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
	050280	A. BUILDING _____ B. WING _____	12/11/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Mercy Medical Center Redding	2175 Rosaline Ave, Redding, CA 96001-2509 SHASTA 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 an inspection visit: Complaint Intake Number: CA00555480 - Substantiated Representing the Department of Public Health: Surveyor ID # 1989, 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 1280.3(g): 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. 1279.1(b)(1)(D) Health & Safety Code 1279.1 (b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events, including the following: (D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained. T22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures			

Event ID:UC3E11 7/19/2018 1:45:30PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: S Todd Smith TITLE: President (X6) DATE: 11/1/18

'gning this document, I am acknowledging receipt of the entire citation packet, *Page(s). 1 thru 6*

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.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050280	A. BUILDING _____ B. WING _____	12/11/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Mercy Medical Center Redding	2175 Rosaline Ave, Redding, CA 96001-2509 SHASTA 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
	(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. The facility failed to follow its policy, nationally recognized standards (Association of Perioperative Registered Nurses, AORN), and manufacturer's instructions for use, when all surgical sponges were not properly counted during Patient 1's surgery. This resulted in a retained surgical, which according to the autopsy, caused Patient 1's death. Findings: A report from the facility, dated 10/3/17 at 3:55 pm, was received by the California Department of Public Health. This report indicated Patient 1 had retention of a surgical sponge from his surgery on 9/19/17. This was discovered on 9/29/17, also the date of death. A review of Patient 1's record indicated he had an aortobifemoral bypass surgery (surgery used to bypass diseased large blood vessels in the abdomen and groin) on 9/19/17. All sponge counts were noted to be correct. Patient 1 suffered complications after surgery including a cardiac/respiratory arrest on 9/29/17. An abdominal x-ray taken on 9/29/17 showed a surgical sponge in Patient 1's lower left abdomen. On 12/4/17 at 1:20 pm an interview was			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050280	A. BUILDING _____ B. WING _____	12/11/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Mercy Medical Center Redding	2175 Rosaline Ave, Redding, CA 96001-2509 SHASTA 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
	conducted with the Director of Risk and Safety (DRS). DRS stated that the discharge note written by Physician 1 indicated he had a discussion with the family about the {retained} sponge. The staff didn't consistently follow the practice for counting in the operating room. When using the sponge holder some pull ties (meaning the x-ray detectable ties) were out. Sometimes the holders break. They were not following the process correctly. They didn't consistently have the surgeon be part of the count process. A review of the facility's policy, "Prevention of Retained Surgical Items" dated 11/2015, was reviewed. It read as follows under Policy: "Consistent with our mission and values, {the hospital} is dedicated to providing a safe patient environment by minimizing the risk of foreign bodies retained during an operative or invasive procedure. Counts are performed to account for all items used during all operative or invasive procedures to ensure that the patient is not harmed by a retained foreign body." Procedure: "All sponges will be placed in the appropriate holders before the patient leaves the room." "The physician must verify with the circulating RN that ALL holder pockets are filled and matches the number on the dry-erase board." AORN standards were referenced at the bottom of the policy. During an interview on 12/11/17 at 9:30 am, the Registered Nurse (RN) 1 who was present during surgery, stated she and the scrub			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050280	A. BUILDING _____ B. WING _____	12/11/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Mercy Medical Center Redding	2175 Rosaline Ave, Redding, CA 96001-2509 SHASTA 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
	technician (ST) performed the counts in their usual manner and the counts were correct. She was told later about the retained sponge. RN 1 stated there was a bag hung to place used sponges which had a partition that divided it down the middle with five sections, so it could hold up to ten lap sponges. She stated if the partition had become separated it could have looked like one sponge was two. RN 1 stated, after this incident, they are now rolling the sponges so they fit the sponge holding bag better and make sure the ties (each lap sponge has a blue tie approximately 7 inches long for the purpose of being visible when a patient is x-rayed) for each sponge hang down. During an interview on 12/11/17 at 10 am, ST stated she and RN 1 performed all counts which were correct. ST stated the bag which held the sponges, had two slots on each side with five sections and could hold a total of ten sponges, one sponge for each slot. ST stated the middle part of the bag could break, and the only thing she could think of was, that this happened, and one sponge covered two slots and looked like two sponges instead of one. The instructions for use from the manufacturer of the sponge holding bag read as follows, "10 soiled sponges may be placed in each bag - 2 in each of the 5 divided pockets. For lap sponges, gently separate the seal between each pocket - 5 sponges per bag." An interview was conducted on 4/30/18 at 12:10			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050280	A. BUILDING _____ B. WING _____	12/11/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Mercy Medical Center Redding	2175 Rosaline Ave, Redding, CA 96001-2509 SHASTA 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
	pm, with the Director of Perioperative Services (DPS) and the Director of Risk and Safety (DRS). DPS confirmed the facility followed AORN standards. The AORN guidelines for the prevention of retained surgical items (RSI) was reviewed. "The Guideline for Prevention of Retained Surgical Items was approved by the AORN Guidelines Advisory Board and was effective January 15, 2016." "An RSI is a rare but serious preventable error that can result in patient harm. Thus, perioperative (surgical) team members are ethically and morally obligated to protect patients by preventing RSIs." "The most common items retained are surgical sponges." "All perioperative team members are responsible for the prevention of RSIs." "Surgeons and surgical first assistants should actively participate in safety measures to prevent RSIs." "The surgeon and surgical first assistant should perform a methodical wound exploration before closing the wound, using both visualization and touch when feasible." "Counted radiopaque (x-ray detectable) surgical soft goods (i.e., 4 x 4 gauze, laparotomy sponges) should be organized after use in a pocketed sponge bag or by a similar system." "Only one sponge should be placed in each pocket of the pocketed sponge bag system." "The radiopaque (x-ray detectable) marker of the sponge should be placed facing forward so that it is readily visible in the pocketed bag system. The radiopaque marker			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050280	A. BUILDING _____ B. WING _____	12/11/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Mercy Medical Center Redding	2175 Rosaline Ave, Redding, CA 96001-2509 SHASTA 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
	is a visual marker that distinguishes one sponge from another. Having the marker visible in the pocket may facilitate the count process." A review of the autopsy indicated the cause of death: peritonitis (inflammation of the tissue that lines the inner wall of the abdomen and covers and supports most of your abdominal organs, usually caused by infection from by bacteria) due to retained surgical sponge in abdomen due to perioperative complication of aorto-bi-femoral bypass surgery with hypertensive (high blood pressure) and atherosclerotic cardiovascular (heart) disease as a significant contributing factor. 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 1280.3(g).			

Mercy Medical Center Redding
2175 Rosaline Avenue, Clairmont Heights
Redding, CA 96001
CA230000010

AMENDED
CORRECTIVE ACTION PLAN
Tag# E-264

A. Immediate Actions

1. Throughout October 2017, education and training of all the procedural area staff members was conducted by the Director of Perioperative Services, using the Mercy Redding policy in effect from November 2015.
   October-2017
2. A revised Dignity Health system-wide Prevention of Retained Surgical Items Policy and Reference Manual went through facility approval and invalidates all equivalent previous policies.
   2/8/2018
3. All procedural area staff underwent education, training and competency assessments using the Dignity Health system-wide Prevention of Retained Surgical Items Policy and Reference Manual as follows:

Finding	Action	Section of Policy and/or Reference Manual	Comments
1. Incomplete knowledge of a cavity count, closing count and final count	Education and testing on the names of and actions performed at each of the 6 surgical counts	Policy: Nurse Procedure A Ref. Manual: Section I A	AORN required surgical counts: Initial, Cavity, Closing, Permanent Relief, Anytime, Final
2. Error in performance of the closing count	Review of Safety Rules for Closing Count	Policy: Nurse Procedure A Ref Manual: I. A-B	
3. No performance and documentation of the final count	Review and training of final count safety rules	Policy: Nurse Procedure A Ref Manual I. A-B. Addendum A	All sponges must be in the pockets of the holders
4. No performance of the Show Us step	Training of team based step	Policy: Nurse Procedure A -B	RN must find "another set of

		Ref Manual I.B.1-2	eyes" to look
5. Errors in the performance of the 10-step Sponge Accounting System (SAS) Nursing Practice a) one sponge per pocket; do not pop the center divider b) put blue tags inside the pocket; do not dangle the tags	Review and training on the 10-step SAS Nursing Practice using the designated handout, video and mandatory teach-back demonstration of sponge placement in the pockets of each holder	Policy: Nurse Procedure B Ref Manual I.B1-2 Addendum F	
7. Completion of a miscount report in the setting of finding a defective surgical item	Instruction on use of miscount report and reporting up Chain of Command	Policy: Nurse Procedure A Ref Manual Addendum D	
8. Complete audits in surgery suites	Eight-element auditing plan	Policy: Nurse Education H	

The staff was assigned the policy to read and acknowledge in the learning management system (MyJourney). By complying with the Dignity Health system-wide policy and reference manual on Prevention of Retained Surgical Items, staff will be in compliance with AORN standards.

6/6/2018

B/ C. Deficient Practice/Corrective Action/Measures & Systemic Changes

1. Upon review of the Medline Industries' Instructions For Use (IFU) of the "sponge counter bags", the facility uses a 10 pocket configuration which is in conformance with IFU#6 - "10 soiled sponges may be placed in each bag – 2 in each of the 5 divided pockets". The IFU for the sponge counter bags is worded to provide flexibility of use when counting sponges in different multiples – either 5 or 10. Confirmation that a 10 lap pad configuration is in compliance with the IFU was obtained in writing from Medline. Medline provided a letter stating the following:

   To Whom It May Concern,

The instructions for use (IFU) printed on Medline's sponge counter bags states "For lap sponges, gently separate the seal between each pocket – 5 sponges per bag." As most Medline lap sponge configurations are in packs of 5, this IFU statement is in concordance with the AORN recommendation to manage the sponges in the unit of issue. However, if your facility counts lap sponges in units of 10, then 10 sponges may be placed into each sponge counter bag (2 sponges in each of the 5 pockets).

8/22/2018

2. Monthly audit reports will be submitted to CDPH Chico District Office.
November-2018 & ongoing

D. Monitor

1. Responsible Party: Director Perioperative Services

Indicator Description: Daily observational audits for performance of the eight elements outlined below are performed on 100% of open chest and abdominal procedures for 6 months, or until 100% is sustained for 3 months. The eight items are as follows:

1. Sponge counts recorded on white boards the same way using superscript running total format;
2. Only blue backed holders used on racks stably mounted to a 2-prong IV stand;
3. Sponges (raytex and lap pads) used only in multiples of 10;
4. Initial counts performed with 2 people using see-SEPARATE-say;
5. Sponges placed in the holders with the blue markers or blue tags inside the pocket facing forward;
6. Surgeon performs a methodical wound exam
7. All sponges (used and unused) are in the holders at the final count;
8. Show Us step performed by circulating nurse with a second pair of eyes looking at holders.

Numerator: Number of cases meeting all eight elements.

Denominator: Number of cases.

Results of audit will be reported to the QA&I Committee, Medical Executive Committee and Governing Board.

Date: **10/1/2018 & ongoing**

2. Responsible Party: Director Perioperative Services

Indicator Description: Daily randomly selected observational audits for all cases with the selected elements 4, 5, 7 and 8 (one month all cases will have item #4 audited, the next month all cases will have item #5 audited, etc.) are sustained for 4 months.

4. Initial counts performed with 2 people using see-SEPARATE-say;

5. Sponges placed in the holders with the blue markers or blue tags inside the pocket facing forward;
7. All sponges (used and unused) are in the holders at the final count;
8. Show Us step performed by circulating nurse with a second pair of eyes looking at holders.

Depending on identified deficiencies or for routine assessments, the hospital will continue to conduct monthly audits for compliance. Monthly reporting of results continues until 100% compliance is sustained for 3 consecutive months.

Numerator: Number of cases meeting monthly selected element.

Denominator: Number of cases.

Results of audit will be reported to the QA&I Committee, Medical Executive Committee and Governing Board.

Date: **10/1/2018 & ongoing**