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| E 000 | California Departrinvestigation of E #CAO0191275 reduring surgery. The investigation substantiated. The inspection was event investigates findings of a full in Representing the Evaluator Nurse Evaluator Nurse Health and Safety For purposes of to jeopardy" means licensee's non-corequirements of | resent the findings of the ment of Public Health during an nitty Reported Event agarding retained foreign object of the reported event was as limited to the specific reported d, and does not represent the aspection of the facility. Department of Public Health: R.N., Health Facilities N., Health facilities Evaluator y Code Section 1280.1(c): this section, "immediate a situation in which the appliance with one or more censure has caused, or is likely injury or death to the patient. | E 000 | Please Note: The following constitutes (Pacific Medical Center (CFPacific Campus Hospital's evidence of correction of a alleged deficiencies cited (California Department of Fin the Statement of Deficiency). The Statement of this crevidence submission or ago the provider of the truth of aileged or the conclusions the Statement of Deficiency. The Statement of Deficiency at the surve completed on 11/18/09 by Kubovicik, RN and Alice Medical Campus Constitute Medical Campus Cam | PMC) – credible all of the by the Public Health encies Form 9. Preparation edible a not reement by the facts set forth in cies. cies form is he hospital y was Andrea | The same and the s |
| E 264 | Policies and Processing (a) Written policies care shall be developed implemented by the state of the process and p | RT3-70213(a) Nursing Service sedures. es and procedures for patient eloped, maintained and he nursing service. It met as evidenced by: | E 264 | E 264, E 269, E 271 Corrective Action: Failure to comply with the Surgical Count policy has be addressed with the staff invevent. | peen | 6/09 |
| | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | LO CEL OPPORTUDE SIGNA | TURE | irector, Rish Max | ment | (6) DATE 02/15/10 |

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| E 269 | Continued From p | age 1 | E 269 | E 264, E 269, E 271 cont. | | |
| E 269 | Policies and Proce | RT3-70213(b) Nursing Service edures. | E 269 | The Surgical Services Policy 27.2.1.54, "Counts, Surgical" revised to state: | | |
| | current standards consistent with the includes: assessn planning, interven | of nursing practice and shall be a nursing process which nent, nursing diagnosis, tion, evaluation, and, a quire, patient advocacy. | e en entrembrane constituente en se el establishe en es entrembranes en entrem | "General Rules: 2. The count process require and continual readiness to for required items include surgical count. Every efformade throughout the particle to be ready to perform a count. | o account ed in a ort should procedure | 12/18/09 |
| E 271 | | met as evidenced by: RT3-70213(d) Nursing Service | E 271 | 3. OR staff will initiate the cl command when faced wi resistance by any member surgical team to comply we surgical count policy. | th er of the | |
| | (d) Policies and proconsistency and concorporating the medical treatment | rocedures that require ontinuity in patient care, nursing process and the plan, shall be developed and poperation with the medical | | The "Counts, Surgical" policy revised to include standardize count boards and count she as the process for document the boards and sheets. | etion of ets as well ting onto | |
| | Based on interview failed to implement procedure when Figure charge nurse) and surgical field with document the add on the instrument to orient staff to insurgery and failed Sales Representations when a retractor a facility the day of | met as evidenced by: w and record review, hospital at its Surgical Counts policy and an 1/CVC (cardiovascular at ded a retractor and blades to the but counting them, and failed to lition of the retractor and blades count sheet. The hospital failed struments being used in to implement its Vendors and attives policy and procedure and blades were brought to the surgery instead of 16 to 24 surgery. This resulted in a | | There is also a record to doccount for extra instrument se instruments brought in by a surgeon. In addition, "Surgical Servic Guidelines" were implement improve critical communicative elements in the OR, i.e. spot sharps, medications, specim Recommended Relief Rules established in an effort to renumber of relief breaks that during a case. | ets, i.e. vendor or es Handoff ed to on nges, iens. were also duce the | |

PRINTED: 02/03/2010 FORM APPROVED California Department of Public Health (3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (2) MULTIPLE CONSTRUCTION COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING B. WING CA220000022 11/17/2009 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION (X4) ID SUMMARY STATEMENT OF DEFICIENCIES ίD PREFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE DEFICIENCY) E 264, E 269, E 271 cont. E 271 E 271 Continued From page 2 retractor blade having been left in Patient 1 who CPMC Administrative Policy 2.98, Current as had to undergo a second surgical procedure to of 11/19/09 "Universal Protocol" states: remove the retained foreign object. J. "Time Out" before starting the Procedure: Findinas: "Time Out" must be conducted in the location where the procedure 1. Patient 1 was admitted to the hospital on 4/14/09 for mitral valve repair and was will be done and must be discharged on 4/18/09. In June 2009, the patient conducted prior to starting the was experiencing chest pain and was seen by her procedure. cardiologist in her home state. A subsequent chest x-ray and ultrasound determined the 10. Members of the care team are presence of a a metal plate in her chest area. expected to speak up Patient 1 was readmitted to the facility on 6/22/09 immediately and stop the and on 6/23/09 had surgery to remove a retained process if they notice any retractor blade. discrepancy or believe any step in the safety check process is On 11/16/09 at 10:50 a.m., Patient 1's missed or incomplete. intraoperative record dated 4/14/09 was reviewed, and indicated that the initial, closing K. Sign Out: and final instrument counts were documented as 1. Prior to leaving the procedure area, the RN verbally confirms There was an intraoperative report dated 6/23/09 with the team... which listed the surgical procedure as "Removal Instruments, sponge and needle Retained Foreign Object." counts are correct Equipment problems to be Patient 1's operative note dated 6/23/09 noted a addressed pre and post operative diagnosis of retained foreign object. The surgeon documented that he Staff education for the "Universal had repaired Patient 1's mitral valve a few Protocol" was provided during Surgical months ago and, "That part of the operation was Services education meetings. successful. It required some additional retractors, however, that were brought in from the outside and these were not properly accounted for at the end of the operation and she ended up with a retractor blade lined posteriorly in her thorax that we did not recognize during her stay in the 12/18/09 Surgical Services Policy 27.3.0.11, hospital. Therefore she was brought back to have "Vendors and Sales Representatives; it be removed." Special Instruments/Equipment/Supplies Guidelines in the Syraigal Services Department" has been revised to state:

Licensing and certification Division STATE FORM

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FORM APPROVED California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (3) DATE SURVEY (2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** COMPLETED A BUILDING B. WING CA220000022 11/17/2009 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 (X5)SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) 1O COMPLÉTION PRÉFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG DEFICIENCY) E 271 Continued From page 3 E 271 E 264, E 269, E 271 cont. On 11/16/09 at 3:25 p.m., RN 2 was interviewed. a. New products, instrument systems, implants or equipment requests are She stated she was the scrub nurse for Patient approved through the following methods 1's first surgery on 4/14/09. She said she was as appropriate: Value Analysis unfamiliar with the approach being used by the Committee, New Technology surgeon and that she made RN 1/CVC aware of Committee, and/or the department this prior to the procedure, RN 2 said "(name of chair/designee. circulating nurse) and I had never done that type b. The operating room manager/designee of case, the approach was different, RN 1/CVC will ensure that the items requested are was there to guide us." She stated that Surgeon 1 approved. works very guickly. She said, "I've never worked Approved new products and with anyone who goes that fast." RN 2 stated the evaluations of products will be retractor and blades were brought into the communicated through a bulletin operating room after the initial count had been from the Value Analysis done and after Patient 1's chest had been Committee. opened. She stated "It was the middle of the d. The confirmation of approved vendor case." She said "I'd never seen these instruments instrument systems/equipment, will be or used them before." She said that Surgeon 1 communicated to the staff by utilizing wanted the retractor and blades immediately. The the Vendor Audit Tool which will follow retractor vendor was in the operating room to the instruments/equipment throughout answer any questions the surgeon may have had the process. The tracking tool will start about the product. When asked if the retractor at the receiving unit and end when the and blades were counted, she stated "I eveballed procedure is completed. it, but myself and the circulator didn't get time to e. Manager/designee and Materials count them. I felt pressured and I didn't get time Management Staff will establish a plan to count." She added "It was a hectic for contacting the vendor. The designated person will make environment, the noise level was very high." arrangement for timely delivery of the equipment/implants required for the RN 1/CVC was interviewed on 11/16/09 at 3:45 procedure. p.m. She stated she was the charge nurse of Manager/Supervisor/Service Leader or cardiovascular services and what happened was designee will arrange for staff "an unfortunate event." She said that Patient 1's education with the vendor prior to procedure was "entirely different to what he using new or unfamiliar instruments or (Surgeon 1) usually does." She stated that a equipment. vendors representative brought the retractor and D. Sterile Processing blades to the facility the morning of Patient 1's 4. Pre-procedure sets will arrive ideally 8 surgery, that she (RN 1) flash sterilized the to 24 hours prior to the start of a instruments, brought them into the operating scheduled elective procedure. room and put them on the instrument table. When asked if the retractor and blades were a. Instruments/implant sets must be inspected, cleaned, decontaminated. counted, she responded "I guess that was not and sterilized by CPMC staff prior to patient use. b. Electrical equipment must be

checked by Biomedical Engineering before use on any CPMC patient.

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| E 271 | Continued From p | age 4 | E 271 | E 264, E 269, E 271 cont. | | |
| | remember specific practice." When as counting the instruction." RN 1/CVC was as blades were brought if the procedure state up there, maybe shown as come away from the said "(Name of Rhinstruments, she with the procedure state up there, maybe shown as table, she probable (Surgeon 1) took of added" I assumed do with the retract when asked how Patient 1, RN 1/C must have just unswound. I can't belief that when the surge and blades were shown as well as were shown as well as | the retractor blade was left in VC responded" He (Surgeon 1) screwed it and left it fall into the eve he did that." She stated gery was finished, the retractor sent downstairs to the SPD g department) for sterilizing. She ador picked up the instruments, blade was missing but he never | | 5. b. An inventory list will be for instrument sets used procedures where an in count is required. If the unable to provide this, to department receiving the or SPD) will complete a /count list. 9. Inventory lists are affixed included with instrument son procedures where an incount is required. F. Operating Room: The circulating RN will: Confirm that the product instrument, or implants approved for use by CP Confirm prior to the seprocedure that the lost instruments have been processed at CPMC, Confirm that a count included if the procedured instruments and instruments have been procedured in the procedured included if the procedured included if the procedured education, Confirm that the staff received education, | ton strument vendor is he e set (OR n inventory to or ets used nstrument t, have been MC tart of the aner en sheet is ure nt count have | 12/18/09 |
| | She stated she was nurse for Patient 1 said she was not 1 used by Surgeon nurse (RN 1/CVC) was the primary c | wed on 11/17/09 at 10:30 a.m. as assigned to be the circulating I's procedure on 4/14109. She familiar with the approach being 1 so she notified her senior 9. She stated that RN 1/CVC irculating nurse for the | AND THE PROPERTY OF THE PROPER | Surgical Services staff has bee informed of the changes to the and are aware of their responsion. Monitoring Process: The Surgical Services staff is a concurrent monitoring of the coprocess including compliance to | policy bilities. ompleting ount o general | Current and ongoing |
| | operating rooms. and final count wit | (RN 3) was going between two RN 3 stated she did the closing th RN 2 and the retractor and sted on the count sheets. She | A company of the comp | rules, initial count, handoff proc closing counts. Monitoring resu reported to the Surgery and Op Room Committee and the hosp Quality Improvement Committee | Its will be erating ital | |

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| AND PLAN | NOF CORRECTION | DENTIFICATION NUMBER: | A. BUI | LDING | COMPLETE | |
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| NAME OF | F PROVIDER OR SUPPLIE | ER | | STREET ADDRESS, CITY, STATE, 3 2333 BUCHANAN STREET | ZIP CODE | |
| CALIFO | RNIA PACIFIC MEDI | CAL CTR-PACIFIC | | SAN FRANCISCO, CA 941 | 15 | |
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| E 271 | Continued From p | page 5 | E 271 | E 264, E 269, E 271 cont | • | |
| E 271 | The facility's Cour Needles, Miscella policy and proced the following: Policy: Surgical counts w following guideline systematic metho sponges, needles during a surgical safety by helping bodies. A. General Rules. 1. It is the responsurgical team to n Room environment of operative tasks should be kept to 2. Counts are perfor the category of 4. Counts are to be circulating Registreson. The circulating Registreson. The circulating the coof every count. 5, The items are concurrently view circulating RN. 12. Sponge types needles, sharps, a recorded separate preformatted whit sheet mirroring the | that retractor that day." Ints, Surgical (Sponge, Sharps, meous Items and Instruments) fure was reviewed and indicated will be performed utilizing the es. The use of a standardized dof accounting for instruments, and specific small items used procedure will promote patient to prevent retained foreign Sibility of all members of the maintain an optimal Operating into allow focused performance. Distractions and interruptions a minimum during the count. formed following the guidelines of the items counted. The performed by two people, the ered Nurse (RN), and a scrub lating RN is responsible for bunts and must be a participant counted audibly, and ed by the scrub person and in free needles, atraumatic and miscellaneous items are ely on the standardized eboard. A preformatted work e whiteboard is used when a | | A monitoring audit tool for associated indicators, has developed. The monitoring is conduct services staff concurrently cases. The audit data is requarterly to Surgical and Room Committee and to Improvement Committee. All vendor products that as hours prior to surgery, reason, will be tracked an system issues and committee included in the reputational to attached for your reference. Responsible Persons: Senior Director, Surgical Director, Outcomes Management Committee. CALIFORNA OFPUBLE. | ted by surgical on all vendor eported Operating the Quality arrive less than egardless of a reviewed for on factors and ort. unt and Vendor ols are se. Services and gement | Current and ongoing |
| } | whiteboard is not | accessible. Instruments are dardized count sheets. | T T | | 9 2010 | |
| } | 13. A running tota | al of needles, sharps, and ms are placed on the boards, | | · · | OIVISI ON YCIT Y | |

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FORM APPROVED California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (2) MULTIPLE CONSTRUCTION (3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING B. WING CA220000022 11/17/2009 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLÉTION PRÉFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 271 Continued From page 6 E 271 worksheets, and instrument count sheets will be done as items are added. The method of documenting additions and totals is standardized. 20. When counts are performed: Instruments b. As new counted items are added to the field. D. Instrument Counts. 1. Instrument counts are performed on all procedures involving, or reasonably anticipated to involve, the opening of a major body cavity such as: d. the pleural/thoracic cavity. 3. Initial instrument count is performed following the order on the standardized count sheet. 4. Use this standardized count sheet to document instruments added during the procedure. The Association of periOperative Registered Nurses, or AORN, is an organization with input and liaisons including CDC (Centers for Disease Control), Association for Professionals in Infection Control and Epidemiology, American College of Surgeons, American Society of Anesthesiologists and the American Association of Ambulatory Surgery Centers. The AORN position papers, standards and recommended practices are widely used not only in the perioperative clinical setting but as an authoritative guide to clarify regulatory requirements. According to 2008 AORN Perioperative Standards and Recommended Practices, pg. 293. "Retained objects are considered a preventable

occurrence, and careful counting and

eliminate, these incidents."

documentation can significantly reduce, if not

Recommended Practices for Sponge, Sharp, and

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| AND PLAN | OFCORRECTION | IDENTIFICATION NUMBER: | A. BU | ILDING _ | | COMPLETI | |
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| E 271 | Continued From p | age 7 | E 271 | | | | |
| | | 111 (pg. 296). d be counted for all procedures ood exists that an instrument | nements indicate interpretabilities and the ferrors | | | | A Company of the Control of the Cont |
| | viewed concurrent whom should be a Concurrent verification | ould be counted audibly and tly by two individuals, one of a registered nurse circulator. ation of counts by two in ensuring accurate counts. | ne officeranian not become out officer | en et e managan (m. e en e | | | |
| | field, they should b | If instruments are added to the be counted when added and if the count documentation. | a | man office a second of the first three . | | | |
| | Surgical (Sponge, Miscellaneous Iter procedure when R blades to the surginstrument count. | ns and Instruments) policy and RN 1/CVC added a retractor and ical field and failed to initiate an RN 1/CVC also failed to ition of the retractor and blades | and the second s | er en | | | |
| | interviewed on 11/2 "the vendor policy that Surgeon 1 had in the retractor and The vendor brought." | erioperative Services was 1/17/09 at 2:30 p.m. and said was not followed." She stated d contacted the vendor to bring d blades for Patient 1's surgery. ht in the instruments the tal's surgery and they were | e como a desenvación de aparece de servicio de la companión de la companión de la companión de la companión de | CONTRACTOR | | | |
| | Guidelines in the S | | in the state of th | Commence of the commence of th | | | |

California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (3) DATE SURVEY (2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING _ B. WING CA220000022 11/17/2009 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5)COMPLÉTION PREFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE DEFICIENCY) E 271 Continued From page 8 E 271 E 271 cont. Sets must arrive at least 16 to 24 hours prior to **Corrective Action:** the start of a scheduled elective procedure. (Instrument sets cannot be wrapped, processed CPMC Surgical Services Policy and Complete and sterilized in less than three hours from Procedure 27.3.0.8 "Flash Sterilization as of receipt of product). in the Operating Room" defines flash 11/19/09 . 7. The SPD (sterile processing department) staff sterilization "as the sterilization of will inspect all trays and process them in a unwrapped items with the use of washer/decontaminator or hand wash them if saturated steam under pressure in a required. gravity displacement or pre-vacuum 8. SPD staff will wrap and sterilize the trays and sterilizer. Saturated steam under place them onto a separate cart/area to be sent pressure should be used to sterilize to the O.R. on the evening before or the morning heat and moisture-stable items". of the procedure. The policy and procedure references the AORN 2008 Standards of Practice. The 2008 AORN Recommended Practices for Sterilization in the Perioperative Practice Setting. The Procedure specifies: pg.578 & pg.579 indicates the following: Specialty instruments or devices Recommendation IV are sterilized according to the manufacturer's Use of flash sterilization should be kept to a recommendations/instructions. minimum. Flash sterilization should be used only Prior to removing the item from the in selected clinical situations and in a controlled autoclave, the person removing the manner. item is responsible for examining the graph/digital autoclave printer Flash sterilization may be associated with tape to ensure that the correct increased risk of infection to patients because of time, temperature, and pressure pressure on personnel to eliminate one or more have been met. steps in the cleaning and sterilization process. 10. Upon removing the item from the sterilizer, and again prior to placing According to 2008 AORN Perioperative the item on the sterile field, Standards and Recommended Practices, p.181, examine the chemical indicator for AORN Guidance Statement: The Role of the changes. Health Care Industry Representative in the Perioperative Setting, "Perioperative team Both the scrub and circulating staff members are responsible for acquiring instruction (or other staff opening the autoclave) on new procedures, techniques, technology, and are responsible for examining the equipment before their use in a surgical indicators for change, indicating that procedure. This instruction may be provided by a sterilization parameters have been health care industry representative and may take

place in a formal inservice program or as a

met.

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FORM APPROVED California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (3) DATE SURVEY (2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED. A. BUILDING ____ B. WING CA220000022 11/17/2009 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5)**PREFIX** COMPLETION PREFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE DEFICIENCY) E 271 Continued From page 9 E 271 E 271 cont. one-on-one instruction. The facility should Monitoring Results: maintain evidence of documented competencies for perioperative team members, especially when Current For every load sterilized, the staff record introducing new procedures, techniques. the patient information, type of case, and and technology, and equipment. items sterilized. This information is ongoing reviewed along with the autoclave The facility failed to implement its Vendors and records. Sales Representatives: Guidelines in the Surgical Services Department policy and procedure when The data is summarized in a Quality the instruments for Patient 1's surgery were Monitoring Report and submitted brought to the facility the morning of the quarterly to the CPMC Infection Control procedure instead of at least 16 to 24 hours prior Committee. to the start of the procedure. This resulted in the instruments being flash sterilized and RN 2 and A copy of the Flash Sterilization Policy is RN 3 being unfamiliar with the retractor and attached for reference and review. blades being used during Patient 1's surgery. RN 2 and RN 3 were also unfamiliar with the surgical approach being used by Surgeon 1 during Patient Responsible Person: 1's surgery. This failure is a deficiency that has caused, or is Senior Director Surgical Services likely to cause, serious injury or death to the Manager, Infection Control patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280,1. CALIFORNIADERARIMENT **OFPLIBLICHEALTH** APR 2 9 2010 L&CDIVISION

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FORM APPROVED California Department of Public Health (3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: A. BUILDING C **B. WING** CA220000022 11/18/2009 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 (X4) ID PREFIX SUMMARY STATEMENT OF DEFICIENCIES iD PROVIDER'S PLAN OF CORRECTION COMPLÉTION (EACH DEFICIENCY MUST BE RPECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG REGULATORY OR LSC IDENTIFYING INFORMATION) DEFICIENCY) Please Note: E 000 Initial Comments E 000 The following constitutes California Pacific Medical Center (CPMC) - Pacific The following represent the findings of the Campus Hospital's credible evidence of California Department of Public Health during an correction of all of the alleged investigation of Entity Reported Event #CAOO198637 regarding retention of a foreign deficiencies cited by the California object during surgery. The investigation of the Department of Public Health in the Statement of Deficiencies Form CMSreported event was substantiated. 2567 dated 11/18/09. Preparation and/or execution of this credible evidence The inspection was limited to the specific submission does not constitute reported event investigated, and does not represent the findings of a full inspection of the admission or agreement by the provider of the truth of the facts alleged or the facility. conclusions set forth in the Statement of Representing the Department of Public Health: Deficiencies. Andrea Kubovcik, RN, Health Facilities Evaluator Nurse Health and Safety Code Section 1280.1(c): For purpose 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. E 264, E 269, E 271 E 264 T22 DIV5 CH1 ART3-70213(a) Nursing Service E 264 Policies and Procedures. Corrective Action: (a) Written policies and procedures for patient Complete care shall be developed, maintained and The Surgical Services Policy# as of 27.2.1.54, "Counts, Surgical" has been implemented by the nursing service. 12/18/09 revised to include the use of sponge pocketed holding bags. B. Sponge counts: This Statute is not met as evidenced by: 15. Separate and unfold all sponges E 269 T22 DIV5 CH1 ART3-70213(b) NUSING Service UEAL HOSE prior to placing in the counter OFFIRM HEALTH 269 bag pockets. Policies and Procedures. 16. Once the bags are full, the APR 2 9 2010

Licensing and certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

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filled

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sponges are counted audibly and concurrently, viewed by the

scrub person and the circulating RN. An empty bag is then placed on top of the counted

(6) DATE

| California | a Department of Public | Health | | | | | |
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| | NT OF DEFICIENCIES OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | | ' ' | ULTIPLE CONSTRUCTION UILDING | (3) DATE SURVEY COMPLETED | |
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| E 269 | Continued From page | e 1 | | E 269 | E 264, E 269, E 271 cont. | | |
| | (b) Policies and proce current standards of consistent with the nuincludes: assessmen planning, intervention circumstances required. This Statute is not me | nursing practice ar ursing process whi t, nursing diagnosi n, evaluation, and, e, patient advocac | nd shall be ch s, as y. | | 17. Final and closure counts Circulator then exposes previously counted bags scrub in order to reconci total number documente count board/sheet. The policy and procedure includ "Guidelines on using Sponge Ba | the to the le the d on the | |
| E 271 | T22 DIV5 CH1 ART3 Policies and Procedure | | Service | E 271 | Monitoring Process: | | Current |
| | (d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff. | | | Surgical Services staff complete concurrent audits in order to ens compliance to the Count Policy a Procedure at each step of the procedure at each step of the protection of the Surgical and Operating Room | nsure and ongoing process. orted to om | | |
| | This Statute is not me Based on interview as hospital failed to deve that mandated that be recounted during the a surgical sponge hav 2, who was forced to procedure to remove | nd record review, telop a surgical cou agged surgical spo final count. This re ving been retained undergo a second | the Int policy Inges be Inges in Inges | | Committee and the hospital wide Improvement Committee. Responsible Persons: Senior Director Surgical Service Director, Outcomes Management | s and | |
| | Findings: 1. Patient 2 was admi 7/9/09, and on 7/15/0 resection, repair of co colorectal anastomos hypertension, chronic | 9 had a sigmoid co lovesical fistula an is. Patient 2 had a | olon id history of | | The Surgical Services Count Pol Procedure, count forms and aud are attached for reference and re | lit tool | |

California Department of Public Health

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | | (2) MULT A. BUILD | IPLE CONSTRUCTION | | (3) DATE SURVEY COMPLETED | |
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| E 271 | Continued From pag disease and underwin 2007. On 7/29/09, facility. In August 20 outside facility for repain and pneumaturi facility determined the foreign body in his at was transferred back and on 8/13/09 he have removal of a surgical upper quadrant. On 11/16/09 at 11: 1 intraoperative case or reviewed, and reveat and final sponge courect. There was a dated 8/13/09 which as revision of colored of colovesical fistula, removal of retained for the procedure including was first paid to the procedure including was first paid to the procedure including was entirely composed the center of this wad retroperitoneum and was entirely composed adhesions between the dissected free using the center of this was some pus was visual sent for culture. The dissected free very contained free | ent kidney transplathe was discharge 109, Patient 2 was sourrent fevers, abdoard rests done at the presence of a rest dominal cavity. Part to the hospital on ad surgery that included that the initial, and series downers and the following: "A diverting loop ileo foreign object. The dated 8/13/09 oreign object. The dated 8/13/09 oreign object. The desired the following: "A diverting loop ileo foreign object. The desired the following: "A diverting loop ileo foreign object. The desired the following: "A diverting loop ileo foreign object. The desired the following: "A diverting loop ileo foreign object. The desired the following: "A diverting loop ileo foreign object. The desired the following: "A diverting loop in the desired of small bowel. The colonic mesent ed of small bowel. The colonic mesent ed of small bowel was read of bowel was read itsed and suctioned intraloop adhesion | d from the seen at an ominal ne outside stained atient 2 8/11/09 luded the n his right 9 was closing, nited as a see record procedure akedown stomy and 9 indicated ecurrent body. The val of right cription of attention or quadrant d bowel in tion was latery. It The e carefully sors. As ched, d out and s were | | | | | |

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

IDENTIFICATION NUMBER:

CA220000022

NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

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| | continued From page taking care not to injust of this, the foreign becarefully brought out using a combination of This was passed off the Continued This was the Continued This was the Continued This was asked to descript the She said when surgical field would "count off five, then bag them." Whe sponges were recount she responded "No, with the Count off the Sponges were recounted the Stated That surgical Patient 2's surgery with the circulating nurses them to him and "wrated them to him and "wrated the Count incorrect. ST 1 added 2's surgery, the operating the final count incorrect. ST 1 added 2's surgery, the operating the final count incorrect. ST 1 added 2's surgery, the operating the final count incorrect. ST 1 responges got package happened, so the counter the Counter This page of the Counter T | ire the bowel. In the dy was visualized from between the of blunt and sharp the field." I. m., RN 4 was in the circulating nursity on 7/15/09. Should the facility and it is a the facility and it is a sponges were at during Patient at sponges were all during the surge show them to the masked if the bag at the during the fin we don't open the and assume it considered off five, is predicted off five, in the could have been onded, "Maybe find as five, I think the int would still be of missing." | d and bowel or dissection. Iterviewed se for e stated ed nurse the closing mician). RN cal 1's surgery. removed ery, she e scrub, gged al count, bags, we stains five 1:25 p.m. during or a bucket, showed le said the recounted, was of Patient e use clear in asked in retained four hat's what correct | E 271 | DEFICIENCY) | | |
| | even if a sponge was During an interview of | Ū | a.m., RN 5 | er ye sakerishi i | | AND THE REAL PROPERTY OF THE P | |

California Department of Public Health STATEMENT OF DEFICIENCIES (3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: A. BUILDING C B. WING CA220000022 11/18/2009 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 PROVIDER'S PLAN OF CORRECTION (X5)SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PREFIX COMPLÉTION (EACH CORRECTIVE ACTION SHOULD BE PREFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL CROSS-REFERENCED TO THE APPROPRIATE DATE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG DEFICIENCY) E 271 Continued From page 4 E 271 stated she was the scrub nurse for part of Patient 2's surgery. She stated that the system of bagging sponges in groups of five during the procedure was "not good," She said that because the bagged sponges are not recounted during the final count, "You are trusting the person before you that there are five sponges in each bag." The facility's Counts, Surgical (Sponge, Sharps, Needles, Miscellaneous Items and Instruments) policy and procedure was reviewed and indicated the following: "Surgical counts will be performed utilizing the following guidelines. The use of a standardized systematic method of accounting for instruments, CALIFORNIADERADIMENT sponges, needles and specific small items used OFPUBLICHEALTH during a surgical procedure will promote patient safety by helping to prevent retained foreign APR 29 LOID bodies. L&CDIVISION B. Sponge Counts 11. The scrub person shall open soiled sponges when possible before discarding. Discard soiled sponges into kick buckets with impervious liners. 15. Once counted, the sponges are confined in an impervious wrapper. CALIFORNIADEPARTMENT 16. As part of the ongoing count process and during the closure counts, the total number of **OFPUBLICHFAITH** bagged sponges must be reconciled with the total number documented on the count board/sheet." AΡ The policy was ambiguous in that it did not L&CDIVISION specify that the bags had to be opened and the DALYCITY sponges contained in them needed to be recounted during the final sponge count The facility failed to develop and implement a surgical count policy and procedure which specified that bags of sponges counted during

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| the course of the sur recounted during the a surgical sponge had who had to undergo it. This failure is a de is likely to cause, ser patient, and thereford jeopardy within the n Code section 1280.1 | rgery be opened as a final count. This reading been left in Passery a second surgery efficiency that has crious injury or deat a constitutes an impeaning of Health. | esulted in attent 2, to remove caused, or the tothe mediate | | | | |
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California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (3) DATE SURVEY (2) MULTIPLE CONSTRUCTION IDENTIFICATION NUMBER: AND PLAN OF CORRECTION COMPLETED A. BUILDING B. WING CA220000022 11/17/2009 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 (X5) (X4) ID SUMMARY STATEMENT OF DEFICIENCIES in PROVIDER'S PLAN OF CORRECTION PREFIX PRÉFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE COMPLÉTION TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE DEFICIENCY) E 000 -The following represent the findings of the E 000 Please Note: California Department of Public Health during an The following constitutes California investigation of Entity Reported Event Pacific Medical Center (CPMC) -#CAO0191275 regarding retained foreign object Pacific Campus Hospital's credible evidence of correction of all of the during surgery. The investigation of the reported event was alleged deficiencies cited by the substantiated. California Department of Public Health in the Statement of Deficiencies Form The inspection was limited to the specific reported CMS- 2567 dated 11/17/09. Preparation event investigated, and does not represent the and/or execution of this credible findings of a full inspection of the facility. evidence submission does not constitute admission or agreement by Representing the Department of Public Health: the provider of the truth of the facts alleged or the conclusions set forth in Andrea Kubovcik, R.N., Health Facilities the Statement of Deficiencies. **Evaluator Nurse** Mary Coulton, R.N., Health facilities Evaluator The Statement of Deficiencies form is Nurse dated 11/17/09, however the hospital Health and Safety Code Section 1280.1(c): records indicate the survey was completed on 11/18/09 by Andrea For purposes of this section, "immediate Kubovicik, RN and Alice Morrisey, RN. ieopardy" means a situation in which the licensee's non-compliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. E 264 T22 DIV5 CH1 ART3-70213(a) Nursing Service E 264 E 264, E 269, E 271 Policies and Procedures. Corrective Action: (a) Written policies and procedures for patient care shall be developed, maintained and Failure to comply with the established 6/09 Surgical Count policy has been implemented by the nursing service. addressed with the staff involved in this event. This Statute is not met as evidenced by: Licensing and certification Division LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE STATE FORM CALIFORNIADERATIMENT on tinuation sheet 1 of 10 HW5G11 **OFPUBLICHEALIH**

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| E 269 | T22 DIV5 CH1 ART3-70213(b) Nursing Service Policies and Procedures. | | E 269 | The Surgical Services Policy: 27.2.1.54, "Counts, Surgical" revised to state: | | |
| E 271 | current standards consistent with the includes: assessm planning, intervent circumstances required. This Statute is not T22 DIV5 CH1 AR Policies and Processistency and coincorporating the numedical treatment implemented in costaff. This Statute is not Based on interview failed to implement procedure when R charge nurse) add surgical field withous document the addition the instrument of to orient staff to insurgery and failed Sales Representations when a retractor a facility the day of states. | ocedures shall be based on of nursing practice and shall be inursing process which ent, nursing diagnosis, ion, evaluation, and, a uire, patient advocacy. T3-70213(d) Nursing Service dures. Ocedures that require ontinuity in patient care, ursing process and the plan, shall be developed and operation with the medical met as evidenced by: y and record review, hospital this Surgical Counts policy and N 1/CVC (cardiovascular ed a retractor and blades to the ut counting them, and failed to tion of the retractor and blades count sheet. The hospital failed struments being used in to implement its Vendors and thives policy and procedure and blades were brought to the surgery instead of 16 to 24 surgery. This resulted in a | E 271 | revised to state: "General Rules: 2. The count process require and continual readiness to for required items included surgical count. Every effor be made throughout the part to be ready to perform a count time. 3. OR staff will initiate the chance command when faced with resistance by any members surgical team to comply we surgical count policy. The "Counts, Surgical" policy revised to include standardization to count sheet as the process for documenting the boards and sheets. There is also a record to doct count for extra instrument self instruments brought in by a virial surgeon. In addition, "Surgical Services Guidelines" were implemented improve critical communication elements in the OR, i.e. sponsharps, medications, specime Recommended Relief Rules established in an effort to red number of relief breaks that reduring a case. | o account d in a rt should rocedure count at any rain of h r of the rith the was ation of ets as well ng onto ument the is, i.e. endor or es Handoff ed to on oges, ens. were also uce the | 12/18/09 |
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| E 271 Continued From page 271 | age 2 | E 271 | E 264, E 269, E 271 cont. | | : |
| retractor blade have had to undergo a seremove the retained. Findings: 1. Patient 1 was ad 4/14/09 for mitral vertical discharged on 4/16 was experiencing of cardiologist in her chest x-ray and ultipresence of a amine Patient 1 was read and on 6/23/09 har retractor blade. On 11/16/09 at 10 intraoperative recovered, and indicated and final instrument correct. There was an intrawhich listed the sure Retained Foreign 6 | be having been left in Patient 1 who go a second surgical procedure to stained foreign object. E 271 E 284, E 289, E 271 cont. CPMC Administrative Policy 2.98, "Universal Protocol" states: J. "Time Out" before starting the Procedure: 1. "Time Out" must be conducted in the location where the procedure will be done and must be conducted prior to starting the procedure. 1. "Time Out" must be conducted in the location where the procedure will be done and must be conducted prior to starting the procedure. 1. "Time Out" must be conducted in the location where the procedure will be done and must be conducted prior to starting the procedure. 1. "Time Out" must be conducted in the location where the procedure will be done and must be conducted prior to starting the procedure. 1. "Members of the care team are expected to speak up immediately and stop the process if they notice any discrepancy or believe any step in the safety check process is missed or incomplete. K. Sign Out: 1. Prior to leaving the procedure area, the RN verbally confirms with the team Instruments, sponge and needle counts are correct Equipment problems to be addressed Staff education for the "Universal Protocol" was provided during Surgical Services education meetings. | | Current as of 11/19/09 | | |
| pre and post opera foreign object. The had repaired Patie months ago and, " successful. It reque however, that were and these were no end of the operation retractor blade lines we did not recogni | | | 12/18/09 | | |

Licensing and certification Division STATE FORM

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California Department of Public Health

| STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (2) MULTIPLE CONSTRUCTION (3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A BUILDING | | | | | | |
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| E 271 | On 11/16/09 at 3:25 p.m., RN 2 was interviewed. She stated she was the scrub nurse for Patient 1's first surgery on 4/14/09. She said she was unfamiliar with the approach being used by the surgeon and that she made RN 1/CVC aware of this prior to the procedure. RN 2 said "(name of circulating nurse) and I had never done that type of case, the approach was different, RN 1/CVC was there to guide us." She stated that Surgeon 1 works very quickly. She said, "I've never worked with anyone who goes that fast." RN 2 stated the retractor and blades were brought into the operating room after the initial count had been done and after Patient 1's chest had been opened. She stated "It was the middle of the case." She said "I'd never seen these instruments or used them before." She said that Surgeon 1 wanted the retractor and blades immediately. The retractor vendor was in the operating room to answer any questions the surgeon may have had about the product. When asked if the retractor and blades were counted, she stated "I eyeballed it, but myself and the circulator didn't get time to count them. I felt pressured and I didn't get time to count." She added "It was a hectic environment, the noise level was very high." RN 1/CVC was interviewed on 11/16/09 at 3:45 p.m. She stated she was the charge nurse of cardiovascular services and what happened was "an unfortunate event." She said that Patient 1's procedure was "entirely different to what he (Surgeon 1) usually does." She stated that a vendors representative brought the retractor and | | E 271 | 3. a. New products, instrument implants or equipment reapproved through the follows as appropriate: Value Arr Committee, New Technologomittee, and/or the dischair/designee. b. The operating room mar will ensure that the items approved. c. Approved new product evaluations of productions of apprint the confirmation of apprint the vendor Audit Tool vendor Audit Tool vendor Audit Tool vendor at the receiving unit and procedure is completed of Management Staff will of for contacting the vendor co | E 264, E 269, E 271 cont. 3. a. New products, instrument systems, implants or equipment requests are approved through the following methods as appropriate: Value Analysis Committee, New Technology Committee, and/or the department chair/designee. b. The operating room manager/designee will ensure that the items requested are approved. c. Approved new products and evaluations of products will be communicated through a bulletin from the Value Analysis Committee. d. The confirmation of approved vendor instrument systems/equipment, will be communicated to the staff by utilizing the Vendor Audit Tool which will follow the instruments/equipment throughout the process. The tracking tool will start at the receiving unit and end when the procedure is completed. e. Manager/designee and Materials Management Staff will establish a plan for contacting the vendor. The designated person will make | |
| | | | procedure. f. Manager/Supervisor/Sedesignee will arrange for education with the venousing new or unfamiliar equipment. D. Sterile Processing 4. Pre-procedure sets will to 24 hours prior to the scheduled elective procedure a. Instruments/implants inspected, cleaned, dand sterilized by CPM patient use. b. Electrical equipment checked by Biomedic before use on any CF | | | |

California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (2) MULTIPLE CONSTRUCTION (3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING C B. WING CA220000022 11/17/2009 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 PROVIDER'S PLAN OF CORRECTION (X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID (X5)COMPLETION PRÉFIX (EACH DEFICIENCY MUST BE REECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE DEFICIENCY) E 264, E 269, E 271 cont. E 271 Continued From page 4 E 271 5. b. An inventory list will be completed 12/18/09 done. I'm sure I counted the pieces but I can't for instrument sets used on remember specifically but that's my usual procedures where an instrument practice." When asked if she documented count is required. If the vendor is counting the instruments, she said "I didn't write it unable to provide this, the down." department receiving the set (OR or SPD) will complete an inventory RN 1/CVC was asked when the retractor and /count_list. blades were brought into the operating room. She Inventory lists are affixed to or stated "I brought it into the operating room after included with instrument sets used the procedure started. (Name of RN 2) was right on procedures where an instrument up there, maybe she didn't have a chance to count is required. come away from the table to count." RN 1/CVC F. Operating Room: said "(Name of RN 2) was unfamiliar with the instruments, she was on the other side of the 6. The circulating RN will: table, she probably couldn't even see when he Confirm that the product, (Surgeon 1) took out the retractor," RN 1/CVC instrument, or implants have been added" I assumed that everyone knew what to approved for use by CPMC Confirm prior to the start of the do with the retractor." procedure that the loaner When asked how the retractor blade was left in instruments have been Patient 1, RN 1/CVC responded" He (Surgeon 1) processed at CPMC. must have just unscrewed it and left it fall into the Confirm that a count sheet is wound. I can't believe he did that," She stated included if the procedure that when the surgery was finished, the retractor requires an instrument count and blades were sent downstairs to the SPD by policy, (sterile processing department) for sterilizing. She Confirm that the staff have said when the vendor picked up the instruments. received education, he noticed that a blade was missing but he never notified the facility. Surgical Services staff has been informed of the changes to the policy RN 3 was interviewed on 11/17/09 at 10:30 a.m. and are aware of their responsibilities. She stated she was assigned to be the circulating nurse for Patient 1's procedure on 4/14109. She **Monitoring Process:** said she was not familiar with the approach being The Surgical Services staff is completing used by Surgeon 1 so she notified her senior Current concurrent monitoring of the count nurse (RN 1/CVC). She stated that RN 1/CVC and process including compliance to general was the primary circulating nurse for the ongoing rules, initial count, handoff process and procedure as she (RN 3) was going between two closing counts. Monitoring results will be operating rooms. RN 3 stated she did the closing reported to the Surgery and Operating and final count with RN 2 and the retractor and Room Committee and the hospital blades were not listed on the count sheets. She Quality Improvement Committee.

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California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (2) MULTIPLE CONSTRUCTION (3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING __ C B. WING CA220000022 11/17/2009 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION (X5)PRÉFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE COMPLETION TAG REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG **DEFICIENCY**) E 271 Continued From page 5 E 271 E 264, E 269, E 271 cont. said" I never saw that retractor that day." A monitoring audit tool for vendors, with Current associated indicators, has been and The facility's Counts, Surgical (Sponge, Sharps, developed. ongoing Needles, Miscellaneous Items and Instruments) policy and procedure was reviewed and indicated The monitoring is conducted by surgical the following: services staff concurrently on all vendor Policy: cases. The audit data is reported Surgical counts will be performed utilizing the quarterly to Surgical and Operating following guidelines. The use of a standardized Room Committee and to the Quality systematic method of accounting for instruments. Improvement Committee. sponges, needles and specific small items used during a surgical procedure will promote patient safety by helping to prevent retained foreign All vendor products that arrive less than bodies. 8 hours prior to surgery, regardless of reason, will be tracked and reviewed for A. General Rules. system issues and common factors and 1. It is the responsibility of all members of the will be included in the report. surgical team to maintain an optimal Operating Room environment to allow focused performance The Surgical Services Count and Vendor of operative tasks. Distractions and interruptions policies and monitoring tools are should be kept to a minimum during the count. attached for your reference. 2. Counts are performed following the guidelines for the category of the items counted. Responsible Persons: 4. Counts are to be performed by two people, the circulating Registered Nurse (RN), and a scrub Senior Director, Surgical Services and person. The circulating RN is responsible for Director, Outcomes Management conducting the counts and must be a participant of every count. 5, The items are counted audibly, and concurrently viewed by the scrub person and circulating RN. 12. Sponge types, free needles, atraumatic needles, sharps, and miscellaneous items are CALIFORNIADEPARTMENT recorded separately on the standardized **OFPUBLICHEALTH** preformatted whiteboard. A preformatted work sheet mirroring the whiteboard is used when a APR 2 9 2010 whiteboard is not accessible. Instruments are recorded on standardized count sheets. L&CDIVISION 13. A running total of needles, sharps, and

miscellaneous items are placed on the boards,

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| AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | A. BUILDING | | (3) DATE SURVEY COMPLETED C 11/17/2009 | |
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| done as items and documenting add 20. When counts b. As new counted D. Instrument Co. Instrument couprocedures involvinvolve, the open as: d. the pieural/tho 3. Initial instrument the order on the 4. Use this stand instruments added The Association Nurses, or AORN and liaisons inclu Control), Associatinfection Control College of Surge Anesthesiologists of Ambulatory Suposition papers, practices are wid perioperative clin authoritative guid requirements. According to 200 Standards and R 293, | instrument count sheets will be added. The method of litions and totals is standardized. are performed: Instruments ad items are added to the field. unts. unts are performed on all ving, or reasonably anticipated to ing of a major body cavity such | E 271 | | | |
| occurrence, and | careful counting and an significantly reduce, if not | e vegenie i Distribute steamen proprie | | | THE PROPERTY OF THE PROPERTY O |
| Recommended F | Practices for Sponge, Sharp, and | | | | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (2) MULTIPLE CONSTRUCTION A. BUILDING | | (3) DATE SURVEY COMPLETED | | |
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| NAME OF PROVIDER OR SUPPLIER CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC | | | STREET ADDRESS, CITY, STATE, ZIP 2333 BUCHANAN STREET SAN FRANCISCO, CA 94115 | | | |
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California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (2) MULTIPLE CONSTRUCTION (3) DATE SURVEY AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: A. BUILDING B. WING_ CA220000022 11/17/2009 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION COMPLÉTION PRÉFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG DEFICIENCY) E 271 Continued From page 8 E 271 E 271 cont. Sets must arrive at least 16 to 24 hours prior to Corrective Action: the start of a scheduled elective procedure. (Instrument sets cannot be wrapped, processed CPMC Surgical Services Policy and Complete and sterilized in less than three hours from Procedure 27.3.0.8 "Flash Sterilization as of receipt of product). in the Operating Room" defines flash 11/19/09 7. The SPD (sterile processing department) staff sterilization "as the sterilization of will inspect all trays and process them in a unwrapped items with the use of washer/decontaminator or hand wash them if saturated steam under pressure in a required. gravity displacement or pre-vacuum 8. SPD staff will wrap and sterilize the trays and sterilizer. Saturated steam under place them onto a separate cart/area to be sent pressure should be used to sterilize to the O.R. on the evening before or the morning heat and moisture-stable items". of the procedure. The policy and procedure references the AORN 2008 Standards of Practice. The 2008 AORN Recommended Practices for Sterilization in the Perioperative Practice Setting. The Procedure specifies: pg.578 & pg.579 indicates the following: Specialty instruments or devices Recommendation IV are sterilized according to the manufacturer's Use of flash sterilization should be kept to a recommendations/instructions. minimum. Flash sterilization should be used only Prior to removing the item from the in selected clinical situations and in a controlled autoclave, the person removing the manner. item is responsible for examining the graph/digital autoclave printer Flash sterilization may be associated with tape to ensure that the correct increased risk of infection to patients because of time, temperature, and pressure pressure on personnel to eliminate one or more have been met. steps in the cleaning and sterilization process. 10. Upon removing the item from the sterilizer, and again prior to placing According to 2008 AORN Perioperative the item on the sterile field, Standards and Recommended Practices, p.181, examine the chemical indicator for AORN Guidance Statement: The Role of the changes. Health Care Industry Representative in the Perioperative Setting, "Perioperative team Both the scrub and circulating staff members are responsible for acquiring instruction (or other staff opening the autoclave) on new procedures, techniques, technology, and are responsible for examining the equipment before their use in a surgical indicators for change, indicating that procedure. This instruction may be provided by a sterilization parameters have been health care industry representative and may take met. place in a formal inservice program or as a

California Department of Public Health (3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING B. WING CA220000022 11/17/2009 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 2333 BUCHANAN STREET CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC SAN FRANCISCO, CA 94115 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) 1D (X5) PREFIX PRÉFIX (EACH DEFICIENCY MUST BE RPECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE COMPLÉTION CROSS-REFERENCED TO THE APPROPRIATE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG DATE DEFICIENCY) E 271 Continued From page 9 E 271 E 271 cont. one-on-one instruction. The facility should Monitoring Results: maintain evidence of documented competencies for perioperative team members, especially when For every load sterilized, the staff record Current introducing new procedures, techniques, the patient information, type of case, and and technology, and equipment. items sterilized. This information is ongoing reviewed along with the autoclave The facility failed to implement its Vendors and records. Sales Representatives: Guidelines in the Surgical Services Department policy and procedure when The data is summarized in a Quality the instruments for Patient 1's surgery were Monitoring Report and submitted brought to the facility the morning of the quarterly to the CPMC Infection Control procedure instead of at least 16 to 24 hours prior Committee. to the start of the procedure. This resulted in the instruments being flash sterilized and RN 2 and A copy of the Flash Sterilization Policy is RN 3 being unfamiliar with the retractor and attached for reference and review. blades being used during Patient 1's surgery. RN 2 and RN 3 were also unfamiliar with the surgical approach being used by Surgeon 1 during Patient Responsible Person: 1's surgery. This failure is a deficiency that has caused, or is Senior Director Surgical Services likely to cause, serious injury or death to the Manager, Infection Control patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280,1. CALIFORNIADERARIMENT **OFPUBLICHEALTH** APR 2 9 2010 L&CDIVISION DALYCITY