

# Filling in the Gaps.

Guidance on the Gray Areas of Sterile Processing



**Mark Duro CRCST, FCS - Director of Education**



**Sterile Processing Direct**

**SPD** **STERILE  
PROCESSING  
DIRECT**

*Devoted to your sterile processing needs. Providing hand selected quality products that provide the best performance and products that promote patient safety and will save you money.*

# Mark Duro CRCST, FCS – Sterile Processing Direct - Director of Education

- Previous Director of Sterile Processing Operations at New England Baptist Hospital. Boston Brookline and Dedham MA
- IAHCMM Approved Instructor, Member since 1994
- Chairperson of IAHCMM Orthopedic Council 2008-2016
- AAMI ST79 Workgroup - Voting Member
- VP of Massachusetts Chapter of Central Service Professionals
- IAHCMM Fellow - 2011
- IAHCMM 2012 Educator of the Year
- IAHCMM President Elect
- Previous AORN Connections news advisor for sterile processing
- Previous AAMI ST79 Advisory Council member
- 2020 AAMI “Building for the future second edition”





# Filling in the Gaps

## Objectives

- Discuss discrepancies in Instructions for use and their inability to provide clear guidance on chemical indicators/integrators.
- Discuss areas that have no clear guidance such as tape usage, indicator placement and packaging usage.
- Discuss ways of implementing standardized changes within a facility.



# Filling in the Gaps

## Instructions for use



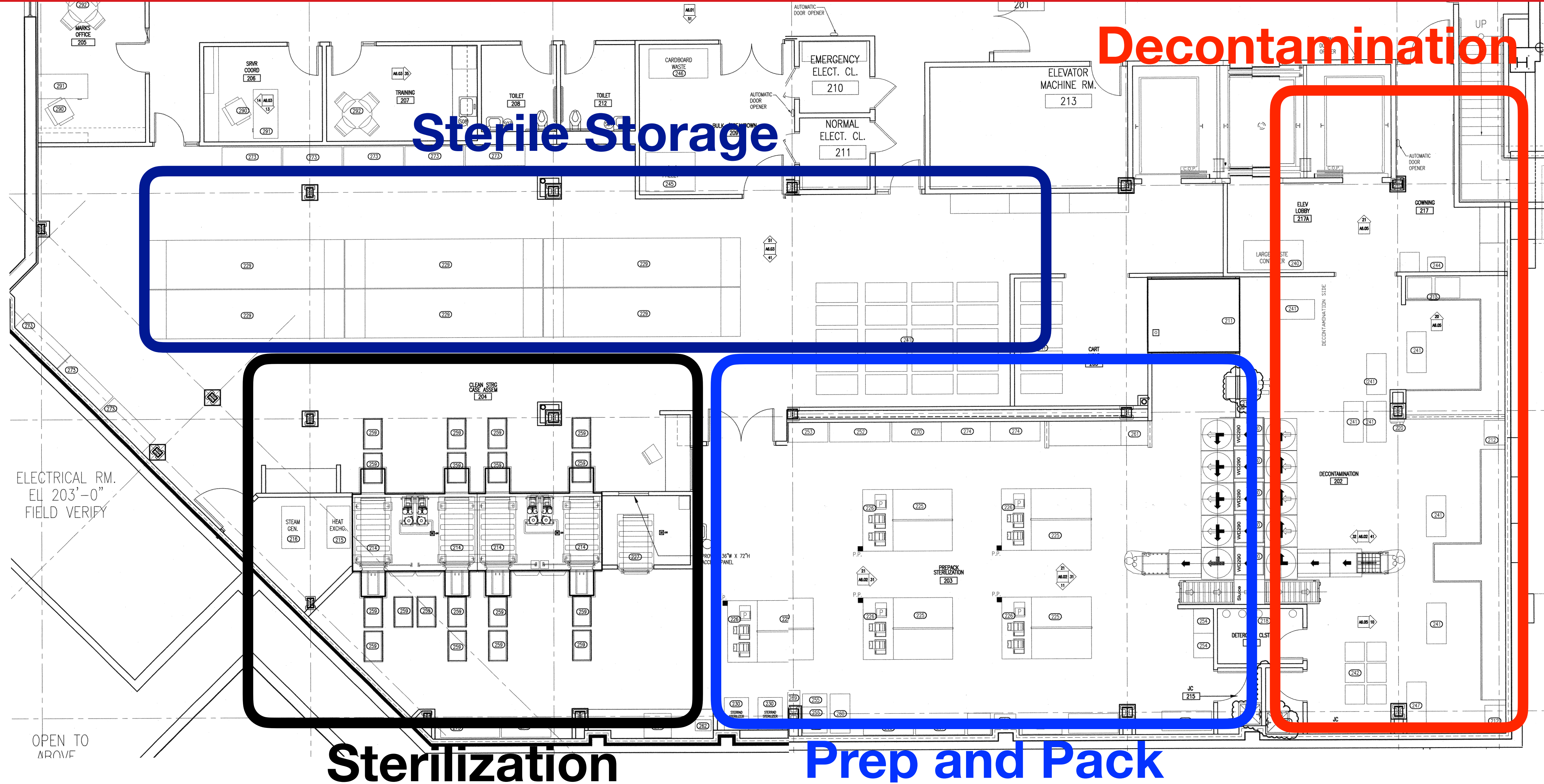
- Instructions for use for surgical instruments are not the only IFU's needed in Sterile Processing.

Let's take a look around the department to see what IFUs you may need to have on hand.....



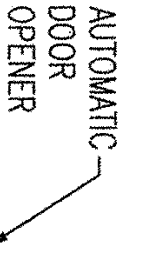


# Filling in the Gaps



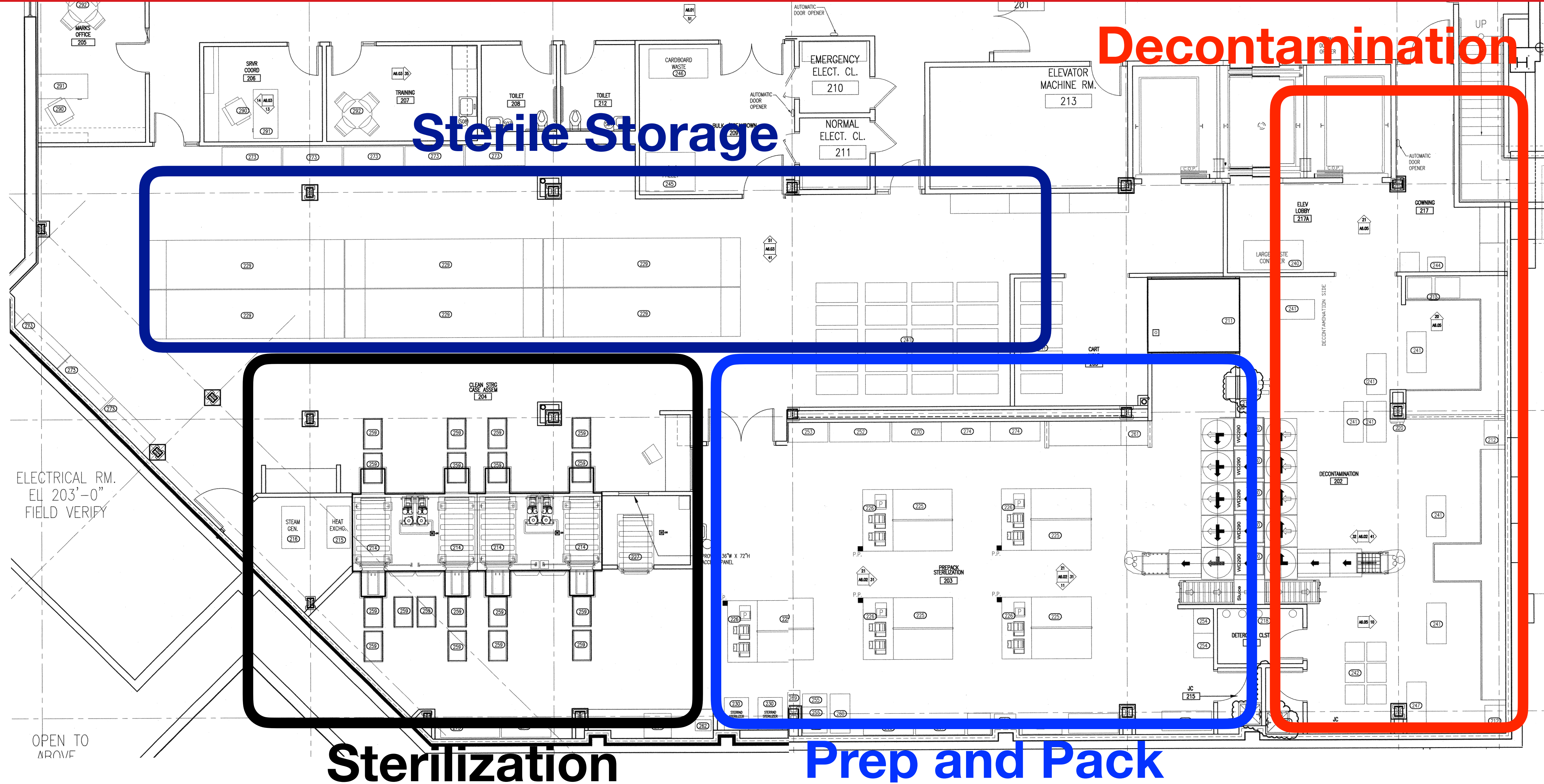


# Decontamination



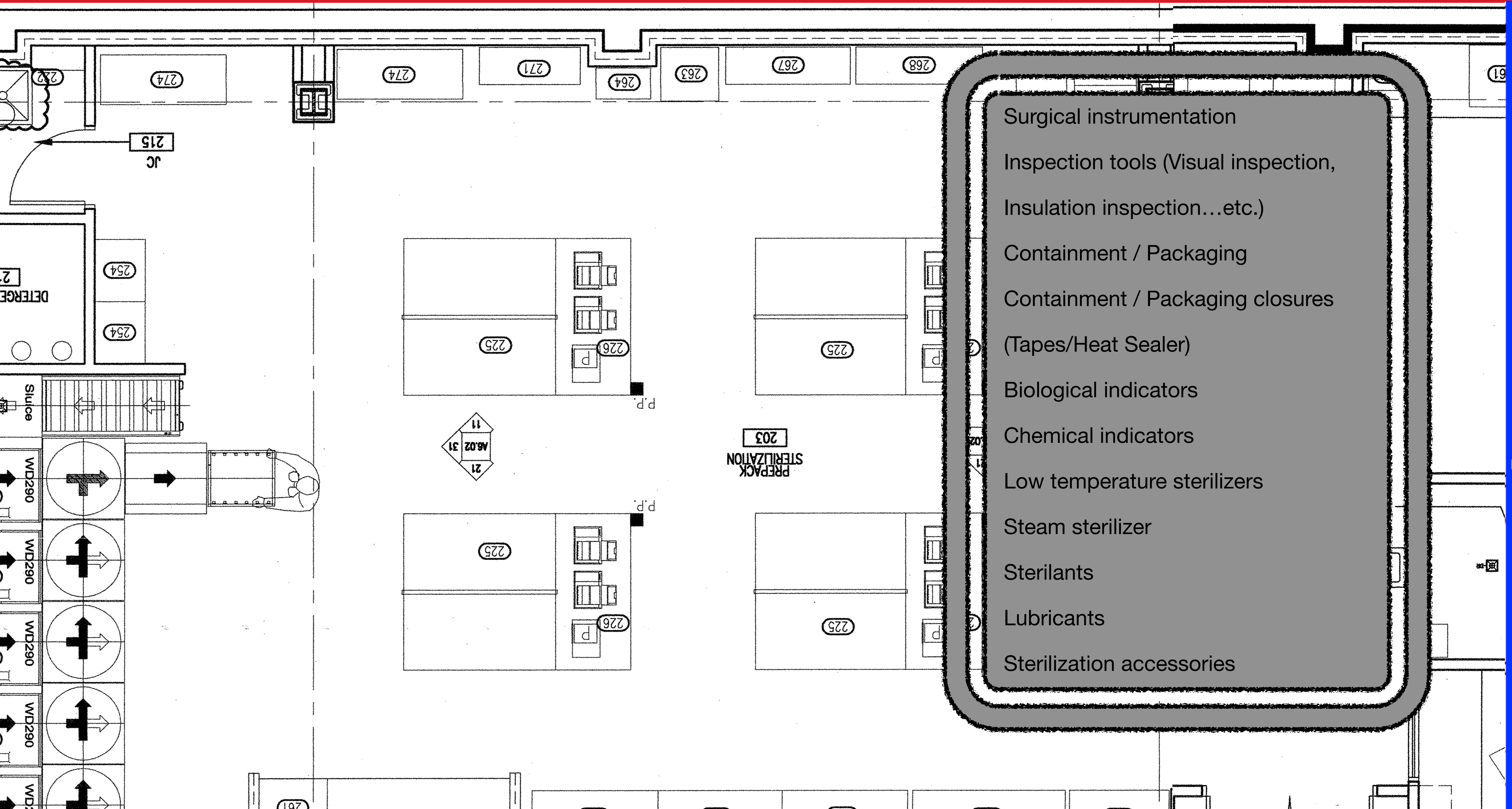


# Filling in the Gaps





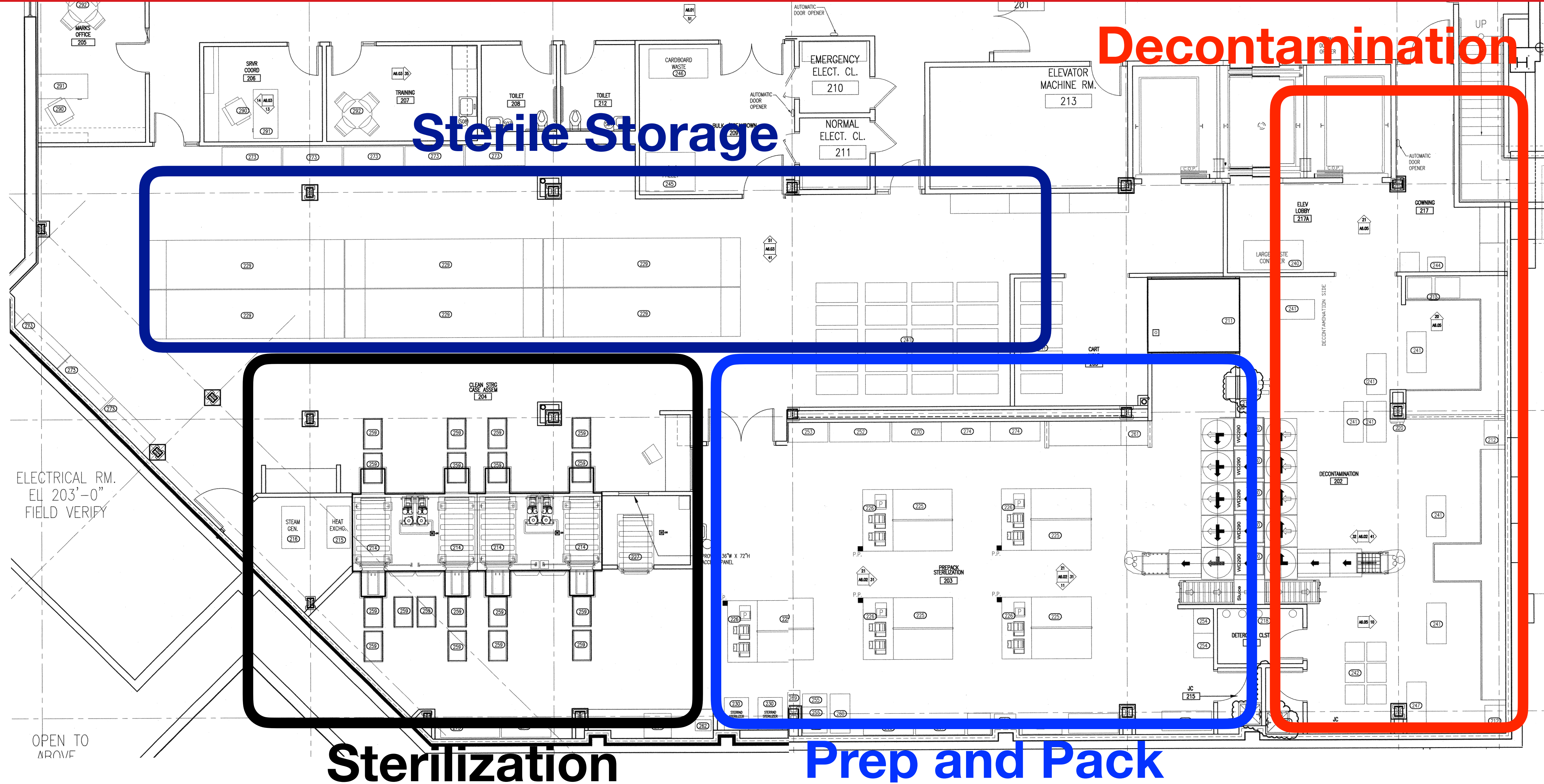
# Filling in the Gaps



# Prep and Pack



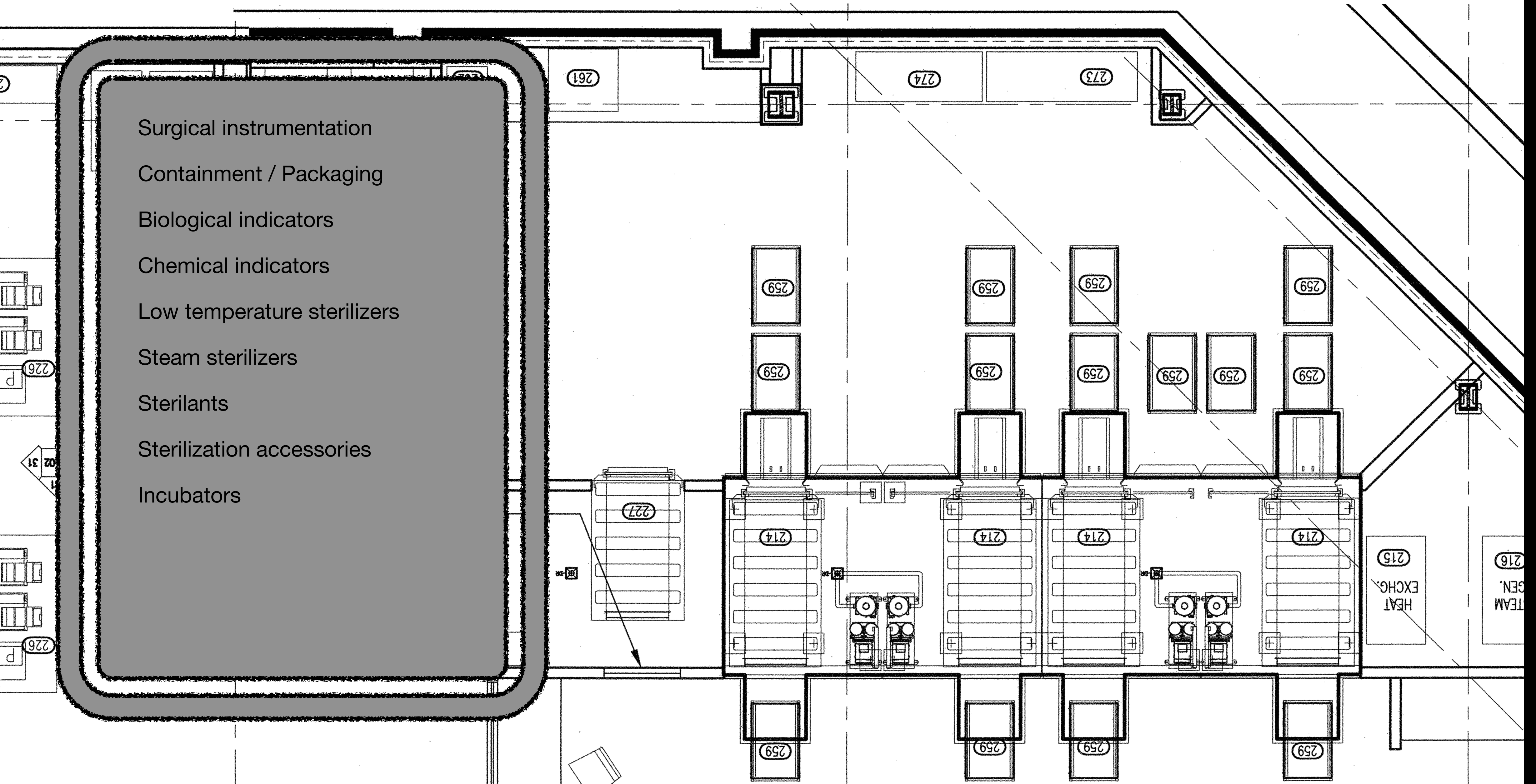
# Filling in the Gaps





# Filling in the Gaps

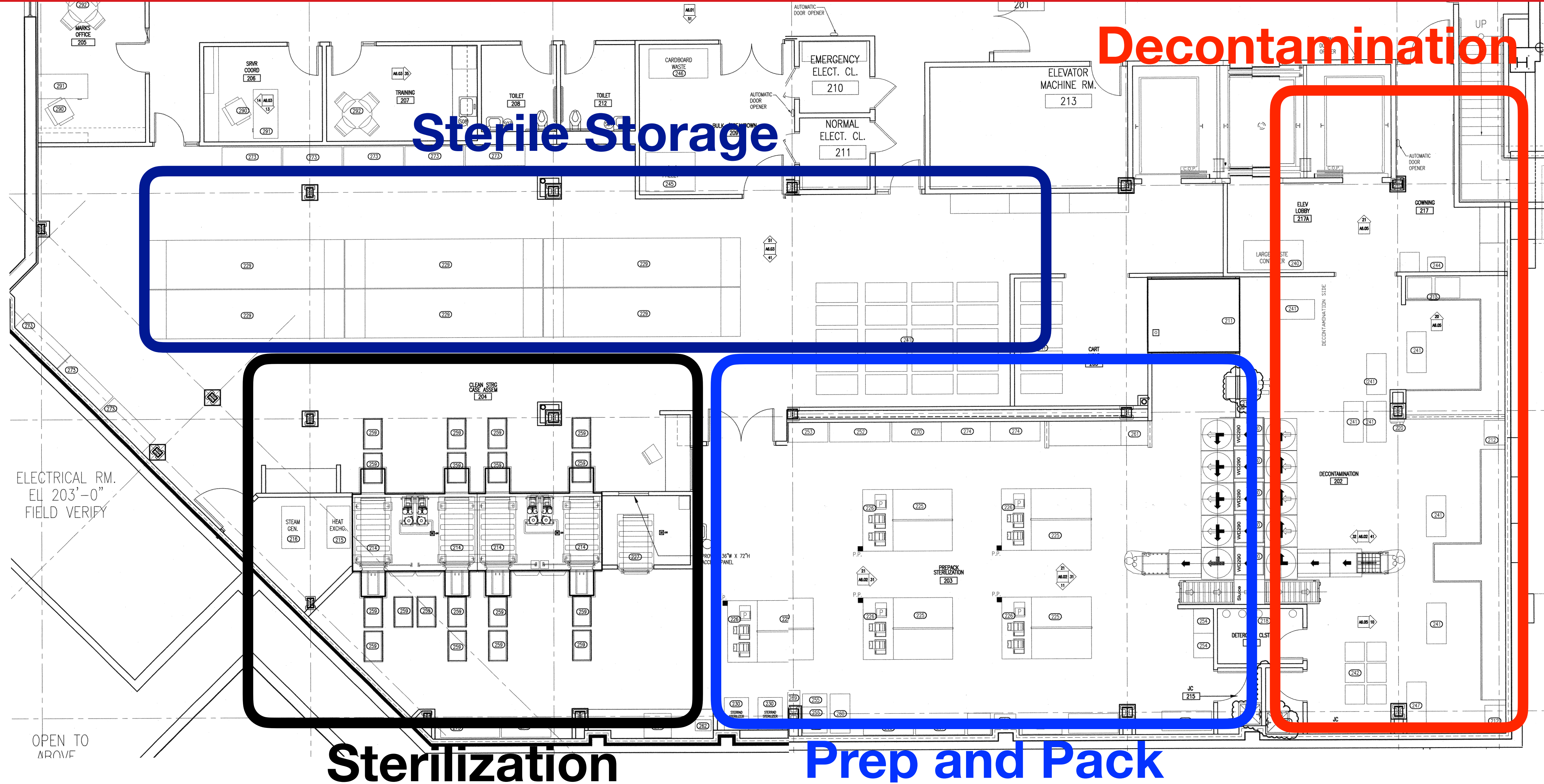
Surgical instrumentation  
Containment / Packaging  
Biological indicators  
Chemical indicators  
Low temperature sterilizers  
Steam sterilizers  
Sterilants  
Sterilization accessories  
Incubators



Sterilization

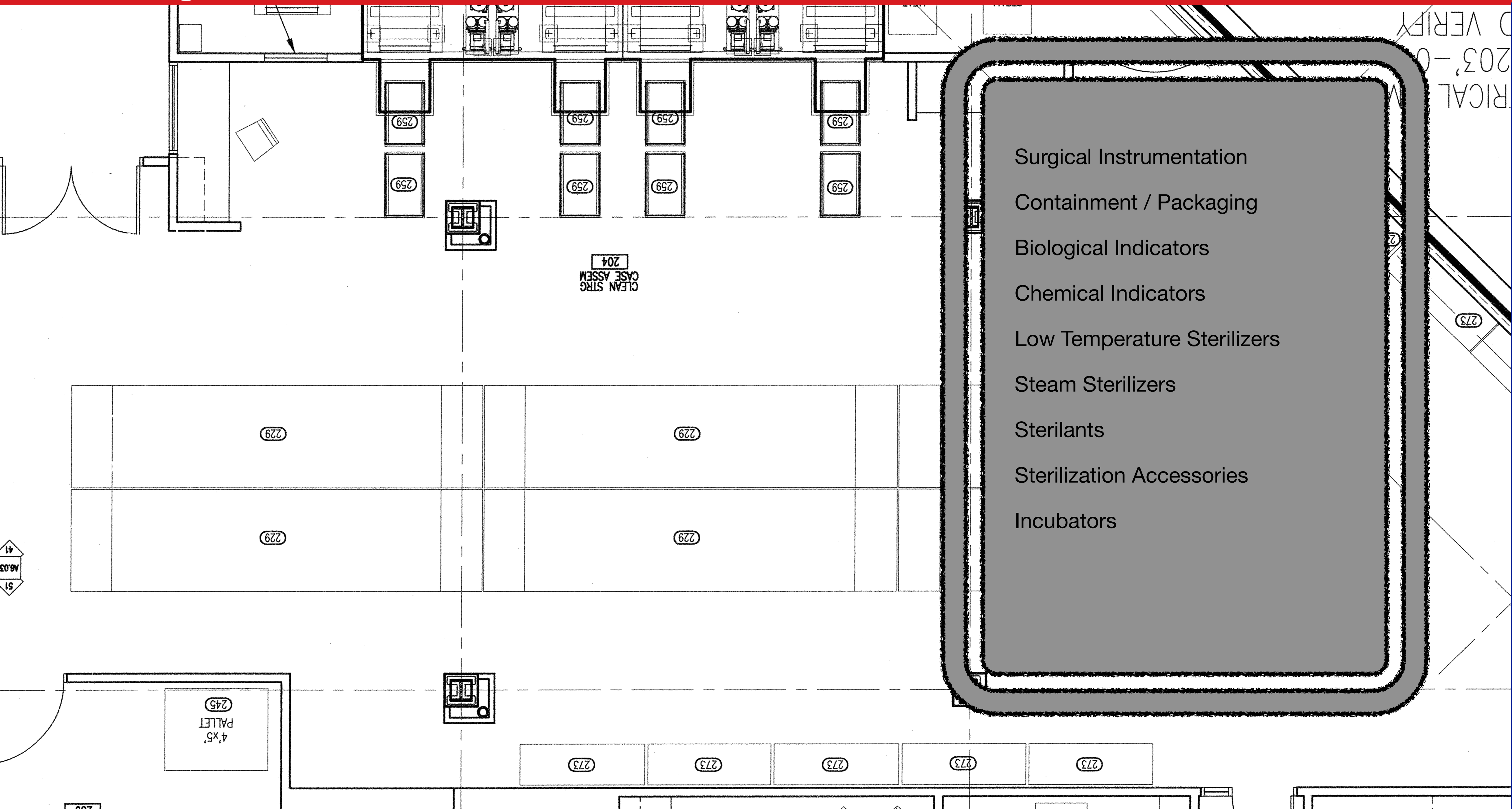


# Filling in the Gaps





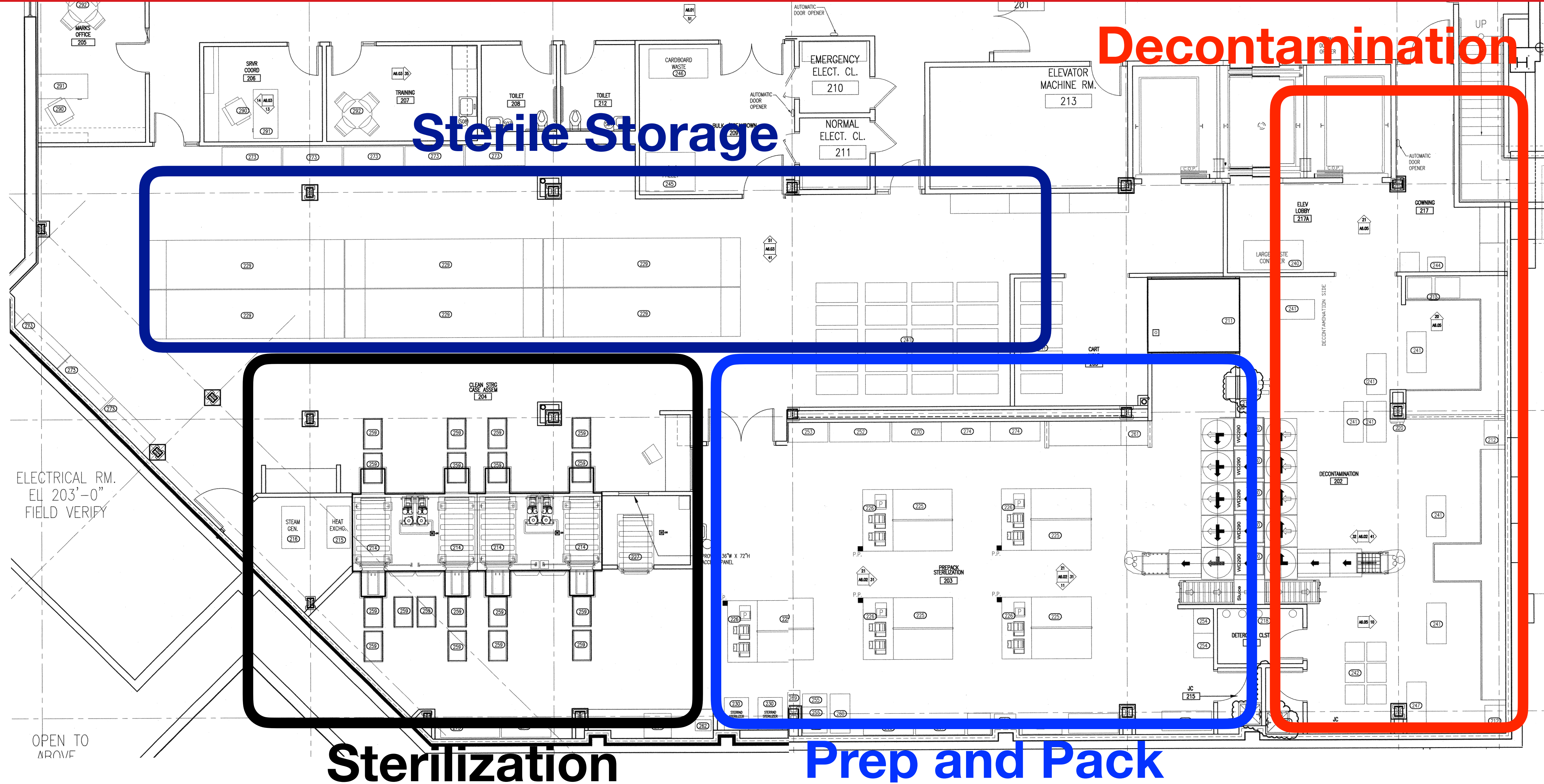
# Filling in the Gaps



Sterile Storage



# Filling in the Gaps



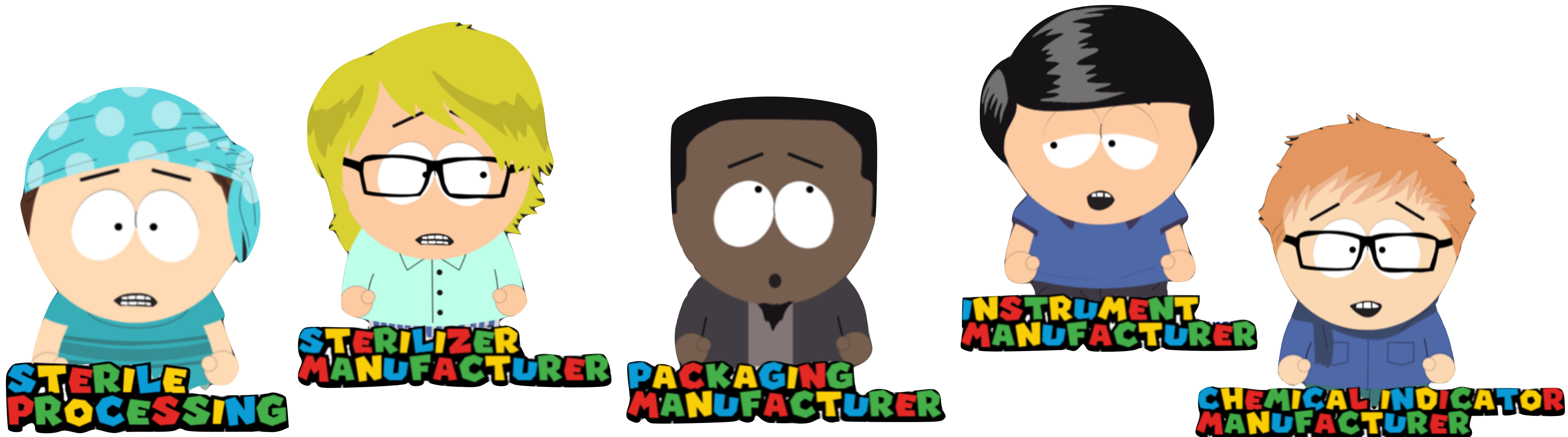


# Filling in the Gaps - Chemical Indicator Placement

## Situation

A new surgical instrument set arrives at your facility. The set is complex.

However the set is now in prep and pack. It was cleaned according to the IFU. Your colleague asks, “Where do we put the indicators and how many?”



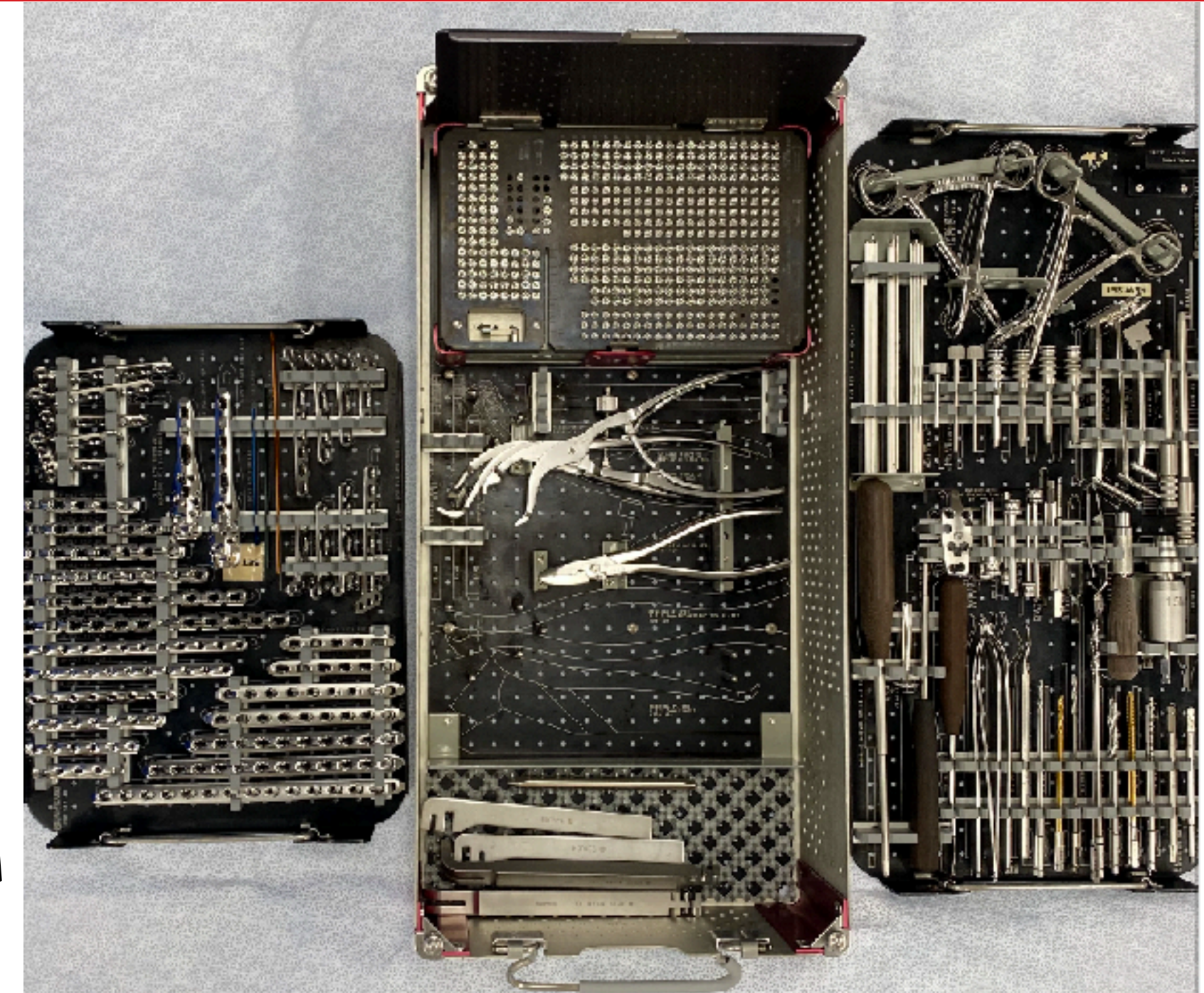


# Filling in the Gaps - Chemical Indicator Placement

## Situation

What we know:

- The set is complex orthopedic instruments.
- We have the IFU.
- Steam sterilize.
- Kit will be wrapped.
- Type 5 migrating integrators used at this facility.





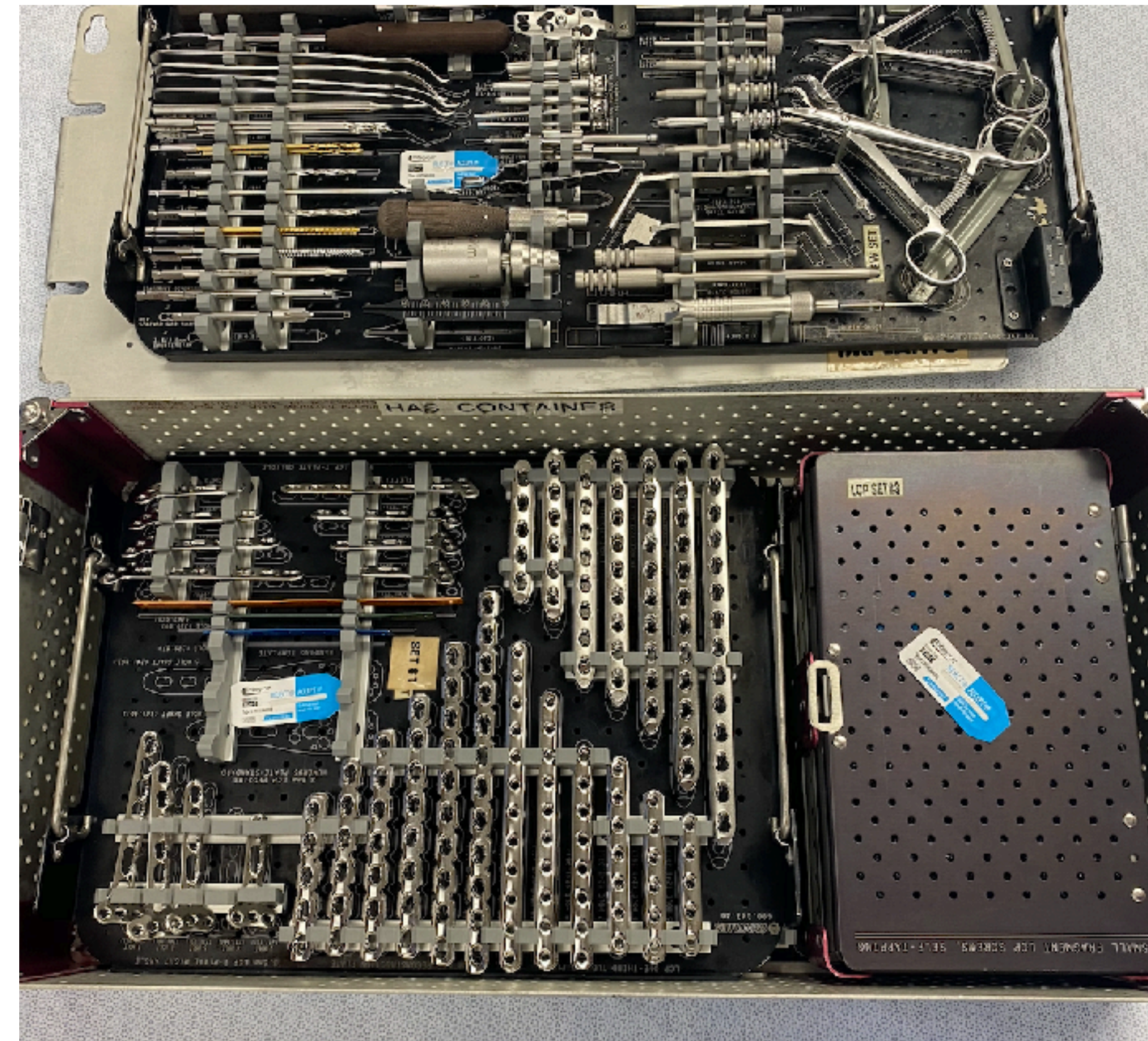
# Filling in the Gaps - Chemical Indicator Placement

## Situation



However, it is now in prep and pack as it was cleaned according to the IFU. Your colleague asks where do we put the indicators and how many?

Where do you start?





# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement



Where do we put the indicators?

What tools do we have to determine this?

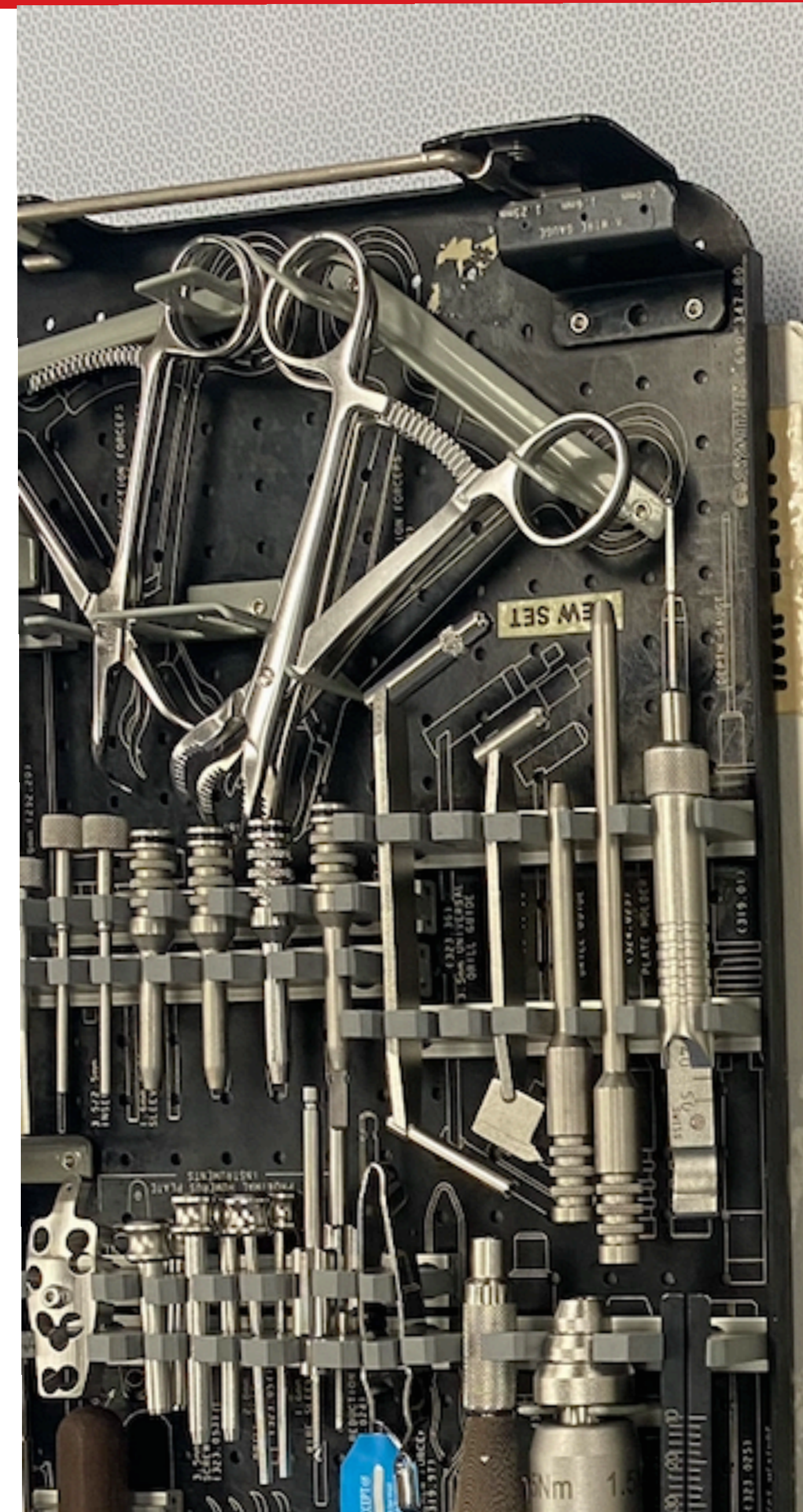
AAMI 

AORN 

Instrument IFU 

Indicator IFU 

Containment IFU 





# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

What does AAMI say?



### 13.5.2.1 General considerations

Chemical indicators should be

- a) used to assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer;
- b) **used in accordance with the CI manufacturer's written IFU;**
- c) used as part of an effective quality assurance program; and
- d) used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process.

The "pass" response of a CI does not prove that the item monitored by the indicator is sterile.





# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

What does AAMI say?



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# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

## Chemical Indicator Types



Type 1 chemical indicators are also known as Process Indicators. These types of indicators are external and indicate whether an instrument set has been fully exposed to the sterilization process. Indicator tape and labels placed on the outside of a peel pack are examples of Type 1 chemical indicators.

Type 2 chemical indicators are indicators for use in specific tests. These types of chemical indicators are used in specific procedures defined by sterilization standards. For example, Bowie Dick tests are used for a steam sterilizer with a pre-vacuum cycle to check the efficiency of the air removal and steam penetration in the autoclave chamber.





# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

## Chemical Indicator Types



Type 3 chemical indicators are known as Single-Variable Indicators. These CIs react to one of the critical parameters (e.g., time, temperature, pressure) of the sterilization process, and indicate exposure to a sterilization cycle at stated values of the specific parameters.

Type 4 chemical indicators, also known as Multi-Variable Indicators, react to two or more critical parameters of the sterilization process, and indicate exposure to the cycle at stated values of the chosen parameters. Time and temperature are examples of critical parameters that would be chosen for a steam sterilization process.



# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

## Chemical Indicator Types



Type 5 chemical indicators are also known as Integrating Indicators, or Integrators. These CIs are designed to react to all critical parameters over a determined range of sterilization cycles. The performance of Type 5 Indicators have been correlated to the performance of biological indicators.

Type 6 chemical indicators are known as Cycle Specific Indicators and are designed to react to all critical parameters for specified sterilization cycles. For example, each Type 6 CI for a steam sterilization monitors the specific temperature and time of a chosen sterilization cycle.



# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

What does AORN say?



4.4.1

**Place the CI in an area within the package that presents the greatest challenge for air removal and sterilant contact.**

**Consult** the IFU from the **CI manufacturer**, the **device manufacturer**, and the **containment device manufacturer** for additional information.

The **number and placement of internal CIs** may be affected by the **contents of the package**, the configuration of the items within the set, and the packaging or containment device.<sup>4,10,62</sup> **The package manufacturer's** IFU provide information about the location that presents the greatest challenge for sterilization.





# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

What does AORN say?

4.4.1



CHEMICAL INDICATOR  
MANUFACTURER



INSTRUMENT  
MANUFACTURER



PACKAGING  
MANUFACTURER

Place the CI in an area within the package that presents the greatest challenge for air removal and sterilant contact.

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The number and placement of internal CIs may be affected by the contents of the package, the configuration of the items within the set, and the packaging or containment device. The package manufacturer's IFU provide information about the location that presents the greatest challenge for sterilization.





# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

What does AORN say?



### 4.4.2

When more than one internal CI is required for multilayered trays, place these according to the **tray manufacturer's IFU** and product quality assurance testing results (See Recommendation 10.2).

The **package manufacturer's IFU** provide information about the location that presents the greatest challenge for sterilization in an empty container. Containers are sometimes purchased empty and the organization builds the set according to the organization's needs. Sets that are customized pose sterilization challenges within the set based on the set configuration. Performing **quality assurance product testing** for these custom sets can assist in determining the location that is most challenging for sterilant contact and optimal CI placement.





# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

What does AORN say?



4.4.2

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# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

What does AORN say?



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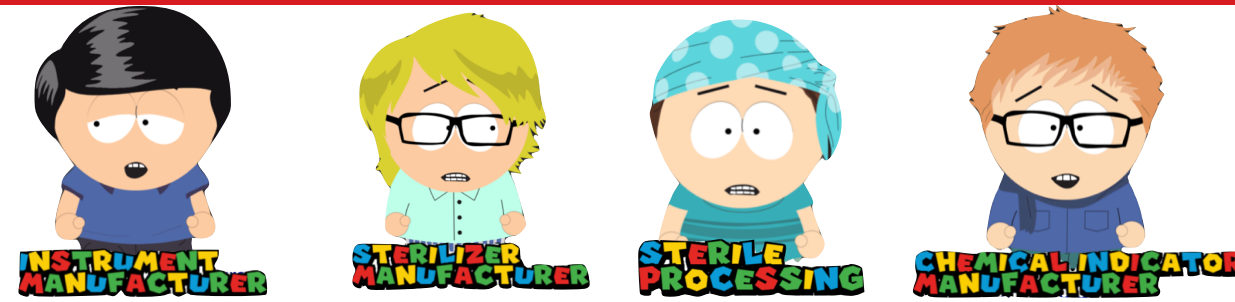
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# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement



What does the packaging (**Container**) manufacturer recommend?



### 6.4 Internal Process Indicators

Per AAMI ST79, internal process indicators are used to indicate that the container has been exposed to the sterilization process. If more than one basket/tray is used inside the container system, **an indicator should be placed on each basket/tray.**

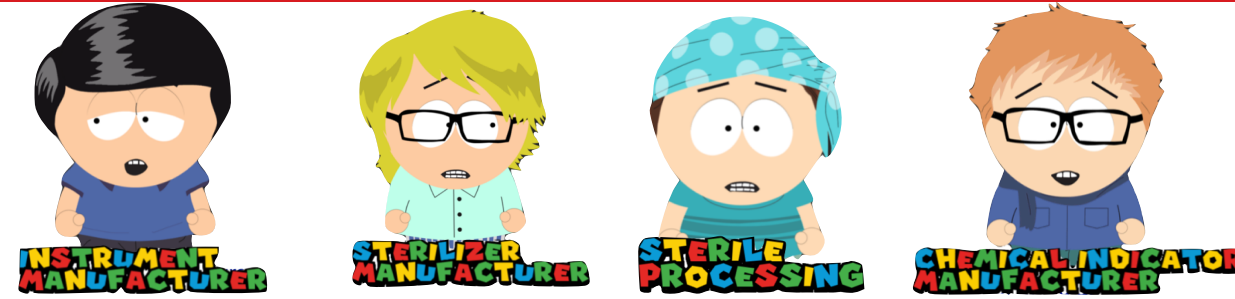
The internal biological and/or **chemical indicators may be placed in the center of each tray, unless the user feels a more challenging position exists elsewhere.** In that case, place the chemical indicator where **the user has determined the most challenging location.** Use of internal indicators should be in accordance with the facility's policies and procedures.

Process indicators are designed to indicate that the device was exposed to the sterilization process while, integrating indicators are designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for Bis. See AAMI ST79 for full description and use of each type of chemical indicator.



# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement



What does the packaging (**Wrap**) manufacturer recommend?



There is not much guidance to specific placement of CI's in numerous wrap IFU's. Many just explain the types of indicators and its usage.

Makes sense as they inevitably tested for the worst case scenario (weights, lumens, complexity..etc) as the container and pouch manufacturer tested for.

So where should the guidance come from??

Let's keep looking.



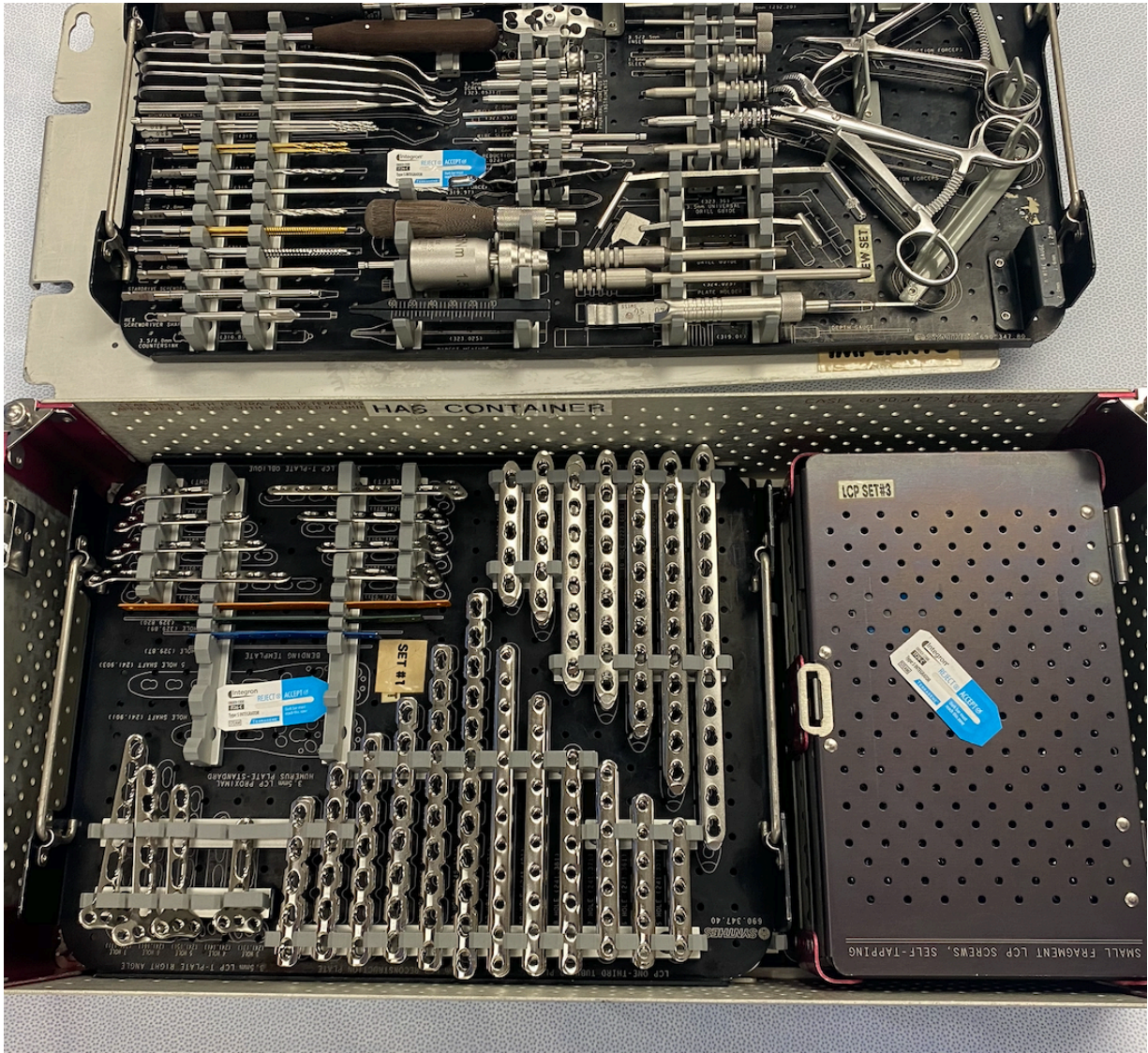
# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

What does the instrument IFU say?



The IFU for this device does not give information on indicator placement. Most Instrument IFU's will not provide this guidance.



|                  |  |
|------------------|--|
| <p>Packaging</p> | <ul style="list-style-type: none"><li>Only legally marketed, FDA-cleared sterilization barriers (e.g. wraps, pouches or containers) should be used by the end-user for packaging terminally sterilized devices.</li><li><b>Rigid Sterilization Container Use Instructions and Considerations</b><br/>In order to ensure proper sterilization of Synthes' devices when using a rigid sterilization container, the following must be taken into consideration:<ul style="list-style-type: none"><li>Only FDA-cleared rigid sterilization containers may be used with Synthes' devices and loaded graphic cases (a graphic case with all or part of its assigned contents).</li><li>The rigid sterilization container manufacturer's instructions for use are to be followed. If questions arise regarding the use of the rigid sterilization container, Synthes recommends contacting the manufacturer of that specific container for guidance.</li><li>The options in using rigid sterilization containers with Synthes' devices and loaded graphic cases are as follows:<ul style="list-style-type: none"><li>No more than one (1) fully loaded graphic case can be placed directly into a rigid sterilization container.</li><li>Instrument trays from no more than one (1) loaded graphic case can be placed in the rigid sterilization container.</li><li>Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.</li></ul></li><li>Rigid sterilization container must have a maximum volume to vent ratio of no greater than 127in<sup>3</sup>/in<sup>2</sup>. For any questions related to the volume to vent ratio, please contact the container manufacturer.</li><li>Only rigid sterilization containers approved for pre-vacuum steam sterilization can be used with Synthes' devices and loaded graphic cases following the sterilization parameters provided by Synthes.</li><li>End-users should follow ANSI/AAMI ST79 for additional information concerning the use of rigid sterilization containers.</li></ul></li></ul> |
|------------------|--|



# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement



What does the CI manufacturers IFU say?



Vendor 1

Place a Steam Chemical Integrator in each pack, peel pouch, container system or tray to be steam sterilized in the area determined to be the least accessible to steam penetration. \*\*Contact device manufacturer and container manufacturer for number and location of indicators.



# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement



What does the CI manufacturers IFU say?



### Vendor 2

Place a Integrator **inside each pack or minimally in every load** (i.e. middle of the load or inside the densest pack) to be sterilized.

Process the load according to the sterilizer manufacturer's instructions.

Release the load or pack if the dark bar on the integrator has entered the blue SAFE area. If the dark bar has not entered into the blue SAFE area, DO NOT release the load or pack.



# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement



What does the CI manufacturers IFU say?

Vendor 3

Place chemical integrator in each pack, peel pouch, container system or tray to be steam sterilized in the area determined to be the least accessible to steam penetration.



**CHEMICAL INDICATOR  
MANUFACTURER**



# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement



What does the CI manufacturers IFU say?

Vendor 4

Place a Integrating Indicator into each pack to be sterilized. Position the integrator in that area judged to be the most resistant to steam penetration. Upon completion of the sterilization cycle, release the sterilized items using departmental procedures.



**CHEMICAL INDICATOR  
MANUFACTURER**



# Filling in the Gaps - Chemical Indicator Placement

## Indicator Placement

AAMI says to check with CI Manufacturer.

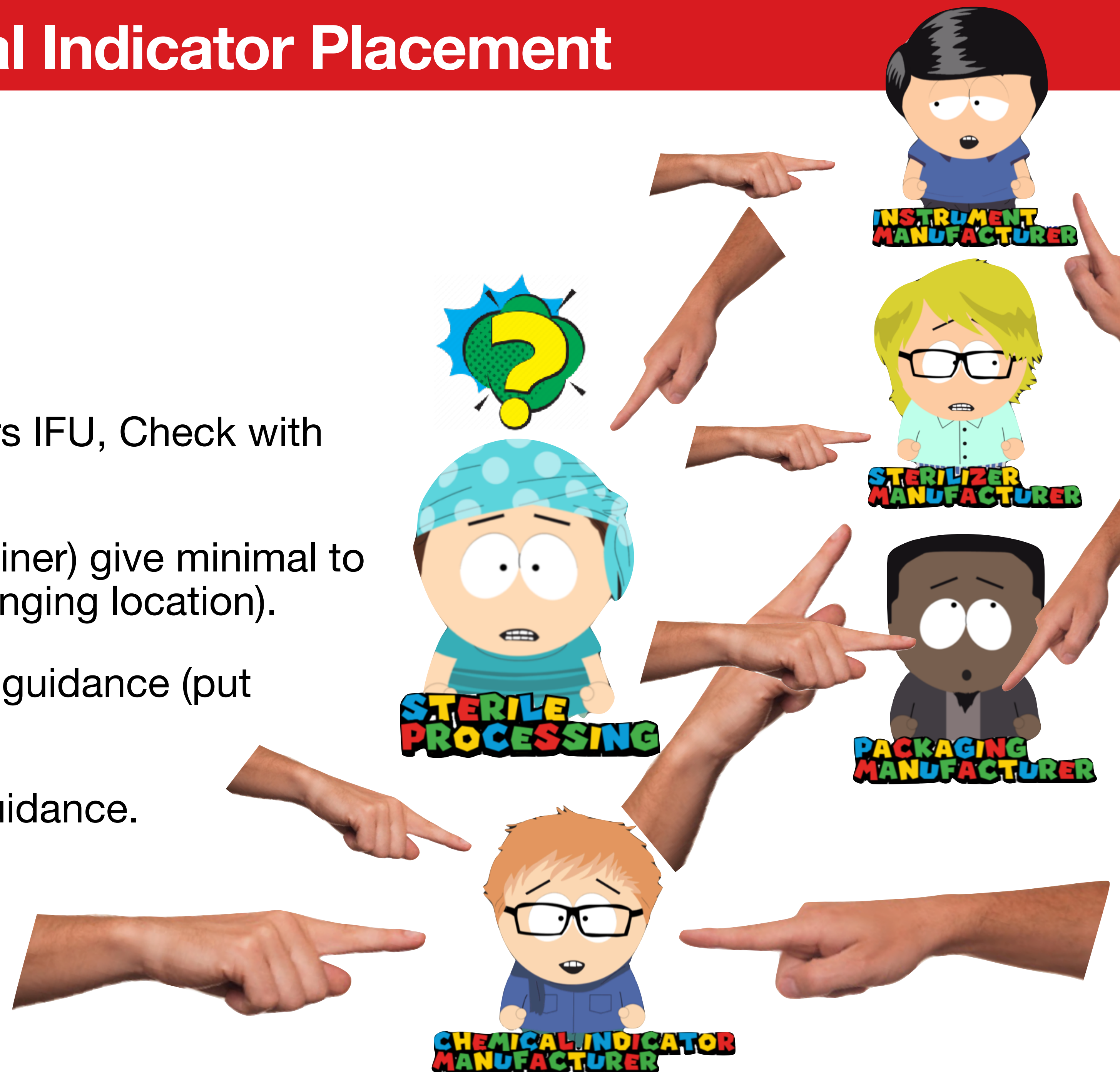
AORN says to consult with tray manufacturers IFU, Check with packaging manufacturer for placement.

Packaging systems (wrap, pouch, rigid container) give minimal to no guidance (put indicators in the most challenging location).

Instrument manufacturers also provide basic guidance (put indicators in the most challenging location).

Sterilizer manufacturers provide little to no guidance.

Are there other resources?





## Comment from Noted Industry Expert

- “Where do I put them? Everywhere. Seriously, put them where the process might have some problems to achieve sterility, such as inside each package where they will be seen when opened in the sterile field. For multilayer trays, use at least one per layer, preferably more, with special attention given to areas where a heavy item is located. Place one between an item and the part of the tray or container holding it. In other words, place them in the easy-to-sterilize locations and the hard ones, too.”

Jonathan A. Wilder, Ph.D., Managing Director:

[www.ultracleansystems.com/cleaning-indicators-what-exactly-are-they-telling-us-about-washer-disinfectors-2/](http://www.ultracleansystems.com/cleaning-indicators-what-exactly-are-they-telling-us-about-washer-disinfectors-2/)



# Filling in the Gaps - Chemical Indicator Placement

## Comments from Industry

| Type 5 Indicator supplemental recommendation  | Rational  |
|---|---|
| Do not fold, bend or cut  | May disrupt the function of the migrating indicator   |
| Do not wrap indicators  | May disrupt the function of the migrating indicator   |
| Do not wedge between instruments  | May disrupt the function of the migrating indicator   |
| Do not weave or place inside stringer ring handles  | May disrupt the function of the migrating indicator   |
| Do not use to prop instruments in the open position   | May disrupt the function of the migrating indicator   |
| Use caution with implants and caddies   | May disrupt implant position, stick or leave residual |
| Avoid placing indicator in a location where pressure is being applied to it   | May disrupt the function of the migrating indicator   |
| Do not use sterilization tape internally to secure any items within the containment device with the exception of product testing. | Tape is a Type1 EXTERNAL indicator                    |
| Avoid moisture prior to sterilization   | May compromise the indicator function                 |



# Filling in the Gaps - Chemical Indicator Placement

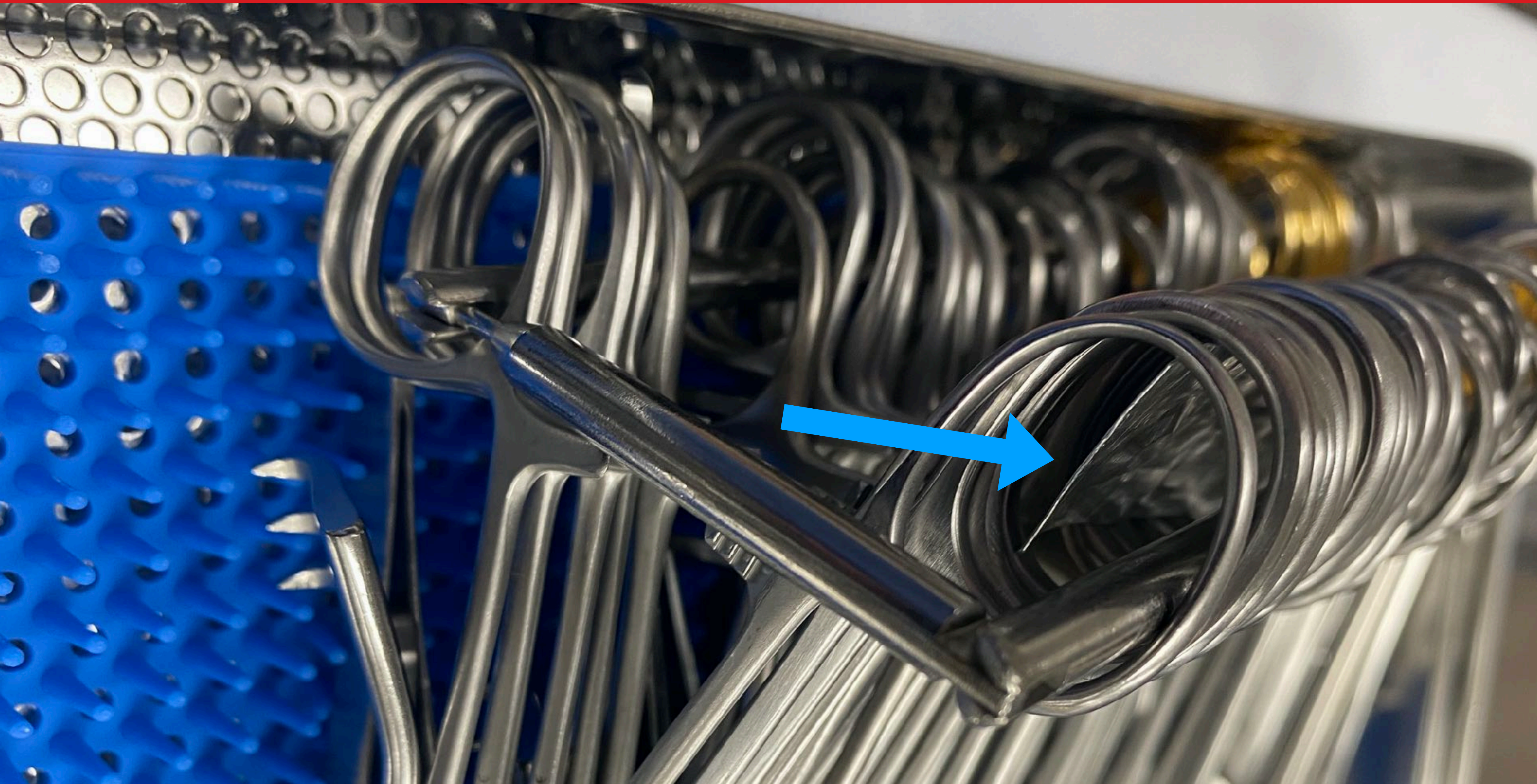
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# Filling in the Gaps - Chemical Indicator Placement

## What we know - The Basics

Basins





# Filling in the Gaps - Chemical Indicator Placement

## What we know - The Basics

Graduates/bowls

One indicator





# Filling in the Gaps - Chemical Indicator Placement

## What we know - The Basics

Towel packs

One indicator

Do you make your own towel packs?





# Filling in the Gaps - Chemical Indicator Placement

## What we know - The Basics

Peel pouches

Place indicator where it can be easily seen.

Avoid placing indicators in a way that it interrupts the seal.

If double pouching place indicator in the inner most pouch.



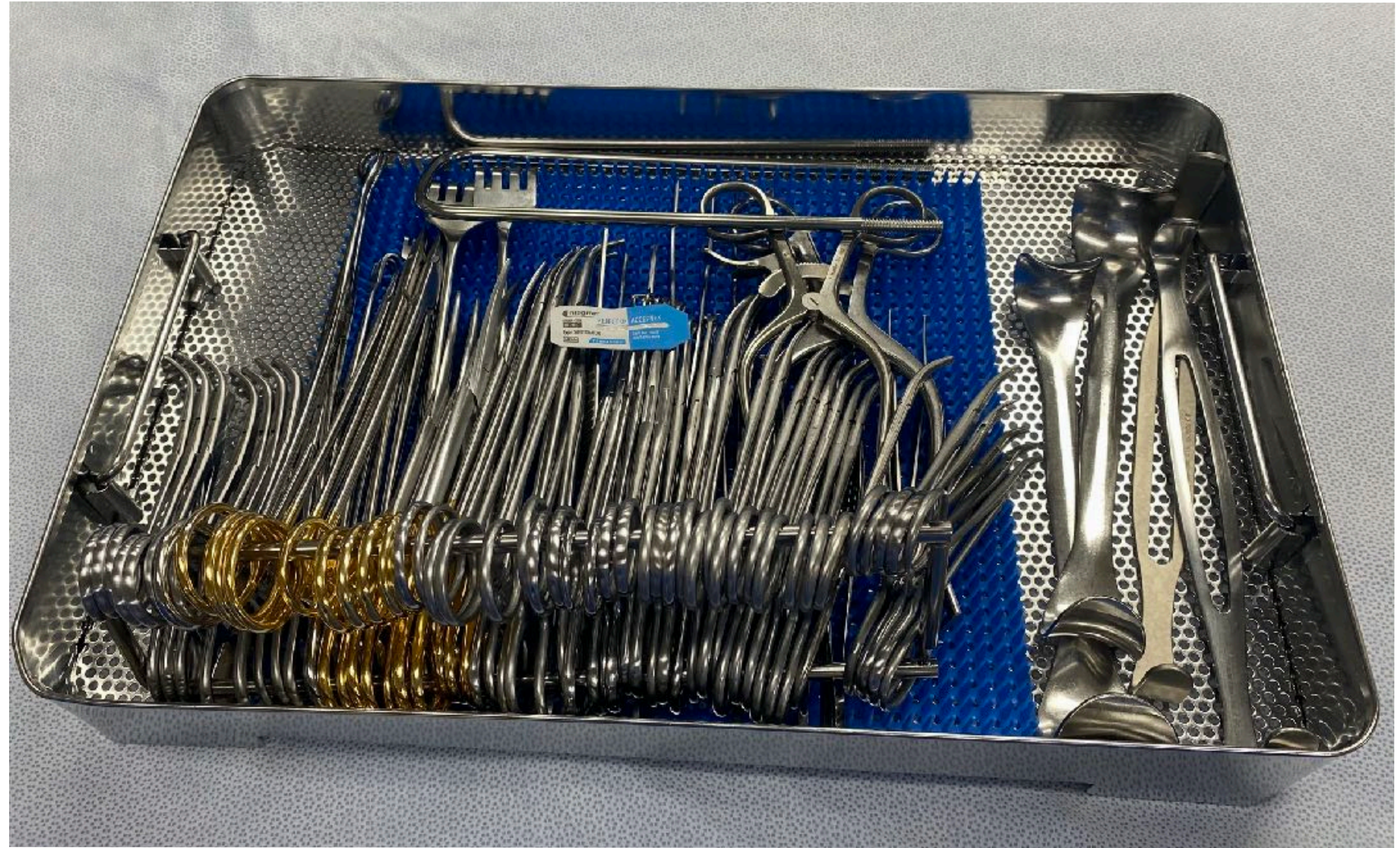


# Filling in the Gaps - Chemical Indicator Placement

## What we know - The Basics

Wrapped kit

One indicator positioned  
in geometric center





# Filling in the Gaps - Chemical Indicator Placement

## What we know - The Basics

Containerized kit

\*Two indicators in opposite corners on each level.





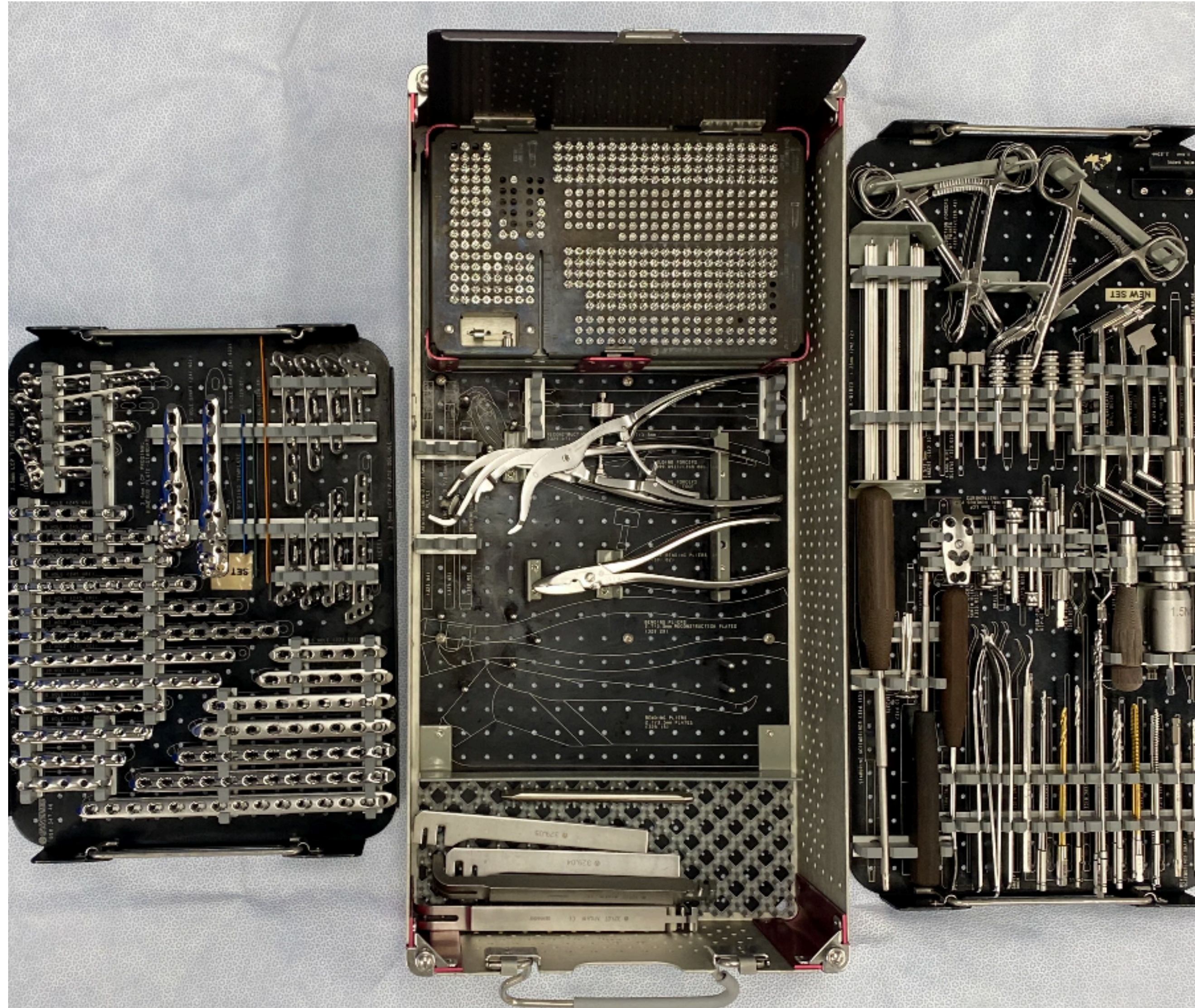
# Filling in the Gaps - Chemical Indicator Placement

**Now what do we do?**

Now that we have this information what is next?

Knowing the data lets also apply critical thinking skills.

...and what is critical thinking?

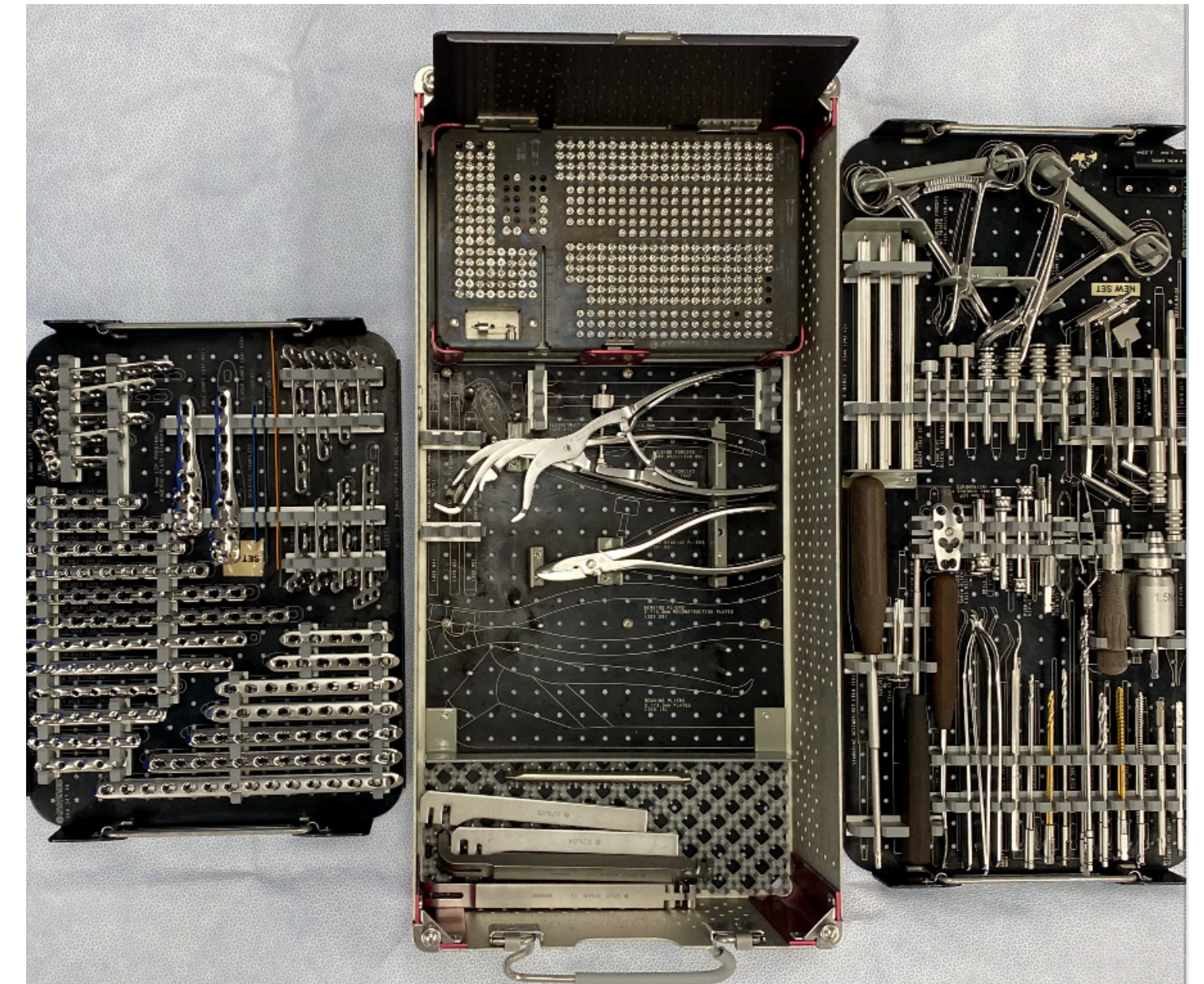




# Filling in the Gaps - Chemical Indicator Placement

## Now what do we do?

Critical thinking is the intellectually disciplined process of actively and skillfully conceptualizing, applying, analyzing, synthesizing, and/or evaluating information gathered from, or generated by, observation, experience, reflection, reasoning, or communication, as a guide to belief and action. In its exemplary form, it is based on universal intellectual values that transcend subject matter divisions: clarity, accuracy, precision, consistency, relevance, sound evidence, good reasons, depth, breadth, and fairness.

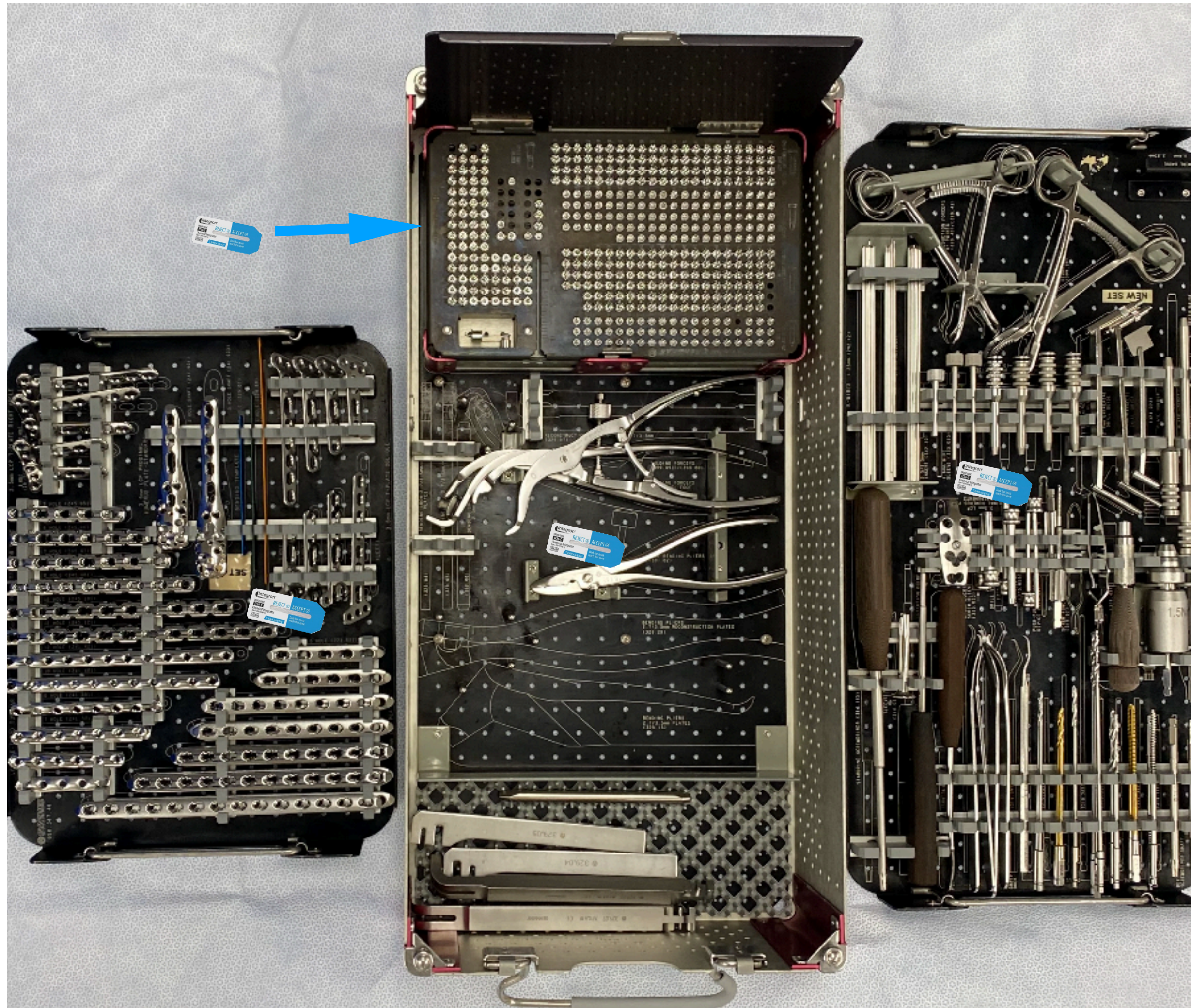


What is this guy saying????????



# Filling in the Gaps - Chemical Indicator Placement

Now what do we do?





# Filling in the Gaps - Tape Usage

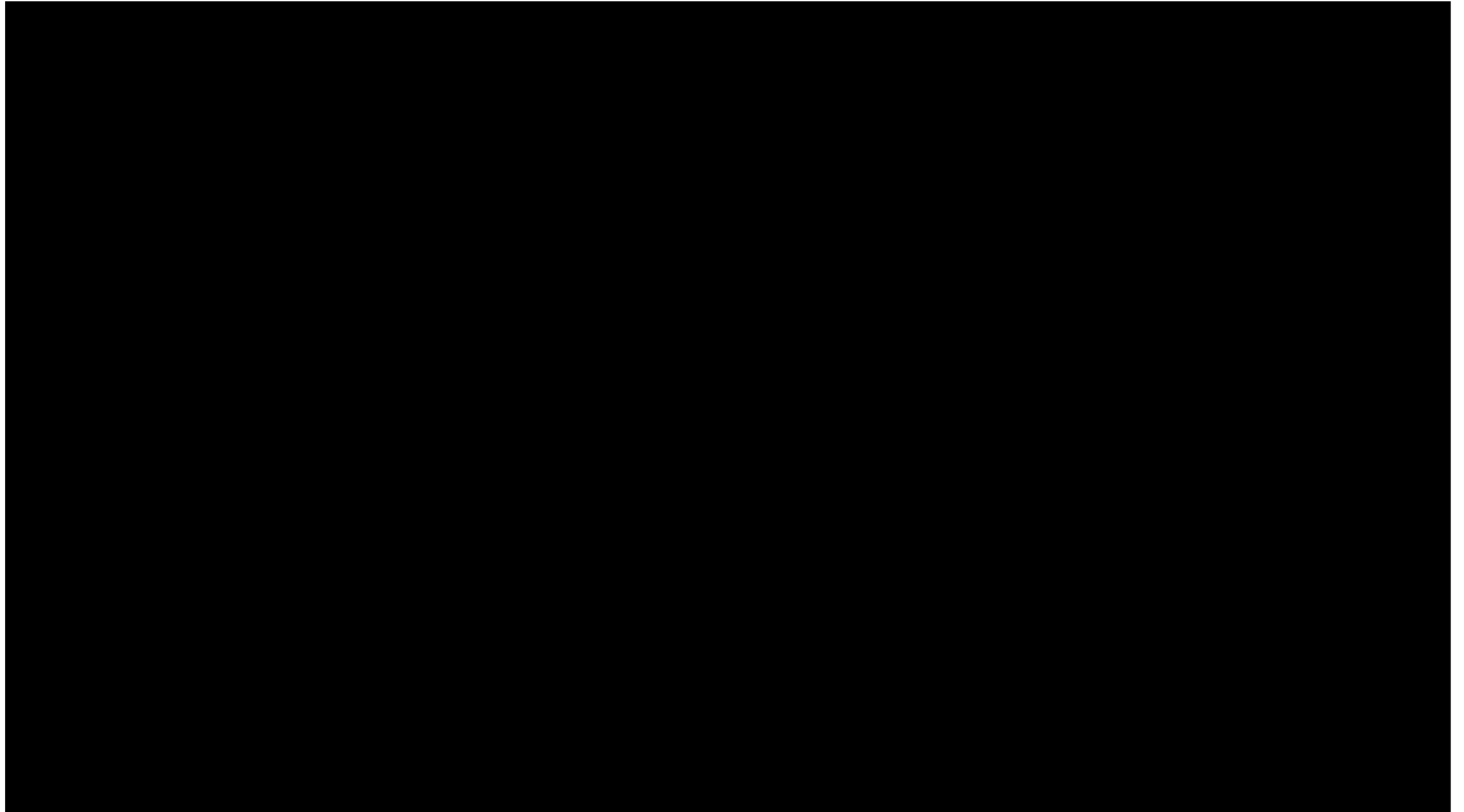
## Using tape should be easy?

Guidance on tape from manufacturers as well as AAMI recommends securing packages with one or two pieces of packaging tape. Depending on the size, weight and design of the item to be wrapped additional tape may be needed.

An important note that was commonly stated in manufacturers' instructions for use is that when tape is applied to a pack it be firmly placed by hand on the package being processed. Failure to firmly place tape on packages could result in adhesive failure or lifting of tape. The length of tape being used to secure packs needs to be long enough to secure the pack over the top and front portion of the package.



# Reducing lost instruments - Infomercial break





# Filling in the Gaps - Tape Usage

## Using tape should be easy?

Guidance from some tape manufacturers are extremely vague.

Some tapes have pliability where others do not.

There is limited guidance for application.

Consistency in facilities (this is how I do it, at my last facility this is how we did it, I saw it done this way on FB) varies based on the preference of the technician.

Does your tape stick well? If not there are options that may help reduce tape adhesive failure.

Its like the wild west.....Have you been on facebook??



# Filling in the Gaps - Tape Usage

## Using tape should be easy?

### Examples of packaging with tape variation

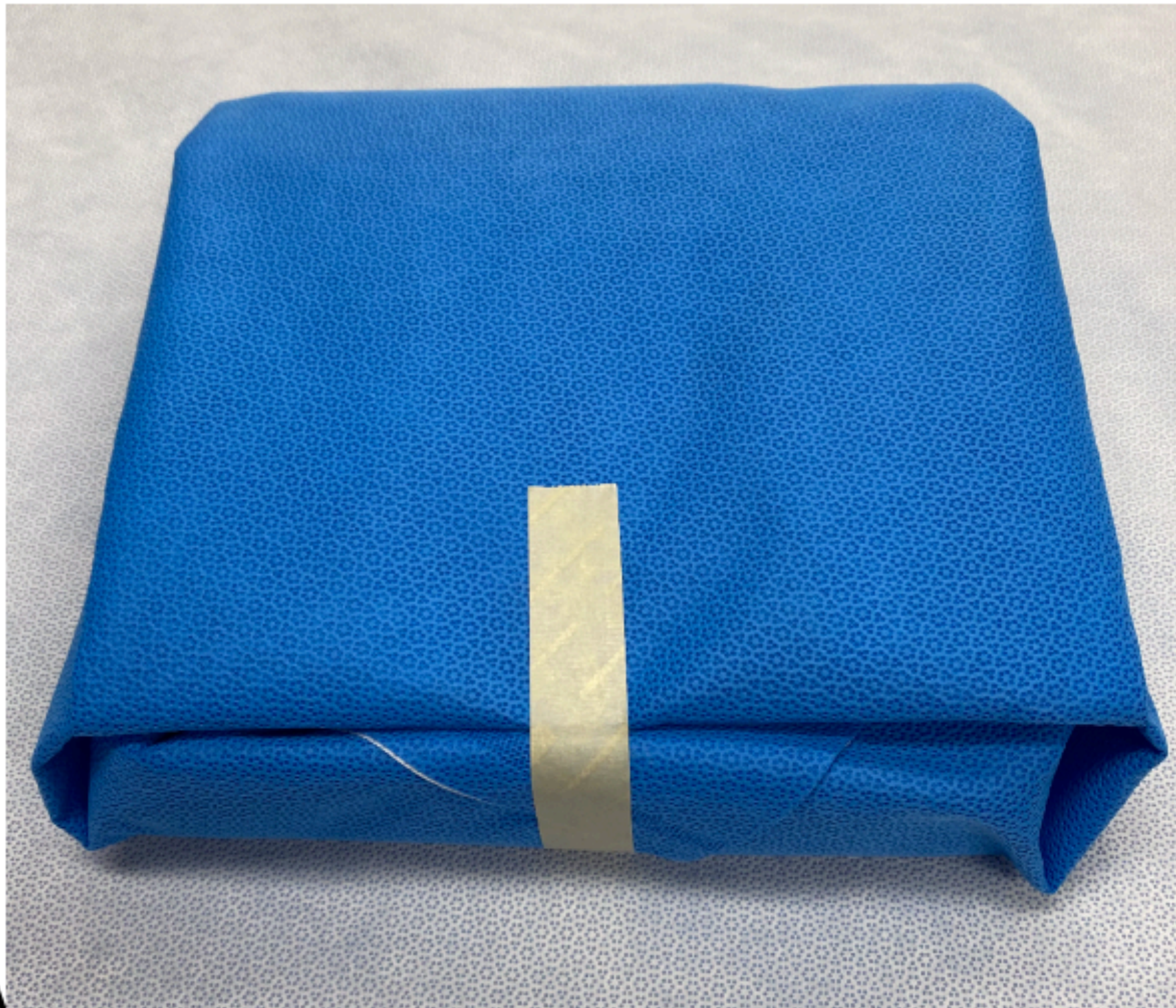


Fig A



FigA1

The above image is commonly used for smaller light weight sets (1-5lbs), if using one strip of tape that will be covering the optional pull tab from the pack. Consideration should be given to adding a tape pull tab (Fig A1).



# Filling in the Gaps - Tape Usage

**Using tape should be easy?**

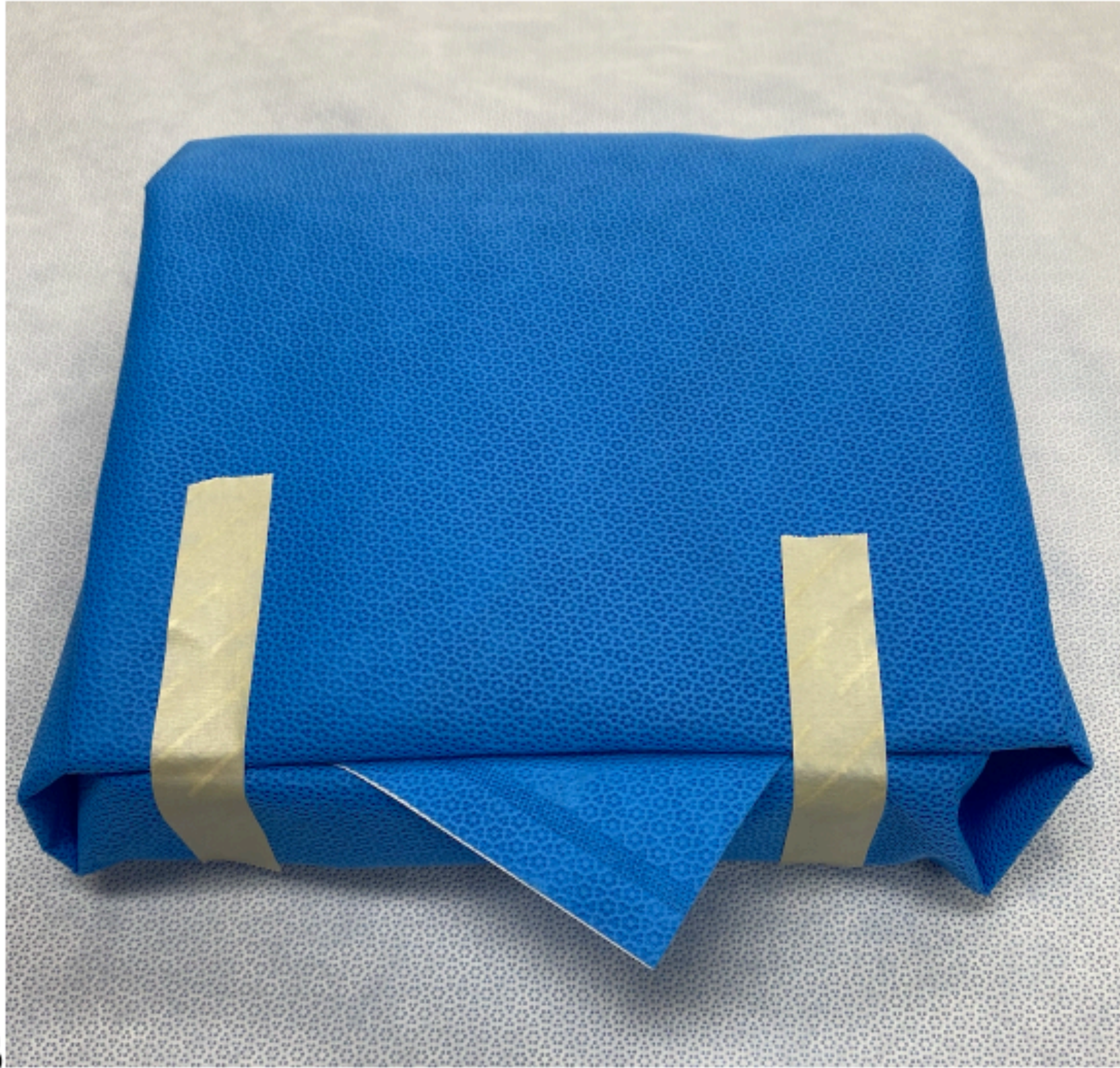


Fig B

The above image shows a very common two-tape package. This should be used with medium weight (5-12Lbs).



# Filling in the Gaps - Tape Usage

**Using tape should be easy?**



Fig C

The above Image shows a three tape package, This provides extra security as well as additional location to adhere tracking system labels.



# Filling in the Gaps - Tape Usage

Using tape should be easy?



Fig D

The above image shows another three tape package, additionally as countsheets are not approved to go into sets a count sheet holder is placed on the vertical strip ensuring it does not get lost.



# Filling in the Gaps - Tape Usage

## Using tape should be easy?

This is a good option if you have issue with tape popping. During sterilization packs expand and contract. As wrap expands and contracts its possible for the tape not adhering. Using less tape across the entire top will reduce this.

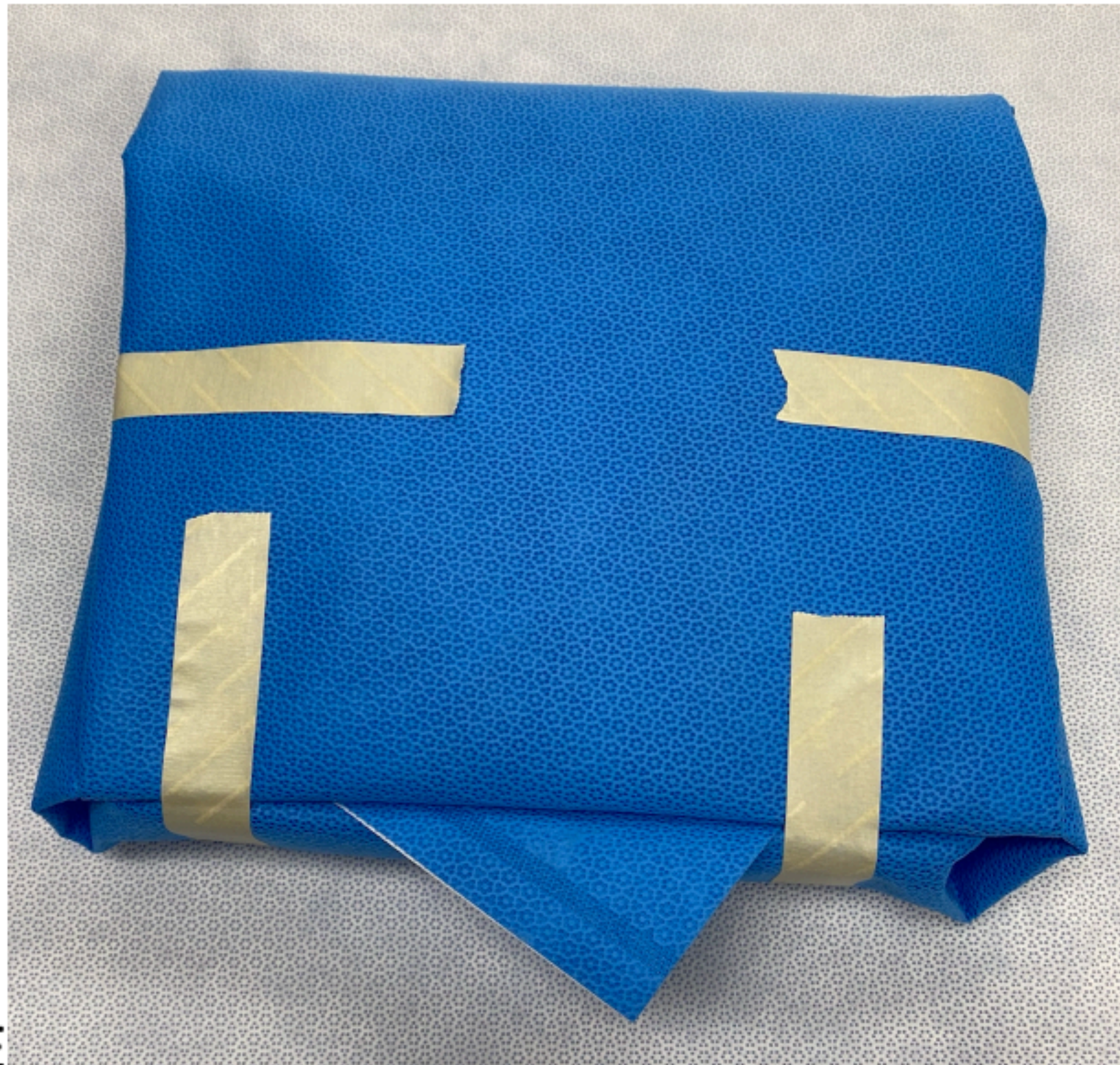


Fig E

The Above image shows a four-tape configuration. This is sometimes done as part of a request from the OR and also can help secure items that may break the plain of the depth of the set.





# Filling in the Gaps - Tape Usage

## Using tape should be easy?

### Tape Evaluation

When evaluating tape the following should be considered by the healthcare facility:

- Adhesive properties of tape – Each tape manufacturer uses similar adhesives however some adhesives may work differently in each healthcare facility. Review the tape manufactures instruction for use when storing tape as improper storage (temperature, humidity and UV light) could affect the tapes performance.
- Width of tape- Tapes can range in width, some manufacturers produce tapes ranging from ½” up to 1 ¾. Width of tapes should be evaluated by the healthcare facility to ensure the tape or tapes selected will effectively secure the wrapped device.



# Filling in the Gaps - Tape Usage

## Using tape should be easy?

### Tape Evaluation

When evaluating tape the following should be considered by the healthcare facility:

- Stability of tape- In recent years the effort to remove latex and lead from tape has been priority by tape manufacturers to meet the changing needs of healthcare facilities. These changes have affected the stability of some tapes. Removal of latex has rendered some facilities with tapes that do not adhere as well after sterilization often becoming loose when sterilized.

Additionally the removal of the lead ink used in the Type 1 indicator has lead to the fading of the processed indicator while in storage. Direct sunlight and fluorescent light can have adverse affects on some sterilization tapes. Fading can be noticed often time days after a product has been sterilized and released to storage. Item that are in storage with faded tape should be reprocessed as the external indicator no longer intact and its contents suspect.

- Tensile strength and tape thickness - Each tape manufacturer can provide product specification to the user. Tensile strength and thickness of tape can dramatically affect the efficiency of tape due to its ability to resist rupturing or tearing after the sterilization process.



# Filling in the Gaps - Tape Usage

## Using tape should be easy?

Inconsistencies in tape usage can be problematic especially in the OR.

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# Filling in the Gaps



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