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# Sterilization Packaging Insights Tool - Risk Assessment

**Date:** _____

The purpose of this assessment is intended to give the user a report out of current practices in an effort to provide actionable information to better or confirm practices. Commentary is based on industry best practices.[1]

- Observe the 6 factors to left as they are currently in your facility.
- Select only 1 scoring value per each of the 6 factors.
- Enter 1 scoring value for each of the 6 factors into the blue boxes below to calculate your facility's score

| #1 Factor: % of Trays Containerized[2] | Scoring Value | | Enter 1 Scoring Value for each Factor In Blue Box |
|---|---|---|---|
| **0-20%** | **1** | | Your sterilization packaging mix leans heavily towards sterilization wrap. Because of this, care must be taken in the proper set weights, transport, and handling of your trays to mitigate and eliminate breaches. |
| **21-40%** | **2** | | Since the majority of your sterilization packaging mix is in sterilization wrap, it is important that your staff take care in preventing sterilization wrap breaches and that they diligently check for breaches. Following IFUs for both containers and wrap is equally important. |
| **41-60%** | **3** | | Your sterilization packaging mix has an equitable combination of both reusable containers and disposable wrap. Assuming your department takes the proper precautions specific to the IFUs, you are most likely deploying each sterilization packaging system effectively. |
| **61-80%** | **4** | | Most of your sterilization packaging mix is in rigid containers. It is important that performance checks are in place, that your maintenance/repair program is followed closely and that your staff adheres 100% to IFUs. |
| **81-100%** | **5** | | Your sterilization packaging mix leans heavily towards rigid containers. Because of this, special care and diligence needs to be given to storage |
| **#2 Factor: Average Age of Container Inventory[3]** | | | |
| **Less than 2 years** | **1** | | Your container inventory is relatively new and, although it is difficult to assess, you should have fewer performance issues than an inventory comprised of older containers. However, your staff's proper adherence to rigid container IFU's will be critical in achieving optimal container performance levels. |
| **2-4 years** | **2** | | Your container inventory is growing older and will be subject to more performance issues compared to an inventory of newer containers. Encourage your staff to adhere strictly to rigid container IFUs to prevent potential performance failures. |
| **5-9 years** | **3** | | Your container inventory is at an age range which requires diligent checks on performance. There exists a potential increased opportunity for repairs. 100% adherence to IFU's is paramount to prevent performance failures. |
| **Over 9 years** | **4** | | With inventory of this age, you are at a moderately-high to high risk of performance failures. Even diligent performance checks can no longer guarantee the efficacy of your sterilization program. |
| **Unknown** | **5** | | Lack of knowledge regarding the average age of your inventory places you at high risk for performance failures. As with all reusable devices, container performance degrades over time. Miss-matched lids and basins, along with aged gaskets can all impact performance. |
| **#3 Factor: Adherence to IFUs** | | | |
| **All Staff Members Always Follow** | **1** | | Your staff does an excellent job of following manufacturer's IFUs when preparing and processing their sterilization packaging. In terms of disposables, this ensures that they are optimizing aseptic opening in the operating room. In terms of reusables, they are minimizing the opportunity for human error. |
| **Most Staff Members Mostly Follow** | **2** | | Your staff is doing an average job of following manufacturer's IFUs. However, an average job will lead to average results. To maximize the effectiveness of your sterilization processing department, all staff members must follow IFUs at all times. |
| **Some Staff Members Sometimes Follow** | **3** | | While some of your staff members follow IFUs diligently, there are others who do not. Not following IFUs can lead to improper processing and may impact sterilization packaging performance. While this may slow down throughputs, it is a critical element when working with your sterilization packaging systems. |
| **Most Staff Members Rarely Follow** | **4** | | In this situation, your staff is at risk of doing more harm than good. By delivering surgical instruments to the OR that haven't been monitored or processed properly, they are providing a false sense of confidence to those who will be utilizing them. |
| **All Staff Members Never Follow** | **5** | | Your staff is not following the recommended IFUs for your sterilization packaging systems. This puts you in a position for a much higher number of performance failures than if IFUs were strictly followed. If breaches are not being monitored in wraps and performance checks aren't being executed on containers, your sterilization processing department is operating in a completely ineffectual manner. |

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| 4 Factor: Rigid Container Repair Program[4] | | | |
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| **All Containers Undergo A Scheduled (yearly, monthly, weekly) Servicing Program** | 1 | | Your repair program is ensuring that all of your containers are being monitored and repaired on a regular basis. This is working to help you optimize the performance of these reusable devices. |
| **All Containers are Regularly Monitored and then Repaired by a Certified Technician** | 2 | | This is a better than average repair program, but it is only serving you to a limited degree. Without a regular, scheduled repair program in place that routinely monitors AND repairs your containers, you may experience performance failures that might otherwise have been prevented. |
| **Your Containers Are Being Repaired As Needed (Based On Visual Cues) by a Certified Technician** | 3 | | While you are catching the most egregious visual clues, you may not be capturing all. This could lead to a reduction in the clinical performance of these sterilization packaging systems. |
| **Your Containers Are Repaired As Needed by a Non-Certified Technician** | 4 | | Only technicians who are certified to monitor and repair rigid containers have been trained properly to work on these particular pieces of equipment. The skills required to assure you of a proper repair program are gained through proper training. |
| **No System Is In Place To Monitor And Repair Your Containers** | 5 | | Without an established system in place to monitor and repair your rigid containers, there is no way to benchmark their performance. This could lead to higher than expected failure rates. |
| **#5 Factor: Integrity Check Demos[5]** | | | |
| **No Containers Tested Failed the Demo** | 1 | | Your containers performed very well when tested. You are optimizing the clinical efficacy you are receiving from these reusable devices. |
| **25% of Containers Tested Failed the Demo** | 2 | | Most of your containers performed well when tested. However, regular monitoring and repairing of your containers and strict adherence to IFUs is paramount in reducing failure rates. |
| **50% of Containers Tested Failed the Demo** | 3 | | While your containers exhibited a lower failure rate than those in the Dynamic Bioaerosol Study, there is still cause for a high level of concern. With a 50% failure rate, your containers overall are operating at sublevel performance. |
| **75% of Containers Tested Failed the Demo** | 4 | | When tested, the majority of your containers failed the demo. This isn't only a high rate of failure, but an unacceptable rate of failure. Steps should be taken to improve your repair program and enhance compliance with your staff's adherence to IFUs. |
| **100% of Containers Tested Failed the Demo** | 5 | | Failure of any one of these demo's at such a high rate suggests your containers are not meeting your clinical standards. |
| **#6 Factor: Tear Rate[6]** | | | |
| **0-2% Tear Rate** | 1 | | Your wrap selection, transport and storage is excellent. Your reprocessing costs are very low. |
| **2-3% Tear Rate** | 2 | | Your wrap selection, transport and storage is less than ideal. However, your reprocessing costs are still low. |
| **3-4% Tear Rate** | 3 | | This tear rate demonstrates that there is room for improvement in your wrap selection, transport and storage. Improving your wrap selection, transport and storage can reduce your reprocessing costs. |
| **4-5% Tear Rate** | 4 | | This is a higher than average tear rate and is resulting in higher reprocessing costs. An assessment of your wrap selection, and transport and storage processes is recommended to lower your reprocessing costs. |
| **Over 5% Tear Rate** | 5 | | A high tear rate corresponds to high reprocessing costs. Your wrap selection, storage and handling should be examined. |
| *Reach out to your Halyard rep for help in optimizing your SPD workflow and storage capabilities. | | | **Your Facility's Score** |

**Score Range:**

| 6-10 | 11-15 | 16-20 | 21-25 | 26-30 |
|---|---|---|---|---|

| | |
|---|---|
| 6-10 | Congratulations --- your sterilization packaging department is doing a great job! This score range shows that you have all of the systems in place to help ensure that surgical instrument sterility is maintained post-sterilization through handling, transport and into the OR. |
| 11-15 | Your sterilization packaging department is doing a better than average job, but there remains room for improvement. Remember, adherence to wrap and container IFUs and having a proper container maintenance program in place is important to ensure clinical performance. |
| 16-20 | This score range shows that you may be experiencing performance failures that could have been prevented were proper care taken in the sterilization of your surgical instruments. An examination of the processes in your sterilization department is recommended to rectify the situation. |
| 21-25 | This is a lower than average score range and points to the fact that the facility most likely does not have the proper systems in place to be 100% certain that the sterility of your surgical instruments is being maintained post-sterilization through transport, handling and to the OR. An immediate examination of your packaging mix, container age, adherence to IFUs and container repair program is recommended to correct improper procedures. |
| 26-30 | Your sterilization packaging is not performing its job properly, nor is the facility maintaining an efficacious program to ensure the sterility of the surgical instruments that you are processing. With a score range this high, the likelihood of performance failures is at an elevated level. It is imperative that you begin to develop a plan to improve the sterilization packaging systems inclusive of IFU adherence, maintenance, and storage of such systems. |

References:

1.These Observations are generally based upon the guidelines and standards on sterilization for the healthcare industry as stated by the Centers for Disease Control (“CDC”), the Association for the Advancement of Medical Instrumentation (“AAMI”) and the Association of periOperative Registered Nurses (“AORN”) where relevant (collectively referred to as the “Standards”).

2. See Guideline for selection and use of packaging systems for sterilization. In: Guidelines for Perioperative Practice. Denverm CO: AORN, Inc; 2018: 943-956. [IVA]. AORN Guidelines support handling and transporting wrapped trays properly to mitigate breaches, to check for breaches before using and stress following manufacturers’ IFUs. Note: this Guideline does not address desired or acceptable mix of sterile packaging systems.

3. AORN Guidelines acknowledge that rigid sterilization containers will suffer wear and tear, but do not specify any age or number of uses for repair, replacement, or other treatment, but instead defer to the individual manufacturers’ IFUs. Different container manufacturers may have different recommendations. Construction, materials and manner of use will all impact wear and tear requiring repair or replacement.

4. Pursuant to the AORN Guidelines, the manufacturers’ IFUs should be the guide on a repair or replacement program. Different manufacturers may have different standards and timing for repair or replacement. Construction, material and manner of use will all impact the wear and tear on the containers.

5. The suggestions in this Factor section are based on a Halyard representative performing a Glo Germ™ test on a sampling of customer’s containers. See AORN Guidelines, Recommendation VIII on rigid sterilization container recommendations for using, cleaning, inspecting, repairing and maintaining rigid sterilization containers. Pursuant to the AORN Guidelines, the manufacturers’ IFUs should be the guide on a repair or replacement program. Different manufacturers may have different standards and timing for repair or replacement. Construction, material and manner of use will all impact the wear and tear on the containers. Note: Glo Germ is a trademark and product of Glo Germ Company.

6. See CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (“CDC Guidelines”), Recommendations, Section C.18.e (p.92). https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html