CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY DEPARTMENT OF PUBLIC HEALTH

AND PLAN OF CORRECTION IDENTIFICATION		(X1) PROVIDER/SUPPLIE IDENTIFICATION NU		A. BUILDI	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED	
		050168	E	B. WNG		_ 10/0	04/2010	
NAME OF PRO	OVIDER OR SUPPLIER		STREET ADDRESS	S, CITY, STATE	, ZIP CODE			
ST. JUDE I	MEDICAL CENTER		101 E. VALENC	IA MESA DR	RIVE, FULLERTON, CA 92835	DRANGE 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 (EACH CORRECTIVE ACTION REFERENCED TO THE APPRO	(X5) COMPLETE DATE		
	The following reflects th	o findings of the Der	artment				1	
	of Public Health during		artificin		-			
	of Public Health during	an inspection visit.						
	Complaint Intake Numb	er.	*					
	CA00242778 - Substan							
	O/100242770 Cabolan	liatoa						
	Representing the Depart	rtment of Public Heal	th:					
	Surveyor ID # 22779, H							
	The inspection was limit	ted to the specific fac	ility					
8	event investigated and							
	findings of a full inspect							
	•	7. Tre 1. 1909 A. 190 A. 190 A. A. 190 A. A. 190 A. A. 190 A. 190 A. A. 190 A. A. 190 A. 190 A. 190 A. 190 A.	1					
	Health and Safety (Code Section 128	0.1(c): For					
	purposes of this s	ection "immediate	jeopardy"					
	means a situation	in which the	licensee's					
	noncompliance with o	one or more requir	rements of					
	licensure has caused,	or is likely to caus	se, serious					
	injury or death to the pa	tient.						
	Health and Safety Code	1270 1					FEB	
	[12] IN BOTO NOTE (11) NOTE (12) N	of this section, "adv	erse event"				B	
	includes any of the follo		CISC CVCIII				<u>i</u> —	
	(1) Surgical events, in	100 Table 100 Ta						
	(D) Retention of a		190				三	
	surgery or other p	170 5						
	intentionally implanted a		.9,				المسم المسمر	
	a planned intervention		ent prior to				2	
	surgery that are intentio						တ	
	Health and Safety Coo	de 1279.1 (c) The f	acility shall					
	inform the patient or	Military mercental bilities in programme in the	Market Street Company of the Company		W			
	patient of the adverse		The state of the s					
	is made.	12						
			1					
							in the second	
Event ID:W	/RJH11		1/25/2012	10:26:	14AM			

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

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(X6) DATE

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PREFIX (EACH DEFICIENCY N	O50168 STREET ADDRESS 101 E. VALENC TEMENT OF DEFICIENCIES MUST BE PRECEEDED BY FULL EC IDENTIFYING INFORMATION)		RIVE, FULLERTON,	CA 92835 ORANGE COUNTY	4/2010
ST. JUDE MEDICAL CENTER (X4) ID SUMMARY STAT PREFIX (EACH DEFICIENCY N	TEMENT OF DEFICIENCIES MUST BE PRECEEDED BY FULL	IA MESA DI	RIVE, FULLERTON,	CA 92835 ORANGE COUNTY	
PREFIX (EACH DEFICIENCY N	MUST BE PRECEEDED BY FULL		DDQ unit		
W.S. W.		TAG	(EACH CORREC	ER'S PLAN OF CORRECTION CTIVE ACTION SHOULD BE CROSS- O THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
patient or the party resadverse event by the time DEFICIENCY CONJEOPARDY T22 DIV5 ART3-70223 General Requirements (b) A committee of assigned responsibility for the committee of assigned responsibility for the committee of assigned responsibility for the administration. Police governing body. Proce the administration and appropriate. This regulation is NOT Mediated to ensure implementation and procedure and curthant it did not perform surgical count identified missing with the result for two and one half healing and the increase.	that the facility informed the sponsible for the patient of the ne the report was made. NSTITUTING IMMEDIATE (a) (b) (2) Surgical Service The medical staff shall be for: Internance and implementation of procedures in consultation to the edures shall be approved by the edures shall be approved by medical staff where such is The as evidenced by: Internation of its written policy that the policy that the education of the procedure in the authorough follow-up after a sed a surgical sponge was that a sponge was retained months with delayed wound		a) How the coraccomplish permanently The following standard work both temporal eliminate the of event. Standard work count process sponge count and reasons taken in the standard sta	g process changes and rk were implemented to arily and permanently a reoccurrence of this type ork was developed for the as that includes the missing at, critical thinking processes why certain actions are sequence required. changes include what to do at the end of a the count is not resolved, atte the potential event, or use to communicate, what to do at the end of a the count is not resolved, atte the potential event, or use to communicate, what decesses are required to the sponge cannot be or. In the process is completed and the count is not resolved, and the potential event, or use to communicate the order of the sponge cannot be ordered and the count is not resolved, and the process is completed and clearly communicate the office was updated to include items: final stitch ent from surgeon to surgical occedure cases where there is the potential is utilized; a tup for a two procedure	2012 FEB 1 AM 11 25
Event ID:WRJH11	1/25/2012	10:26	case as well	as counting for the final	

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[마음 : 10] [[[[[[[[[[[[[[[[[[(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050168	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED - 10/04/2010	
NAME OF PR	OVIDER OR SUPPLIER	STREET ADDRESS	CITY, STATE, 2	ZIP CODE		
	MEDICAL CENTER			VE, FULLERTON, CA 92835 OF	RANGE COUNTY	
01. 00DL	MEDIONE GENTER	701 2. 7722110.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,	5 to 2 000 ii 1 1	
					20	
(X4) ID PREFIX TAG	(EACH DEFICIENCY	MUST BE PRECEEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTION SI REFERENCED TO THE APPROP	HOULD BE CROSS-	(X5) COMPLETE DATE
	Continued From page	2				
	retained foreign objereported that Patient office on 10 for of irritation at a rigi. The physician exam sponge protruding, w sponge is defined as fluids, protect tissue traction). The patient 10 at the hospital. Review of the hos "Count: Sponge, Sh 1/2010, showed count the procedure to closure of a cavity closure, and before sprocedure. The Policy when a discrepancy surgical team's actio check of the surgical surgical counts cite (Association of Perio Standards and Recommon Con 9/27/10, a review showed, on the pudated 10, the put the assessment form The patient was obe operative report show mastectomies and	ct in a patient. The hospital at A, while in the physician's a post-surgical visit complained that axilla (armpit) incision site. Inced the area and found a chich the physician removed (a a gauze pad used to absorbe, and/or apply pressure or had surgery in this area on a pital's Policy and Procedure, arp and Instrument," revised that would be counted before establish a baseline, before within a cavity, before wound within a cavity, before wound in closure or the end of the procedure also showed in counts was identified the ens would include a manual site. The hospital's P& P for d, as a reference, AORN perative Registered Nurses) the nended Practices 2008. of Patient A's medical record reoperative assessment form attent's weight was listed on under special circumstances. See. A review of Patient A's wed the patient had bilateral breast reconstruction with		count only those sponge been removed, not those utilized as packing. A process was developed ordering of an x-ray for a potential RFB, adding the number of incisions, read the Radiology tech and nurse are to communicate area of concern to better results. The potential retained for considered a critical test of a second x-ray is taken has left the operating roof the hospital to verify the within the patient if it was found in the operating roof the thospital to the document ation to include document multiple University. The process for handoff between surgeons in a trease when each surgeon one of the procedures we include the count within sponges removed from patient of the process to provent recorders to provent recorders.	e that are still ed for the verification of a de specific site, son for x-ray. Circulating te regarding the r focus the x-ray verign body is result. once the patient om and still in sponge is not s not initially form. The software de an ability to dersal Protocols. communication wo procedure on performs only as modified to the handoff, coatent and those on of the person tion dices de monitoring	2012 FEB 1 1111 11 12
	physicians, MD 1 and M	two stages with two different ID 2. The first stage of the		process to prevent rec deficiency. Each two procedure cas monitored at 100% for the	e will be	
Event ID:V	VRJH11	1/25/2012	10:26:1	4AM		

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050168				B. WING		10/04/2010	
				SS, CITY, STATE, ZIP CODE CIA MESA DRIVE, FULLERTON, CA 92835 ORANGE 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
	Continued From page 3 surgery was performed by MD 1 and was a bilateral mastectomy (removal of the breasts) and axillary lymph node dissection (the axillary lymph nodes are located under the arm). Axillary lymph node dissection is performed to determine if cancer has spread beyond the breasts. MD 2 performed breast reconstructive surgery as the second part of the patient's surgery. On 9/27/10 at 1515 hours ST 1 (Scrub Technician) was interviewed. ST 1 stated she wasn't present for the first stage of the surgery done by MD 1 but joined the surgical team during MD 2's stage of the surgery. According to ST 1, when the second count was done, prior to MD 2's closure of the surgical site, one raytec sponge was missing. ST 1 stated she told MD 2 a raytec sponge was missing and MD 2 replied he did not use raytec sponges. A thorough search of the OR (operating room) suite was conducted; however, the sponge was not found. MD 2 ordered an x-ray to determine if a foreign body was in the patient. The radiologist report, reviewed on 9/27/10, showed a chest x-ray was done at 1715 hours and there was no foreign object seen. On 9/27/10 at 1550 hours RN 1 (the circulating nurse) was interviewed. According to RN 1, after MD 1 finished the first part of the surgery, MD 2 took over using a separate set of instruments. There was no count done after MD 1 was finished with the first part of the surgery. After the count discrepancy was noted, and MD 2 was informed, a chest x-ray was performed. According to RN 1, MD 2 did not review the chest x-ray, and instead, the				months. The monitoring will conthe compliance with the Univer Protocol and compliance with the policy, the radiologic process of potential retained foreign body observation audits of the hand communication between the sum There will be ongoing monitori Universal Protocol on a 10% of going forward.	rsal the count for any for and off urgeons ng of the	
Event ID:W	/RJH11	——————————————————————————————————————	1/25/2012	10:26:1	4AM		
ARORATORY	DIRECTOR'S OF PROVIDE	RISUPPLIER REPRESEN	TATIVE'S SIGNATU	RE	TITLE		(X6) DATE

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050168		B. WING	B. WNG		10/04/2010		
NAME OF PROVIDER OR SUPPLIER STREET ADDRESS ST. JUDE MEDICAL CENTER 101 E. VALENCI.					ZIP CODE VE, FULLERTON, CA 92835 ORANGI	COUNTY	
			*1				
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	Continued From page	4					
	results were read to subsequent review of the x-ray did not e area.	the chest x-ray s	howed that		ž		
	On 9/27/10, the Distated MD 1, when in not remember be discrepancy.		event, did	2			2
	On 9/27/10, a review showed an incision three lymph nodes testing. There was no closed by MD 1.	was made in the were removed and	axilla and sent for				
	On 9/27/10, a review report showed no me incision and no do count.	ntion of closure of t	the axillary			2012 F	7
	On 10/1/10 at 1100 interview, MD 2 stated almost positively belief incision prior to the structure surgery as that was stated that the actual and that he was not the sponge count discrete.	d that, although not eved MD 1 closed to art of the second state the usual practice. chest x-ray was no aware if MD 1 was	t sure, he he axillary age of the MD 2 also t reviewed		26	EB 1 8M 11 26	
	The hospital's failure its policies and proce sponges, instruments, of the axillary incision manual search of the su	dures for a surgical and sharps prior on of Patient A, a	I count of to closure and for a ne				
Event ID:V	/RJH11		1/25/2012	10:26:1	4AM		

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	IDER OR SUPPLIER		STREET ADDRESS				
S1. JUDE ME	EDICAL CENTER		101 E. VALENCI	A MESA DRI	VE, FULLERTON, CA 92835 OR	ANGE 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 CO (EACH CORRECTIVE ACTION SH REFERENCED TO THE APPROPR	OULD BE CROSS-	(X5) COMPLETE DATE	
C	Continued From page	5					
s h d ir	xillary surgical incision urgical sponge was as caused or is like eath to the patient, mmediate jeopardy and Safety Code Section	missing, is a de- ely to cause serion and therefore co- vithin the meaning	ficiency that us injury or nstitutes an				
T de se	his facility failed to escribed above that erious injury or death onstitutes an immediating of Health 280.1(c).	prevent the deficie caused, or is likely to the patient, ar ediate jeopardy	y to cause, nd therefore within the				
						2012 FEB 1 AM 11 26	
Event ID:WR	JH11		1/25/2012	10:26:1	4AM		

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