

**Sample Aggregate Review - Root Cause Analysis  
Unintended Retention of Surgical Sponges (Adverse Event type 4)**

<b>Casual or Contributory Factor <i>Opportunity for Improvement</i></b>	<b>Risk Reduction Strategy (Action Item)</b>	<b>Person(s) Responsible for Implementation</b>	<b>Follow-up Actions and Date of Implementation</b>	<b>Measurement Strategy</b>
<p>Leadership, communications, and human factors</p> <p><i>Lack of awareness of surgical events and scope of accountability</i></p>	<p>1. Transparency- enhance awareness and share knowledge of retention of sponges in recent surgical cases</p>	<ul style="list-style-type: none"> <li>▪ Chief Medical Officer</li> <li>▪ Assoc. Medical Director, Surgery</li> <li>▪ Chief Nursing Officer</li> <li>▪ Surgical Services Nursing Leadership</li> <li>▪ Patient Safety Officer</li> <li>▪ Risk Manager</li> <li>▪ Chief, Radiology Services</li> <li>▪ Director, Materials Management</li> </ul>	<p>Discussion of events involving retention of sponges during surgical procedures at:</p> <ul style="list-style-type: none"> <li>▪ Surgery Mortality and Morbidity Conferences (date)</li> <li>▪ Surgical Services Management Committee (date)</li> <li>▪ Surgical Services Staff Meetings (date), and email communication</li> <li>▪ Patient Safety Committee (date)</li> <li>▪ Medical Leadership Council (date)</li> <li>▪ Nurse Executive Council (date)</li> <li>▪ Weekly Executive Staff Council Meetings</li> <li>▪ Product Evaluation Committee (date)</li> </ul>	<p>--</p>
<p>Human Resources/Staffing, clinical processes, equipment, communication, education, leadership/culture</p> <p><i>Reoccurring events involving retained foreign objects despite implementation of risk reduction strategies</i></p>	<p>2. Conduct a Failure Mode and Effect Analysis (FMEA) with the Surgical Services staff to identify potential causes, and solutions, and finalize priority improvement opportunities</p>	<ul style="list-style-type: none"> <li>▪ Surgical Services               <ul style="list-style-type: none"> <li>○ Nursing Director</li> <li>○ Nursing Manager</li> <li>○ Nursing Staff</li> </ul> </li> <li>▪ Patient Safety Officer</li> <li>▪ Risk Manager</li> </ul>	<ul style="list-style-type: none"> <li>▪ Review FMEA plan at staff meeting (date)</li> <li>▪ Identify multi-disciplinary team to oversee FMEA process</li> <li>▪ FMEA completed including creation of process flow document (date)</li> <li>▪ Standardized sponge county policy education plan for surgeons and anesthesia providers (date)</li> <li>▪ Present findings to medical</li> </ul>	<p>Strategy: Evaluate compliance to new policy regarding RN and surgeon direct communication at time of sponge count</p> <p>Type of Measurement: "Real time" audit by Surgical Services RN staff</p> <p>Sample Size: 10% of total cases per month</p>

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			and Surgical Services leadership (date)	Target for Compliance: 100% of audits reveal RN and surgeon direct communication
<p>Human factors, controllable environmental factors, Human Resources staffing, information, management, leadership</p> <p><i>Lack of role clarity and specific expectations regarding the sponge counting process in the operating room</i></p>	<p>3. Revise Surgical Services policy and sponge counting procedure to include an end of case verbal exchange between the circulating RN and surgeon</p> <p>The circulating RN will verbalize to the surgeon that the sponge count is accurate followed by the surgeon verbalizing confidence that any foreign bodies have been removed.</p>	<ul style="list-style-type: none"> <li>▪ Surgical Services <ul style="list-style-type: none"> <li>○ Nursing Director</li> <li>○ Nursing Manager</li> </ul> </li> <li>▪ Associate Medical Director, Surgery</li> </ul>	<ul style="list-style-type: none"> <li>▪ Revise Surgical Services sponge counting policy to standardize details of procedure (completed date)</li> <li>▪ Update policy for review and approval at Surgical Services Management Committee (date)</li> <li>▪ Disseminate policy to Surgical Services clinical staff (date)</li> <li>▪ Implementation of revised policy and procedure, including direct RN and surgeon communication by (date)</li> </ul>	<p>Strategy: Evaluate compliance to new policy regarding RN and surgeon direct communication at time of sponge count</p> <p>Type of Measurement: "Real time" audit by Surgical Services RN staff</p> <p>Sample Size: 10% of total cases per month</p> <p>Duration: 3 months</p> <p>Target for Compliance: 100% of audits reveal RN and surgeon direct communication</p>
<p>Human factors, information management issues, clinical practice, education, communication</p> <p><i>Variability in sponge counting practices</i></p>	<p>4. Standardize the sponge count policy</p>	<ul style="list-style-type: none"> <li>▪ Surgical Services <ul style="list-style-type: none"> <li>○ Nursing Director</li> <li>○ Nursing Manager</li> <li>○ Nursing Staff</li> </ul> </li> <li>▪ Patient Safety Officer</li> <li>▪ Risk Manager</li> <li>▪ Surgical Technician</li> <li>▪ Associate Medical Director and Chief of Anesthesia</li> <li>▪ Associate Medical Director, Surgery</li> </ul>	<ul style="list-style-type: none"> <li>▪ As a result of the FMEA process, the most pertinent major action was determined to be standardization of the sponge counting process and need for specific clarification in the policy</li> <li>▪ Revise sponge counting policy based on AORN guidelines with specific details about process and products (completed date)</li> </ul>	<p>Strategy: Evaluate compliance to new policy regarding RN and surgeon direct communication at time of sponge count</p> <p>Type of Measurement: "Real time" audit by Surgical Services RN staff</p> <p>Sample Size: 10% of total cases per month</p>

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			<ul style="list-style-type: none"> <li>▪ Draft circulated through medical and nursing leadership for further input</li> <li>▪ Policy completed (date)</li> <li>▪ Dissemination of policy initiated with Medical Leadership Council (date) and implementation in the operating room on (date)</li> </ul>	<p>Duration: 3 months</p> <p>Target for Compliance: 100% of audits reveal RN and surgeon direct communication</p>
<p>Human factors, equipment, communication</p> <p><i>Inability to directly visualize separated sponges</i></p>	<p>5. Implement standardized sponge counter device in all Operating Rooms at time of roll out of revised sponge counting policy</p>	<ul style="list-style-type: none"> <li>▪ Surgical Services               <ul style="list-style-type: none"> <li>○ Nursing Director</li> <li>○ Nursing Manager</li> </ul> </li> <li>▪ Associate Medical Director, Surgery</li> <li>▪ Materials Management Director</li> </ul>	<ul style="list-style-type: none"> <li>▪ Review of the literature or product information to identify possible sponge counting devices (completed date)</li> <li>▪ Pilot project of device to improve the display of sponges as they are removed from the OR table (completed date)</li> <li>▪ Product found not to be acceptable by Surgical Services staff</li> <li>▪ New product selected on (date) and implementation to begin the week of (date)</li> </ul>	<p>Strategy: Product evaluation- Biomedical Services Director and Surgical Services Circulating RN staff to identify that a sponge counting device improves the process and accuracy of the counting process</p> <p>Type of Measurement: Ongoing evaluation of sponge counting device by Surgical Services staff</p> <p>Sample Size: all Surgical Services circulating RN staff</p> <p>Duration: 1 month</p> <p>Target for Compliance: 80% of circulating RN staff will submit evaluation form</p>

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<p>Human Resources, Staffing, Communication, Leadership</p> <p><i>Multiple competing demands at the critical time of sponge counting</i></p>	<p>6. Enhance staffing support at the critical time of sponge counting when required</p>	<ul style="list-style-type: none"> <li>▪ Surgical Services               <ul style="list-style-type: none"> <li>○ Nursing Director</li> <li>○ Nursing Manager</li> <li>○ Assistant Nurse Manager</li> <li>○ Charge RN</li> <li>○ Staff</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Review facilitator role to prioritize support and assistance for sponge counting</li> <li>▪ Written “Guidelines for Facilitators” completed (date)</li> <li>▪ Surgical Services Nursing Leadership to develop communication and education plans for revised “Guidelines for Facilitators”</li> </ul>	<p>Strategy: Surgical Services Nursing Leadership and RN staff to develop written guidelines for facilitators</p> <p>Type of Measurement: Guidelines completed and implemented</p> <p>Target for Completion: (date)</p>
<p>Human factors, communication</p> <p><i>No standard protocol for when to take x-rays post un-reconciled sponge/instrument count</i></p> <p><i>No standard procedure regarding the quality of the x-ray and plan if x-ray fails to properly cover the surgical field</i></p>	<p>7. Update and implement the Surgical Services Policy and Sponge Counting Procedure to assure compliance to the following points:</p> <ul style="list-style-type: none"> <li>- If the count is incorrect, the patient remains under anesthesia and the attending surgeon stays in the OR until a satisfactory radiograph is performed. (A satisfactory radiograph includes an image of the entire peritoneal cavity, thoracic/pleural cavity, or operative field in non-body cavity surgery.)</li> <li>- The surgeon collaborates with the radiology technician regarding x-ray plate placement to assure adequate coverage of the operative field. (Adequate</li> </ul>	<ul style="list-style-type: none"> <li>▪ Surgical Services:               <ul style="list-style-type: none"> <li>○ Nursing Director</li> <li>○ Nursing Manager</li> </ul> </li> <li>▪ Associate Medical Director, Surgery</li> <li>▪ Associate Medical Director and Chief of Anesthesia</li> <li>▪ Patient Safety Officer</li> </ul>	<ul style="list-style-type: none"> <li>▪ Review of literature to determine best practices</li> <li>▪ Group of clinical experts from Radiology and Surgical Services met to prepare recommendations for the Surgical Services Steering Committee (date)</li> <li>▪ Present recommendations to the Surgical Services Steering Committee (attachment, and date); the recommendations were approved and assigned to a physician champion for policy revision</li> <li>▪ Present new policy to OR RN, scrub technician and anesthesia Continuous Quality Improvement Teams (date)</li> <li>▪ Implement revised Surgical Services Policy and Sponge Count Procedure (date)</li> </ul>	<p>Strategy: Evaluate compliance to new policy regarding x-ray procedure for all cases with incorrect sponge and instrument counts</p> <p>Type of Measurement: Audit of event reports/all cases that have reconciled sponge and instrument counts by RN staff</p> <p>Sample Size: 100% of total reconciled count cases</p> <p>Duration: 3 months</p> <p>Target for Compliance: 100% of audits reveal compliance with new policy</p>

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	<p>coverage may require multiple films.)</p> <ul style="list-style-type: none"> <li>- The surgeon evaluates the film and communicates directly with the radiologist that the purpose of the film is for an incorrect post-operative county.</li> <li>- The surgeon and radiologist confirm that the film covers the entire operative cavity and agree on whether or not the films show a foreign body.</li> <li>- If adequate films cannot be accomplished in the OR the surgeon, anesthesiologist, radiologist, and OR charge nurse perform and immediate "huddle" to determine how to get adequate images of the patient's operative cavity. (This may include additional diagnostics procedures such as CT scan.)</li> </ul>			