WINTER 2020 | VOL 22 ISSUE 4

THE CRITERION

Official Newsletter of the CBSPD

In this newsletter:

President's Message

The CBSPD is abuzz with many changes and growing excitement as we enter the new year. I am eager to celebrate and share with you the many exciting, positive things we have been doing. The leadership and reporting structures have been reorganized. It is with honor that I assume the position of President of the Board of Trustees of the CBSPD.

The Board of Trustees and certificants that represent each of CBSPD's certifications came together in Newark N.J. in November 2019 for our annual meeting. We heard reports from each of the Committees and discussed what each had been doing. It was encouraging to hear the success stories and the lessons we have learned from each other.

The development of our relationship with South America as well as several Middle Eastern countries has continued to grow. We sincerely appreciate the efforts of Livia Zuniga, International Liaison to the CBSPD Board of Trustees, to expand the CBSPD certification in these areas. Amber Moore, Chairperson of the CBSPD Item Review Committee, recently had the privilege of attending their national conference and was impressed with the dedication of the individuals that are certified. They have requested that CBSPD be written in English on their Spanish certificates.

We have multiple exciting things happening with the Item Review Committee. To make the exams more secure and

CBSPD's President of the Board of Trustees Message, continued:

easier to manage, Tony Bonell, CBSPD Statistician, has developed a computer program that will do this for us. So exciting!

If you are interested in the development of questions for any of the certification exams, please let us know and we will send you the information that you would need to do this.

Nominations and positions are open on the Board. Board business is carried out throughout the year via email and conference calls. The annual Board Meeting is held the second weekend in November each year. Please nominate someone who is willing to serve, or, consider nominating yourself. Check the new CBSPD website for more information, www.cbspd.net

Speaking of websites, if you haven't visited the CBSPD website, you are missing a lot of good information. Heidi has done a great job making it very easy to navigate. Also, the 7th edition of the "Basics of Sterile Processing" is now available. Look for them on the web site.

Sue McManus
President, Board of Trustees CBSPD

Association for the Advancement of Medical Instrumentation (AAMI) Update

The 2019 Sterilization Standards Week meetings were held in March and October, 2019 at the AAMI Center for Excellence (ACE).

The Endoscope Committee met for 2 days and resolved most, but not all of the comments received on the update to ST-91 (Processing of Flexible and Semi-Rigid Endoscopes in Health Care Facilities.) It was determined that a conference call would be held in July to continue to review and respond to the comments. Under the auspices of the Endoscope Committee, another Committee was formed to develop a new Technical Information Report (TIR) on Processing ultrasound probes and transducers. The Committee met and reviewed the first draft.

Ethylene Oxide Committee - Document ST-24 "Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities" is being updated.

2020 Exam Dates

Examination Dates	Application Deadlines
February 3-8, 2020	January 28, 2020- TUESDAY
May 4-9, 2020	April 28, 2020-TUESDAY
August 3-8, 2020	July 28, 2020- TUESDAY
November 2-7, 2020	October 27, 2020- TUESDAY

Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities - ST-79 - Committee met to consider 5 amendments to the document that was published in 2017. One amendment was approved. There were comments on the other four that still need to be addressed. AAMI is considering how to provide the updated amendments to the public, once completed .

The Chemical Sterilant and High Level Disinfectant Committee (ST-58) met and is continuing to update this document.

The AAMI Board approved the development of a new Technical Information Report (TIR) on Off-Site Processing. This document was approved because many facilities are performing off-site processing for satellite facilities and more guidance is needed for facilities on this practice.

Respectfully submitted,
Nancy Chobin, RN, AAS, ACSP, CSPM, CFER

CBSPD visits Mexico City for the First Mexican Association for Sterile Processing Election of Board of Directors Event.

BY: Amber Moore, CSPM, CSPDT, CFER, CST, AAS
CBSPD Item Writing/Review Chairperson

On August 24th, 2019, Livia Sentíes Zuniga and I were invited to represent the CBSPD by our attendance at the Mexican Sterile Processing Association's (AMEXPE) voting and announcement of the newly elected Board of Directors to serve four year terms. The election event was held at the beautiful Hospital San Angel Inn Patriotismo in downtown Mexico City, Mexico.

This was a very historic event, not only for Mexico, but for Latin America as well, as it was the first election held in Mexico for the Mexican Sterile Processing Board. Seventeen years ago, Nancy Chobin, President and Founder of the then NICHSPDP, met with Livia and Antonio Tellitud to discuss the start of the detailed process.

You can easily maintain your certificaton with CEUS, by submitting your programs for CEU approval within 6 weeks.

Remember! We also have a Youtube Channel with a video on how to recertify as well. Learn more at:
https://www.youtube.com/watch?v=LKry-DfvoNw&t=67s

Since that time, a lot of hard work has been put into making certification possible in Mexico and Latin America. The first CSPDT exams were administered in 2003 in Mexico City and in 2005 in Guatemala. Since then, 13 additional Latin American countries have joined forces and administer CBSPD certification exams for Technician and Management.

Soon to come to Mexico, with the culmination of a lot more hard work, will be the Certified Flexible Endoscope Reprocessor (CFER) exam. (for more information about the history of CBSPD Certification in Sterile Processing in Mexico and LA, please visit Livia's article in the Summer 2019 Criterion: https://www.cbspd.net/newsletters/)

Previous and Past Board of Directors. From left to right: Alicia Hernandez, Carlos Ridaura, David Velez, Carlos Vazquez, Lourdes Melendez, Jessica Morales, Carlos Carmona, Livia Senties and Carlos Cabralt

On this historic day, Livia and I were not only asked to attend, but also to deliver a bi-lingual presentation (in English and in Spanish) to celebrate the international growth of the CBSPD. We delivered a powerful message about the Professionalization of Sterile Processing Personnel - of which, certification is key for the success of the Sterile Processing Department and for optimal patient outcomes. We not only discussed the rapid advances and technology of our profession, but also spoke of maintaining certification as essential to ensure Sterile Processing Manager and personnel are keeping up with such advances for the future safety of patient care.

CBSPD visits Mexico City- Continued.

After our dynamic presentation, we were met with applause and many questions from those in attendance, including members of the press. Once we had concluded our presentation, the exciting time came for voting, a brief recess and then the highly anticipated announcement of the new Secretary, Treasurer, Vice President and President! Each of these individuals gave emotional and promising speeches.

During the conclusion of the event, elegant Mexican hors d'oeuvres were served with sparkling water or juice. During this time many photos were taken. Many people asked to take photographs of the CBSPD certification pins I wore on my suit jacket, as they had only seen two of these pins before (Technician and Management). Also during this time, the AMEXPE Sterile Processing President explained that, he had just attained his Management Certification 3 weeks before this event, and that he especially wanted to share, his pride that this now means that all 12 Presidents of the various Sterile Processing Boards in Mexico and LA are certified in Management! There were too many to count, numerous, individuals who came to tell me their stories about their certification(s) and what it means to them. They were all so incredibly proud to be CBSPD certified, and everyone in attendance was extremely excited about the highly anticipated CFER certification!

Over the past 17 years, a lot of hard work has paid off for the Certification of Sterile Processing personnel in Mexico and Latin America! The people I met at this event were highly thankful and proud of this history and of their ties to the CBSPD in the United States. They were especially grateful for everything Livia, CBSPD International Liaison and Nancy Chobin have done to grandfather their organizations.

The new Board of Directors From left to right: Carlos Cabral, Vice President, Jessica Morales, Secretary, Carlos Ridaura, Treasurer, Carlos Vazquez, President

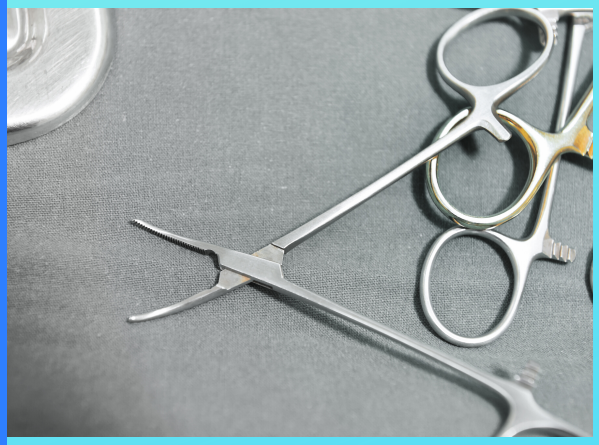
How to Handle Explanted Implants

Author: Nancy Chobin, RN, AAS, ACSP, CSPM
Sterile Processing Consultant/Educator

BACKGROUND: The FDA defines an implantable device as "a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. The FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also 'implants.' [21 CFR812.3(d)]. Orthopedic trauma related screws and plates fall into this category. Technically (and legally in many states) the patient has the right to the explanted implants because they paid for them. However, there are Occupational Safety & Health Administration and manufacturer's instructions for use issues that need to be considered.

According to Healthcare Risk control," A Healthcare Risk Control (HRC) member recently wrote seeking guidance on developing a policy for explanted medical devices, especially regarding how long devices must be retained if they are not involved in litigation and how to handle manufacturer or patient requests for the devices (e.g., orthopedic implants).

HRC notes that a host of risk management issues surround the explanation, handling, and ultimate disposition of medical devices. As a "final distributor" that implants medical devices, the hospital has varied obligations upon explanation, including the following:



· Internally, to manage all related risks in a manner that protects the organization from potential litigation, whether anticipated or unanticipated.
· To the patient, who has an ownership interest in the device.
· To the U.S. Food and Drug Administration (FDA), which requires hospitals that distribute medical devices to collect information about certain medical devices used in patient care so that the device can be promptly identified and recalled if it presents a serious risk to patients' health. HRC goes on to state, "When developing a policy for explanted medical devices, organizations must balance all of these obligations. The following resources provide guidance regarding strategies for achieving that balance."

The discussion "A Risk Management Perspective on Explants" in the guidance article Implants and Explants details concepts that a policy should address, including but not limited to cleaning and sterilization, chain of custody, and third-party analysis. This discussion also addresses the patient's right to determine the explant's disposition, and issues to consider before any release to the and waiver-of-liability form addressing the release of an explanted device to a patient.

How to Handle Explanted Implants- continued.

Organizations should consult their legal counsel for guidance on how long to keep the implant in various situations. Their answer will likely address the following factors:

· All applicable local, state, and federal regulations.
· Any legal precedent regarding the application of a statute of limitation or repose in your jurisdiction that could influence policy development.
· The generally unpredictable nature of whether or when litigation regarding a device may occur.

The guidance article Medical Device Tracking and accompanying List of Tracked Devices contain additional information about FDA requirements. For example, if the tracked device is a medical device implant, the facility collects information at three times: at receipt, at implantation, and at explanation or other permanent disposal of the device (e.g., patient death, permanent discard).

Members may also find helpful the Frequently Asked Questions, "How should explanted medical device specimens be handled?" and "How should explanted orthopedic hardware being returned to the patient be handled?" from the Association of Perioperative Registered Nurses. [1]

It is interesting to note than in England, which has socialized medicine, meaning the patient did not pay for the implant or the surgery, there is a Guidance Document that states, "On implantation, an implant becomes the property of the whom it has been implanted and it remains his or her property even if it is subsequently removed. Following the patient's death, it forms part of her estate unless there is any specific provision to the contrary." [2]

DECISION TIME: Based on the available data, the first thing to do is to obtain and review the implant manufacturer's written instructions for use. Follow their recommendations. Usually, implant manufacturers specify that "used implants should not be reprocessed." This means that if the implant came in direct contact with the patient, it should not be processed; it should be removed from the set. Some manufacturer's specifically state that if the implant was in contact with blood, it should not be processed. Since the recommendations can vary, you need to begin with your specific implant manufacturer's written instructions for use (IFU). Make sure you have the most current IFU. It is recommended to obtain this from the home office of the company as webpages and sometimes sales representatives do not always have the most current information. This information should always be in writing, not verbal.

Also, understand that in some instances (e.g. explanted breast implants) there may be a specific reason the implants were removed such as possible defect in the product. In these cases, the implant might have to be returned to the manufacturer if requested. This information needs to be addressed with Risk Management first. Second, the company should provide specific instructions to permit safety returning the explanted implant which may include decontamination procedures.

Second, if it is confirmed that the manufacturer does not recommend reprocessing, then you have no information how to make the implant safe to give to the patient. Cleaning and/or sterilization instructions have not been provided because these items were not intended to be reprocessed.

Since the implant cannot be safely decontaminated, it must be considered contaminated and labeled as such. OSHA states, "Specimens of blood or other potentially infectious materials shall be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping. The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph and closed prior to being stored, transported, or shipped. Labels required by this section shall include the following legend. These labels shall be fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color." [3]
This would include the explanted implant.

1 Ask HRC: Retaining Explanted Medical Devices. Published 12/27/16 at website: https://www.ecri.org/components/HRC/Pages/AskHRC122716.aspx.)
2 https://www.clarkewillmott.com/blog/ownership-of-medical-implants/
3 Occupational Safety and Health Administration, Blood Borne Pathogens Ruling, 1991, 2001.

How to Handle Explanted Implants - POST TEST- (Preapproved by CBSPD for 1 CEU)

QUESTIONS AND ANSWERS:
Multiple Choice:

1. A medical device that remains in a patient for at least 30 days is called an

A. Explant
B. Implant
C. Indwelling catheter
D. Reusable devicet

2. The Federal Agency that oversees implants is the

A. Occupational Safety & Health Administration
B. Food and Drug Administration
C. Association for the Advancement of Medical Instrumentation
D. Centers for Disease Control

3. When considering processing screws and plates for implantation

A. use high alkaline detergents for cleaning.
B. sterilize in ethylene oxide gas.
C. follow the manufacturer's instructions for use.
D. Soak bloody implants in bleach.

4. Which of the following has guidelines for handling hardware removed from patients?

A. Association for the Advancement of Medical Instrumentation
B. Association of peri-Operative Registered Nurses
C. American Academy of Orthopedic Surgeons
D. American Hospital Association

5. When forming an Ad-Hoc Committee to develop a policy for explanted implants which of the following departments is NOT necessarily required?

A. Operating Room
B. Sterile Processing Department
C. Purchasing
D. Risk Management

TRUE OR FALSE:

6. _____ An implant that is placed in a patient belongs to the implant manufacturer.

7. _____ An implant that is removed from a patient may have to be returned to the implant manufacturer.

8. _____ The most current instructions for use should be obtained directly from the sales representative.

9. _____ In England, an implant that is still in the patient at the time of death, can be considered part of the patient's estate.

10. _____ If a tracked device is a medical device implant, the facility collects information at two times; at receipt and at implantation.

2019 CEU COMMITTEE REPORT

Summary 2019 Approvals

In-Services: 675
Seminar: 215
Multi Day Seminar: 12
Corporate Web: (Webinars by Vendors approved for a 5 year period) 111
Corporate Lecture: (Lecture programs given by Vendors approved for a 2 year period) 247
Corporate Study Guide: (Written programs by a Vendor approved for a 5 year period) 15
Denial: 74
Seminar After: 7
IN LATE: (requests for programs older than 6 weeks) 29
Podcasts: 10
Pre-Approved CE Adult Program: 1

- There were 30 programs submitted later than 6 weeks after the program date. 7 programs did not meet CBSPD protocol criteria.
- There is a new approval code, POD for Hank Balch from Beyond Clean. He does podcasts pertaining to sterile processing.
- There is a new website the Committee members obtain requests from, there were problems for a week.
- Jeanette Bakker approves the Healthcare Purchasing News articles monthly on behalf of CBSPD.
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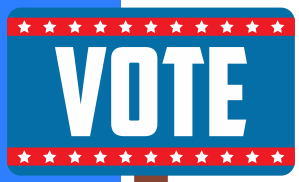
KEY: 1.B, 2.B, 3.C, 4.B, 5.C, 6.F, 7.T, 8.F, 9T, 10.F

-CEU Committee Report continued..

Healthcare Purchasing News has a new editor Ebony Faber, Valerie Diamond has left.
- Our Committee welcomed Relias a new vendor applying for CEU'S.

Respectfully submitted,
November 4, 2019

Jeanette Bakker CSPM
Angela Jensen CSPDS



Voting for Nominees to the CBSPD Certificant Board Members Vacancies

Voting is now open for five positions on the CBSPD Certificant Board: Technician, Ambulatory Surgery Technician, Surgical Instrument Specialist, Management and Flexible Endoscope Representative. The nominees on the ballot are actively certified by the CBSPD and work at the capacity for that credential. For example, the nominee for the CFER vacancy works as an Endo Tech, processing scopes. This is a requirement for all positions, the certificant must be working as a Technician, AMBU Tech, GI Scope/Endo Tech, Surgical Instrument Specialist and in SPD Management.

For the Certificant Board positions that don't have a nominee: If you'd like to nominate yourself or someone you think will be an ideal fit for the position, please write in the person's name. We will accept the nomination and vote, provided the nominee meets the aforementioned criteria.

The elected candidate will be required to submit verification of employment and position held on facility letterhead verified by Human Resources. In addition, the candidate's employer must provide a letter stating the individual will be granted the time off for the annual Board meeting in November. If the candidate's employer will not award the time off for the annual Board meeting, we will allow the certificant to attend via teleconference. If the candidate cannot verify that he/she works in the specified position required for the Board vacancy, then the position will be forfeited and awarded to the candidate who placed second.

Please note, you must only vote for a candidate that represents your job title (i.e. if you're an Ambulatory Surgery Tech, you can only vote for that nominee, etc., AND you MUST be CBSPD certified in order to vote.) Each certificant is permitted to vote ONCE for a nominee. We will not count any duplicate ballots, as we must be fair to all the candidates. Finally, please use the official CBSPD ballot below. The ballot can be reproduced.

To Vote, you may scan and email the ballot to: mailbox@sterileprocessing.org, FAX to 1.908.236.0820 OR mail it to our office at:

CBSPD
1392 US Hwy 22 W. Ste. 1
Lebanon, NJ 08833

Voting will be open for 60 days. All ballots are due in the CBSPD office by the close of business on Friday, March 16th at 5:30PM, EST.

OFFICIAL CBSPD BALLOT
SELECT OR WRITE IN A NAME

TECHNICIAN Nominee: Jenna Eckert _____
MANAGEMENT Nominee: Jason Marosi _____
GI SCOPE Nominee: Lorraine Thorton _____

SURGICAL INSTRUMENT SPECIALIST: OPEN

_____

AMBULATORY SURGERY TECH: OPEN

_____

Name of certificant voting: _____
CBSPD Certification ID number: _____
Last four of your Social Security number: _____

ALL BALLOTS MUST BE RECEIVED IN THE CBSPD OFFICE BY FRIDAY, MARCH 16th, 2020
Mail to: CBSPD, 1392 US Hwy 22, Suite #1, Lebanon, NJ 08833, scanned and emailed to: mailbox@sterileprocessing.org or Fax to: 1-908-236.0820.
Important: ONLY CBSPD OFFICIAL BALLOTS WILL BE ACCEPTED.
THIS FORM MAY BE REPRODUCED.

Sterile Processing University LLC

Sterile Processing University provides textbooks, workbooks and on-line courses to meet the educational needs of sterile processing and flexible endoscope reprocessing personnel. All materials are routinely updated to ensure the most current information is provided. In addition, all educational materials are based on scientific data, recommended practices, regulations, etc. which includes the Association for the Advancement of Medical Instrumentation standards.

Online Continuing Education Programs - SPD offers a full line of Continuing Educational programs at a nominal fee. All are approved for Continuing Education points from the Certification Board for Sterile Processing.

Textbooks available:
The Basics of Sterile Processing Textbook (7th edition) UPDATED. This book is for Sterile Processing Technicians and Ambulatory Surgery sterile processing technicians.

The Basics of Sterile Processing Workbook (7th edition) UPDATED. To be used in conjunction with the textbook and offers hundreds of study questions and quizzes.

The Basics of Flexible Endoscope Reprocessing Textbook (2nd edition). Is intended for those individuals who are responsible to reprocess flexible endoscopes.

The Basics of Flexible Endoscope Reprocessing Workbook (2nd edition). To be used in conjunction with the textbook and offers hundreds of study questions and quizzes.

Management Basics for Sterile Processing Textbook- (4th edition) UPDATED This book encompasses all Management concepts for the Sterile Processing Manager or Supervisor and includes performance appraisals, interviewing, safety, labor laws, budgeting, career ladders, etc.

Instructional CD- NOTE TO EDUCATORS - SPU offers an instructional CD in Power Point to facilitate teachng a Central Service/SPD course. The CD follows the course content for The Basics of Sterile Processing Textbook. If you previously purchased a CD, you are eligible for an upgrade.

On-line courses available: If you or your staff do not have access to a formal course, the following courses are available online. There is no time limit, so they can learn at their own pace. A quiz is given after each chapter is completed, and there is a practice final exam at the completion of the course.

Basics of Sterile Processing Technician course - conforms to the 6th edition of The Basics of Sterile Processing Textbook (2016). The updated course will be available in 30 days.

Basics of Sterile Processing Ambulatory Surgery Technician course - conforms to the 6th edition of The Basics of Sterile Processing Textbook (2016) and includes only those areas of practice that relate to the Ambulatory Surgery practice setting. The updated course will be available in 60 days.

The Flexible Endoscope Reprocessor course - conforms to the 2nd edition of the Basics of Flexible Endoscope Reprocessing Textbook.

Sterile Processing Policies, Procedures and Forms - SPU offers policies, procedures and documentation forms online! Pick a la carte or all the policies and forms. All policies are reference to AAMI standards and federal regulations where applicable.

Visit: www.SPDCEUS.com for all your sterile processing education needs.
SPU…Quality education at affordable prices!

****Reminder to All Upcoming May 2020 Re-certs****

Why re-take the exam when after working full time for 5 years, you only need 10 points of education per year to re-certify (except for Supervisors/Managers)?

If you became certified or re-certified in May 2015, you are due for re-certification in May 2020. Please have your completed re-certification packet with payment into the CBSPD office no later than 4/7/20.

The CBSPD e-mails and mails out re-certification packets 6 months before your certification is due to expire. If you have not received your packet yet, please contact our office to update your address and/or print one out from our Recertification page at:

https://www.cbspd.net/recertification/

If you're interested in the latest news in SPD and GI/Endo, announcements from the Board of Trustees or maybe need a laugh, follow or like us on social media!

Like us on facebook **https://www.facebook.com/theCBSPD**

@theCBSPD