Shelf-Life for Autoclaved Medical Instruments

The issue of shelf-life has been addressed by several organizations. After reviewing the literature on topic of shelf-life for autoclaved medical instruments I found that the Centers for Disease Control and Prevention (CDC) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) do not provide specific shelf-lives for sterile items. The current recommendation is for healthcare facilities to develop policies that establish "event-related" shelf-lives for the autoclaving of medical instruments.

In 1983 the CDC published recommended storage times for a variety of sterile packs. Many healthcare organizations still follow those recommendations; however, many consider the recommended shelf-life to short resulting in wasted time, supplies, and manpower.

The concept of event-related shelf life for sterilized items is widely accepted. This approach recognizes that autoclaved medical instruments would remain sterile indefinitely, unless an event causes them to become contaminated, e.g., torn or wet packaging. There have been several studies supporting this.

The healthcare facility should choose either an event-related or date-related policy for managing the process. Each healthcare facility should have a written policy that addresses the shelf-life of a packaged sterile items based on the quality of the wrapped material, storage conditions, conditions during transport, and the amount of handling. The processing of instruments requires care be taken to avoid contamination of the instrument(s) during storage; instruments need to be stored in a way to preserve the package; and packages must be examined before use to ensure integrity and dryness.

Storage Recommendations for Autoclaved Medical Instruments
1. Allow packages to dry in the autoclave before handling to avoid contamination.
2. Store packaged sterile instruments in a clean, dry and dust and lint free area (covered or closed cabinets are recommended.
3. Store clean and sterile materials at least 8 to 10 inches above the floor, 18 inches below the ceiling, and 2 inches from the outside walls.
4. Keep like items together—sterile with sterile and clean with clean.
5. Rotate stock with older items being used first.
6. Do not store sterile supplies under sinks or other location where they may become wet, on the floor, windowsills or other supply areas than designated shelving or cabinets.
7. Do not store sterile supplies with items not intended for clinical use, e.g., office or cleaning supplies.
8. Do not handle sterile packages unnecessarily to avoid contamination.
9. Items stored and not used within 12 months should be evaluated as to the condition of the packaging as well as the necessity of stocking infrequently used items.

Checklist for Sterility Before Opening Package
1. Check the expiration or sterilization date.
2. Check for the indicator color change.
3. Check how it had been stored.
4. Check the general condition of the wrapper.
5. Check how the package has been stored.
6. Check for any holes or moisture damage.

Event Related Policy/Procedure Guidance

The Health Unit must have a policy for managing the autoclaving of medical instruments. If adopting an Event-Related Shelf Life Policy you must address the following in your policy:
1. Statement that all sterile items will no longer have an expiration date.
2. Loss of sterility is event-related.
3. Sterilized items may be used as long as the integrity of the package is not compromised, e.g., wet, torn, damaged, contamination suspected.
4. An indefinite shelf-life label is placed on each sterilized item.
5. Each packaging label should be documented with sterilized identification number, operator's initials, and sterilization date.
6. Procedures for wrapping and sterilizing medical equipment.
7. Autoclaved items should not be used if mechanical or chemical indicators indicate inadequate processing.
8. Packages compromised during storage require re-cleaning, repacking, and rasterizing.
9. Proper storage of items to reduce package contamination and compromise.
10. Rotate stock so older items are used first.

Monitoring Methods
To ensure patient safety when it comes to instrument processing and sterilization, three methods of monitoring should be use. They include mechanical, chemical and biologic.

Mechanical monitoring is done by monitoring the cycle time and the temperature of each load. The temperature and pressure for each load should be recorded and tracked.

Chemical indicators are affixed to the outside and/or inside of each package to demonstrate the package has been processed through the sterilization cycle. Ideally chemical indicators should be placed inside each pack to verify sterilant penetration.

Biological indicators are recognized as being closest to the ideal monitors of the sterilization process since they measure the sterilization process directly by using the most resistant microorganisms and not merely testing the physical and chemical conditions necessary for sterilization. The results of the spore testing should be recorded and tracked.

If the spore testing results are positive the test should be re-run. If the results remain positive the item should be taken out of use. The next step should be to discuss with the Infection Control Committee (ICC) in the Health Unit and identify a solution based on industry standards.

The ICC should routinely review the procedures for use of the sterilizer:
1. Identify correctable variances in operator competence.
2. Documentation of sterilization records, including chemical and biological indicator test results.
3. Sterilizer maintenance and wrapping.
4. Reviews may identify improvement activities to ensure that operators are adhering to established standards.

References
Centers for Disease Control and Prevention (CDC)
Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)