New weight limit for instrument sets

A new standard for the first time sets a weight limit of 25 pounds for rigid sterilization containers and their contents. In recent years, orthopedic and neurosurgery loaner sets, in particular, have gotten bigger and heavier, causing strain for the staff. There are also concerns about whether these big sets can be sterilized and dried.

The standard from the Association for the Advancement of Medical Instrumentation (AAMI) titled Containment devices for reusable medical device sterilization (ANSI/AAMI ST77:2006), “is a long-awaited and sorely needed document,” says Nancy Chobin, RN, SCPDM, a member of the working group that developed the standard. Previously, there was no standard on the manufacture, cleaning, or sterilization of rigid containers or organizing cases.

ST77 includes recommendations for:

- durability of materials
- compatibility with the sterilization process
- biocompatibility of container materials with the devices being processed.

Also addressed are corrosion, performance, labeling, and testing.

The 25-pound weight limit applies to the container, instruments, and any accessories or wrappers when the container load is configured according to the manufacturer’s instructions.

AAMI also says it chose the 25-pound limit because sterilization and drying can be compromised when containers and contents are too heavy. AAMI also consulted the equation for manual lifting set by the National Institute for Occupational Safety and Health.

If a health care facility requests a set that is heavier than 25 pounds or chooses to exceed the weight limit, AAMI says the facility is responsible for verifying that the set can be sterilized and dried.

The standard recommends that facilities validate containers for use with their sterilization methods and cycles. Included are helpful tables with cycle parameters.

AAMI says it recognizes manufacturers will need time to comply with the standard but believes the weight limit is important. AAMI standards are voluntary. They are not legal requirements (unless written into government laws or regulations).

AORN updates packaging recommendations

In concert with AAMI, the Association of periOperative Registered Nurses (AORN) includes a 25-pound weight limit in its revised Recommended Practices for Selection and Use of Packaging Systems.

Two other changes to the recommendations raised questions at the AORN Congress in March in Orlando, Fla:

- AORN is advising that count sheets not be placed inside wrapped sets or rigid containers.

Though there are no known reports of adverse events related to sterilized count sheets, AORN says there also is no research on the safety of toners or papers that have been through a sterilization process. Because of the lack of evidence, the committee thought “this is the prudent and patient-safety thing to recommend,” Chobin said in a talk at Congress. AORN plans to work with some toner and paper manu-
facturers to see if toxicology studies can be done. A suggestion is to put the count sheet on the outside of the container.

One member of the audience questioned the advice, to applause, saying, “I’m concerned we are basing this on a theoretical risk,” adding she had “significant concern we are sacrificing one safety concern for another.”

AORN added recommendations on paper-plastic pouches, advising the pouches should:

—be used only for small, lightweight, low-profile items like 1 or 2 clamps or scissors, not heavy items like drills or retractors because of problems such as wet packs and broken seals

—not be used in wrapped sets or sterilization containers because the pouches cannot be positioned to assure adequate air removal, sterilant contact, and drying and have not been validated for this purpose.

Instead, facilities should consider types of smaller containers designed to go in larger containers.

Chobin noted, “You shouldn’t use any additional material in rigid containers unless it has been validated by the manufacturer in writing.”

**AORN recommends double gloving**

The association now recommends wearing 2 pairs of gloves, one over the other, for invasive procedures, as part of its revised Recommended Practice for Prevention of Transmissible Infections in Perioperative Practice.

AORN says it reviewed 18 clinical trials that “clearly demonstrate that double gloving minimizes the risk of exposure to blood during invasive procedures.”

A meta-analysis of 9 of these studies found, among other things:

• perforation rates of the glove closest to the skin are lower with double gloves

• more perforations are detected when wearing a colored underglove.

Other clinical trials found, in addition to other findings:

• a single orthopedic glove provides the same protection as 2 pairs of standard latex gloves

• wearing a glove liner between 2 layers of gloves in orthopedic cases reduced perforations to the innermost glove.

The Centers for Disease Control and Prevention, the American College of Surgeons, and the American Academy of Orthopaedic Surgeons support double gloving.

Also for 2007, AORN has updated recommended practices for:

• managing the patient receiving local anesthesia

• pneumatic tourniquets

• reducing radiological exposure.

---


The AORN Recommended Practices are available at [www.aornbookstore.org](http://www.aornbookstore.org). The standards can be purchased both as a book and on CD.