

Design for Media Fills:

Considering Sterility from the Ground Up

18 October 2023



Media Fills

- Aseptic Process Simulation (APS)

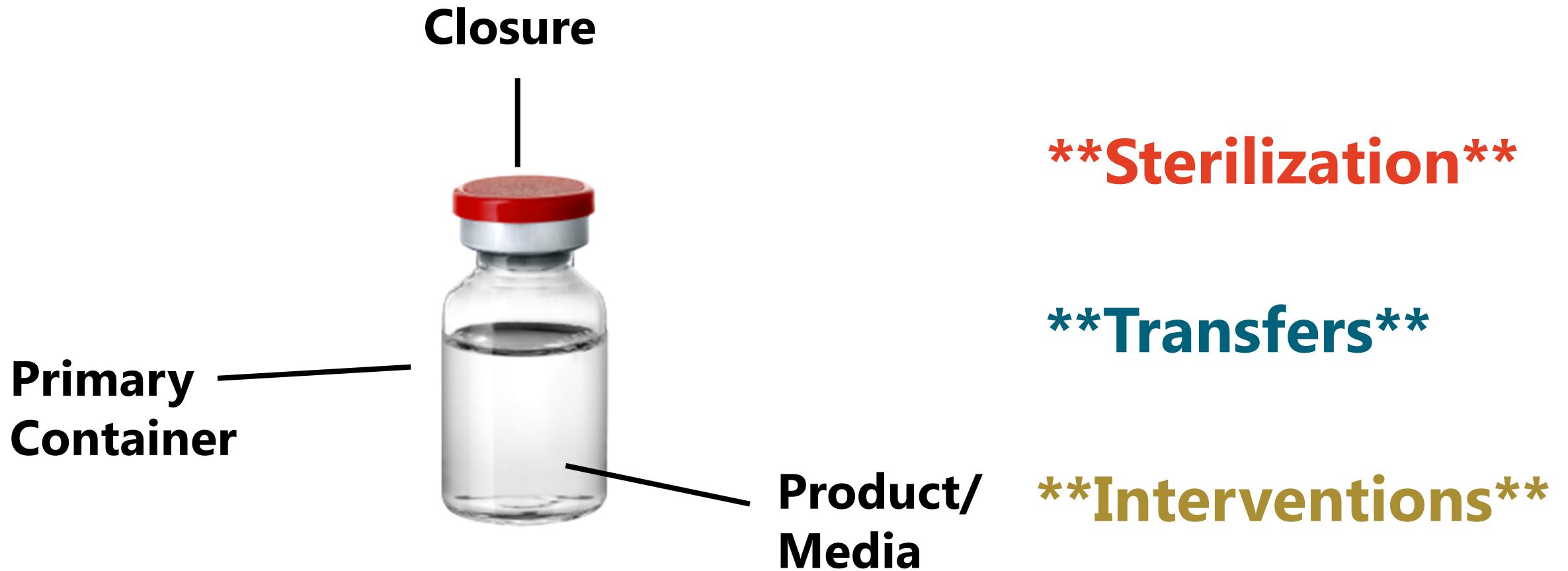
Design

- to devise for a specific function or end

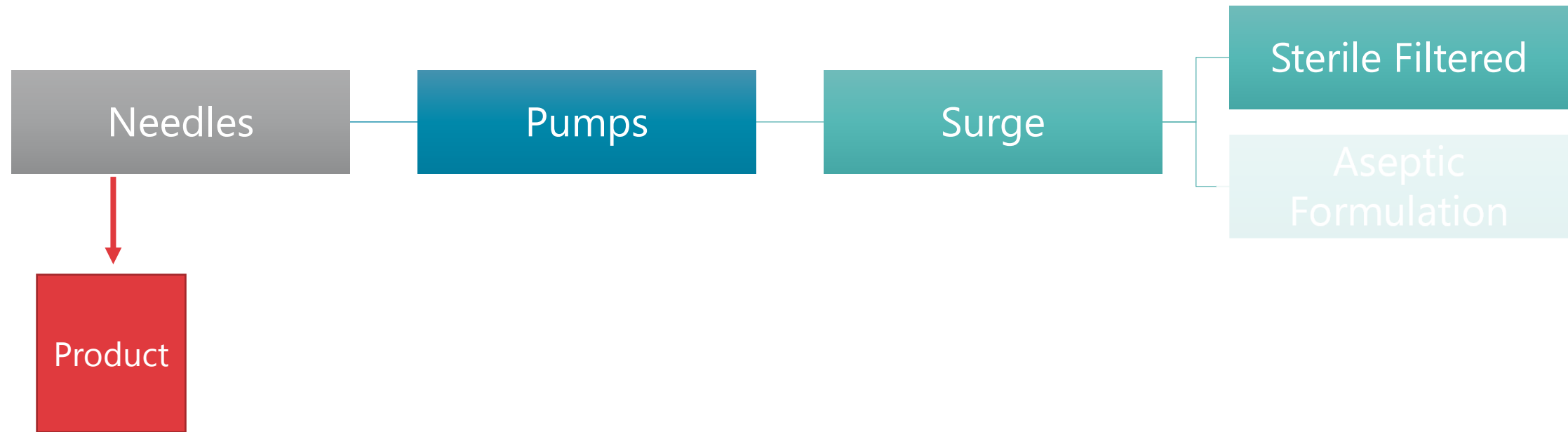
10,000 Foot View



Pulling Threads from the Inside Out



Product Path Thread



Product Path - Pumps

Rotary Piston Pump

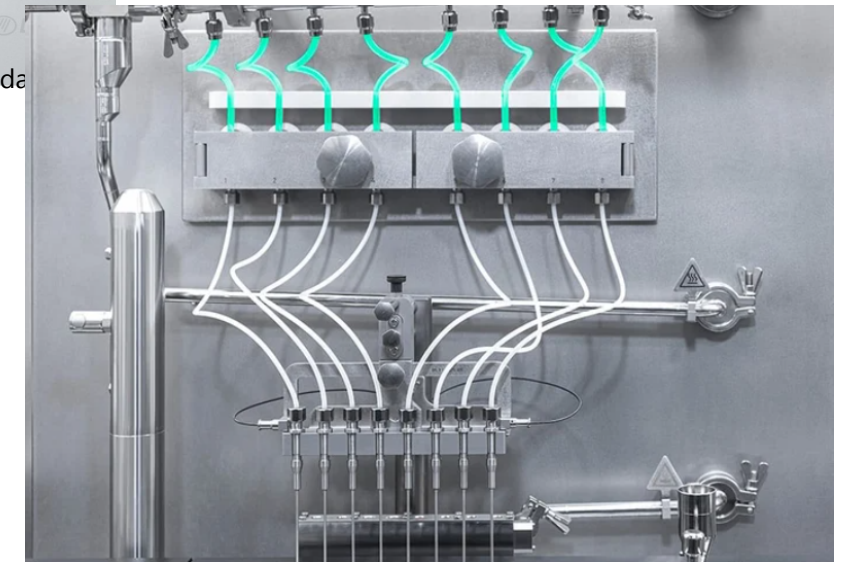


colanar.com

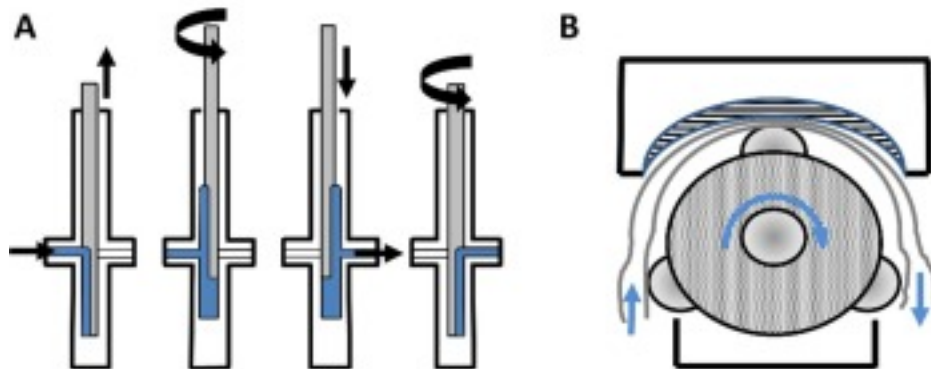
Peristaltic Pump



Time/Pressure System

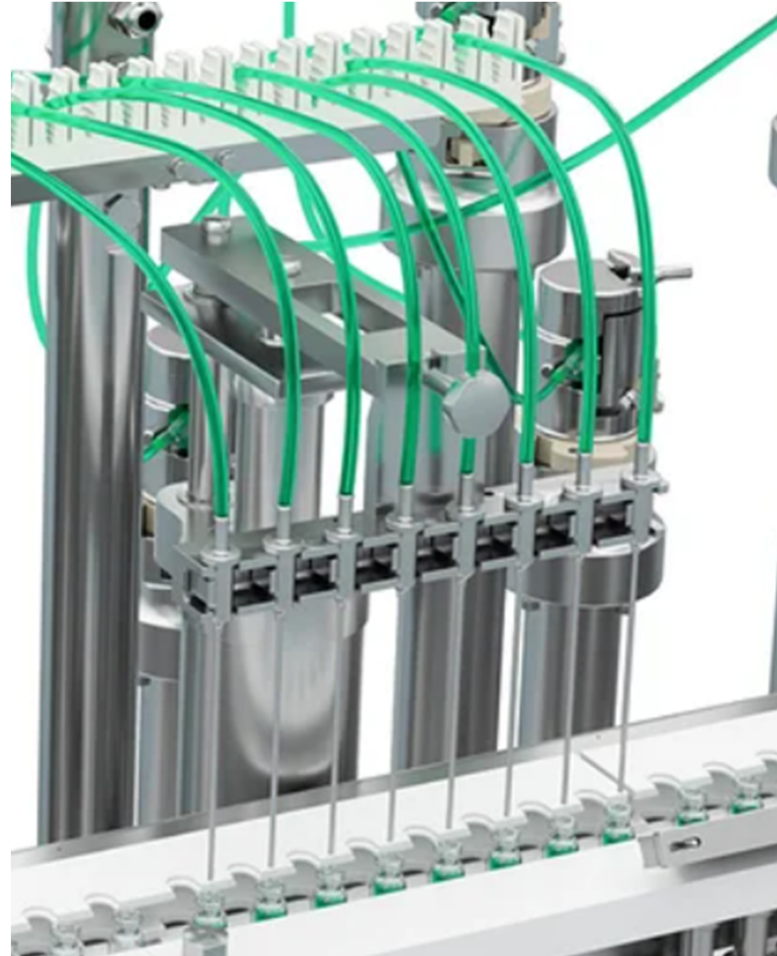


Pumping Flows



Tim Dreckmanna, Julien Boeuf, Imke-Sonja Ludwig, Jörg Lümekemann, Jörg Huwyler
 Low volume aseptic filling: Impact of pump systems on shear stress
<https://www.sciencedirect.com/science/article/pii/S0939641119313177>

Product Path - Needles



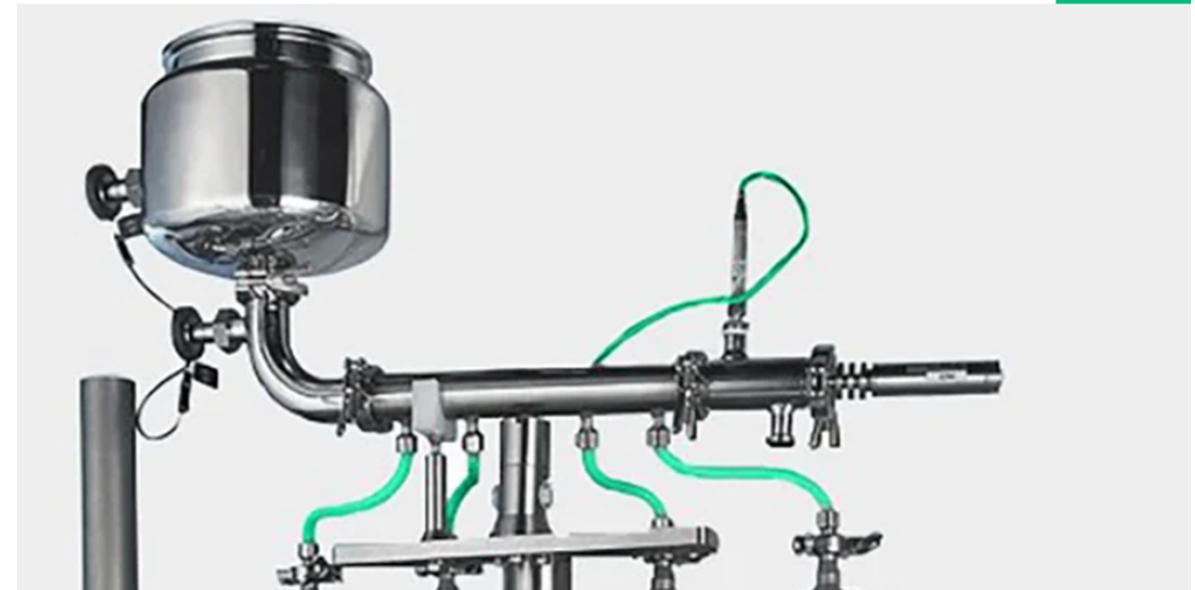
syntegon.com

Product Path – Surge Vessel

Single Use Surge Bag



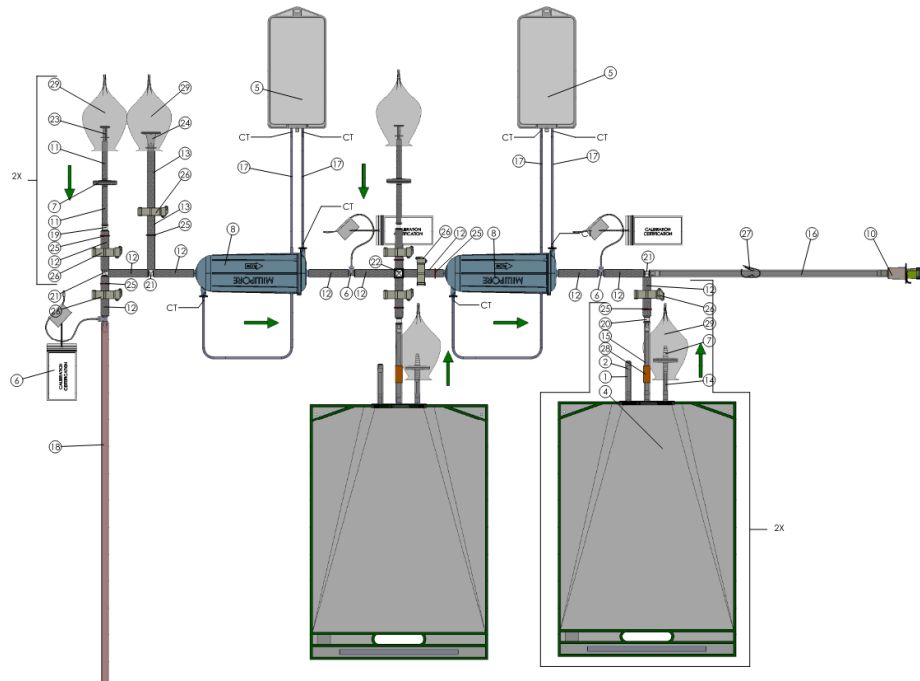
Stainless Steel Surge Vessel



syntegon.com

Product Path – Sterile Filtration

Single Use Filter Assembly



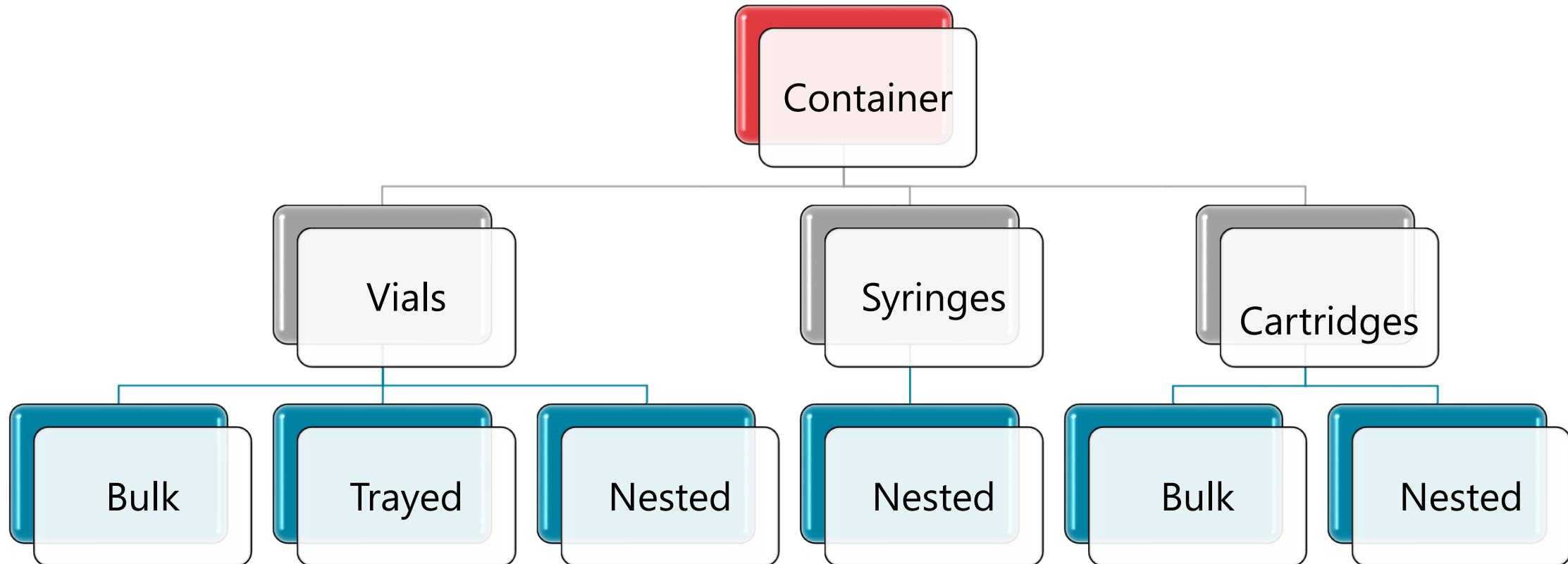
Courtesy of Millipore

Fixed Filter Skid



Suncombe.com

Primary Container Thread - Presentations

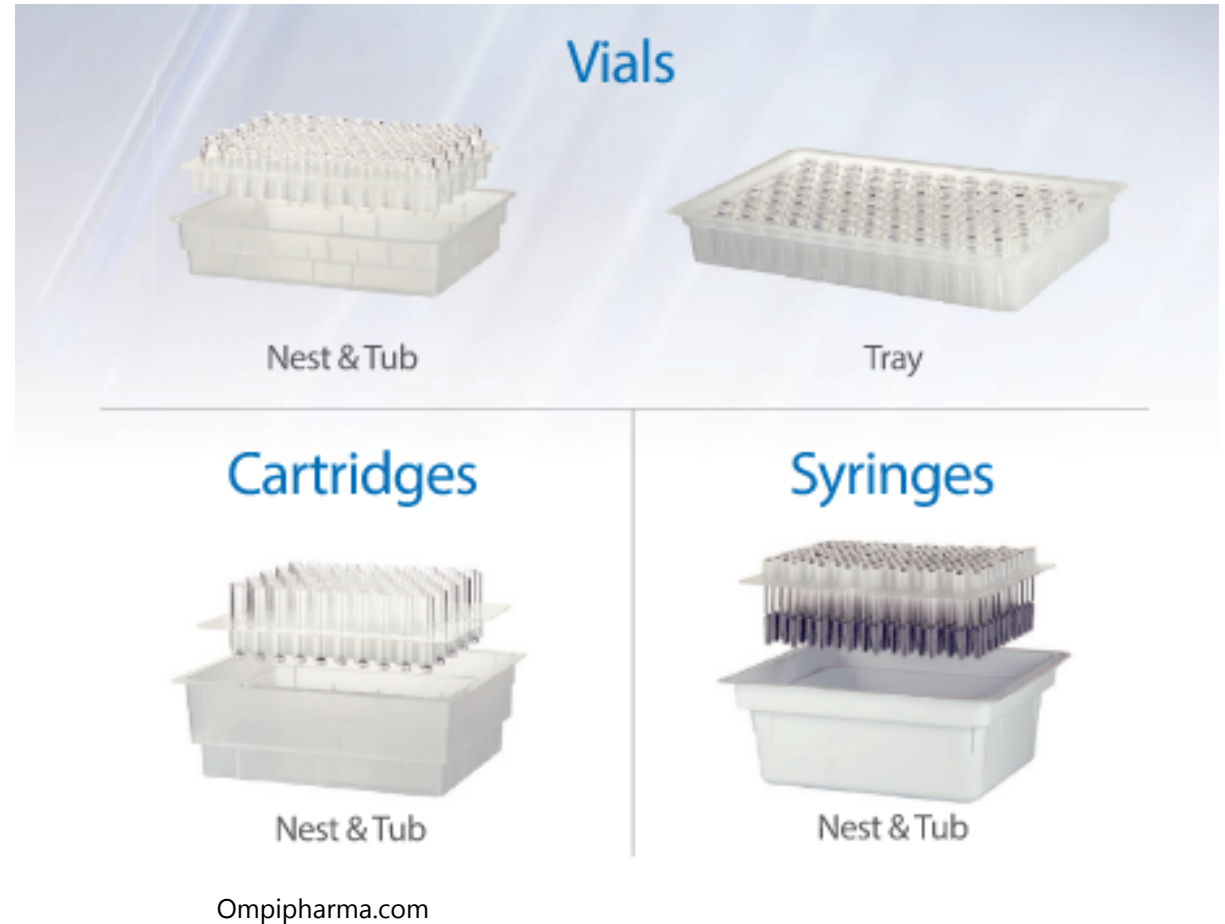


Container – Presentations

Bulk



Ready To Use (RTU)



Primary Container - Sterilization

****Sterilization****

Bulk

RTU

Wash &
Depyrogenate

Pre-Washed
Depyrogenate

Manual Wipe

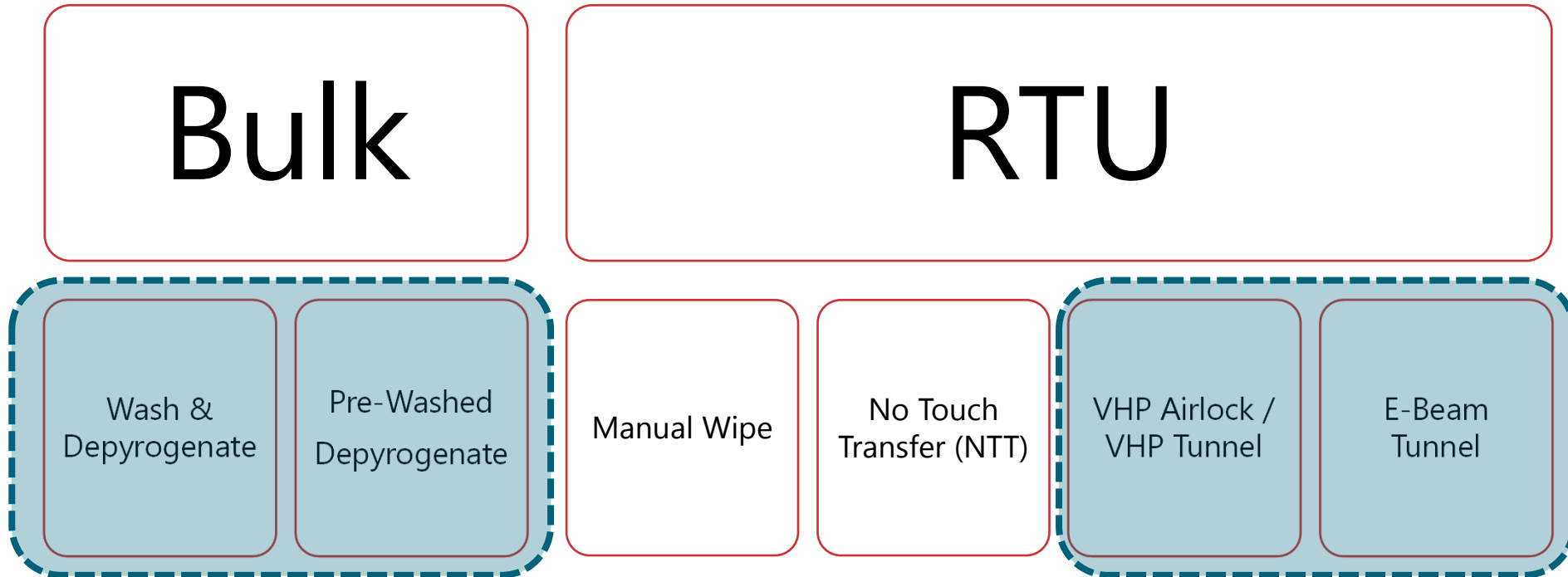
No Touch
Transfer (NTT)

VHP Airlock /
VHP Tunnel

E-Beam
Tunnel

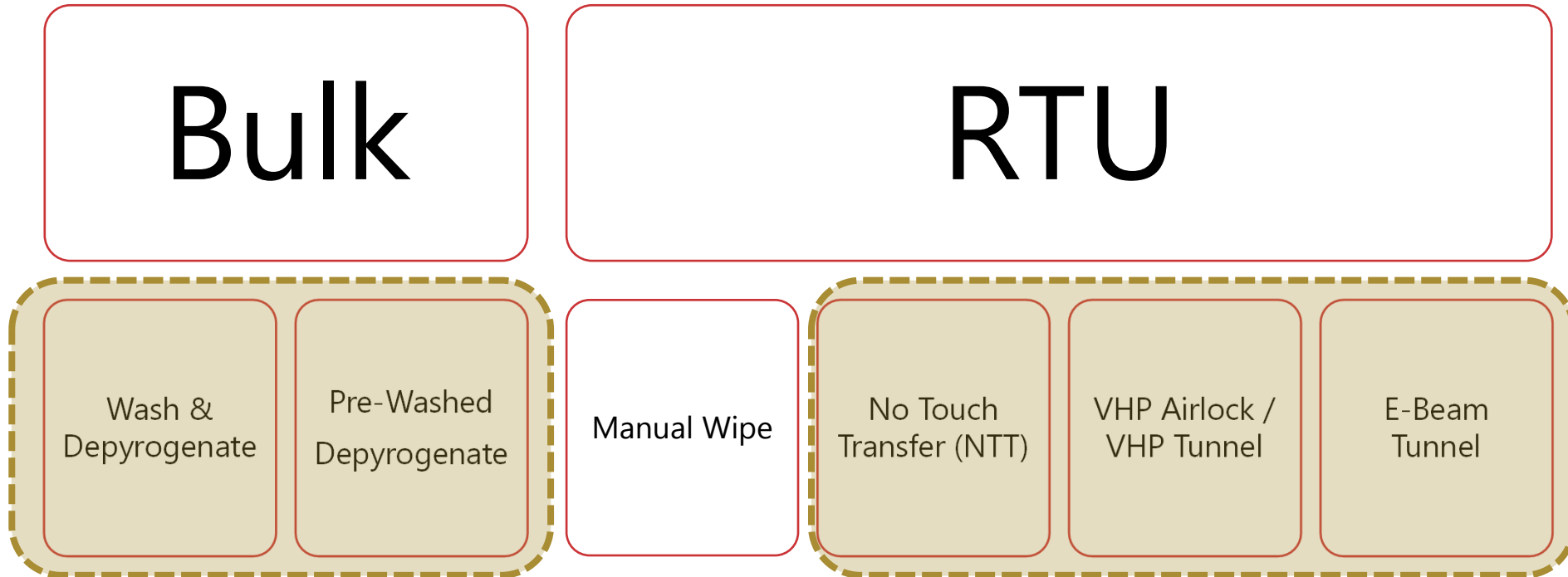
Primary Container - Transfers

****Transfers****

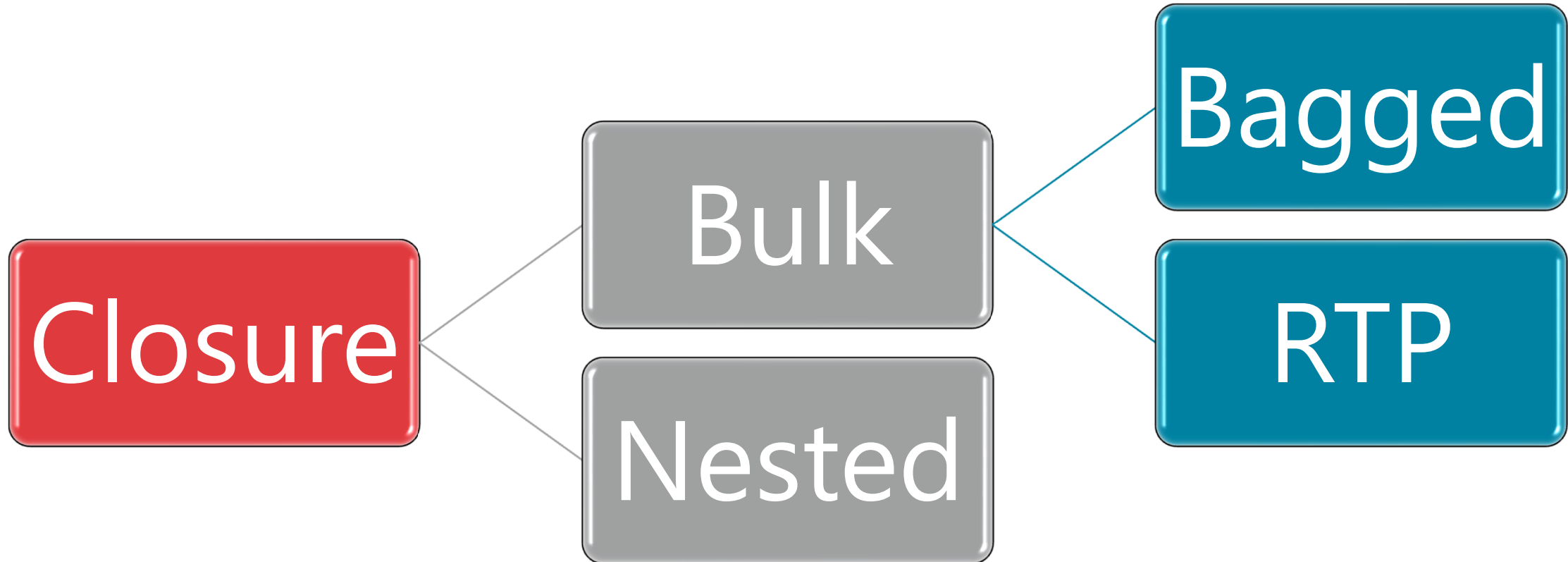


Primary Container - Interventions

****Interventions****



Closure Thread



Closure Thread

Stopper Processor



atecgroup.de

RTP Transfer

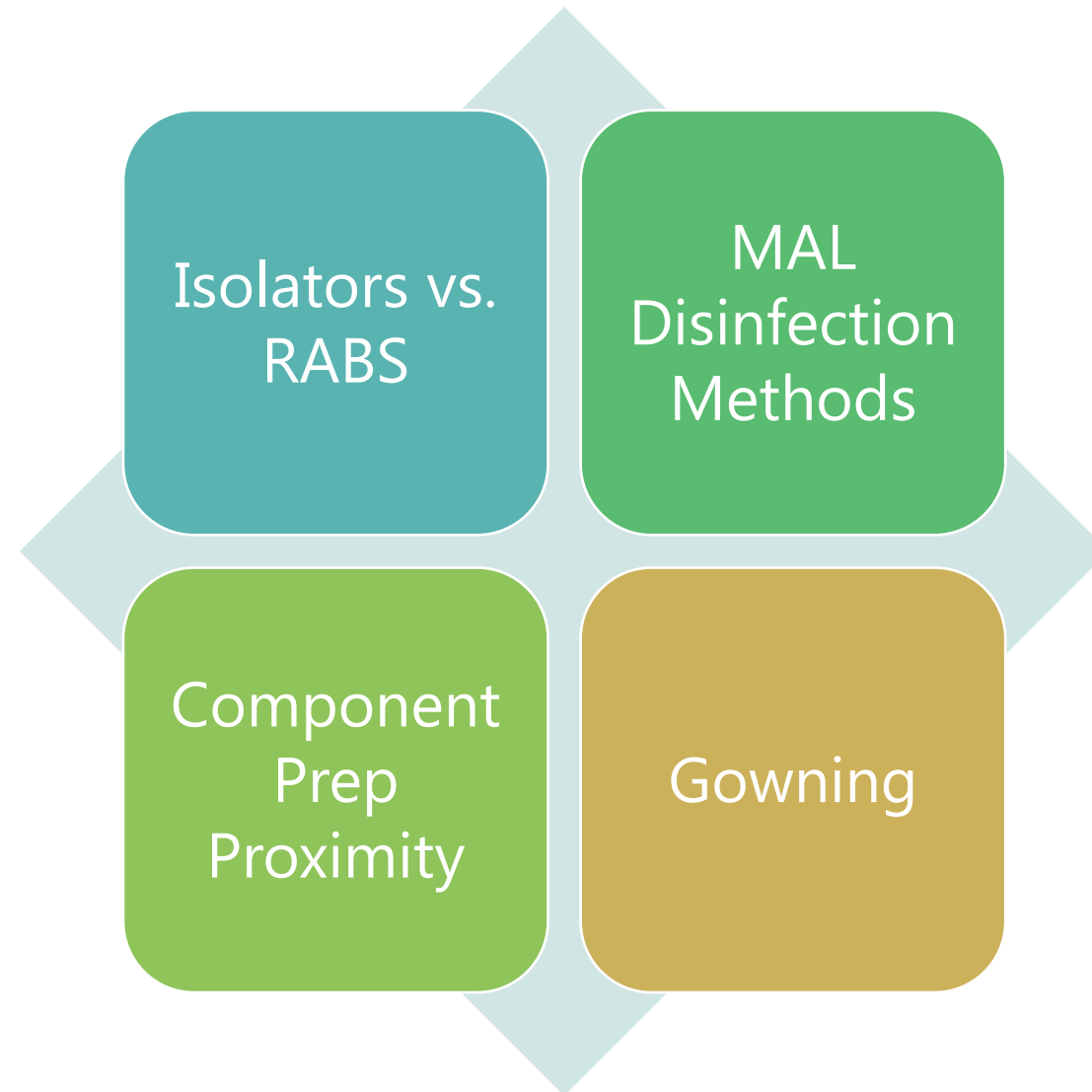


getinge.com



Autoclave Bag

Broader Facility Links



[illegible]

5.0 Identification of Potential Effects of Failure Mode						
Tag #:	Device:	Expected Result :	Severity Of Failure Mode:	Current Design Safeguards:	Recommended Additional Risk Mitigation:	Qualification Activities For Design Safe Guards
-95B4	Pressure Too Low Compressed Air	Equipment would hard stop. CIP/SIP would abort.	L, M, H	Alarm to indicate low compressed air pressure. Normally high logic.	N/A	10.9 Alarms & Interlocks
-96G2	Tare Weigh Load Cell Power Supply	Equipment would hard stop.	L, M, H	Alarm to indicate scale fault(s).	N/A	10.9 Alarms & Interlocks
-96A2	Tare Weigh Load Cell	Equipment would hard stop.	L, M, H	Alarm to indicate scale fault(s).	N/A	10.9 Alarms & Interlocks
-97A2	Tare Weigh Load Cell	Equipment would hard stop.	L, M, H	Alarm to indicate scale fault(s).	N/A	10.9 Alarms & Interlocks
-98A2	Tare Weigh Load Cell	Equipment would hard stop.	L, M, H	Alarm to indicate scale fault(s).	N/A	10.9 Alarms & Interlocks
-99A2	Tare Weigh Load Cell	Equipment would hard stop.	L, M, H	Alarm to indicate scale	N/A	10.9 Alarms & Interlocks

Conclusion

