Sterilization Standards: Fact or Fiction?

Presented by Chuck Hughes, General Manager
SPS medical Supply Company

AAMI

Association for the Advancement of Medical Instrumentation

Meets in Washington, DC throughout each year and establishes *best practices* for sterilization which become our American National Standards.

Membership includes:

- Healthcare facilities
- Healthcare organizations
- Government agencies
- Medical device manufacturers
- Testing labs and Consultants

CSA STANDARDS

CSA standards are developed by volunteer technical committees consisting of representatives of government, industry, and users impacted by the standard.

SPS Medical becomes First U.S.-based Corporate Sustaining Member

Canadian representatives serve on AAMI committees and many CSA documents reference AAMI standards.

CSA STANDARDS

The Canadian Standards Association (CSA) currently offers twelve standards dealing with decontamination, sterilization, and infection prevention and control in health care facilities.

Most of these are National Standards of Canada, meaning they meet the requirements set out and enforced by the Standards Council of Canada.

CSA STANDARDS

In CSA Standards, "shall" is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard; "should" is used to express a recommendation or that which is advised but not required; "may" is used to express an option or that which is permissible within the limits of the standard; and "can" is used to express possibility or capability.

Why is adhering to Standards important?

Standards should be adhered to in any profession because they reflect the values of that profession. In healthcare, adherence to sterilization standards is critical to ensure patient safety as one of our greatest threats is healthcare-associated infections (HAIs).

HAIs are infections that patients acquire during the course of receiving treatment for other conditions within a healthcare setting.

DID YOU KNOW?

In the United States, more than 5,000 patients each day come down with a HAI and over 360 die per day.

In Canada, over 250,000 patients each year come down with a HAI and 8-12,000 die each year. 1/9 Canadians admitted to a hospital will acquire an infection, thereby eroding public trust and it is estimated that a severe HAI costs and additional $12,000 - $35,000 per patient.

Healthcare Acquired Infections

While the delivery of *non-sterile* instruments certainly is not a leading cause of surgical site infections, it has been documented as one of the causes.

You and I must do everything possible to reduce HAIs, which means compliance with *best practices* not some of the time, not most of the time, but all of the time!

Program Objectives

At the end of this program, participants will be able to:

- identify CSA Standards for preparation of soiled reusable items at point of use,
- explain CSA Standards for terminal reprocessing of reusable items in the MDR department,
- discuss CSA Standards for sterility assurance and storage of sterile items prior to use.

Fact or Fiction?

Cleaning of soiled instruments starts at point of use where all gross soil shall be removed.

FACT!

This is good ☺⟹

CSA

Immediately after use, the user shall clean medical devices of gross soil if present. The devices should be kept moist in a transport container by adding a towel moistened with water (not saline) or a foam, spray, or gel product specifically intended for this use.

Fact or Fiction?

Soiled instruments should be transported in covered, fully enclosed containers that are designed to prevent spill of liquids.

FACT!

CSA

Contaminated items shall be transported in covered, fully enclosed containers that are designed to prevent spill of liquids.

Retrieval and transport of contaminated items shall be scheduled so that decontamination procedures can be initialed immediately after use. All carts containing contaminated items shall be identified.

Here is a Great Idea!

Implement a Case Cart Check List that OR fills out after Surgery. This form is attached to each Case Cart returned to Decontamination for reprocessing.

CASE CART CHECK LIST

	Yes	No
Linen has been removed	☐	☐
All sharps have been removed	☐	☐
Lumens have been flushed	☐	☐
Instruments have been sprayed	☐	☐

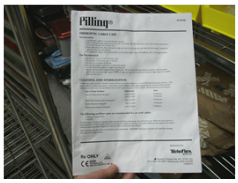
Date _____

Room _____

Surgical Technician _____ Nurse _____

True or False?

You should clean instruments using a standard cleaning procedure, if written instructions are not available from the device MFG.



False!

CSA

The device manufacturer's cleaning instructions shall be followed, including detergent type, water temperature, and cleaning methods.

Prior to purchasing a new medical device, health care facility personnel shall review the MFG's instructions.

CSA

If the instructions are unclear, incomplete, or inadequate, the MFG. shall be contacted for clarification or additional information.

In the event that a medical device cannot be adequately reprocessed, the device shall be contained, removed from service, and the appropriate health care personnel (e.g. staff from OR, IC, Purchasing) shall be notified.

EXAMPLE - MFG's Cleaning IFU
Popper & Sons Biopsy Needle

1. Submerge in neutral pH enzyme solution for at least 20 minutes and flush vigorously.
2. Rinse under running warm water.
3. Clean with stiff nylon brush in neutral pH detergent.
4. Rinse under running water. Vigorously flush under pressure all lumens, holes and other areas.
5. Disassemble devices.
6. Ultrasonic for minimum of 10 minutes w/equipment manufacturer's detergent.

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EXAMPLE - MFG's Cleaning IFU
Popper & Sons Biopsy Needle

7. Vigorously rinse with warm running water. Flush parts under pressure.
8. Perform second sonication for 10 minutes.
9. Inspect.
10. Vigorously rinse with deionized water. Flush lumens, holes and other parts with deionized water under pressure.

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EXAMPLE - MFG's Cleaning IFU
SYMMETRY Orthopedic Instruments

1. Submerge in enzymatic detergent.
2. Flush port with 50 ml enzymatic detergent.
3. Soak for 10 minutes in protein soluble detergent.
4. Scrub with soft bristled brush (agitate instrument while scrubbing).
5. Rinse with warm tap water (38-49°C)
6. Flush port with 50 ml warm tap water.
7. Place in bath of warm water (agitate by hand for at least 1 minute). Repeat this process 2 additional times.

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EXAMPLE - MFG's Cleaning IFU
SYMMETRY Orthopedic Instruments

8. Ultrasonic for 10 minutes with neutral pH detergent (flush port with 50 ml prepared detergent before sonication).
9. Flush port with clean tap water (3 times).
10. Rinse for at least 1 minute with tap water.
11. Dry with clean, lint free cloth.
12. Inspect.
13. Lubricate tip mechanism and finger slot (do not lubricate flush port).

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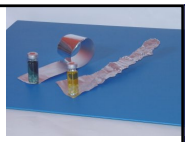
EXAMPLE MFG's Cleaning IFU
Zimmer Orthopedic Surgical Instruments

1. Completely submerge instruments in enzyme solution and allow to soak for 20 minutes.
2. Rinse in tap water for minimum of 3 minutes.
3. Ultrasonic clean for 10 minutes.
4. Rinse in purified water for at least 3 minutes.
5. Repeat sonication and rinse steps.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

CSA Standards



Decontamination

Upon completion of ultrasonic cleaning, the devices shall be rinsed thoroughly to remove any debris suspended in the solution and device surface.

The ultrasonic cleaning solution shall be changed at least daily and tested at least weekly for cleaning performance.

The final rinse for lumens of intravascular and intrathecal devices shall be performed with commercially prepared, sterile, pyrogen-free water.

True or False?

Mechanical cleaning is so effective, it does not matter how you load the equipment as long as you use the correct amount of detergent and have good quality water.

False!

CSA

When loading washers, the following principles shall be followed:

a) Devices shall be completely opened or disassembled to expose all parts.

b) Trays of instruments shall not be stacked.

c) Cupped surfaces shall face toward the spray source, usually downward to avoid pooling of water.

CSA

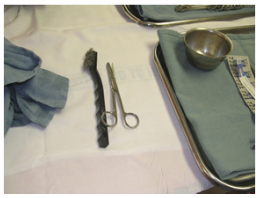
When loading washers, the following principles shall be followed:

d) Hollow devices (e.g. bags or bottles) shall be positioned on purpose built manifolds that spray clean the insides as well as the outsides.

e) Small parts and devices should be placed in a mesh container suitable for use with the washer.

Yes or No?

If you see a dirty instrument during inspection in the Prep & Pack area, it is important to brush off the soil prior to packaging.



No!

CSA

Decontaminated devices shall be visually inspected for cleanliness and integrity prior to sterilization, disinfection, or subsequent use.

Devices that are not clean shall be returned to Decontamination.

Yes or No?

It takes time, temperature and sterilant contact to sterilize medical devices; therefore, proper loading of sterilizer carts is important.

Yes!

CSA

The facility shall have procedures for sterilizer loading and operation. Packages shall be placed in the sterilized chamber in a manner that facilitates air removal, steam penetration, and steam evacuation for drying.

Wrapped items shall not contact the interior surfaces of the sterilizer chamber, as contact can damage the wrapper. Packages shall not be compressed, and a package shall not be wrapped in another package.

Pass or Fail?

What if an instrument set requires an extended cycle and the MDR technician runs a standard cycle. A biological indicator PCD was included with the load and passed.

Is the sterilization of the instrument set a Pass or is it a Fail?

Fail!

CSA

The health care facility's written procedures shall be followed to ensure the proper sterilization cycle is selected for the load being processed, i.e. that the cycle used is one that has been validated by the medical device manufacturer for use with that device.

Extended Cycles (examples)

Instrumentation	Sterilization Time @ 270°F		Sterilizer Mode
Acufex ACL Tray	10 min		Gravity
Acufex Meniscal Repair	10 min		Gravity
Acufex T-Fix	10 min		Gravity
Arthrex Bio-Fastak	18 min		Gravity
Arthrex Chondro pick	18 min		Gravity
Arthrex Gotham	18 min		Gravity
Aesculap Laparoscopic grasper	20 min		Gravity
Aesculap Laparoscopic scissor	20 min		Gravity
Bariatric Basic	15 min		Gravity
Biopsy tray cysto	15 min		Gravity
Cataract tray	20 min		Gravity
Globus Spine Tray Implants- Independence	10 min		Gravity
Globus Spine Tray Instr - Independence	25 min		Gravity

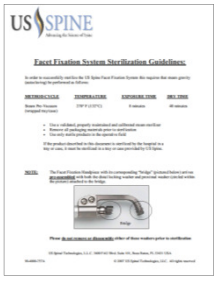
Partial list of instruments processed in the OR at a healthcare facility in NY.
This facility trained staff to adjust their Flash sterilizers to the Mfg's times.

Extended Cycles (examples)

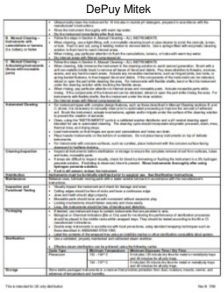
Instrumentation	Sterilization Time @ 270°F		Sterilizer Mode
SYMMETRY Endoscopic	5 min		Prevacuum
Biomet Orthopedics	5 min		Prevacuum
Innomed Knee & Tibial Triangle	6 min		Prevacuum
DePuy Hand Innovations	10 min		Prevacuum
Katena Instruments	15 min		Prevacuum
Stryker Spine Set	15 min		Prevacuum
Abbott Spine Set	15 min		Prevacuum
	Sterilization Time @ 273°F		**Sterilizer Mode**
Keeler Cryomaster	5 min		Prevacuum
Scientix SACP System	18 min		Prevacuum
Vilex CHI Sets	20 min		Prevacuum
Mentor Gel Breast Implant Sizer	20 min		Prevacuum
OSTEOMED Rigid Fixation System rev. 01/10	30 min		Prevacuum

Partial list of instruments processed in the SPD at a healthcare facility in CA.
This facility was using a standard 4 minute - 270°F prevacuum cycle for all loads.

Extended Cycles (examples)



DePuy Mitek

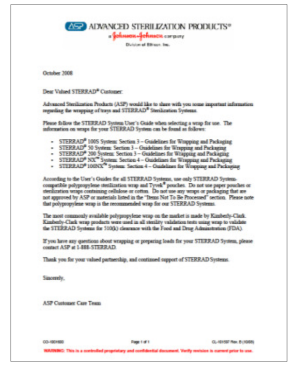


CSA Standards

Annex F
The health care facility needs to ensure that the medical device manufacturer's instructions are followed for extended cycle times unless the manufacturer provides written documentation that the device can e properly sterilized for 4 min at 132°C or 3 min at 135°C.

The health care facility <u>should</u> request information from the manufacturer as to the means whereby the extended cycle <u>should</u> be monitored in order to ensure that effective sterilization of the device is assured.

This is similar to asking the sterilizer MFG. what packaging system they used to validate their process.



ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.

October 2008

Dear Valued STERRAD® Customer:

Advanced Sterilization Products (ASP) would like to share with you some important information regarding the wrapping of trays and STERRAD® Sterilization Systems.

Please follow the STERRAD System User's Guide when selecting a wrap for use. The information on wraps for your STERRAD System can be found as follows:

- STERRAD® 100S System: Section 3 – Guidelines for Wrapping and Packaging
- STERRAD® 50 System: Section 3 – Guidelines for Wrapping and Packaging
- STERRAD® 200 System: Section 3 – Guidelines for Wrapping and Packaging
- STERRAD® NX™ System: Section 4 – Guidelines for Wrapping and Packaging
- STERRAD® 100NX™ System: Section 4 – Guidelines for Wrapping and Packaging

According to the User's Guides for all STERRAD Systems, use only STERRAD System-compatible polypropylene sterilization wrap and Tyvek® pouches. Do not use paper pouches or sterilization wraps containing cellulose or cotton. Do not use any wraps or packaging that are not approved by ASP or materials listed in the "Items Not To Be Processed" section. Please note that polypropylene wrap is the recommended wrap for our STERRAD Systems.

The most commonly available polypropylene wrap on the market is made by Kimberly-Clark. Kimberly-Clark wrap products were used in all sterility validation tests using wrap to validate the STERRAD Systems for 510(k) clearance with the Food and Drug Administration (FDA).

If you have any questions about wrapping or preparing loads for your STERRAD System, please contact ASP at 1-888-STERRAD.

Thank you for your valued partnership, and continued support of STERRAD Systems.

Sincerely,

ASP Customer Care Team

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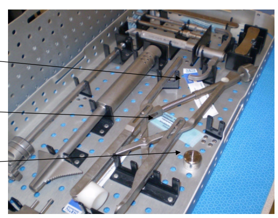
WARNING: This is a controlled proprietary and confidential document. Verify revision is current prior to use.

Validation Testing

Placing indicators in the most difficult to reach locations inside the instrument set is what test laboratories do to validate the cycle:

- Class 5 integrator
- Biological Indicator
- Temperature probe



Fact or Fiction?

After sterilization, the load should be protected and not touched until they have cooled to room temperature.

Fact!

CSA
When the load is removed, it <u>shall</u> be placed in a draft-free location where it will be undisturbed.

For large sterilizers using carts, a manufacturer-approved carriage <u>may</u> be used for this purpose.

CSA
Sterile packages <u>shall not</u> be touched, removed from the carts, or otherwise handled until the load is cooled to room temperature.

Warm items <u>should</u> never be transferred from the cart to cold metal racks or shelves for cooling, nor <u>should</u> they be placed within dust covers before they are completely cooled.

Fact or Fiction?

Sterilized items can be stored with other supplies and sterility is assured as long as the sterilizer passed and the items are used within 60 days.

Fiction!

CSA
Sterile processing areas shall not be used for the storage of supplies and materials other than those used in reprocessing.

Items that have been dropped on the floor, or that are compressed, torn, or wet, shall be considered to be contaminated and they shall be repackaged and reprocessed.

DID YOU KNOW?

KimGuard® and One-Step® Wraps

(Directions For Use)

Caution: Do not stack trays. Stacking trays can result in damage of the wrap caused by undue pressure from the weight.

This is now considered bad ☹ ⇨

CSA Standards

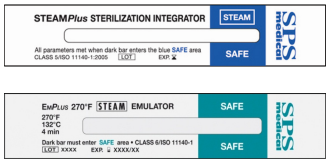
If the integrity of the package has been compromised or is questionable, the package shall be considered non-sterile and the contents reprocessed.

"A non-sterile instrument in surgery, is like a loaded gun!"

Dr. Bertha Litsky

True or False?

Class 5 indicators are referred to as "integrating" indicators and **Class 6** indicators are referred to as "emulating" indicators.



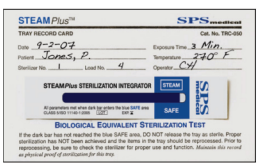
True!

CSA defines six classes of chemical indicators:

- Class 1 – Process Indicators
- Class 2 – Specific Test Indicators
- Class 3 – Single-variable Indicators
- Class 4 – Multi-variable Indicators
- Class 5 – *Integrating* Indicators
- Class 6 – *Emulating* Indicators

Sterilization Standards

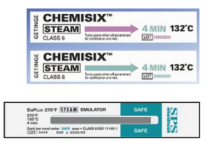
Class 5 chemical indicators react to all critical variables over a specified range of sterilization cycles and their performance *correlates* to BI performance as stated on their labeling.



Sterilization Standards

Class 6 chemical indicators measure the entire cycle and are cycle specific. This means you must use a different indicator for <u>each cycle</u> you use.

250ºF/121ºC - 30 min
270ºF/132ºC - 3 min
270ºF/132ºC - 4 min
270ºF/132ºC - 10 min
273ºF/134ºC - 4 min
275ºF/135ºC - 3 min



True or False?

Loads containing implants should be monitored with a BI and a Class 5 or Class 6 CI. If the implant is needed before the BI results, it should be released on the passed C5 or C6 results and documented with an early release form.

True!

CSA
It is strongly recommended that a Class 5 or 6 CI be included along with the BI in a PCD when monitoring a load with an implant.

If the implant must be released, the results of the Class 5 or 6 CI <u>can</u> assist the user in making a judgment regarding the risk of early release.

CONCLUSION

While we see thousands of instruments each and every week, it is important to remind ourselves, that behind every instrument is a **PATIENT**!