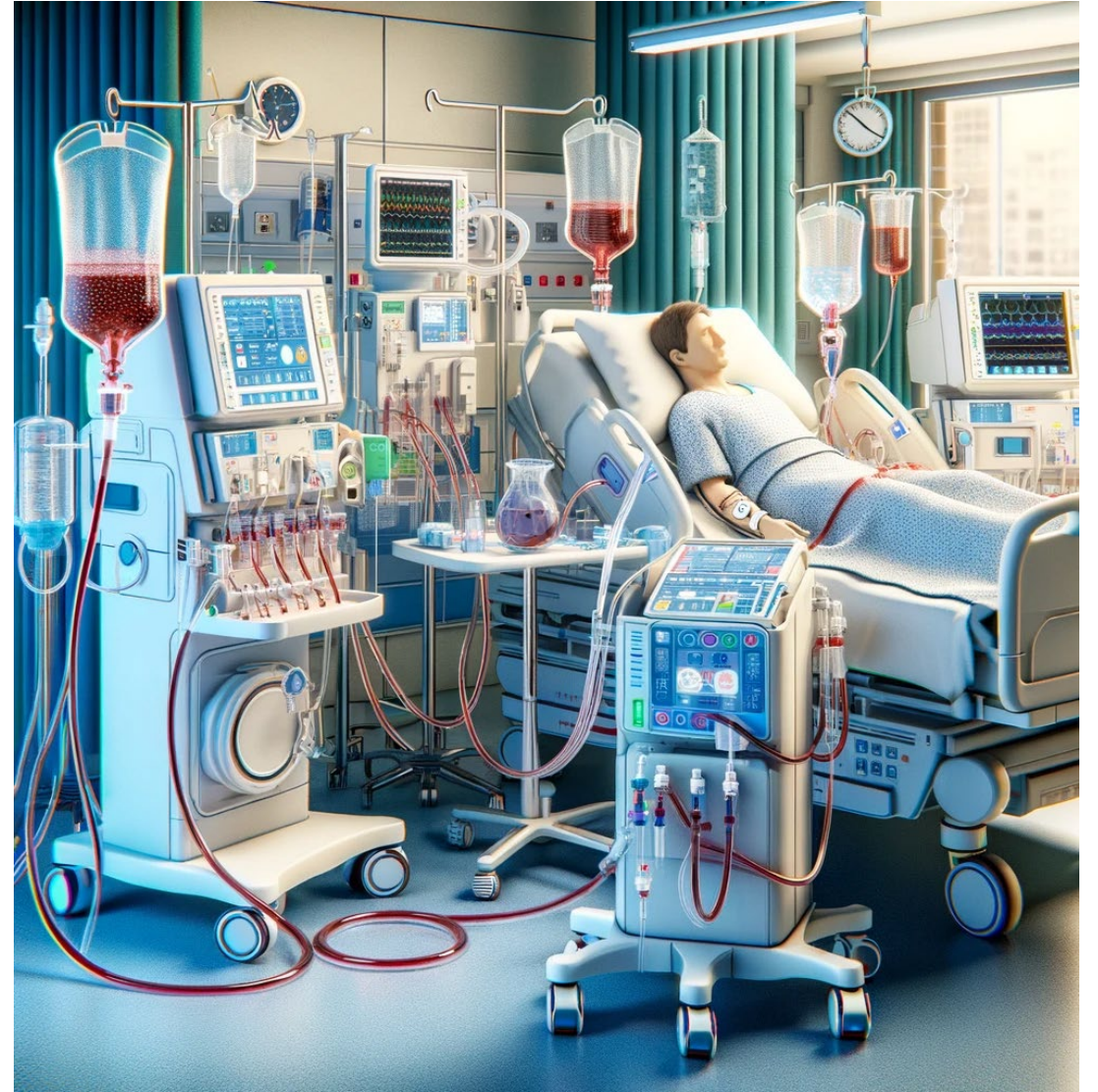
# Hemostasis

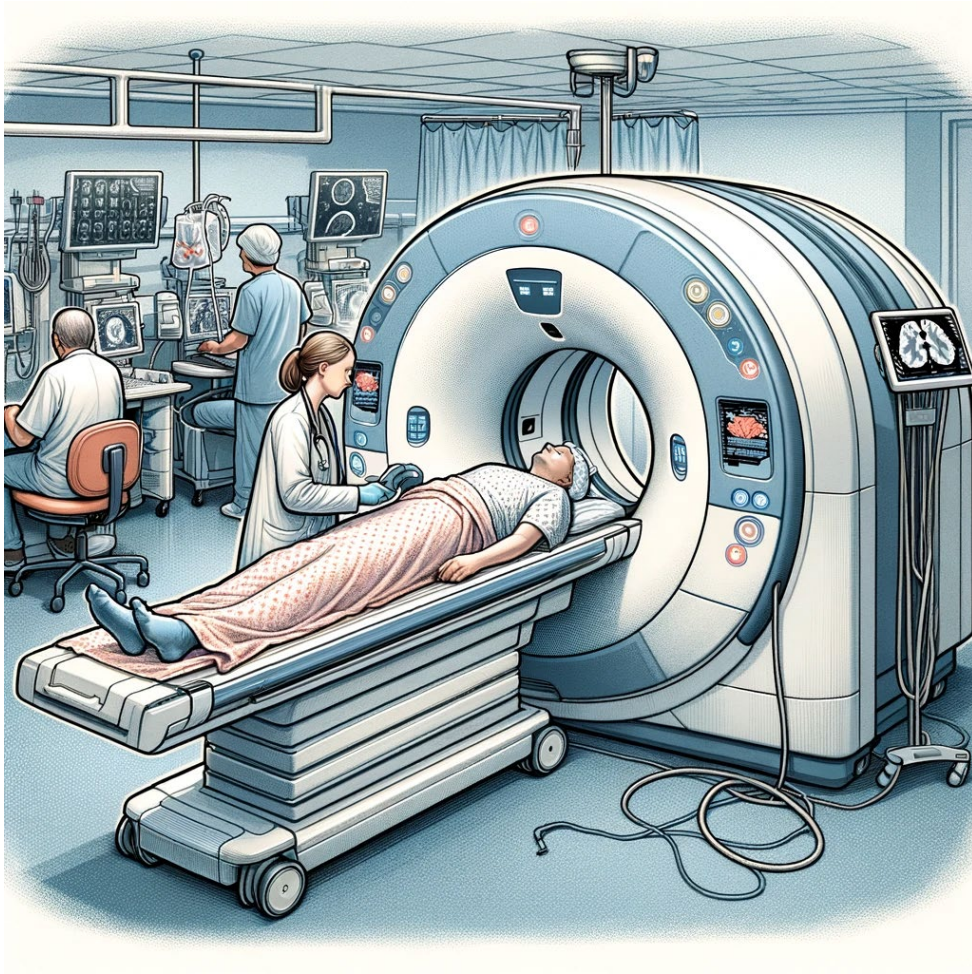


## Institution Capability and Expectations

# Advanced critical care devices

- 2<sup>nd</sup> and 3<sup>rd</sup> order consequences:
  - Distribution
  - Allocation
  - Supply chain
  - Ancillary/ support equipment
    - Filters, tubing, etc.
    - Heparin
      - bleeding complications
    - Insulin
    - Intravenous fluids
    - Prophylactic antibiotics
    - Volume and Frequency of laboratory testing





**Imaging, Transport, Portability**



# Space constraints



# Disposable and Single Use Devices

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# Point-of-Care laboratory testing

Rajsic S, Breitkopf R, Bachler M, Trembl B. Diagnostic Modalities in Critical Care: Point-of-Care Approach.

Diagnostics (Basel). 2021 Nov 25;11(12):2202. doi: 10.3390/diagnostics11122202.

PMID: 34943438; PMCID: PMC8700511.



## Centralized diagnostic

- Indication for diagnostic
- Order processing
- Collection of supplies
- Diagnostic (e.g. US, sampling)
- Specimen labelling
- Specimen ready for transport
- Transport of sample
- Specimen arrival in laboratory
- Specimen receipt within laboratory
- Analysis of sample
- Results of diagnostic
- Results available in medical chart
- Results reported to physician
- Specialty medical report
- Diagnosis
- Potential treatment update

**Turnaround time 1**

## Point-of-Care diagnostic

- Collection of supplies
- Diagnostic (e.g. US, sample)
- Analysis of sample
- Results of diagnostic at bedside
- Results reported to physician
- Diagnosis
- Potential treatment update

**Turnaround time 2**

# Reimagining Stakeholders

## Who?

- Changes over time
- Forgotten
- Maybe don't even know they exist?
- Relationship in a different capacity than previously

## Ethics

## Patient populations

- Health literacy
- Expectations
- Morbid obesity
- High prevalence of drug abuse
- Change in alcohol use patterns



# Population

Obesity

Substance use, abuse

- Alcohol withdrawal during COVID
- Opioid abuse

Psychiatry

OB

# Transport

Ability to transfer to definitive care

Open channels

Air

Land



# Agility

- What don't you need on this list?
- Reduce waste
- Iterative approach
  - Can you create a “living guideline” that is periodically updated



Questions?