



Surveyor Panel Discussion

By

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&
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October 7, 2016

Objectives

- Provide baseline objectives for a successful survey as it relates to 416.51 - Infection Control
- Understand what is currently trending
- Present and discuss opportunities for improvement
- Provide an opportunity for attendees to ask unfiltered questions of a surveyor

How It Works.....



The Basis for the Rules

42 CFR 416
Federal Requirements
Posted in the Federal Register
PLUS
State Guidelines
PLUS
AAAASF/AAAH/HHFAP/TJC/IMQ

Trending Citations & Solutions

Medication Safety

MDV - patient care areas

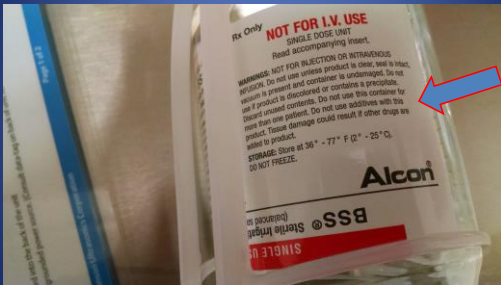
SDV – no preservatives!

Newly opened vials -




Expired meds – try red dot system

Medication Safety



Medication Safety



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 018469-S-056

SUPPLEMENT APPROVAL

Alcon Laboratories, Inc.
Attention: Suzanne Cadden MSc
Head of Regulatory Affairs - USA
6201 South Freeway
Fort Worth, TX 76134

This Prior Approval supplemental new drug application proposes the removal of the sentence "Do not use additives other than the BSS PLUS Concentrate Part II (20 mL) provided with this bottle" from the reconstitution directions section of the label for the 500 mL (Part I) bottle container label and the 250 mL (Part II) bottle container label.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

WILEY A CHAMBERS
04/27/2016

Trending Citations & Solutions

Hand Hygiene

- ABHS
- Technique
- After Removing Gloves
- Nails




Trending Citations & Solutions

Glucometer

- Manufactures Guidelines
- Cleaning & Disinfecting
- Controls – weekly, new bottle of test strips or control, dropped or replaced battery, ?? results

Trending Citations & Solutions

Surgical Attire

- Caps
- Masks



Trending Citations & Solutions

PPE

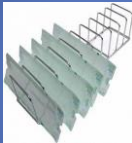
- Goggles
- Impervious Gowns
- Gloves



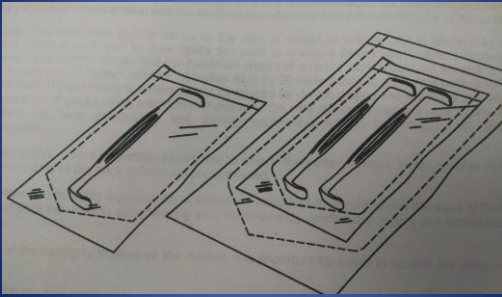
Trending Citations & Solutions

Sterilization Processes

- Process
- Tracking



Double Pouching



Monitoring & Documentation

Monitoring Sterilization

- Mechanical Indicators
 - Gauges, displays, printouts
 - Indicates if device working properly
 - Not indicator of sterility
- Chemical Indicators
 - Change color with timed exposure to heat, steam
 - Not indicator of sterility
 - Used to show items have gone through sterilization process
- Biological Indicators
 - Indicator of sterility
 - Demonstrates bacterial spores on test strips or in vials/containers have all been killed



Instructions for Use: Weekly biological monitoring is recommended.¹

1. Write the indicator number, load and date on the indicator.
2. Place (text) indicator into a package that is similar to the typical packs used (e.g., in an autoclave bag) and in the area of the indicator that is the most difficult to sterilize, i.e., over the drain or in the corner of a full load. Run cycle.
3. Caution: After sterilization, the contents of Attest biological indicators are hot and under pressure. Always allow to cool. Failure to cool for at least 10 minutes may cause the glass ampule to burst which may result in injury from flying debris.
4. Check the chemical indicator on the Attest indicator for a color change from rose to brown.
5. Activate (crack) processed indicator by inserting into the ampoule.
6. Use of a Control: Incubate a non-processed, activated Attest indicator at the same time. A control ensures space variability.
7. Examine both the test and the control indicators for any color change at regular intervals and finally at 24 hours for the 120P or 48 hours for the 120P indicators. Act on a positive test (yellow) immediately.
8. Record results in the log book.

Indicator Selection for Steam Autoclaves

Sterilization Process	Time (minutes)	Package Material	Attest Indicator Strip Color
120P (120°C) (Gaseous)	15	None	120P
120P (120°C) (Gaseous)	20	Wetpak	Biological Indicator (12)
120P (120°C) (Gaseous)	20	Wetpak	120P (20min)
120P (120°C) (Gaseous)	20	Wetpak	Biological Indicator (12)

3M™ Attest™
Biological Monitoring System (Form No. 116K)
Includes one ampoule and 120P test of 12 indicators and one log book.

Results
Negative (not cracked)
Positive Control (2-Gram)

Interpretations
Spores were killed. The sterilization process was successful.

Disinfection process follow: Recall all loads once test negative test. Determine cause the disinfection process failure. Repeat test. Do not process, until other loads with biological indicators test negative in three successive cycles.

There is a problem with space within the growth media on the ampoules: Check dating of the Attest indicators used. Repeat test if results on the same test location is for 3 or more.

Reference: 1. NABH, C. JADA, March 1993.

3M Reliability

Trending Citations & Solutions

Miscellaneous Issues



Some General Solutions

- Stay up to date with Appendix L – 4/1/15
- Watch the CMS memos – 6/20/16
- Consider a second outside opinion
- Network with local facilities for state
- Watch posting on state website
- Watch postings on accreditation websites

Questions????

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INFECTION PREVENTION STRATEGIES
FOR
AMBULATORY SURGERY CENTERS
