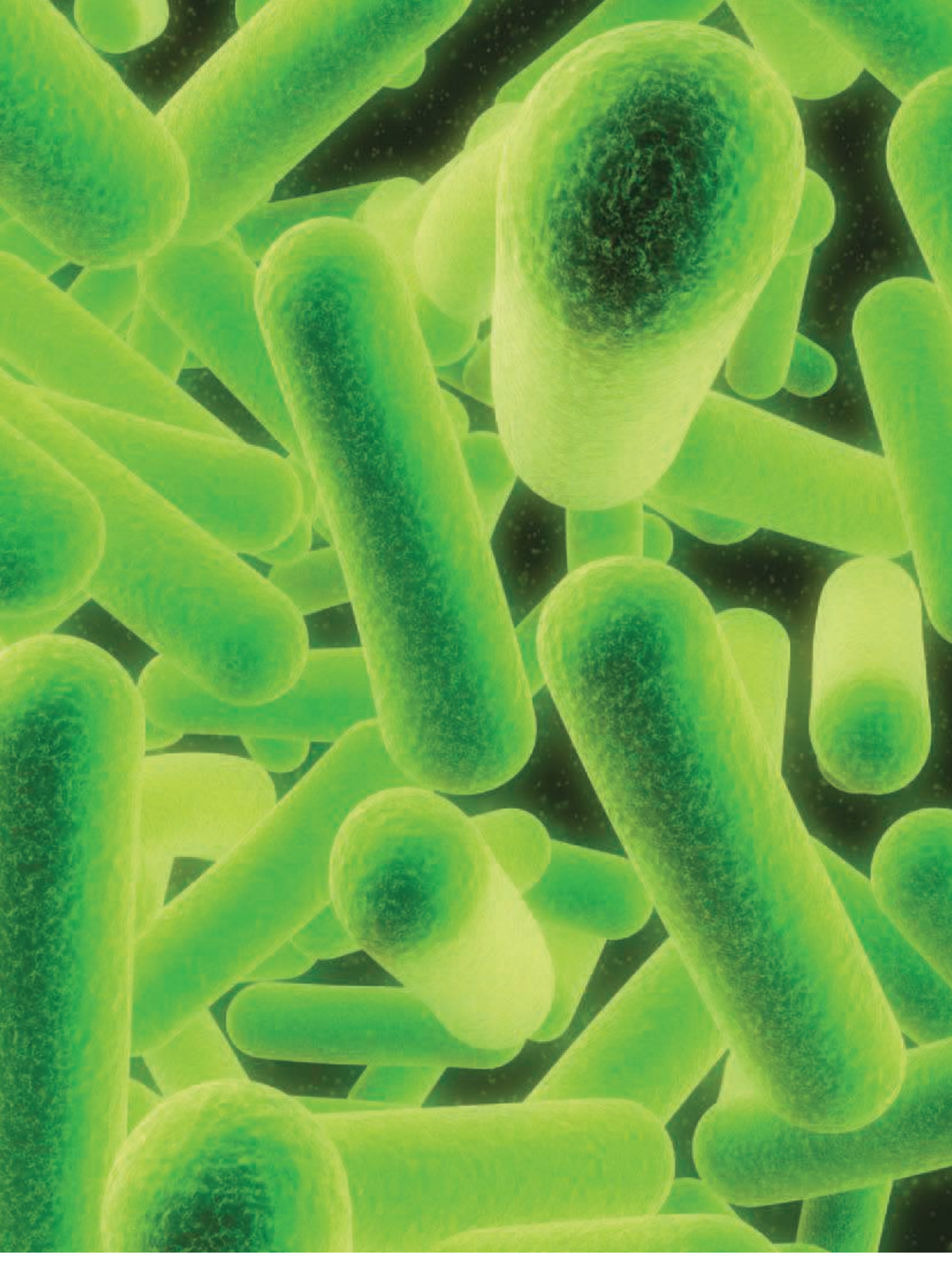

STERILIZATION—

Killing the Prehistoric Beast

Jinnie Cook, cst, cfa

Geobacillus stearothermophilus is not the name of an ancient dinosaur, but it may have been around during prehistoric days. *Geobacillus stearothermophilus* is a spore-forming bacteria found in soil, hot springs, arctic waters, ocean sediment and spoiled food products. Judging by the locations where this spore-former is found, it is apparent that it is able to resist and survive in extreme environments.

This particular bacterium is found to be the most resistant to steam. That is why it is the microorganism that is used in biological indicators to determine whether resistant forms of bacteria have been destroyed during the sterilization process.

UNDERSTANDING SPORES

To completely understand the significance of this microorganism, it is important to understand exactly what a spore is. Spores, simply put, are microorganisms which are able to survive in an unfavorable environment. They can survive in ultraviolet light, as well as in many harmful chemicals.

A spore can be thought of as a shield or "force field" around the important components of bacteria.

During spore formation in bacteria, the cell is in the process of reproducing itself. The mother cell makes a duplicate daughter cell. When unfavorable conditions arise for the spore-forming bacteria, the protective mother cell engulfs the daughter cell.

There are now two plasma membranes surrounding the daughter's cell DNA. Between the two plasma membranes, a hard shell develops.

This is the spore coat or "force field." The spore protects the new daughter cell and the important DNA. The cell remains dormant until external conditions become favorable.

THEIR POTENTIAL FOR DANGER

Why is knowledge of spores important? Because spores can live on surgical instrumentation if not properly cleaned and sterilized. Knowledge of spores is especially important when dealing with surgically implanted devices.

Spores on surgical instrumentation can have devastating results, but implanted devices represent a higher degree of risk of infection, since they are retained in the body.

Spores on implanted devices can remain dormant in the body for up to one year after the surgery. Once the dormant bacterium wakes up, it becomes an opportunist and begins to multiply rapidly, causing infection within the body.

Orthopedic implants can have more of a devastating impact than other implants. The reason for this is due to the interrupted blood supply when the periosteum is removed from the bone.

The blood supply to the bone travels through the periosteum. When the periosteum is stripped away to allow for plate placement, the blood supply to the area of injury is decreased.

Package closures

From the nationally accepted standard, ANSI/AAMI ST79:2006, 8.3.3 Package closures:

Accessories used to close or secure packages should be chosen to allow the steam sterilization process to occur, avoid constriction of the package, and maintain package integrity. Tape (other than sterilization indicator tape) should not be used to secure packages, nor should safety pins, paper clips, staples, or other sharp objects. Elastomer bands designed specifically for sterile packaging are acceptable as outside closures only if the wrapper manufacturer explicitly recommends their use and only if case is taken to choose the proper size (relative to the length and width of the package) so that the elastomer band fits snugly yet does not constrict the package (eg, create an "hourglass" effect) or cause excessive wrinkles or folds in the package. Rubber bands or tape should not be used to hold instruments together in a group.

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Once the blood supply is decreased, it becomes more difficult for antibiotics to reach the bone through the bloodstream.

Spore-forming bacteria include, but are not limited to, the following:

- *Clostridium perfringens*—a source of gas gangrene
- *Clostridium botullinum*—a source of botulism
- *Clostridium tetani*—a source of tetanus
- *Bacillus anthracis*—a source of anthrax

PREVENTION

How can we as surgical technologists and important members of the operating room team prevent these infections?

Besides strict adherence to aseptic technique, properly reprocessing and sterilization of surgical instrumentation can and will reduce the morbidity and mortality rate in the surgical patient.

THE PROCESS

Many hospitals do not carry multiple instrument sets for each specialty. The reason is that specialty instrumentation is expensive.

So, how do we make our work environment safe for our patients?

Consider, for example, a hospital that performs a high volume of neurosurgical procedures. This hospital may only have three neurosurgery pans.

If six neurosurgery cases are scheduled in two rooms simultaneously, and there are only three neurosurgery pans, what needs to be done to ensure the patients are safe from potentially harmful microbes?

Answer… The instrument sets need to be thoroughly cleaned and decontaminated before being resterilized.

This process begins with placing the soiled instrumentation into an enzymatic cleaner. The enzymatic cleaner aids in loosening and breaking down the adhered blood and tissue.

Next, the instruments are scrubbed individually with a scrub brush, and a bottle brush and/or syringe are used to clean the lumens of the instruments. The instruments are flushed and brushed until they are free of visible blood and tissue.

Next, the instruments are placed into an ultrasonic cleaner and/or washer-sterilizer to remove the embedded bioburden. Ideally, the instruments should be allowed to dry before they are assembled, placed into an instrument pan, wrapped or placed into a closed system sterilizing pan. Sterilization should be accomplished by the use of a gravity displacement sterilizer or prevac sterilization system.

Unfortunately, this isn't always possible. Surgeons and anesthesiologists don't want to wait more than an hour for the complete sterilization process to be performed, and facilities continue to demand quick turnover times.

Therefore, instruments are usually flash sterilized while the O.R. room is being cleaned and the supplies are being opened for the next surgical procedure.

Is this right? No!

PATIENTS DESERVE CONSISTENT CARE

Biological indicators are run in each autoclave daily. These biological indicators are the only means of ensuring that resistant microorganisms have been killed.

An autoclave that is used for flash sterilization has a biological test run each day. Flash sterilization *does* sterilize the instrumentation. However, there is controversy surrounding flash sterilization and the lack of proper pre-cleaning and disinfecting of the instrumentation.

Therefore, in order to ensure quick turnovers, instrumentation that needs to be turned over quickly generally does not go through the entire decontamination process.

Patients have the right to receive continuity of care. Each patient deserves to have instruments processed to the same degree as the instruments that were used in the first case of the day.

Hospitals should strive to ensure that patients receive this continuity of care by allowing surgical cases to be scheduled in such a way that proper instrument reprocessing can be accomplished without causing delays in the overall surgery schedule.

QUESTIONS THAT MUST BE ADDRESSED

Flash sterilization was designed to be used if a necessary instrument was dropped during a surgical procedure. The instrument is cleaned and flashed sterilized, so that it can be used again on the same patient.

Since the practice of flash sterilization has deviated from its original intended use, there are questions that need to be asked and a process that needs to be adhered to.

Chemical and biological indicators

Chemical indicators (CIs) may be used externally (eg, the thermochromic indicator tape shown here) or internally. The nationally accepted standard, ANSI/AAMI ST79:2006, 10.5.2.1 General Considerations, states:

Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile.

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Biological indicators (BIs) should consist of spores of *Geobacillus stearothermophilus* (formerly named *Bacillus stearothermophilus*) that are intended to be killed during the sterilization process. According to the ANSI/AAMI ST79:2006, 10.5.3.1 General Considerations:

Biological indicators provide the only direct measure of the lethality of the sterilization process. Biological indicators must be incubated for various periods of time (depending on the specific product) until it is determined whether the microorganisms grow (ie, they survived the sterilization process) or fail to grow (ie, they were killed by the sterilization process).

Question #1

Which cycle is being used?

This is important, because it determines the time needed for sterilization.

Parameters for Gravity Displacement at 270-272°F

Open Instrument/Flash Pan	*Time*
Metal, nonporous, without lumens	3 min
Metal with lumens, porous, implantable	10 min

Parameters for Dynamic Air-Removal (Pre-Vac) at 270-272°F

Open Instrument/Flash Pan	*Time*
Metal, nonporous, without lumens	3 min
Metal with lumens, porous, implantable	4 min

*Note: In a closed flash pan system, all instruments are processed for 10 minutes gravity, unless the manufacturer's recommendations differ. A closed flash pan system is recommended to help ensure safe, sterile transport of sterile instrumentation from the flash autoclave to the operating room.

Question #2

Which temperature should be used?

Temperature will determine time. Flash cycles will be set at 270-272°F. It is important to check for correct temperature setting before beginning flash sterilization.

Question #3

Which type of internal indicator should be used?

The traditional practice has been to use a chemical indicator only. A chemical indicator is the strip that changes color when exposed to heat.

A chemical indicator does **NOT** determine sterility, though. It only determines that an instrument has been exposed to the sterilization process. Only biological indicators provide direct evidence that the sterilization process is able to kill spores.

The AST Education and Professional Standards Committee has determined that as a profession we should adopt the standards set forth by the American Society for Healthcare Central

Service Professionals (ASHCSP) of the American Hospital Association.

The ASHCSP policy states:

Biological monitoring should be used to challenge the performance of the sterilizer. They should be used routinely in steam sterilization loads, daily preferably, in EACH load that contains critical items, eg, instrument sets, individual surgical instruments, or any item that comes in contact with sterile tissue.

Question #4

How many instruments can be flashed in one pan during a flash cycle?

There is controversy on the amount of instruments that can be flashed at a given time.

According to ANSI/AAMI/ISO standards, the biological indicator test, which is performed each morning on every autoclave and run on all cycles, is placed in the most difficult place for steam to penetrate, such as in the center of an instrument pan, in a corner, or in the center of a layered pan.

If the biological test is negative for the spore-forming bacteria *Geobacillus stearothermophilus*, then the assumption is that subsequent flash loads will have the same negative results.

If this principle is true, the amount of instruments in one flash pan does not matter, because the correct time and exposure of the steam sterilization process will reach all the difficult areas of the instrument pan.

*Note: AAMI standards for 2008 indicate that instrument pans should not exceed 17 lbs. This weight limit has been lowered from the organization's previous guideline of 25 lbs.

Best advice? Follow your facility's policies and procedures.

Question #5

Do any of the instruments have a cannula?

If the answer is yes, there is a process that must be followed before flashing instruments with lumens.

After thorough cleaning, all instruments with lumens must have sterile, distilled water run through each lumen before the flash sterilization process is begun.

The sterile, distilled water does not sterilize the lumens; it is simply the most noncorrosive fluid found in the O.R.

The purpose of running distilled water through the lumens is so the steam is able to penetrate each lumen in the reduced sterilization time of the flash sterilization cycle.

If there is no fluid in the lumen before sterilization begins, there is no guarantee that the steam will be able to heat the inner lumen to the temperature required for sterilization.

Question #6

Are any of the instruments porous?

Porous items, eg magnetic items—as well as items with lumens—take longer to sterilize. These items need to be flash sterilized for 10 minutes, when the need arises.

Question #7

Are the instruments going to be used on bone?

Since postoperative bone infections have such devastating results on a patient, the theory is that more exposure time to the sterilization process is better.

For example, consider a key elevator. The key elevator meets the criteria for minimal flash time of three minutes. It is metal, nonporous and does not have a lumen.

Therefore, does the 10-minute flash cycle at 270-272°F in a gravity displacement sterilizer make the key elevator *more* sterile than it would be following a three-minute cycle at the same temperature?

If one believes that a three-minute flash cycle at 270-272°F in a gravity displacement or prevac sterilizer is sufficient time to kill resistant, spore-forming bacteria for metal, nonporous, noncannulated instruments, then why is it not sufficient for a key elevator, which is used to strip the periosteum off of bone?

If we do not believe this, then we may want to consider increasing the minimum flash time on all flash cycles.

Release criteria for implants

According to the nationally accepted standard, ANSI/AAMI ST79:2006, 10.6.3 Release criteria for implants, implantable devices should not be used until the results of biological indicator (BI) testing are known. When emergency conditions dictate the use of implantable devices prior to receiving the results of BI testing, the standard indicates that written documentation—an Exception Form for Premature Release of Implantable Device/Tray—accompany the device to the O.R., where surgical staff complete the form and then return it to Central Service within 24 hours.

When documented medical exceptions dictate (eg, the need for trauma-related orthopedic screw-plate sets), it could be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented. It is critical that this documentation be fully traceable to the patient. Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule… Steps should be taken to reduce the frequency of emergency release of implantable items.

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Question #8

Are instruments implantable?

It is not the recommendation of AAMI, ANSI, ISO and ASHCSP to flash sterilize implantable devices.

Again, the question is, if all the appropriate flash times and temperatures are adhered to, then why is it not recommended?

Some of the objections to this practice include the lack of proper cleaning and decontamination of the implant prior to the flash sterilization cycle.

Question #9

Do I need to use a biological indicator on each flash cycle?

Yes! Always!

Since the biological indicator is the **ONLY** method to verify that sterility has taken place, it must be used every time for our patients' safety.

Question #10

Which biological indicator should be used?

For flash sterilization, the rapid readout is used most frequently.

The biological indicator with the *BLUE* cap is used for gravity displacement sterilization. The biological indicator with the *BROWN* cap is used with pre-vac.

Both of these biological indicators contain the resistant, spore-forming bacteria *Geobacillus stearothermophilus*. It is classified a *thermophile*, which means it is able to resist extreme temperatures.

Geobacillus stearothermophilus is the most resistant bacteria to heat, and the most difficult to kill. If it is killed, than the other less resistant strains of bacteria are killed as well.

Question #11

How do I use a biological indicator?

Adhere to the following steps:

Important: Do not pop the cap before the sterilization process!

1. Place the biological indicator in the pan
2. Run a complete cycle—Blue cap for gravity; brown cap for pre-vac
3. After the completed cycle, the sterile team member removes the biological indicator from the pan of sterilized instruments.
4. The sterile team member hands off the biological indicator to the nonsterile team member.
5. The nonsterile team member pops the cap, places it into the crusher and rocks it back and forth.
6. The crushed vial is then placed into the appropriate color-coded incubator. The color of the cap matches the color of the appropriate incubator well.

7. The first readout is taken at 20 minutes.
8. The final readout is taken after one hour has elapsed. (One hour applies to the time before the flashed implant can be implanted.)

Note: The brown-capped vial for pre-vac takes three hours before a final readout is available. After 24 hours, the readouts are conclusive that indeed the ancient prehistoric bacteria have been killed.

The flashed instrument set or implantable device is placed onto a separate sterile table, in order to prevent possible cross-contamination, until a negative biological indicator readout has been determined.

After this process is complete, the sterile item can be placed safely on the back table or Mayo stand.

CONCLUSION

Flash sterilization between cases is not a recommended practice. It is not to be used as the standard of care for lack of sufficient surgical instrumentation.

When flash sterilization is necessary, it should be performed in a designated covered flash pan. The covered pan will help ensure sterility of the surgical instrumentation.

The use of flashing multiple instrument sets between cases needs to stop. The risk of contamination increases with each flash pan moved from autoclave to the operating room.

If we believe the patient is our primary focus, then we need to find methods within our individual facilities to reduce this practice, even if we kill the prehistoric beast *Geobacillus stearothermophilus*.

FOR MORE INFORMATION

Association for the Advancement of Medical Instrumentation (AAMI) ***www.aami.org***

American National Standards Institute (ANSI) ***www.ansi.org***

American Society for Healthcare Central Service Professionals (ASHCSP) ***www.ashcsp.org***

International Standards Organization (ISO) ***www.iso.org***

ABOUT THE AUTHOR

Jinnie Cook, CST, CFA, currently works at Medical Center of Arlington in Arlington, Texas. Due to a recent injury to her wrist during a fall in the O.R., she is working in the center's education department, where she trains nurse interns, O.R. and labor/delivery staff.

Jinnie also has made significant contributions to the profession as author and contributor of many educational products. She currently serves on the AST Education and Professional Standards Committee.

EDITOR'S NOTE

The AST Education and Professional Standards Committee is writing a new standard on instrumentation sterilization, which will be published in the spring. As a benefit of membership, all AST members will have free access to the new standard on AST's website.

References

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST77:2006, 5.8. 2006.
2. Beaver M. SPD Staffs Face Old Problems, but New Standards Offer Help. *Infection Control Today.* August 1, 2007. Available at: ***http://www.infectioncontroltoday.com/articles/412/78h177181545724.html.*** Accessed February 12, 2008.
3. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2006.* Association for the Advancement of Medical Instrumentation: Arlington, Va; 2006.
4. Dix K. Gram-negative and Gram-positive Bacteria. *Infection Control Today.* September 1, 2003.Available at: ***http://www.infectioncontroltoday.com/articles/391Clinical.html.*** Retrieved November 26, 2007.
5. Kenneth Todar, Gram-positive, Aerobic or Facultative Endospore-forming Bacteria (formerly, The Genus Bacillus. *Todar's Online Textbook of Bacteriology.* Available at: ***http://www.textbookofbacteriology.net/Bacillus.html.*** Accessed November 15, 2007.
6. Maria Do Carmo Noronha Cominato Bergo. Evaluation of Cleaning and Disinfection Processes Performed by Automatic Washer/Disinfectors. *Infection Control Today*. May 1, 2005. Available at: ***http://www.infectioncontroltoday.com/articles/412/412_551inside.html.*** Accessed February 12, 2008.
7. Microbial Spore Formation. Microbeworld. Available at: ***http://www.microbeworld.org/know/spore.aspx.*** Accessed November 26, 2007.
8. The Chemical Basis of Microbiology. Microbiology 101. Available at: ***http://www.universalclass.com/i/crn/31712.htm.*** Accessed November 26, 2007. [Available by paid subscription only].
9. Young M. Class 5 Integrating Indicators for Steam Sterilization Process. Available at: ***http://www.hpnonline.com/ce/pdfs/0504cetest.pdf.*** Accessed February 12, 2008.