



Don't Get Weighed Down by Instrument Sets That Are Too Heavy

by Rose Seavey, RN, MBA, CNOR, ACSP

NO!

Many thanks to the team at 3M Health Care for working with *Managing Infection Control* to provide the following accredited course. IAHCSSM has awarded one (1) contact point for completion of this continuing education lesson toward IAHCSSM re-certification. The CBSPD has pre-approved this inservice for one (1) contact hour for a period of five (5) years from the date of publication, and to be used only once in a re-certification period. This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication. Instructions for submitting results are on page 97.

Managing Infection Control and 3M Health Care will be working collaboratively to provide continuing education courses in monthly editions of *Managing Infection Control*.

Objectives

After completion of this self-study activity, the learner will be able to:

1. Identify the Association for the Advancement of Medical Instrumentation's (AAMI's) recommended practice on what the weight of an instrument set should be based.
2. Perform product testing on medical devices routinely processed.
3. Discuss reprocessing and ergonomic concerns with heavy instrument trays.
4. Discuss ways to eliminate heavy instrument sets.

Test Questions

True or False

1. Overweight instrument sets and sets that do not have the metal mass evenly distributed can create concerns about inadequate steam contact with all surfaces.
2. The approved sterilization method and cycle exposure times for each rigid container system should be provided in the manufacturers' data and instructions.
3. Users must test all reusable sterilization containers with biological and chemical indicators before placing into routine use.
4. Quality assurance testing of routinely processed items does not need to be performed on an ongoing basis.
5. Preparation and assembly procedures should take into account the size of the sterilization container, the number of instruments and total set weight as well as density of the instruments.
6. Overweight instrument sets can be broken down into multiple containers that meet the needs of the sterilization processing department and operating room.
7. If the information about placement of biological (BI) and chemical (CI) indicators cannot be obtained from the medical device manufacturer, then place multiple BIs and CIs in the center of the tray.
8. If additional items are added to a set, you do not need to repeat the sterilization verification testing unless the supplementary items add excessive weight to the tray.
9. The need for sterilization efficacy verification via product testing applies to loaner instrumentation.
10. Instrument sets cannot be redistributed by the user to even out metal mass.

Introduction

Imagine working in a Sterile Processing Department (SPD) or Operating Room (OR) where there is a maximum weight limit on instrument trays. Imagine that this maximum weight limit policy is routinely enforced. Picture your staff no longer complaining about having to repeatedly lift heavy trays. Imagine if you did not have to deal with wet pack problems or other sterilization concerns due to heavy trays. This vision

can come true by just saying “NO” to instrument trays that are too heavy.

Do instrument trays that are too heavy cause you frustration? You bet. But are they uncommon? No, they are not. We may be quick to blame vendors for designing their trays with everything but the kitchen sink in them, or the doctors for wanting everything in one tray; nevertheless, we must take partial responsibility for this processing concern. As patient and employee advocates, we can and must do something about it. We have it within our power to just say “NO” to heavy sets.

While there is no magic number that pertains to instrument set weights, the recommended combination weight (tray, instruments and wrappers) used to be 16-17 pounds or less.¹ Over the past decade, the average instrument set weight has gradually increased.

New Technology

In the healthcare area, technology is dramatically changing and demanding how we deliver patient care. This is especially true in the Operating Room. Technology is constantly

changing to improve clinical outcomes. This is good news for the patients, but may also come at a price. Part of that price is the need for additional, often complicated instrumentation. At some facilities there are several types of instrument sets used for the same procedure. This is usually dictated by the physician’s preference or experience.

Newly introduced instrumentation, due to improved technology, often shows up following physician attendance at medical conventions, especially orthopedic conferences. We often hear of facilities referring to the *spine (or hip or knee) of the month club* due to the unremitting changes in instrumentation or types of implants. More often than not, the Medical Device Manufacturers (MDMs) of the implants are willing to “give” the facility the instrumentation that goes along with the implants as long as the facility purchases the implants. This instrumentation comes in a nice, custom-designed tray or container intended to hold all the necessary, and sometimes not so necessary, items used in the procedure. Sometimes more consideration should have been given to the overall weight of the set or the ability to adequately

sterilize or dry the set in hospital routine sterilization load parameters.

The “Growing” Instrument Set

Trays tend to grow over time due to instruments being added to an existing set. This happens for several reasons. A surgeon may request a special scissor, an additional pair of needle holders or another type of retractor when he or she performs a certain procedure. These extra instruments are added to the set, even if it is a standardized set that many surgeons use. This action gets repeated when another surgeon who uses this standardized set requests other instruments be added. The surgeons may ask for these items to be put in the set, but what they really want is to ensure they have the additional items available if/when they need them. Do these extra items really need to be placed in the set? Or is this done for convenience or for a “what if” situation?

A perioperative nurse or scrub tech may ask to have additional instruments added because they remember a surgeon having asked for them in the past. Sometimes this is

a result of not being able to find the requested instrument wrapped separately, or it not being sterile when they needed it. So to make sure this does not happen again, they want it in the set “just in case,” even if it was a one-time request for a special use.

Another possible reason for instrument trays being too heavy can be due to financial considerations. Some facilities may believe it makes economic sense to have sets so standardized that they can use them for almost any type of case. This may mean having less inventory of sterilization containers or wrappers. The problem is that these trays then frequently end up weighing a lot. Besides the issue of weight, this causes other processing concerns. The AAMI *Steam sterilization and sterility assurance in healthcare facilities* (ANSI/AAMI ST 46), 2002 recommended practice (p.32, Section 5.6.2.7 Instruments) states the weight of an instrument set should be based on (a) whether personnel can use proper body mechanics in carrying the set, (b) the design and density of the individual instruments comprising the set, and (c) the distributing of mass (the density) in the set and sterilizer load.²

Reprocessing Concerns

No matter what the reason for an instrument set being on the heavy side, it can be a problem when it comes to the sterilization process. Overweight sets and sets that do not have the metal mass evenly distributed can create concerns with adequate steam contact with all surfaces. In addition, a problem with drying may result in the potential for wet packs.

The Association of periOperative Registered Nurses's (AORN's) 2006 recommended practice for *Packaging Systems* states rigid container systems should be used according to manufacturers' instructions. The approved sterilization method and cycle exposure times for each rigid container system should be provided in the manufacturers' data and instructions.³

There are many types of containment devices. Some are generic containers that are purchased by facilities to house and protect instrument sets they have created. Others are provided by the instrument manufacturer, such as orthopedic or neurosurgery specialty instruments that have been distinctively designed to hold particular instruments or implants.

Another reprocessing concern is the fact that every time a set is opened, every one of those instruments must be reprocessed—cleaned, inspected, sharpened, sorted, counted, sterilized, etc., whether each instrument is used or not. These additional reprocessing steps add up in resources as well as time. It is more efficient to leave out the “what if” items from a tray, and to wrap or peel pack them separately, so they are readily available. Be sure to add the change to the physician's preference list so the item(s) can be picked for the case cart.

Product Testing

For both generic containment devices and containment devices containing instrument sets, the MDM should provide the recommended type and placement of instruments, maximum weight, type of filters or wraps, the most challenging area for the placement of biological indicators (BIs) and internal chemical indicators (CIs) for both routine monitoring and product testing. Instructions for inspection and routine maintenance of the containment devices should also be provided.

According to AAMI, if a sterilization container system is used as packaging, the container manufacturers' recommendations regarding sterilization exposure time should be consulted and compared with those of the sterilizer manufacturer. Any differences between the hospital's sterilizer programmed cycle parameters and those recommended by the instrument or container manufacturer should be investigated and resolved before the items are sterilized. The correct cycle parameters should be selected and verified based on the results of product testing.² It is the institution's responsibility to determine if the set can be sterilized and dried effectively in its

facility. Container systems vary extensively in size, design, technicalities and construction materials. Institutional work practices, sterilizer performance characteristics, and the functions of the hospital utilities supplying the sterilizer can also affect the dynamics of the sterilization process. Users must test all reusable sterilization containers before placing into routine use.

Preparation and assembly procedures should take into account the size of the container, the number of instruments and total set weight as well as density of the instruments. Facilities must remember that the instrument container manufacturers' instructions do not cover additional instruments added to a set. The manufacturers' instructions only cover what was validated by the MDM at the time they sell the set; the instructions do not cover additional instruments added by users. If a facility chooses to add items, it must perform the sterility verification testing using the additional instrumentation.²

When new instrumentation and/or packaging material, including containers, are brought into the facility, or when changes are made in the sterilization process, it is imperative to perform additional product testing to ensure the sterilization process is still effective. This testing should be part of your ongoing quality assurance testing program.²

The AAMI ST 46 recommended practice calls this Product testing, section 7.8 (p. 54):

“Quality assurance testing of routinely processed items should be performed on an ongoing basis. A program should be established to periodically test products routinely sterilized. Product testing always should be performed when major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper used. The test program should include both BI testing and an evaluation of poststerilization moisture content (i.e., the occurrence of “wet packs”).

“Biological indicators, as described in 7.4.3.2, should be placed within the product test samples; CIs of Class 3, 4, or 5 may also be used. The number of BIs and CIs used with each product test sample will depend on the size and configuration of the pack being tested. Product test samples should be properly identified and placed among other products in a routine sterilizer load. The product test samples should be placed strategically throughout the load at the points most difficult to sterilize (i.e., the most resistant to steam penetration). After inspection and retrieval of the BIs and CIs, sample packs used in product testing should be disassembled and the contents within reprocessed or discarded as appropriate.

“*Rationale:* The standardized BI test pack of 7.5.2 presents a known challenge to the sterilization process. However, the pack does not reflect the items routinely processed in a healthcare facility. Therefore, product testing is

recommended as part of a complete quality assurance program to ensure the effectiveness of the sterilization process and avoid wet packs. The products to be tested will vary from institution to institution, depending on the types of products routinely sterilized. The contents of the sample packs are exposed to a greater population of bacterial spores than are other products, and, therefore, should not be used in patient care unless reprocessed. Also, inspecting the pack and retrieving the BIs and CIs contaminates the contents.”²

Using the instrument/implant manufacturer directions, the product testing can be performed as described above by placing biological and chemical indicators in the most resistant areas in the package. If the information about placement of BIs and CIs cannot be obtained from the medical device manufacturer, then place multiple BIs and CIs throughout the package in the area determined to be the least accessible to steam penetration, such as corners and next to the instruments with the heaviest metal mass. Bear in mind this may not be the center of the tray. Packs should also be examined for moisture droplets or stains. After processing, there should be no evidence of excessive moisture if the sterilizer is performing properly and correct procedures such as package assembly, loading, selection of cycle parameter, drying, unloading and cooling have been performed. Once all BIs are negative and all CIs reach their endpoints, the verification has been completed, and the sterilization container can be put into use.

Again, facility staff must remember that the MDM’s instructions do not cover additional instruments added to a set. The instructions only cover what was validated by the company. No additional instruments should be added to the set either by the sales representative or by the hospital staff because the MDM’s sterilization validation and the facility’s sterilization verification testing would no longer be valid. If a facility chooses to add items, it must contact the MDM for new sterilization instructions and repeat the sterilization verification testing (i.e., product testing) which would include any additional instruments.

The need for sterilization efficacy verification via product testing applies to loaner instrumentation also. It is the users’ responsibility to ensure the borrowed items are effectively sterilized. Following the medical device and container manufacturer’s reprocessing instructions is imperative to ensuring safe patient care.

Ergonomic Concerns with Heavy Sets

In the hospital setting we see many injuries of staff due to repeated lifting of heavy instrument containers. The health and safety of healthcare workers should be protected through reasonable weight restrictions, especially when these trays must be lifted an average of 12 to 15 times each time the set is used and reprocessed (see Photo 1). When an instrument set is

used for a surgical procedure, the set is lifted on and off case carts, on and off surgical areas, in and out of instrument washers, onto and off of processing tables, lifted to be wrapped or containerized, into and out of the sterilizer, on and off storage shelves, etc. This repetitive lifting can be an ergonomic nightmare, particularly when the set weight exceeds 25 pounds or if there are several heavy sets.



Photo 1: SPD personnel lifting container.

At the upcoming AORN Congress in Washington, DC, in March, the House of Delegates will be voting on the Ergonomically Healthy Workplace Practices position statement. This position statement discusses the need for administrative controls such as limiting the weight of instrument trays. There is a lot of discussion in our professional arena regarding limiting the combined weight to 25 pounds for the reasons listed above.⁴

One Hospital that “Just Said No” to Overweight Sets

In July 2004, The Children’s Hospital of Denver’s Sterile Processing Department (SPD) took a stand against overweight surgical instrument trays. SPD was experiencing wet loads. In research, we discovered that the wet loads occurred most often when certain orthopedic instrument sets were run. Some of these trays weighed up to 35 pounds. In addition to the wet pack issue, staff complaints of back, neck, shoulder and wrist pain raised ergonomic issues as well.

The majority of our instrument sets are placed in rigid STERILECONTAINER™ systems by Aesculap™. The manufacturer’s written recommendations for *instrument and STERILECONTAINER™ Assembly* states, “The weight of the basket and basket contents **should not exceed 16-20 pounds** for effective sterilization and drying.”⁵ Based on this recommendation, we decided 20 pounds would be our maximum total weight limit, whether instruments are wrapped,

placed in our rigid container, or in a metal or plastic container provided by the instrument manufacturer.

Working with surgical services and with the support of infection control and risk management, we created and implemented the instrument tray weight limit policy. The policy statement read, “no instrument set, including its package is to exceed 20 pounds.” Once we had the policy in place we could enforce it.

SPD purchased a scale for the instrument room (see Photo 2), and weighed all of the sets that we owned that seemed heavy (see Photo 3). We found about 25 sets that exceeded the 20-pound weight limit. The majority of hefty sets were orthopedic, and we also found some urology, neurology, cardiovascular and retractor sets that exceeded our weight limit. We put together a list and then asked the OR service leader for each area to help us eliminate some items in each set or to separate the sets. We then added a deadline of three weeks to complete this project, knowing that if we set a deadline it was more likely to be completed in a timely manner.



Photo2: Scale used to weigh instrument sets.



Photo 3: Instrument set being weighed.

In some instances we were able to remove infrequently or unused instruments that were added to the set in case they were needed. We put these additional items in peel packs or small wrappers. In other cases, such as cardiovascular (CV) sets, we separated the string instruments and the retractor and put them in separate smaller pans (see Photo 4).



Photo 4: CV set before (left) and two pan CV set after (right).

**Once we had
the policy in place
we could enforce it.**

About this same time, we purchased a Fukushima-Day Universal Retraction System from Integra NeuroSciences for neurosurgery. The retractor set came in a nice, customized plastic container with three levels that weighed 28 pounds! (See Photo 5.) It looked good and was well-organized, with a special section for each part. However, it was over our weight limit. We removed one of the levels and wrapped it separately. (See Photo 6.) We labeled the trays as Fukushima Day retractor A and B. We informed Integra NeuroSciences that we had to separate the Fukushima-Day Universal Retraction System into two separately wrapped packages due to its weight.

We believed the more MDMs hear complaints and explanations for “work arounds,” the more likely they will consider the weight issue next time they have a specialty tray made.

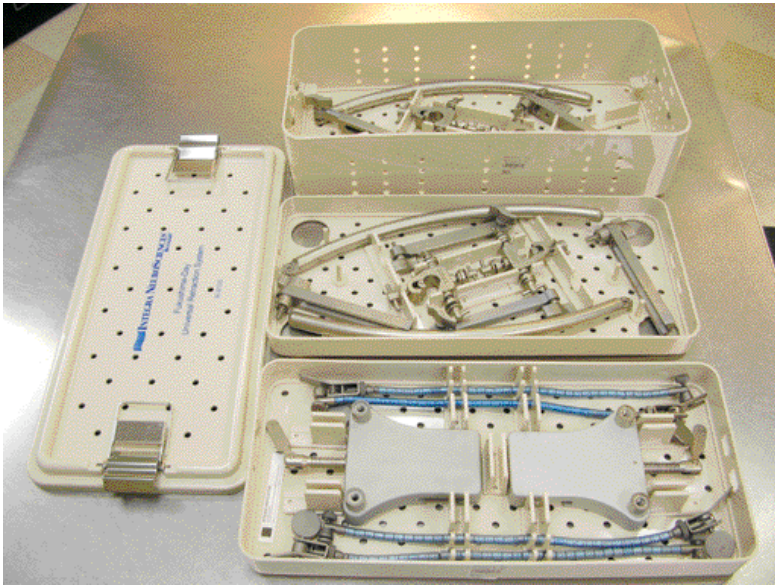


Photo 5: Fukushima Day Retractor set in three levels.



Photo 6: Fukushima Day Retractor set with one level wrapped separately.

Even though the instrument set sizes were reduced, the MDM’s instructions for sterilization were maintained because extended cycles are due to the complexity of the instruments (lumens, crevices, hinges and ratchets), the set density and the complexity of the case/container. We did not at any time reduce the sterilization time, but we were able to reduce the drying time. Once the set was finalized, we followed the AAMI instructions for product testing to conduct our own sterilization verification testing.

Now, if the SPD gets asked to add an instrument to a set, we ask if we can remove anything first.

Once the changes had been made, and the sterilization process was verified, the surgeon's preference lists were updated to reflect the changes and the need to pick both parts of a set, since some were now in more than one package (i.e., trays are labeled A and B). In addition, we made sure the "pick list" made note of "just in case" items to be picked that were taken out of sets and wrapped or peel packed separately.

We realize that even though surgeons may say they want everything in one pan, all they really want is to make sure they have what they need, when they need it. It doesn't matter if it is in one or more pans. The number of pans is irrelevant to the outcome of the procedure, as long as the correct items are readily available. Moreover, in addition to being readily available, the sterility assurance of each device had been verified, which is essential for safe patient care. Now, if the SPD gets asked to add an instrument to a set, we ask if we can remove anything first.

Loaner Sets

Next, the biggest concern came from those instrument sets that we did not own. How could we enforce the weight limit on those sets that we borrowed or that the company brought in for us to "use" as long as we purchased their implants? Once again, the answer was in the policy. We also added the weight limit statement into our loaner policy. We shared this policy with the MDM representatives that had surgical instrument sets in our facility. We asked the MDMs to work with us to get their set weights down to 20 pounds. Some were very helpful and made suggestions on how we could divide the sets, while others took a little convincing and negotiating to get them to see that if they wanted us to sterilize their sets, they had to follow our policy. In some cases we had to go above the local MDM representative and talk to someone with more seniority in the company. We even purchased an additional instrument container or two to "house" the items removed from the vendor-owned sets. We believed that if the sets were validated for sterilization by the MDM, and we made them even lighter by placing them in two containers, we could use its sterilization process recommendation. We followed its original instructions and also conducted our own sterilization verification testing per AAMI's recommendation on product testing.² When it comes to MDMs' sterilization validation testing, we never take the representatives' verbal

word for it. We always ask for that information in writing directly from the MDM.

How do you keep an MDM representative from adding to a set that meets the 20 pounds? Each time we get a loaner set, we ask for an inventory sheet; and if one is not available, we create one. The inventory sheet is used every time we put the set up to be sterilized. The instrument technician uses the inventory sheet to ensure that the correct items are in the set. If additional items are found in the set, the technician notifies the supervisor, who will weigh the set and re-do the sterilization product testing. If the set is overweight, the additional item is wrapped separately and the MDM representative notified.

Our loaner policy extends to sets borrowed from other hospitals. If we borrow an instrument set, it is reprocessed before we use it. One of the first steps we take is weighing it. If it is more than 20 pounds, we separate its items and put some parts in another container or tray and wrap. Once used, we place all items back in the original container before returning it to the owner.

Once in a while trays will slip through the cracks; however, all of the SPD technicians are empowered to weigh the sets and report any heavy sets to the supervisor, manager or director.

We have been very successful in implementing this policy. We initially had some complaints from the surgical staff who were not used to having additional sets to open. There were a few instances in which the second set was not pulled for a case. However, once we explained the reasons for the policy and made sure the preference cards were correct, the complaints stopped. Another point worth noting is that you may need more storage space for the additional instrument containers. In some cases, such as with cardiovascular sets, we were able to stack the smaller containers on top of each other in place of the larger container in which they were previously.

Summary

It has been more than a year and a half that The Children's Hospital of Denver has been successful in this instrument tray weight reduction program. Complaints of back, neck, shoulder and wrist pain from employees have been significantly reduced, and wet loads have been virtually eliminated. If we can do it, so can you. Just follow these steps:

- ▶ With input from surgical services, establish the maximum acceptable weight limits for your facility prepared loaner and borrowed instrument sets.
- ▶ Add the established weight limit to your policy, with approval of surgical services, infection control and risk management.
- ▶ Inform your facility staff and loaner instrument vendors.
- ▶ Obtain written reprocessing and sterilization guidelines from all MDMs.
- ▶ Redesign the instrument sets to even out the metal mass.



- ▶ Perform AAMI product testing using biological and chemical indicators inside representative sets in the areas determined to be the most challenging and following the MDMs' sterilization parameters.
- ▶ Place the sets into use.
- ▶ Routinely monitor sets to ensure the weight does not increase over time.

And finally, just say "NO" so you do not get weighed down by instrument sets that are too heavy. ✚

References

1. STERIS. Preparing Instruments, Utensils, and Textiles for Sterilization and Wet Pack Problem Solving:2003, p. 3.
2. Association for the Advancement of Medical Instrumentation, Steam sterilization and sterility assurance in healthcare facilities, ANSI/AAMI ST46: 2002.
3. Association of PeriOperative Registered Nurses (AORN) Standards, Recommended Practices and Guidelines. Packaging Systems, Recommended Practice: 2006.
4. AORN Journal. Proposed AORN Position Statements for Consideration by House of Delegates., Vol. 83, No. 1, January:2006, p. 108-121.
5. Aesculap, Inc., AESCULAP STERILE-CONTAINER™ System. User's manual, Instrument and STERILECONTAINER Assembly, NOTE: 2003, p. 2.

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ANSWERS	
1. T	6. T
2. T	7. F
3. T	8. F
4. F	9. T
5. T	10. F

Sterile Process and Distribution CEU Information

CEU Applicant Name _____
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The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for one (1) contact hour for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding CBSPD certification, contact: CBSPD, 2 Industrial Park Road, Suite 3, Alpha, NJ 08865 or call 908-454-9555 or visit www.sterileprocessing.org.

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Nursing CEU Application Form

This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication.

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3. Add your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the CE questions.
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Application

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