State of California
CDPH – L&C
APR 23 2010

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050007	A. BUILDING _____ B. WING _____	01/08/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PENINSULA MEDICAL CENTER	1501 TROUSDALE DRIVE, BURLINGAME, CA 94010 SAN MATEO COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	The following reflects the findings of the Department of Public Health during a complaint/adverse investigation visit: Complaint Intake Number: CA00213018 - Substantiated Representing the Department of Public Health: [redacted], HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Title 22 70223(b)(2) Surgical Service General Requirements (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.		The following constitutes Peninsula Medical Center's (the "Hospital") plan of correction of the alleged deficiencies cited by the Department of Public Health in the Statement of Deficiencies Form State-2567 dated January 8, 2010. Preparation and/or execution of this plan of correction does not constitute admission or agreement by the Hospital of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. It has been prepared and/or executed solely because it is required by federal and state law. **The facility allegedly " failed to implement its surgery P&P to do sponge counts on all surgical procedures when a small fragment of a sponge was retained in the patient's right eye..."** **1. How the correction was accomplished (temporarily and permanently):** First, a root cause analysis was done on 2/26/10 which involved the surgeon, OR nurses, Director and Assistant Director of Perioperative Services and the Director of Risk Management. Second, The surgeon contacted his colleagues around the world to see what material they were using if not using the Weck-cel spheres. Third, The Assistant Director of Perioperative Services contacted the manufacturer of the Weck-cel sphere and special ordered smaller sponges that have a string attached. He also ordered other sponges for the surgeon to trial within 1 week of the root cause analysis.	2/26/10 2/26/10

4/26/10 VA

Event ID:IVRX11 4/7/2010 10:02:3

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE
Bonnie Holland RN Director Regulatory Compliance

(X6) DATE 4/23/10

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be e
that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findin
of survey whether or not a plan of correction is provided. For nursing homes, the above findings and pl
the date these documents are made available to the facility. If deficiencies are cited, an approved plan
participation.

POC accepted

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	Continued From page 1 Based on record review, policy review, and staff interview, the hospital failed to ensure that Surgical Services staff implemented the policy and procedure titled: "Sponge Counts, To establish and maintain an accurate method of accounting for surgical sponges" resulting in a cellulose sponge being retained in Patient 1's right eye following surgery. Patient 1 had to undergo another surgical procedure to remove the cellulose sponge, placing the patient at increased risk for complications due to additional surgery. Findings: Patient 1's clinical record dated 12/14/09 was reviewed and indicated that Patient 1 was taken to surgery and had a bleb (a small swelling, vesicle, or air bubble) revision and new trabeculectomy of the right eye (helps the eye drain liquid more effectively to treat glaucoma). After spending time in the recovery room Patient 1 went home the same day. Patient 1's clinical record, dated 12/23/09 indicated he complained of discomfort in his right eye in the outpatient clinic. On examination by the Physician, a small fragment of sponge was seen to have extruded from the conjunctiva (thin membrane that covers the white surface of the eyeball) of the right eye. Patient 1 was taken to surgery again that same day, eight days after his first surgery. Review of the Operating Room Report dated 12/23/09 indicates the surgeon removed a retained cellulose sponge foreign body from the right		Fourth, While waiting for the new sponges to trial, the surgeon made a template of circular sponges and strung them together with a nylon suture so it would be apparent if a sponge fragment was left behind. Fifth, though the American Operating Room Nurse Association (AORN) has stated that a hospital may define in policy when sponge counts can be omitted and gave as examples cystoscopy and opthalmology cases. (attachment), MPHS' Asst. Director of Perioperative Services developed a revision to the Sponge Count policy to reflect that sponge counts are required during glaucoma and pterygium surgeries. The policy now states specifically "before closure of any extraocular or intraocular space, if sponges were used for any purpose, including the instillation of medication" a sponge count will be taken. (attachment) Though the only opthalmology surgeries likely to use a sponge are trabulectomy cases, MPHS thought it would be a "best practice" for OR staff to include this.	2/26/10 12/23/09

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	Continued From page 2 eye. In an interview with the Operating Room Nursing Director (ORND) on 1/8/09 at 2:00 p.m., the ORND was asked about Patient 1's first eye surgery on 12/14/09. The ORND said, "The eye surgery was uneventful three small sized sponges soaked with an antibiotic solution were placed by the surgeon and removed." The ORND was asked if a sponge count was done by the surgeon, circulating nurse (the circulating nurse is responsible for patient safety and coordinates care of the patient with the surgeon) or scrub technician (nurse/technician who supports the surgeon by passing instruments during the operation maintaining patient safety). The ORND said, "They don't count sponges during eye surgery, the surgeon does an 'internal' count in his head." During a telephone interview on 2/2/10 at 2:00 p.m., RN-A (the circulator nurse for the first eye surgery) was asked if a verbal sponge count was done during Patient 1's first eye surgery. RN-A said," The procedure is under the microscope the surgeon counts to himself. Counting sponges in eye surgery is an exception to the rule. We don't count eye sponges." In a telephone interview on 2/2/10 at 2:30 p.m., ST-B (the scrub technician who was present during both surgeries) was asked if a verbal sponge count has been done during Patient		Lastly, the surgeon involved in this case trialed all the different microscopic sponges(made of different materials) available by soaking them in mitomycin and found that all of them had the potential to shred. Since 12/23/09 he has performed all trabulectomies by instilling the mitomycin into the conjunctival space and then removes it by suction/aspiration and blotting with a full size, uncut Weck-cel sphere (sponge). **2. Title or position of person responsible for the correction:** **1. Chair, Opthamology Section assisted by:** **a. Director, Perioperative Services** **b. Assistant Director, Perioperative Services** **c. Vice President of Acute Care Services**	12/23/09

Event ID: IVRX11 4/7/2010 10:02:30AM

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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	Continued From page 3 1's first eye surgery. ST-B said, "We don't routinely count sponges for eye surgery. I was there for the second eye surgery and Patient 1 definitely had a retained sponge pulled out from the prior surgery." The policy and procedure titled "Sponge Counts", dated 6/2009, read under policy:"...sponge counts will be done on all surgical procedures in which the possibility exists that a sponge could be retained. The circulating RN and Scrub Technician will simultaneously, visually and verbally count all countable items." The facility failed to implement it's surgery policy and procedure to do sponge counts on all surgical procedures when a small fragment of a sponge was retained in the patient's right eye that caused him eye discomfort and had to have another eye procedure to remove the remaining fragment of a sponge. This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).		**3. A description of the monitoring process to prevent a recurrence of the deficiency:** 1. Sponges will no longer be inserted into the conjunctival space during trabulectomy surgery thereby totally preventing the possibility of a recurrence of the shredding of a microscopic fragment of a microscopic sponge. 2. OR nurses will now document sponge counts for any sponges used in the extraocular or intraocular space if sponges were used for any purpose during any other type of eye surgery. 3. There will be a final surgical pause during eye surgeries, as is currently done in all other surgeries, to confirm that every object was removed and accounted for. **4. List of Attachments** **Attachment 1:** Sponge Count Policy **Attachment 2:** Needle, Sharp and Miscellaneous Count Policy **Attachment 3:** 2009 AORN Perioperative Standards and Recommended Practices: Sponge, Sharp and Instrument Counts **Attachment 4:** Manufacturer Information on Weck-cel Spheres with photo	12/23/09 1/1/10 1/1/10

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5. The date the Immediate Correction of the Deficiency was Accomplished:

The Sponge Count Policy and Needle, Sharp and Miscellaneous Count policy were revised and changes went into effect on January 1, 2010. 1/1/10

OR nursing staff and opthalmology surgeons were educated on the policy changes the last week of December, 2009 and first week of January, 2010. 12/30/09 1/3/10

During January and February, 2010, the surgeon involved in this case as well as the Chair of the Opthalmology Section trialed sponges of different material to see if they had the potential to tear or shred. These trials were not done on patients but were done by soaking the different types of sponges in mitomycin. 2/26/10
At the same time, the surgeon who performed this surgery contacted his colleagues around the world to see what they use for trabulectomies besides Weck-cel spheres.

A Root Cause Analysis was conducted on Feb. 26, 2010. 2/26/10

Mills and Peninsula campus OR nurses implemented the "Best Practice" of documenting sponge counts for all eye surgeries by January 8, 2010. 1/8/10

List of Attachments

Attachment 1: Sponge Count Policy
Attachment 2: Needle, Sharp and Miscellaneous Count Policy
Attachment 3: 2009 AORN Perioperative Standards and Recommended Procedures on Sponge, Sharp and Instrument Counts
Attachment 4: Manufacturer information and photo of Weck-cel Sphere

Attachment I

Mills-Peninsula Health Services
A Sutter Health Affiliate
With You, For Life.

Originated E Surgical Services
Origination Da 05/2007

Last Reviewe 06/2009
Last Revise 01/2010

TITLE: **Sponge Counts**

PURPOSE: To establish and maintain an accurate method of accounting for surgical sponges.

POLICY: Using AORN Standards, Recommended Practices, and Guidelines, sponge counts will be done on all surgical procedures in which the possibility exists that a sponge could be retained. The circulating RN and the scrub will simultaneously, visually and verbally count all countable items.

PROCEDURE:

1. Initial sponge counts are to be performed to establish a baseline. All sponges will be removed from containers. Any confirming bands are to be removed and each sponge will be individually counted
    a. No lap tape shall be counted without identifying the string
    b. No group of sponges shall be counted by the folded edges. The x-ray strip shall be identified
    c. Any package containing an incorrect number of sponges should be removed from the field, bagged, labeled, and isolated from the rest of the sponges in the OR
2. Sponge counts should be preformed:
    - Before the procedure
    - Before closure of a cavity within a cavity
    - Before wound closure begins
    - At skin closure or end of procedure
    - At the time of permanent relief of either the scrub person or the circulating nurse (although direct visualization of all items may not be possible)
    - Before closure of any extraocular or intraocular space, if sponges were used for any purpose, including the instillation of any medication.
3. The closing sponge counts should be conducted in the same sequence each time, and begin with items on the surgical field, continue to items on the back table and end with any sponges off the field.
4. No counted sponge shall be used as a dressing or as packing
5. There will be a final surgical pause prior to closure of peritoneum, retro- peritoneum or the chest cavity to confirm every object was removed that was accounted for.
6. In the case of an incorrect count, the surgeon will be informed and an X-ray taken and read by a Radiologist. The results of the X-ray will be documented in the Intraoperative Nursing Care notes before the patient leaves the OR.
7. All counts will be documented in the Intraoperative Nursing Care Plan

Reference: AORN Standards, Recommended Practices, and Guidelines, 2007

TITLE: **Sponge Counts**

PURPOSE: To establish and maintain an accurate method of accounting for surgical sponges.

Mills-Peninsula Health Services
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With You, For Life

Originated E Surgical Services
Origination Da 05/2007

Last Reviewe 06/2009
Last Revise 01/2010

TITLE: **Needle, Sharp And Miscellaneous Count**

PURPOSE: To establish and maintain an accurate method of accounting for needles, sharps and miscellaneous items.

POLICY: Using AORN Standards, Recommended Practices, and Guidelines, needle, sharp and miscellaneous counts will be done for all procedures in which the likelihood exists that such an item could be retained. The circulating RN and the scrub will simultaneously, visually and verbally count all countable items.

PROCEDURE:

1. The assortment of surgical sharps appropriate to the individual procedures includes: suture needles, hypodermic needles, cautery blades, cautery scratch pads, scalpel blades, vessel loops, vascular inserts, and umbilical tapes.
2. All needles will be visualized and counted
3. Counted needles, sharps and miscellaneous items will not be removed from the operating room during the procedure.
4. Broken items shall be accounted for in their entirety. All parts will be kept in the OR until the finish of the case.
5. Needle, sharp and miscellaneous counts should be taken:
    - Before the procedure to establish a baseline
    - Before closure of a cavity within a cavity
    - Before wound closure begins
    - At skin closure or end of procedure
    - At the time of permanent relief of either the scrub person or the circulating nurse (although direct visualization of all items may not be possible)
    - Before closure of any extraocular or intraocular space, if sponges were used for any purpose, including the instillation of any medication.
6. The closing counts should be conducted in the same sequence each time, and begin with items on the surgical field, continue to items on the back table and end with any items off the field
7. There will be a final surgical pause prior to closure of peritoneum, retro-peritoneum, or chest cavity to confirm every object was removed that was accounted for
8. In the case of an incorrect item count, the surgeon will be informed, and an x-ray taken and read by a Radiologist. The results of the X-ray will be documented in the Intraoperative Nursing Care Notes before the patient leaves the OR. A Quality Assurance Occurrence Report must be made out stating what was lost and that an x-ray was taken.
9. All counts will be documented in the Intraoperative Nursing Care Plan
10. Sharps will be disposed of in their proper receptacle after use to ensure adherence to the Infection Control Standards

TITLE: **Needle, Sharp And Miscellaneous Count**

PURPOSE: To establish and maintain an accurate method of accounting for needles, sharps an miscellaneous items.

Reference: AORN Standards, Recommended Practices, and Guidelines, 2007

Attachment 3

Recommended Practices for Sponge, Sharp, and Instrument Counts

The following recommended practices were developed by the AORN Recommended Practices Committee and have been approved by the AORN Board of Directors. They were presented as proposed recommended practices for comments by members and others. They are effective January 1, 2006.

These recommended practices are intended as achievable recommendations representing what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented.

AORN recognizes the numerous settings in which perioperative nurses practice. These recommended practices are intended as guidelines that are adaptable to various practice settings. These practice settings include traditional operating rooms, ambulatory surgery centers, physicians' offices, cardiac catheterization suites, endoscopy suites, radiology departments, and all other areas where operative and other invasive procedures may be performed.

Purpose

These recommended practices provide guidance to perioperative registered nurses in performing sponge, sharp, and instrument counts in their practice settings. Counts are performed to account for all items and to lessen the potential for injury to the patient as a result of a retained foreign body. The expected outcome of primary importance to this recommended practice is outcome O2, "The patient is free from signs and symptoms of injury due to extraneous objects."[1] Complete and accurate counting procedures help promote optimal perioperative patient outcomes and demonstrate the perioperative practitioner's commitment to patient safety.

Legislation does not prescribe how counts should be performed, who should perform them, or even that they need to be performed. The law requires only that foreign bodies not be negligently left in patients.[2] The doctrine of res ipsa loquitur (or, "the thing speaks for itself") is most applicable in cases involving retained foreign objects, rendering those litigations nearly indefensible.[2,3] Retained objects are considered a preventable occurrence, and careful counting and documentation can significantly reduce, if not eliminate, these incidents.[4,5] The "captain of the ship" doctrine is no longer assumed to be true, and members of the entire surgical team can be held liable in litigation for retained foreign bodies.[6-11] All team members should be committed to and involved in establishing meaningful policies and procedures related to surgical counts.[12,13]

Recommendation I

Sponges should be counted on all procedures in which the possibility exists that a sponge could be retained.

1. Sponge counts should be performed
   - before the procedure to establish a baseline,
   - before closure of a cavity within a cavity,
   - before wound closure begins,
   - at skin closure or end of procedure, and
   - at the time of permanent relief of either the scrub person or the circulating nurse (although direct visualization of all items may not be possible).

2. Initial sponge counts should be performed and recorded, establishing a baseline for subsequent counts on all procedures in which the possibility exists that a sponge could be retained. Policies in the health care organization may identify situations in which this possibility does not exist and counts are not required.[14]

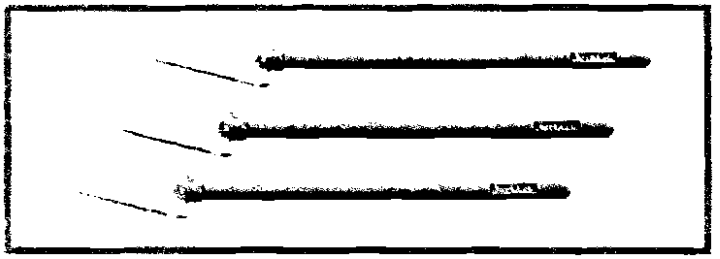
3. Accurately accounting for sponges throughout a surgical procedure should be a priority of the surgical team to minimize the risks of a retained sponge.[2,4,15,16] The Institute of Medicine has identified avoiding injuries from the care that is intended to help patients to be one of six aims to a better health care system.[17]

4. Established policies in the health care organization may define when additional counts must be performed or may be omitted (eg, cystoscopy, ophthalmology).[14] Closed claim studies conducted during the past 20 years have demonstrated that roughly two-thirds of reported cases of retained surgical items are attributed to sponges.[5,18-20] Although the majority of retained sponges are found in the abdomen and pelvis, there are reports in the

WECK-CEL

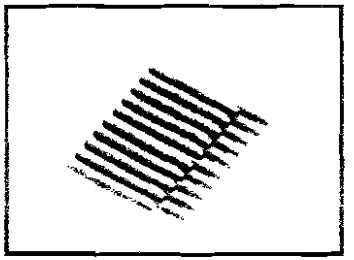
CELLULOSE SPONGE PRODUCTS

The standard in eye surgical fluid control. Made of highly absorbent, natural, sterile cellulose material. Triangle shaped spearhead, set on a malleable, polypropylene handle, is designed for use in delicate, surgical areas. Maintains rigidity during wicking process. Single use, packaged sterile.



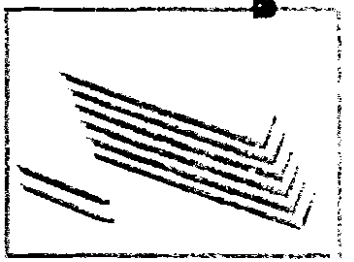
Weck-Cel Spears

0008680 144 count. 6 spears/pouch 24 pouches / box
0008685 180 count. 10 spears/pouch 18 pouches / box



Weck-Cel Sponge Points

0008661 240 count, 20 points / pouch. 12 pouches / box



Weck-Cel Sponge Points and Strips

0008660 2 points and 6 strips per pouch. 24 pouches / box

EYE BANDAGES

SURGICAL AFTERCARE PRODUCTS

Protects the eye from symptoms caused by "dry eye", medical conditions, drug reactions and environmental factors. Forms a moisture chamber over the eye area during rest. Easy to apply, hypo-allergenic, self-adhesive.

PROTECTIVE SHIELDS

POST-OP/POST-INJURY PROTECTION

Hard protective shields for post-operative or post-injury use. Universal, or Left/Right specific. Packaged 12 per box.