

The following manuscript is on analysis of adverse events of robotic surgical systems using system-theoretic accident causality models. The results of this work has been presented in part at the 2014 STAMP Conference and it is currently under submission. Please also see appendix for more details and results.

System-Theoretic Analysis of Adverse Events in Robotic Surgery

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Abstract

Objective: To understand causes and patient impact of incidents in robotically-assisted surgery, in order to improve systems safety and prevent future incidents.

Methods: We analyzed the adverse events data related to systems and instruments used in robotic surgery, reported to the FDA MAUDE database, from January 2000 to December 2013. We determined the impact of device-related incidents on patients, with a specific focus on catastrophic events such as major complications, patient injuries, and deaths. Using a systems-theoretic accident analysis technique, STAMP, we modeled the safety control structure of the system (including the robot and human operators), to determine the multi-dimensional causal factors that led to unsafe control within the system and resulted in accidents. The novelty of this method lies in its ability to model the accidents as dynamic control processes in order to identify the causes of unsafe interactions among system components and human operators.

Results: Out of 10,624 total reported events, 1,535 (14.4%) had significant negative patient impacts, including *injuries* (1,391 cases) and *deaths* (144 cases), while the majority (75.9%) were attributed to *device and instrument malfunctions* (8,061 cases). Applying *systems-theoretic analysis (STAMP)* to select accidents drawn from different surgical specialties, we found several important factors in the human-machine interactions that contributed to the accidents, such as inadequacy of safety controls, inadequate feedback to human operators, inaccurate mental models of operators due to limited training and experience, and inefficient troubleshooting practices.

Conclusions: Despite widespread adoption of robotically-assisted surgical systems, a non-negligible number of technical difficulties and complications are still being experienced during procedures. Adoption of systems-theoretic techniques in design and analysis of surgical systems may reduce these preventable incidents in the future.

Introduction

Robotic surgical systems are one of the most complex medical devices on the market. They enable performing minimally-invasive procedures with better visualization and increased precision through 3-dimensional magnified views of the surgical field and accessing the body cavity using tele-manipulating arms and instruments that mimic human hand movements. During the last 14-years, surgical robots have been used in over 1.75 million procedures in the U.S, across various surgical specialties, including gynecology, urology, general, cardiothoracic, and head and neck surgery [1].

There have been several reports by different surgical institutions on occasional software-related, mechanical, and electrical failures of system components and instruments during robotic procedures [2]-[15] (Table 1 in Appendix). A few studies analyzed the adverse event reports [16]-[22] related to robotic surgical systems, collected by the FDA MAUDE database [23] (Table 2 in Appendix). However, most of the previous work targeted only two common surgical specialties, that of gynecology and urology, analyzed small subsets of data, and only focused on specific device-related failures, e.g., electro-cautery failures [12], electrosurgical injuries [19], or instrument failures [20]. We are not aware of any study that has systematically analyzed the multi-dimensional causal factors leading to adverse events in robotic surgery.

Our study is the first comprehensive analysis of all the nation-wide adverse events reported to the FDA MAUDE database during the 14-year period of 2000–2013. We analyzed the safety-related incidents, including deaths, injuries, and device malfunctions, in a variety of surgical specialties, to understand their causes and measure their impact on patients.

We take an important step towards applying a new causality model based on systems and control theories, called STAMP (Systems-Theoretic Accident Model and Processes) [24][25] which has been successfully employed in many safety-critical domains (e.g., aviation [26], railway [27][28], space missions [29][30],

medical devices [31][32], and pharmaceutical safety [33]) to analyze the causal factors leading to accidents in complex robotic surgical systems. More specifically, based on our knowledge of the system functionality, augmented with the insights gained from the analysis of real accidents, we modeled the safety control structure of the system and performed an in-depth analysis using STAMP to identify:

- 1) **System hazards** and **possible unsafe control actions** that could lead to health-threatening events, such as patient injuries and deaths.
- 2) **Potential causal and contextual factors**, including inadequacies in system design or operational practices in robotic surgery that could contribute to unsafe control actions.

Representative example reports on patient complications, injuries, and deaths which occurred during the robotic procedures were analyzed to demonstrate the effectiveness of STAMP in identifying the causal factors.

The results of this study may be used to provide insights on design of future surgical systems that by taking advantage of advanced safety mechanisms, improved human machine interfaces, and standardized operational practices can minimize the adverse impact on patients and surgical teams.

Methods

Data Sources

The FDA MAUDE database is a publicly available collection of device-associated adverse event reports, submitted by mandatory (user facilities and manufacturers) and voluntary (healthcare professionals and patients) reporters [23]. Each report contains information such as *Device Name*, *Manufacturer Name*, *Event Type* (malfunction, injury, or death), *Event Date*, *Report Date*, and human-written *Event Description* and *Manufacturer Narrative* fields, providing a description of the event, as well as any comments made or follow-up actions taken by the manufacturer to address problems.

While the MAUDE database, as a spontaneous reporting system, suffers from underreporting and inconsistencies [34]-[36], it provides valuable insights on real incidents that occurred during robotic

procedures and impacted patient safety. We treated the reported data on deaths, injuries, and malfunctions provided by the MAUDE as a *sample set* to estimate the *lower bounds on prevalence of adverse events* and identify *examples* of their major causes and patient impacts. The insights gained from the manual review of several reports and extensive consultation with medical device and surgical experts helped us to develop a framework for automated analysis of adverse event reports.

Preliminary Data Analysis

We first performed a preliminary analysis on the adverse events data in order to characterize the incidents and trends in adverse events over the years. This was done using MedSafe, a framework for automated analysis of FDA reports (Figure 1 in Appendix). MedSafe first uses several filters to remove redundant records as well as non-essential terms from the data. Then it employs a natural language processing engine that uses several domain-specific dictionaries (e.g., keywords related to patient complications, surgery types, surgical instruments, and malfunction types) as well as parts-of-speech (POS), negation, and temporal taggers [37] to interpret the semantics of human-written event descriptions.

Using MedSafe, we extracted all the reports related to the systems and instruments used in robotic surgery by searching for related keywords in the *Device Name* and *Manufacturer Name* fields of over 2.5 million records in the MAUDE database. In addition to the structured information that was directly available from the reports, we extracted the following information by semantic parsing of the *Event Description* and *Manufacturer Narrative* fields:

- Patient injury (such as burns, cuts, or damage to organs) and death events that were reported under another *Event Type*, such as “Malfunction” or “Other”.
- Surgical specialty and type of robotic procedure during which the adverse events occurred.
- Major types of device or instrument malfunctions.
- Adverse events that caused an interruption in the progress of surgery, by leading the surgical team to troubleshoot technical problems (e.g., restarting the system), convert the procedure to non-

robotic surgical approaches (e.g., laparoscopy or open surgery), or abort the procedure and reschedule it to a later time.

We estimated the annual numbers of adverse events (in general) and injury/death events (in particular) per 100,000 procedures. The annual numbers of procedures performed in the U.S. were extracted from the device manufacturer's reports [1][38] for 2004–2013. The 2-sided P values (< 0.05) and 95% confidence intervals (CI) were used to determine the statistical significance of the results.

Systems-theoretic Hazard Analysis

Based on the manual review of accident descriptions in several adverse event reports, we classified the robotic surgery accidents into four types of: patient deaths (A-1), patient injuries during the procedure or serious complications experienced after the procedure (A-2), surgical personnel injuries caused by the system (A-3), and costly damage to surgical system or instruments (A-4). We also identified three main types of hazards or set of system conditions that could lead to those accidents (Table 1.a).

We used STAMP causality model to systematically analyze the safety hazards of the system and potential causal factors involved in the events. In STAMP the systems are modeled as hierarchical control structures, where the components at each level of the hierarchy impose safety constraints on the activity of the levels below, and communicate their conditions and behavior to the upper levels. The layers of control structure could span from the physical components to human operators, up to higher levels in manufacturing, management, and regulation. Accidents are considered as complex dynamic processes resulting from violation of safety constraints at different layers of control structure [24].

We first identified the main entities involved in a robotic surgical system, including the human operators (e.g., surgeons, surgical staff), the automated controllers and components of the robot, and the patient, based on the typical system setup in a robotic procedure (Figure 1.a) [39]–[43]. Then using STAMP, we

modeled the hierarchical safety control structure of the system as shown in Figure 1.b. In that structure, the interactions among system components and operators are modeled as control loops (e.g., loop 3) composed of the actions or commands (e.g., hand and foot movements) that a controller (e.g., main surgeon) takes/sends to a controlled process (e.g., robot) and the response or feedback (e.g., images/status messages on surgeon's console) that the controller receives from the controlled process.

Every controller in the system uses an algorithm to generate the control actions based on a model of the current state of the process that it is controlling. For example, control loops 3 and 6 (outlined by dashed lines in Figure 1.b) are further refined in Figure 1.c to illustrate details on the interactions among the main surgeon, robot control, and robotic arms/instruments. The control action generation, process model, examples of control action, and components that enable the action and feedback between the main surgeon and the robot are highlighted here (see Tables 3 and 4 in Appendix for more details).

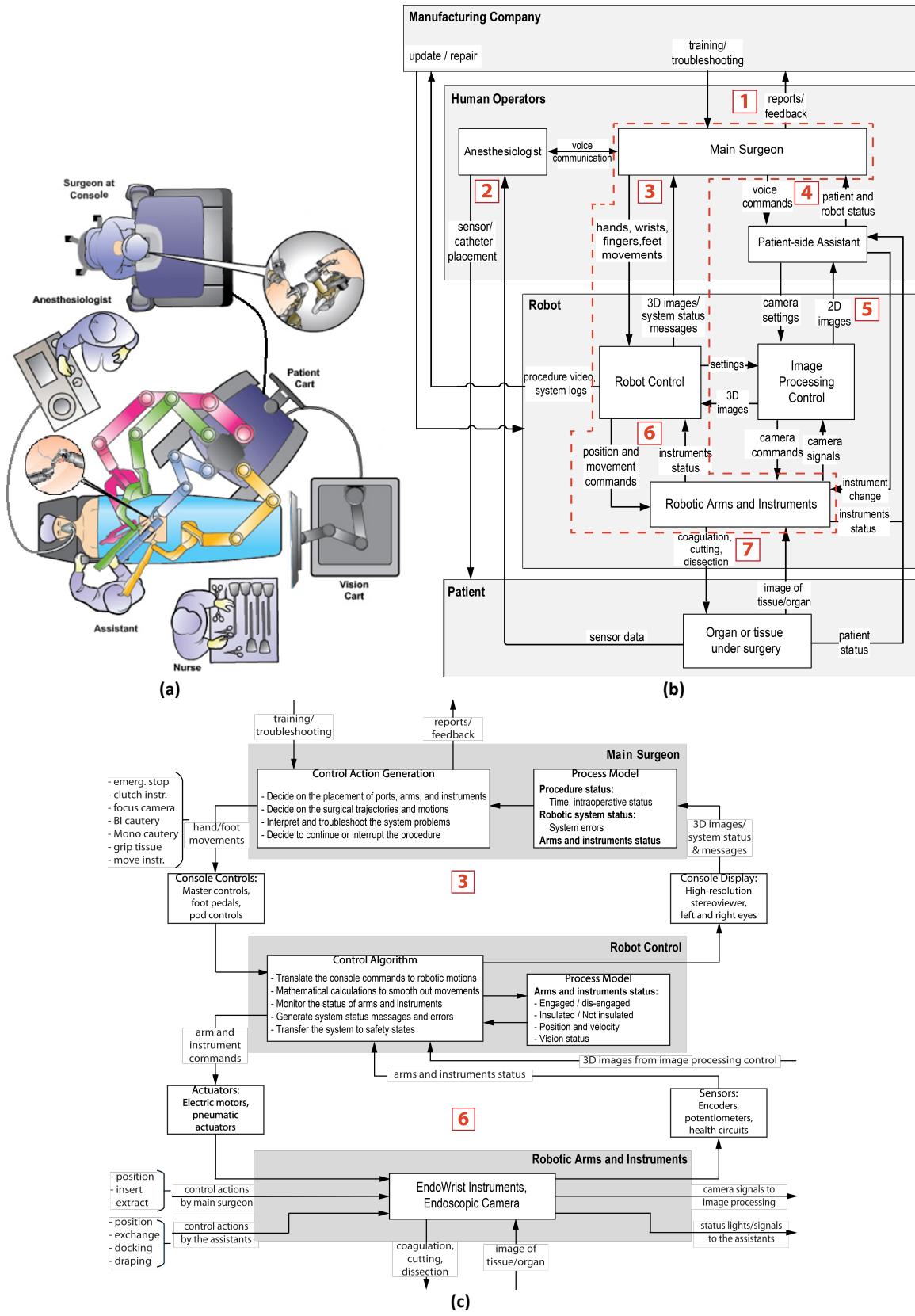


Figure 1 - (a) A typical setup of robotic surgical systems for minimally-invasive surgery (Courtesy of Intuitive Surgical, Inc.), (b) Hierarchical control structure of the robotic surgical system, (c) Control Actions and Process Models for Control Loops 3 and 6 (highlighted in part (b)).

In every control loop, the control actions taken (e.g., clutch an instrument) by the controller (e.g., surgeon) change the state of the controlled process (e.g., the instrument will be engaged). The feedback (e.g., messages on the console) sent back from the controlled process (e.g., robot control) updates the process model used (e.g., surgeon’s mental model) by the controller (e.g., surgeon observes on the console that the instrument is registered). Any flaws or inadequacies in the algorithm, process model, or feedback used by a controller could possibly lead to unsafe control actions and hazardous states in the system.

Using the STAMP methodology, we identified the set of conditions (or context) under which the control actions could possibly be unsafe and lead to hazardous system states. We specifically considered the following unsafe scenarios [24]: *i*) a required control action was not performed, *ii*) a control action was performed in a wrong context, leading to a hazard, *iii*) a control action was performed at an incorrect time, *iv*) a control action was performed for an incorrect duration, *v*) a control action was not followed by the controlled process. We then determined the potential causes for those unsafe scenarios by examining the operation of components and their interactions in each loop of the control structure.

Finally, in order to demonstrate the effectiveness of STAMP in identifying the causal factors leading to accidents, we analyzed selected examples of adverse events submitted to the MAUDE database. We reviewed the textual description of more than 1,500 injury and death reports (A-1 and A-2 accident types) and selected a subset from a variety of surgical specialties that included relatively more detailed event descriptions. Then from the description of each report, we extracted the information related to unsafe control actions that contributed to the adverse events and identified examples of potential causes and underlying context for those actions; including inaccurate models used by the controllers, inadequate feedback sent to the controllers, and improper operation of system components. In each case, the root cause of event, which would be possibly concluded using a *chain-of-events* root causal analysis (RCA) technique, was compared with the causal factors identified by STAMP.

Results

We identified 10,624 reports related to the robotic systems and instruments used in minimally-invasive surgery, submitted to the FDA over 2000–2013. About 98% of the events were reported by device manufacturers and distributors, and the rest (2%) were voluntary reports.

Data included 144 deaths (1.4%), 1,391 injuries (13.1%), and over 8,061 (75.9%) device malfunctions. For the rest of the events (1,028 cases), the *Event Type* information either was not available or was indicated as “Other.” Of all the identified injuries, 160 (1.5%) were reported as a “Malfunction” or “Other.”

The majority of reports were related to gynecology (30.1%, 95% CI, 29.2–31.0), urology (14.7%, 95% CI, 14.0–15.4), and cardiothoracic (3.7%, 95% CI, 4.0–8.8) surgeries, such as hysterectomy (2,331), prostatectomy (1,291), and thoracic (110) procedures, respectively (Table 5 in Appendix).

Trends of Adverse Event Reports

Figure 2 in the Appendix shows the overall trends in the annual number of reports and the estimated number of events per 100,000 procedures over 2004–2013:

- The absolute number of reports has significantly increased (about 32 times) since 2006, reaching 58 deaths, 938 patient injuries, and 4,124 malfunctions in 2013.
- While the annual average number of adverse events was about 550 per 100,000 procedures (95% confidence interval (CI), 410–700) between 2004 and 2011, in 2013 it peaked at about 1,000 events per 100,000 procedures.
- The number of injury and death events per procedure have stayed relatively constant since 2007 (mean=83.4, 95% CI, 74.2–92.7).

Device and Instrument Malfunctions

We identified five major categories of device and instrument malfunctions experienced during procedures that impacted the patients either by causing injuries and complications or by interrupting and/or prolonging procedures (Table 6 in Appendix):

- **System errors and video/imaging problems** contributed to 787 (7.4%) of the events and were the major contributors to procedure interruptions (82% of system resets, 59.2% of procedure conversions, and 81.8% of reschedulings).
- **Falling of the broken/burnt pieces into the patient's body** constituted about 1,557 (14.7%) of the events. In almost all those cases, the procedure was interrupted so the surgical team could search for the missing pieces and retrieve them from the patient. In 119 cases, a patient injury, and in one case a death, was reported.
- **Electrical arcing, sparking, or charring of instruments** and burns or holes developed in the tip cover accessories constituted 1,111 of the reports (10.5%), leading to nearly 193 injuries, such as burning of tissues.
- **Unintended operation of instruments**, such as uncontrolled movements and spontaneous powering on/off, happened in 1,078 of the events (10.1%), including 52 injuries and 2 deaths.

In total, 9,382 reports were about technical problems, including 927 cases (9.8%) in which the procedure was interrupted and additional time was spent on troubleshooting the errors, resetting the system, and/or converting the procedure or rescheduling it to a later time.

Unsafe Controls and Causal Factors

Table 1.b shows an example set of conditions under which the actions taken by the surgeon (in control loop 3 of Figure 1) could possibly lead to a hazardous system state. In each case, the type of **unsafe control action (UCA)**, the **system condition** under which the action could lead to a hazard, and the type of **system hazards** are highlighted. For example, an unsafe situation is that the surgeon does not clutch the active instrument in order to move or extract it from surgical field or does not perform an emergency stop, when an intraoperative urgency comes up (UCA-1). Another example is use of cautery or gripping tissue by the surgeon when the system is in error, the vision or power is lost, or the target instrument is not properly engaged, not insulated, or the instrument is very close to another unintended instrument or anatomical structure (UCA-4).

Table 1.c provides further details on the possible causes of unsafe controls shown in Table 1.b. These causal scenarios may include any possible flaws in the algorithm and models used by the surgeon, missing or inadequate feedback sent from the robot control to the surgeon, the malfunctions of console controls and robotic components, or missing/inadequate external inputs to the surgeon and the robot. For example, some of the potential causes for the unsafe control action (UCA-4) include: surgeon being under impression that the tip cover accessory is properly installed and checked, missing feedback on the status of the instrument tip from the system to surgeon, incorrect port placement or electro-cautery settings, or improper instrument usage that causes damage to instrument insulation. The last column of Table 1.c lists example events reported to the MAUDE database, which involved the example unsafe scenarios and causal factors.

Table 1. (a) Accidents and System Hazards in Robotic Surgery, (b) Example Conditions under which Control Actions may lead to Hazards, (c) Unsafe Control Actions, Potential Causal Factors, and Example Adverse Event Reports

(a)				
Accidents				
A-1. Patient expires during or after the procedure.				
A-2. Patient gets injured during procedure or experiences serious complications after the procedure.				
A-3. Surgical personnel are injured by the surgical system.				
A-4. Surgical system or instruments are damaged or lost.				
System Hazards (Possible accidents)				
H-1. Robot arms/instruments move/cut/apply energy either to an unintended location, in an unintended amount, or with unintended timing (A1, A2, or A3).				
H1-1. Right location, right amount, wrong timing				
H1-2. Right location, wrong amount, right timing				
H1-3. Right location, wrong amount, wrong timing				
H1-4. Wrong location				
H-2. Procedure continues for a prolonged time (A2).				
H-3. Robotic system, arms, or instruments are subjected to collision or unintended stress (A4).				
(b)				
Type	Control Action	Context (System Condition)	UCA No.	Possible Hazards
Required Action Not Performed	Clutch instrument or emergency stop	Intraoperative urgency (bleeding, burning or damage to tissue)	UCA-1	H1 H3
	Focus, move, or change settings of camera	Vision is lost, obstructed, out of focus, the endoscope not aligned with the target anatomy, or insufflation device has low CO ₂ level	UCA-2	H1-4 H3
	Disable instrument arm	Intraoperative urgency (bleeding, burning or damage to tissue), or arm/instrument malfunction	UCA-3	H1 H2 H3
Hazardous Action Performed	Cauterize or grip tissue	Intraoperative urgency (bleeding, burning or damage to tissue)	UCA-4	H1-2 H1-4
		Incorrect electro-cautery settings or instrument insulation broken		H1-2
		Insufflation device has low CO ₂ level or vision lost/obstructed		H1-4 H2
		Power lost or system in error		H2 H-3
		Instrument too close to another instrument or non-target anatomy		H1-4
Incorrect Timing/Order	Remove hands from manipulators	Before removing head from console viewer	UCA-5	H1-4 H3
	Move camera arm	After camera arm is disabled	UCA-6	
	Cauterize or grip tissue	Before the target instrument is activated (clutch instrument)	UCA-7	
		Before the target anatomy is gripped	UCA-8	
Incorrect Duration	Cauterize tissue	Applied too long	UCA-9	H1-1 H1-3
	Clutch instrument	Applied too short	UCA-10	H1-4 H3
(c)				
Example Unsafe Control Actions		Potential Causal Factors		MAUDE Report Number ^a

UCA-1	Clutch instrument or emergency stop <u>is not performed when an intraoperative urgency (bleeding, burning or damage to tissue) is occurred.</u>	1. Main surgeon may not be well trained or experienced with handling the emergency or use of emergency stop. 2. Main surgeon may not notice the intraoperative urgency or doesn't interpret the situation as urgent. 3. Missing or delayed visual feedback to surgeon. 4. Console display malfunctions (vision lost). 5. Emergency stop button or clutch pedal malfunctions. 6. Robot control algorithm may not perform the clutch or emergency stop command accurately. 7. Robot control or arm/instrument malfunctions.	2543963 2883607 3444257 1554085 1669451 3502026
UCA-4	Cauterize or grip is performed when instrument insulation is missing/broken.	1. Main surgeon may be under the impression that the instrument insulation was installed and checked before the procedure but it was not. 2. Main surgeon may not notice or may not get informed of the missing/broken insulation on the instrument. 3. Incorrect port placement or instrument usage may cause collision of instruments and missing/broken insulation. 4. Missing feedback on the instrument tip status from the robot/instruments to surgeon. 5. Instrument tip failure or degradation over time. 6. Incorrect electro-cautery settings may damage insulation.	2853531 2632716 2184632 2925864 2637842 875685 1617090
UCA-5	Remove hands from manipulators <u>is performed before removing head from console viewer.</u>	1. Main surgeon may not be well trained or experienced. 2. Missing or inadequate feedback from the robot. 3. Master manipulators or the head sensor malfunctions. 4. Robot control still remains active after hands are removed. 5. Robot control may not stop movements or delivering energy when the hands are removed from the manipulators.	1961862 1570678 2147492 2644122
UCA-9	Cauterize tissue is <u>applied too long</u>	1. Main surgeon may not be well trained or experienced. 2. Main surgeon may not notice that cauterizing is prolonged. 3. Missing or delayed visual feedback from the robot. 4. Console display malfunctions (vision lost). 5. Cauterize pedal or electro-cautery device malfunctions. 6. Incorrect electro-cautery settings or cable connections. 7. Robot control may not stop delivering energy when the surgeon stops cauterizing. 8. Robot control or arm/instrument malfunctions.	966367 1016400 2494890 3293519 2970427

^a Full descriptions of example MAUDE reports shown in the manuscript are provided in the Supplements. They are also accessible through searching the report numbers in the FDA MAUDE database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>

Table2. Analysis of example adverse event reports: Important pieces of information used for analysis of the accident are underlined in the description.

Event Date: 07/17/2008	Event Type: Injury	Patient Outcome: Required Intervention, Life Threatening
Event Description: It was reported that during da vinci's bilateral internal mammary arteries revascularization procedure, the customer experienced a system error code #23. With the assistance of the company representative, the site powered down the system to clear the fault. The site continued with the procedure; however, the system error reoccurred. The site disabled the endoscopic camera manipulator (ecm) to continue the case. The site then elected to manually manipulate the camera and endoscope for approximately 5 to 6 hours when a loss of carbon dioxide insufflation occurred resulting in the heart pushing up into the endoscope two times causing lacerations to the patient's right ventricle. The procedure was converted to a thoracotomy to perform a non-robotic repair of the damaged ventricle with several stitches and to complete the planned procedure. After the 14-hour procedure, the patient could not be extubated necessitating a tracheostomy.		

Manufacturer Narrative: The investigation concluded that the system error code #23 experienced by the customer was associated with a configured embedded sterilizer setup-joint (cfg, essj) and remote arm controller (rac). The embedded sterilizer for setup-joint is the printed circuit assembly (pca) inside a system arm that monitors the potentiometer for each of four joints and their associated backup potentiometers. The rac consists of five printed circuit assembly boards which operate together to provide control of the system arms. The system was repaired by replacing the affected cfg, essj, and rac. System error code #23 is reported by software to denote that the hardware wheel "wdog" has tripped on one of the digital communication links in the system. This means that the system cannot reliably communicate over the digital link and therefore cannot continue normal operation. Communication faults occasionally occur due to typically either faulty electronics or poor connections in the communication link. The error 23 fault indicated by the system in this case pointed to a communication error involving the ecm's rac and essj modules. The system was repaired as the electronics that could have experienced an intermittent failure were removed and all of the connections involved were re-secured.

Analysis

Safety Hazards:

- H-1. Robot arms/instruments move/cut/apply energy to an unintended location:
 - Heart pushed up to the endoscope two times.

- H-2. Procedure continues for a prolonged time:
 - Procedure continued for 14 hours.

Unsafe Control Actions:

Loop 1:

- Further support on resolving the system error not provided by company representative after system reset.

Loop 3:

- Unsafe decision made by surgeon to manually operate the endoscopic camera for a long period of time.
- Unsafe action made by surgeon to continue the procedure with low level of carbon dioxide insufflation.

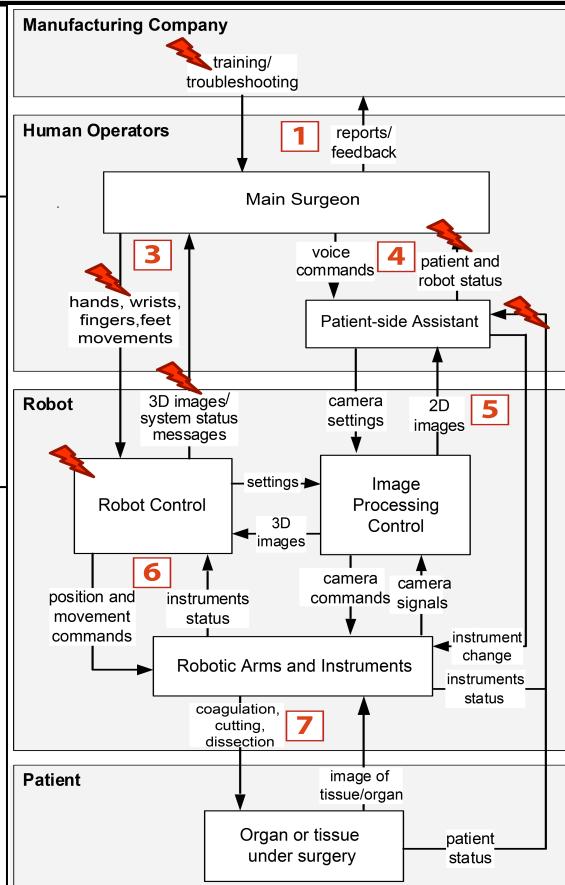
Possible Causal Factors:

Loop 1:

- Inadequate consulting with the company about manual manipulation of endoscopic camera.

Loop 3:

- Electronic component failure prevented the robotic manipulation of the endoscopic camera.
- Lack of detailed information on the system error and best troubleshooting procedures from robotic system.
- Missing feedback from the robot or assistants on the patient insufflation status.
- Main surgeon believed that continuing the procedure is safer than converting to a non-robotic surgical approach.



Multiple Causes Contributing to Adverse Events

The majority of the injury and death reports provided little or no detailed information on the possible causes of events or only reported on single causes, such as inherent risks of surgery, human errors, or device malfunctions. By careful review of injury and death reports we identified several reports that included information on multiple contributing causal and contextual factors. For example, Table 2 shows the description of an event reported in 2008 (MAUDE report no. 2240665), where an electronic component failure, a non-recoverable system error, inadequate troubleshooting of technical problems, and possibly ineffective decisions made by human operators, each played a role in a very long procedure time and consequently, a patient injury.

According to the manufacturer narrative, a *chain-of-events*-based analysis concluded that the root cause of the event was an electronic component failure and the recovery actions taken based on such conclusion were to repair the faulty components of system. But a systems-theoretic analysis of the accident based on STAMP methodology provides us with a different view on other multi-dimensional causal factors that were involved. We examined the characteristics and responsibilities of each of the controllers in the safety control structure (Figure 1.b), the interactions among the components, and the context in which the actions were taken. As shown in Table 2, we identified the system hazards (e.g., robotic arms/instruments move/cut/apply energy to an unintended location), the potentially unsafe control actions taken in each control loop (e.g., surgeon deciding to manually operate the endoscopic camera for a long period of time, in control loop 3), and possible causes for those unsafe actions (e.g., electronic component failure preventing the automatic manipulation of camera or lack of detailed troubleshooting procedures). The potentially flawed controls and feedbacks in different loops of control structure are highlighted in Table 2.

Table 3 shows more examples on analysis of injury and death events from the MAUDE database. The last column of the table shows a single root cause, which might be concluded using root cause analysis. Examples of common factors involved in these events included limited training of surgical teams (control loop 1), inadequate procedures used for troubleshooting technical problems (control loops 1 and 3), inadequate interactions between surgeon and robot at the console (control loop 3), and device and instrument malfunctions.

Table 3. Unsafe control actions and potential causes of example adverse events

Report No. (Date)	Accident Type: Hazards	Control Loop No. (see Figure 1.b): Unsafe Control Actions: - Potential Causal Factors	Procedure Type, Outcome	Root Cause Analysis
2567858 (04/2012)	A1: H1-4	<p>Loop 1: Manufacturing company did not provide training on guided tool change to surgical assistants: - No regulations on providing training to surgical assistants. - Company assumed that assistants get trained by the site.</p> <p>Loop 4: Surgeon asked a change of instrument by an assistant who was not trained for guided tool change: - Assumed that the assistant is trained for guided tool change. - Assumed that the manual tool change will be done safely.</p> <p>Loop 5: Assistant either manually changed the instrument or incorrectly used the guided tool change: - Assistant was not trained for guided tool change. - Manual instrument insertion from cannula to patient is unsafe.</p>	N/A,	
1891889 (08/2010)	A2: H1-4	<p>Loop 1: Company representative did not notice the status of camera cable before the procedure (or during a service visit): - The camera cable got broken during the procedure.</p> <p>Loop 3: Surgeon continued the procedure with only one camera eye in 2D: - Assumed continuing the procedure is safer than converting it. - Left eye image interfered/lost due to a faulty camera cable.</p>	Hysterectomy, Ureteral injury	Assistant Mistake
1760256 (06/2010)	A2: H2	<p>Loop 3: Surgeon performed atrial retraction while the patient side manipulator (psm) instrument was malfunctioning (not rotating): - Distracted by multiple malfunctions, psm changes, power loss.</p> <p>Loop 5: Assistants did not properly inspect the system before procedure: - Assumed system works properly based on system feedback.</p>	Prostatectomy, Severe leg injury	Component Failure
3206001 (06/2013)	A2: H1-4	<p>Loop 3: Surgeon performed atrial retraction while the patient side manipulator (psm) instrument was malfunctioning (not rotating): - Distracted by multiple malfunctions, psm changes, power loss.</p> <p>Loop 5: Assistants did not properly inspect the system before procedure: - Assumed system works properly based on system feedback.</p>	Mitral valve repair, Heart punctured	Component Failure
2476271* (02/2012)		<p>Loop 3: Surgeon cauterized the tissue using incorrect electro-cautery: - Assumed that electro-cautery settings were correct. - Inadequate feedback on electro-cautery status on console.</p>	Hysterectomy, Bowel damage	
2494890* (02/2012)	A2: H2	<p>Loop 5: Assistant performed an incorrect bipolar cautery connection: - Inadequate user interface or design of electro-cautery unit - Inadequate experience with a specific electro-cautery unit</p>	Cardiac (CABG), Diaphragm burn	Assistant Mistake
3024317* (02/2013)		<p>Loop 3: Surgeon cut the tissue while the vision was obstructed: - Not well-trained or experienced with the use of instruments. - Distracted and frustrated to keep all instruments in view. - Incorrect port placement. - No feedback from assistants on the status of instruments/ports</p>	Prostatectomy, Bowel injury	
3473388 (10/2013)	A2: H1-4 A4: H-3	<p>Loop 3: Surgeon cut the tissue while the vision was obstructed: - Not well-trained or experienced with the use of instruments. - Distracted and frustrated to keep all instruments in view. - Incorrect port placement. - No feedback from assistants on the status of instruments/ports</p>	Myomectomy, Artery nicked, Converted to open surgery	Surgeon Mistake
2963870 (01/2013)	A2: H1-4	<p>Loop 1: Manufacturing company did not provide adequate training to surgical team on proper way of releasing vessel sealer instrument - Company representative not present during the procedure. - Assumed that surgical team read the manual for instrument.</p> <p>Loop 3: Surgeon manually released vessel sealer instrument from patient: - Not well-trained or experienced with releasing vessel sealer. - Instrument did not get released using emergency release tool</p>	Splenectomy, Vein nicked, Converted to open surgery, Tear to vessel	Surgeon Mistake

DISCUSSION

Analysis of adverse events data provides valuable insights on possible system hazards and can be used to assist enhancement of system safety in order to prevent future accidents. However, traditional accident analysis techniques are insufficient for understanding all the causes contributing to accidents in today's complex medical systems [44][45]. Such analysis techniques typically focus on the *root causes* based on direct causal relationships between the chains of events [46] leading to an accident and often conclude with a single root cause, such as a component failure or a human error [24]. Recommendations made based on such analysis often fail to enhance safety and similar accidents recur.

In safety-critical industries such as aviation, a great deal of effort has been made in employing systems-theoretic hazard and accident analysis techniques (such as STAMP [24]) that go beyond root cause analysis by reasoning about multi-dimensional causal factors and underlying conditions involved in accidents and by considering additional factors, such as unsafe interactions among system components and human operators; inaccurate operators' mental perspectives of the system; or the circumstances (context) under which actions are taken or decisions are made [47].

We proposed the application of systems-theoretic techniques to analyze adverse events in medical devices. Specifically, we used STAMP to identify the unsafe interactions among robotic components and human operators and determined the potential flaws in the design and operation of system that led to those interactions. To exemplify the value of STAMP, we selected three relevant reports (marked with “*” in Table 3) on accidents that occurred during gynecologic, cardiothoracic, and urologic procedures. In these examples, a burning or damage of tissue due to applying incorrect amount of electro-cautery occurred. Each of the reports specified that the bipolar cautery was incorrectly connected to the monopolar connection of the electrosurgical unit. Our experience is that frequently root cause analysis of such an accident ends up in blaming the surgical assistants for not performing the robotic setup correctly. STAMP

provided us with a detailed view on all the potential causal factors involved and identified two unsafe actions that were performed by the surgeon and surgical assistant in these three events: i) the surgical assistant connected the bipolar cautery to a monopolar connection on the electro-cautery unit and ii) the surgeon cauterized the tissue using the incorrect electro-cautery. Some of the potential causal and contextual factors that led to those actions include: i) the robot was not designed to provide enough feedback on the status of connections and the surgeon had an inaccurate mental model about the connections, ii) the electro-cautery unit was not designed by adequate safety mechanisms to prevent such mistakes and the surgical assistant might not have been well-experienced or distracted at the time. This analysis shows that design of both the robot and electro-cautery unit as well as the communication protocols and training for the surgeons and surgical assistants should be improved in order to prevent similar events in the future.

Our experience with STAMP shows that the systems-theoretic accident analysis techniques do not only enable an *in-depth understanding of adverse event causes*, but can also *improve the reporting of adverse events by guiding how to investigate and report* the important factors involved in the accidents. Furthermore, the systems-theoretic causality models can be *used by the manufacturers and regulatory organizations to identify the possible hazards and causal factors leading to accidents* early in the design and approval process to mitigate adverse patient impacts by design of proper safety monitors and control mechanisms.

We analyzed the trends in robotic surgery adverse events over time and found that despite a relatively high number of reports, with improvements in technology and greater adoption of robotic procedures the vast majority of procedures were successful. However, the likelihood of system-related incidents that negatively impact patients (in terms of injuries and deaths (14.4%) and procedure interruptions (10.4%)) is not negligible (23.6%). This suggests that a better appreciation and understanding of the nature of adverse events is required. Also, a non-negligible number of procedures (927 out of 9382) were

prolonged, converted, or rescheduled due to technical problems. This confirms the fact that in addition to device problems, lack of training and standard procedures for troubleshooting technical problems has a major role in the adverse events. Table 4 shows common types of device and instrument malfunctions and incorrect operational practices used by the human operators that contributed to catastrophic events during the procedures:

Table 4. Common types of device malfunctions and incorrect operational practices

Device and instrument malfunctions	Incorrect operational practices
<ul style="list-style-type: none"> - Master tool manipulator malfunctions - Video and imaging problems at the surgeon console - Recoverable and non-recoverable system errors - Broken instrument tips and arcing of instruments - Broken parts of instruments falling into patients 	<ul style="list-style-type: none"> - Inadequate experience with handling emergency situations - Lack of training with specific system features - Inadequate troubleshooting of technical problems - Inadequate system/instrument checks before procedure - Incorrect port placements - Incorrect electro-cautery settings - Incorrect cable connections - Inadequate manipulation of robot master controls - Inadequate coordination between hand & foot movements - Incorrect manipulation or exchange of instruments

These findings are also corroborated by a recent FDA survey on a sample of experienced robotic surgeons. The survey highlighted some of the biggest challenges in robotic surgery: “hand-eye coordination, use of foot pedals at the console, the system setup procedures, learning of platform (e.g., port and arm insertion), and training of surgical staff” [48].

Finally, we would like to emphasize that as cautioned by the FDA, the absolute number of MAUDE reports should not be used to evaluate the changes in rates of events over time, because the increased reporting of events could be due to multiple factors, e.g., the increasing use of surgical systems [1], changes in the manufacturers’ reporting practices [49], and/or better awareness and increased publicity resulting from product recalls, media coverage, and litigation [50]. Therefore, instead of focusing on the absolute number of reports, we estimated the number of events reported per procedure over the measurement period.

Limitations

We acknowledge that only one of the authors has used the robotic surgical systems in minimally-invasive surgery. The example analysis results presented here are limited to our knowledge of the system and the information provided in the MAUDE reports. There might be other system hazards and causal factors involved in the adverse events that could be determined using STAMP, but were missed in our analysis. Further, the estimated number of adverse events per procedure is likely to be lower than the actual incident rate in robotic surgery due to the underreporting and inconsistencies of the MAUDE database.

Conclusions

While the robotic surgical systems have been successfully employed in various surgical specialties, this study demonstrates several important findings: (1) the number of system-related incidents that negatively impacted patients is not negligible, (2) device and instrument malfunctions impacted patients and surgical teams by causing complications or prolonging procedure times, (3) causes of accidents were not limited to device malfunctions or operator mistakes; adverse events are often resulted from a combination of causal and contextual factors, such as inadequate safety controls, inadequate interactions among the system and human operators, lack of training and experience, and improper technical troubleshooting. As the surgical systems continue to evolve with new technologies, uniform standards for surgical team training, advanced human machine interfaces, systems-theoretic accident investigation and reporting, and safety-based design should be developed to reduce incident rates in the future.

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Table 1. Summary of related work on failures of robotic surgical systems

Ref. No. (Year)	Surgery Types	Medical Institute	No. of Cases	Total Number of Failures (Failure Rate) Types of Malfunctions	Converted	Rescheduled
Eichel ³ (2005)	Urologic	UC Irvine	200	Total = 5 (2.5%) Software (4), Mechanical (1)	N/A	N/A
Kozlowski ⁴ (2006)	Radical Prostatectomy (RLRP)	Virginia Mason Medical Center (VMMC)	130	Total = 6 (4.6%) Setup joint (2), Software incompatible (1), Robotic arm (1), Power-off (1), Monitor loss (1)	Laparoscopic (1) Open (1)	1
Borden ⁵ (2007)	Laparoscopic Prostatectomy	Virginia Mason Medical Center (VMMC)	350	Total = 9 (2.6%) Setup joint (2), Robotic arm (1), Camera (1), Power error (1), Console metal break (1), Software incompatible (1), Monitor loss (1)	Laparoscopic/ Open (3)	6
Zorn ⁶ (2007)	Radical Prostatectomy (RLRP)	University of Chicago Pritzker School of Medicine (2003–2006)	800	Total = 7 (Recover. = 0.21%, Non-Recover. = .05%) Power-up failure (1), Optical malfunction (3), Surgeon handicap (3), Robotic arm (1), Camera (2)	Completed (3)	4
Fischer ⁷ (2008)	Radical Prostatectomy	Klinik Hirslanden, Zurich, Switzerland	210	Total = 2 (1%) Robotic arm (2)	Conventional Laparoscopic	N/A
Lavery ⁸ (2008)	Radical Laparoscopic Prostatectomy (RALP)	11 Institutions 700 Surgeons	8,240	34 critical failures (0.4%) Robotic arm (14), Optical system (14), Masters (4), Power supply/circuit (6), Unknown error (3)	Laparoscopic (2) Open (8)	24
Ham ⁹ (2009)	Radical Laparoscopic Prostatectomy	Yonsei University College of Medicine, Korea	1	Case report of Surgeon's console failure	Delayed 15 min	
Kim ¹⁰ (2009)	Urology, General Surgery, Obstetrics and Gynecology, Thoracic Surgery, Cardiac Surgery, Otorhinolaryngology	Yonsei University College of Medicine, Korea (2005–2008)	1,797	Total = 43 (2.4%) Robot failures (24): On/off failure (1), Console malfunction (5), Robotic arm (6), Optic system (2), System error (10) Instrument failures (19): Shaft injuries (9), Wire cutting (2), Unnatural motion (2), Instrument tip (2), Limitation in motion (1)	Laparoscopic/ Open (3)	N/A
Kaushik ¹¹ (2010)	Robot-assisted Radical Prostatectomy (RARP)	Survey of 176 Surgeons from 4 Countries	N/A	Total failures = 260 Robotic arm (38%), Camera (17.6%), Setup joint (13.8%), Power error (8.8%), Ocular monitor loss (8%), Instruments (7.6%), Console handpiece break (3%), Software (1.9%), Backup battery (0.3%), Instrument identification (0.3%)	Open (18.8%), Laparoscopic (15%), Another robot, with one fewer robotic arm (8.7%)	57.5%
Finan ¹² (2010)	Gynecologic Oncology	Mitchell Cancer Institute, University of South Alabama (2006–2008)	137	Total = 11 (8.02%) Robotic arm (2), Light or camera cord (2), Maylard bipolar (1), Power failure (1), Port problem (1), Others (3)	Delayed 25 min.	N/A
Mues ¹³ (2011)	Urology, Gynecology, Cardiothoracic, General surgery, Otolaryngology, Neurosurgery	Ohio State University Medical Center, James Cancer Hospital (2008–2009)	454	Tip cover failures = 12 (2.6%) Significant patient complications (25%)	Repaired at the time of surgery	N/A
Ageooglu ¹⁴ (2012)	General Surgery	Cleveland Clinic	223	Total = 10 (4.5%) Robotic instrument (4), Optical system (3), Robotic arms (2), Robotic console (1)	Open surgery (6)	N/A
Chen ¹⁵ (2012)	Urological Surgery	Veterans General Hospital, Taiwan (2005–2011)	400	Total = 14 (3.5%) Robotic arm/joint (11), Optical system (1), Power system (1), Endoscopic instrument (1), Software incomp. (1)	Completed (10), Laparoscopy (3)	1
Buchs ¹⁶ (2014)	General Surgery	A Teaching Institution (2006–2012)	526	Total = 18 (3.4%) Robotic instruments (9), Robotic arms (4), Surgical console (3), Optical system (2)	Laparoscopic (1) (0.2%)	N/A

Table 2. Summary of related work on analysis of MAUDE data of robotic surgical systems

Murphy et al. ¹⁷ identified 38 system failures and 78 adverse events related to the da Vinci robotic system, reported from 2006 to 2007; most of them were related to broken instrument tips or failure of electrocautery elements.
Andonian et al. ¹⁸ found an estimated failure rate of 0.38% for robotic-assisted laparoscopic surgeries by reviewing 189 adverse events related to the ZEUS and da Vinci surgical robotic systems, reported to the MAUDE database between the years 2000 and 2007.
Lucas et al. ¹⁹ compared the rates of adverse events for two different models of da Vinci surgical systems (dVs and dV) during the period of 2003–2009 and showed that both device malfunctions and open conversions were reduced by increased robotic experience and newer surgical systems.
Fuller et al. ²⁰ reviewed 605 adverse events involving the da Vinci system during 2001–2011, and identified 24 (3.9%) reports related to electrosurgical injuries (ESI) that occurred during gynecological and prostatectomy procedures.
Friedman et al. ²¹ analyzed the da Vinci robotic system instrument failures reported to the MAUDE database in 2009 and 2010. They found a total of 565 instrument failures, of which the majority were related to the instrument wrist or tip (285), 174 were related to cautery problems, 76 were shaft failures, and the rest were cable and control housing failures (36).
Gupta et al. ²² reviewed a total of 741 adverse events reported to the MAUDE database in 2009 and 2010. They found that 43.5% of the events were related to the use of energy instruments, that 30.97% were associated with the surgical systems and instruments, and that the severity of events correlated with the type of surgery and the type of device used.
Finally, Manoucheri et al. ²³ evaluated the adverse events reported during robotic gynecologic procedures and found that the majority of reported injuries (65%) were not directly related to the surgical system; 21% were related to operator error; and 14% were due to technical system failures.

Table 3. Tasks and Control Actions in a Robotic Procedure

Example scenario in a procedure:
<ul style="list-style-type: none">• Mitral valve repair
Example Tasks (S teps):
<ul style="list-style-type: none">• Instrument Control• Camera Control• Arm Control• Needle handling• Electrocautery• Tissue Cutting• Tissue Retraction• Tissue Handling• Vessel Dissection• Knot Tying
Micro-Actions before Procedure:
<ul style="list-style-type: none">• Power on/off• Camera port insertion• Other ports insertion• Set the electro-cautery device and camera settings
Micro-Actions during Procedure:
<ul style="list-style-type: none">• Insert/extract instruments• Clutch instruments to extract or move• Focus• Cauterize (Mono- to Bi-polar)• Grip• Move• Emergency stop

Table 4. Robot Control Process Model Variables used by the Main Surgeon (Control loop 3)

Procedure Status:
<ul style="list-style-type: none">• Procedure time<ul style="list-style-type: none">◦ Ok◦ Prolonged• Intraoperative status:<ul style="list-style-type: none">◦ Ok◦ Intraoperative urgency (bleeding, burning tissue, damaged tissue)• Electro-cautery device status<ul style="list-style-type: none">◦ Ok◦ Incorrect settings◦ Incompatible• Insufflation device status<ul style="list-style-type: none">◦ Ok◦ Low level of CO₂
Robotic System Status:
<ul style="list-style-type: none">• Vision status:<ul style="list-style-type: none">◦ Ok◦ Vision lost◦ Vision obstructed◦ Out of focus◦ Not aligned with the target anatomy• Power status:<ul style="list-style-type: none">◦ Ok◦ Power lost◦ Battery level• System error:<ul style="list-style-type: none">◦ No error◦ Recoverable error◦ Not Recoverable error
Arms and Instruments Status:
<ul style="list-style-type: none">• Positioning/docking of robotic arms:<ul style="list-style-type: none">◦ Ok◦ Not Ok• Instrument activation:<ul style="list-style-type: none">◦ Engaged◦ Dis-engaged• Instrument insulation:<ul style="list-style-type: none">◦ Ok◦ Broken• Instrument position/orientation:<ul style="list-style-type: none">◦ Ok◦ Close to a non-target anatomy◦ Close to another instrument• Instrument status:<ul style="list-style-type: none">◦ Working◦ Hanged/Stopped

**Table 5. Adverse events in different surgical specialties:
Deaths, injuries, malfunctions, procedure conversion or rescheduling, common types of surgery**

No. (%) 95% Confidence Interval							
	Gynecology	Urology	Cardiothoracic	Head & Neck	Colorectal	General	N/A
Overall ^a	3,194 (30.1) [29.2–31.0]	1,565 (14.7) [14.0–15.4]	393 (3.7) [3.3–4.1]	71 (0.7) [0.5–0.9]	301 (2.8) [2.5–3.1]	197 (1.9) [1.6–2.2]	4,903 (46.2) [45.3–47.1]
Event Type ^b							
Death	46 (1.4) [1.0–1.8]	30 (1.9) [1.2–2.6]	25 (6.4) [4.0–8.8]	14 (19.7) [10.4–29.0]	11 (3.7) [1.6–5.8]	11 (5.6) [2.4–8.8]	7 (0.1) [0.0–0.2]
Injury	818 (25.6) [24.1–27.1]	272 (17.4) [15.5–19.3]	64 (16.3) [12.6–20.0]	14 (19.7) [10.4–29.0]	58 (19.3) [14.8–23.8]	56 (28.4) [22.1–34.7]	109 (2.2) [1.8–2.6]
Malfunction	2,103 (65.8) [64.2–67.4]	902 (57.6) [55.2–60.0]	226 (57.5) [52.6–62.4]	35 (49.3) [37.7–60.9]	209 (69.4) [64.2–74.6]	110 (57.8) [48.9–62.7]	4,476 (91.3) [90.5–92.1]
Other	227 (7.1) [6.2–8.0]	361 (23.1) [21.0–25.2]	78 (19.8) [15.9–23.8]	8 (11.3) [3.9–18.7]	23 (7.6) [4.6–10.6]	20 (10.2) [6.0–14.4]	311 (6.3) [5.6–7.0]
Conversion	236 (7.4) [6.5–8.3]	212 (13.5) [11.8–15.2]	66 (16.8) [13.1–20.5]	6 (8.5) [2.0–15.0]	29 (9.6) [6.3–12.9]	14 (7.1) [3.5–10.7]	217 (4.4) [3.8–5.0]
Rescheduling	26 (0.8) [0.5–1.1]	148 (9.5) [8.1–10.9]	11 (2.8) [1.2–4.4]	1 (1.4) [0–4.1]	1 (0.3) [0–1.0]	6 (3.0) [0.6–5.4]	77 (1.6) [1.3–1.9]
Common Surgery Types							
Hysterectomy (2,331)		Prostatectomy (1,291)	Thoracic (110)	Thyroidectomy (19)	Cholecystectomy (118)	Hernia repair (37)	
Myomectomy (328)		Nephrectomy (138)	Lobectomy (67)	Tongue base resection (19)	Colectomy (61)	Nissen fundoplication (34)	
Sacrocopropexy (170)		Pyeloplasty (31)	Mitral valve repair (54)	Transoral robotic (18)	Low anterior resection (44)	Gastric bypass (28)	
Oophorectomy (120)		Cystectomy (48)	Coronary artery bypass (23)		Colon resection (25)	Gastrectomy (15)	

^a Percentages are over all the adverse event reports (n = 10,624).

^b Percentages are over the total adverse events reported for a surgical specialty.

The higher percentage of adverse events reported in gynecology and urology could be due to the higher number of these procedures performed.

Of all the reports, only 5,721 (53.8%) indicated the class and type of surgery involved. However, the majority of reports with missing information on the type of surgery were related to device malfunctions and “Other” events (97.6%). In order to compare the adverse events across different specialties, we focused only on injuries, deaths, and procedure conversions for which the surgery type information was mostly (92.2% of injuries, 95.1% of deaths, and 72.2% of procedure conversions) available.

Table 6. Major categories of malfunctions

Malfunction Category ^a	Description	No. of Reports (% of all)				Surgical Team Actions (% of malfunction category)			
		Total	Event Type ^b			System Reset		Procedure Converted	Procedure Rescheduled
			M	IN	D	O			
System Errors	- System error codes and faults - System transferred into a recoverable or non-recoverable safety state	536 (5.0%)	44	23	1	468	231 (43.1%)	330 (61.6%)	133 (24.8%)
Video/ Imaging Problems	- Loss of video - Display of blurry images at surgeon's console or assistant's touchscreen	275 (2.6%)	21	18	0	236	53 (19.3%)	145 (52.7%)	94 (34.2%)
Broken Pieces Falling Into Patients	- Burnt/broken parts and components - Fell into surgical field or body cavity - Required additional procedure time to be found/removed from the patient	1,557 (14.7%)	1,396	119	1	41	3 (0.2%)	38 (2.4%)	5 (0.3%)
Broken Tip Covers/ Elec. Arcing	- Tears, burns, splits, holes on tip cover - Electrical arcing, sparking, charring	1,111 (10.5%)	900	193	0	18	2 (0.2%)	18 (1.6%)	0 (0.0%)
Unintended Instrument Operation	- Unintended or unstoppable movements started without the surgeon's command - Instruments not working, open/closed - Instruments not recognized by system	1,078 (10.1%)	919	52	2	105	31 (2.9%)	93 (8.6%)	21 (1.9%)
Other	- Issues with electrosurgical units, power supplies/cords, patient-side manipulators, etc. - Other events reported as "Malfunction"	5,026 (47.3%)	4,962	31	1	32	20 (0.4%)	41 (0.8%)	10 (0.2%)
Total (% of all)	All malfunctions ^c	9,382 (88.3%)	8,061	444	9	868	305 (3.2%)	631 (6.7%)	246 (2.6%)
	All Adverse Events	10,624 (100%)	8,061	1,391	144	1,028	334 (3.1%)	780 (7.3%)	270 (2.5%)

	System Errors	Video/Imaging Problems	Broken Pieces Fell into Patients	Burns/Holes in Tip Covers/Elec. Arcing	Unintended Instrument Operation	Other
Broken Instruments (n = 5,054)	33 (6.2%)	27 (9.8%)	1,166 (74.9%)	275 (24.8%)	400 (37.1%)	3,201 (63.7%)

^a The malfunction categories and actions taken by the surgical team are not mutually exclusive, and in many cases two or three different malfunctions or two actions were reported in a single event. Figure 3 in Appendix uses Venn diagrams to depict the intersections among different malfunction categories and actions taken by the surgical team.

^b Event types as indicated by reporters: Malfunction (M), Injury (IN), Death (D), and Other (O).

^c In 1,019 of cases (10.9% of all the malfunctions), the device or instrument malfunction was detected prior to start of the procedure, of which in 20 cases the procedure was rescheduled to a later time and in 2 cases it was converted to a non-robotic approach.

Figure 1. Data extraction and analysis flow from the FDA MAUDE database

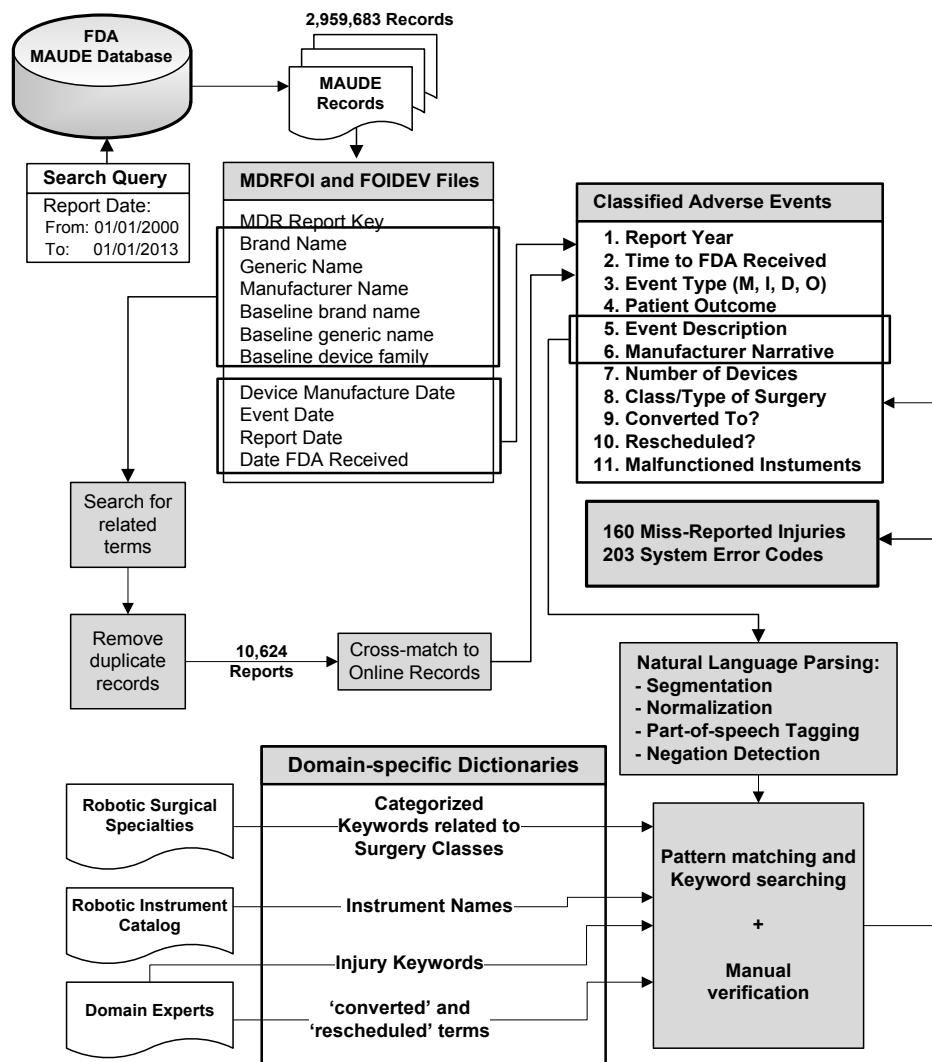
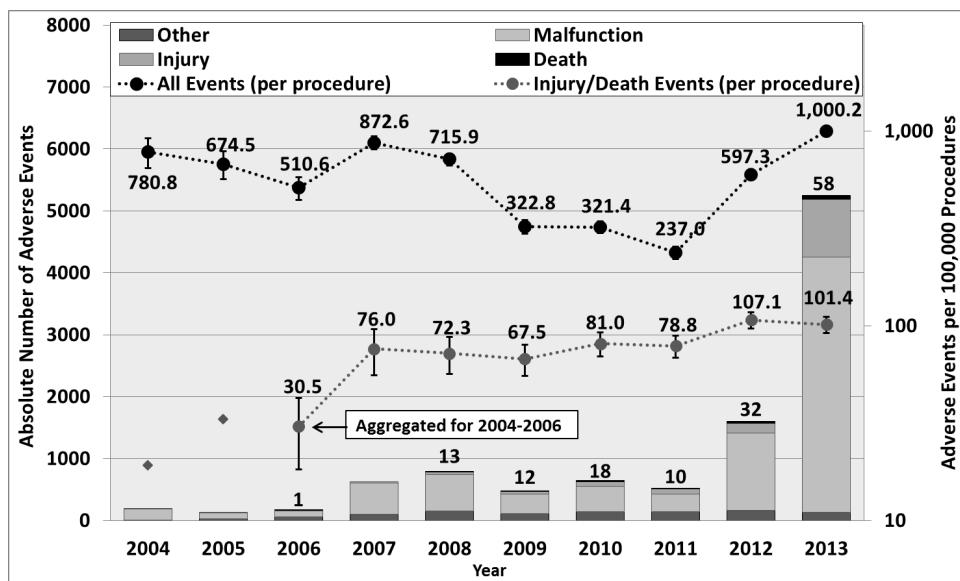
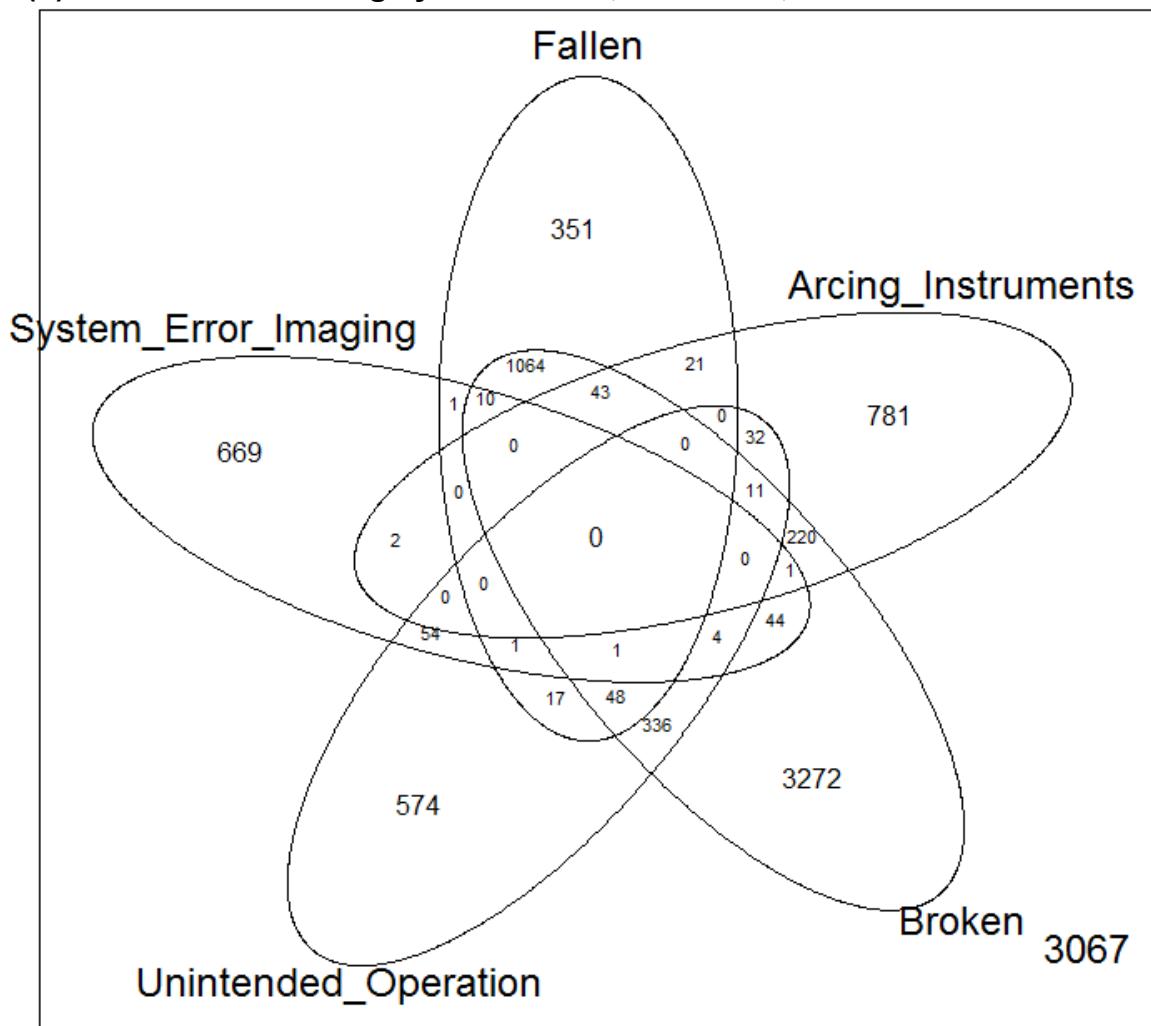


Figure 2. Annual Numbers of Adverse Event Reports and Number of Events per Procedure

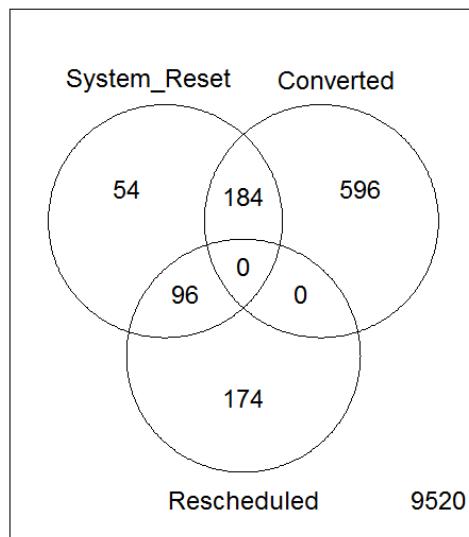


The left Y-axis corresponds to the bars showing the absolute numbers of adverse events (based on the year that reports were received by the FDA). The right Y-axis corresponds to the trend lines showing (in logarithmic scale) the annual number of adverse events per 100,000 procedures (based on the year the events occurred). Numbers on the bars indicate number of deaths reported per year. Error bars represent 95% confidence intervals for the proportion estimates. Because of the small number of injury and death events reported for 2004 and 2005, a combined rate was calculated for 2004–2006. Note that of all the events, 40 were reported as part of the articles or the legal disputes received by the manufacturing company.

Figure 3. (a) Intersections among different malfunction categories, (b) Intersections among system resets, converted, and rescheduled cases



(A total of 3,067 adverse event reports were not classified by MedSafe in any of the malfunction categories.)



(For 9,520 adverse events, no system resets, conversions, or reschedulings were reported.)

MAUDE Report 2543963

Event Date: 03/23/2012	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported that during a robotic pulmonary lobectomy procedure, the patient's pulmonary artery was lacerated, requiring hemostasis of the affected vessel using a cadiere forceps instrument to allow for completion of the planned surgical procedure using open surgical techniques. After obtaining adequate exposure, the site attempted to manually open the grips on the cadiere forceps instrument using several different allen wrenches, however, the instrument grips would not release. The site then attempted to release the instrument using the master tool manipulators (mtm), however, the error message unable to align masters was observed. Unable to resolve the issue, the site contacted isi technical support engineering (tse) for troubleshooting assistance. After performing an emergency stop/recover of the system, the grips on the cadiere forceps instrument opened. No other information concerning the reported event was provided.

Manufacturer Narrative: On (b)(6) 2012, supervisor of technical support engineering contacted the surgeon, dr. (b)(6) at (b)(6) to discuss the difficulties experienced while attempting to release the cadiere forceps instrument. Dr. (b)(6) indicated that after damage to the patient's pulmonary artery occurred, he used a cadiere forceps instrument to clamp down on the vessel to stop the blood flow to allow for conversion of the procedure to open. Dr. (b)(6) made the decision to release the cadiere forceps instrument from the patient bedside, instead of from the surgeon side cart. However when the surgical staff attempted to use an allen wrench to release the instrument, the instrument would not release. The tse reiterated that the instructions in the system user manual states that the emergency grip release mechanism facilitates removal of an instrument in the event of a system fault. Dr. Abbas was advised to perform an emergency stop in these situations to remove instruments from the patient side without a system error. Several follow up attempts with the site have been made concerning the patient's status, however, no additional information has been provided. A follow-up mdr will be submitted to the fda if additional information becomes available. As of (b)(4) 2012, there have been no reported recurrences of this issue at this hospital.

MAUDE Report 2883607

Event Date: 11/27/2012	Event Type: Injury	Patient Outcome: Required Intervention
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Event Description: It was reported that during a robotic hysterectomy procedure, while the surgical staff was undocking the system from the patient, it was noted that the patient suffered a bowel tear during the procedure. According to the information provided by initial reported clinical sales representative, the tips of the prograsp forceps instrument were not used to grab the bowel, but the shaft of the instrument was used to retract the bowel.

Manufacturer Narrative: According to the information provided by the clinical sales representative, the gyn surgeon (he had performed 4-5 cases) was performing a lengthy dvh. There was a bowel perforation and tears in the serosa of the sigmoid colon, which were not noticed until the robotic portion was complete and the surgeon was ready to undock the robot system. The csr was in the operating room for most of the case and did not see a specific cause for the injury. The surgeon was using a prograsp forceps instrument to push/sweep the bowel back with the shaft/wrist, but did not grab bowel. The assistant was blindly inserting a lap suction/irrigator throughout the case. Once the surgeon noticed some unusual fluid in the abdomen at the end of the case, she called a colorectal surgeon who repaired the bowel laparoscopically. The patient recovered well and had no further complications. A review of the system logs showed no system malfunction occurred during the procedure performed on (b)(6) 2012.

MAUDE Report 3444257

Event Date: 10/02/2013	Event Type: Injury	Patient Outcome: Required Intervention
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Event Description: It was reported that during a robotic ovarian cystectomy procedure, the patient sustained a serosal tear to the bowel that was noticed after insufflation was lost. The injury was repaired during the surgical procedure. On (b)(6) 2013, intuitive surgical inc. (isi) contacted the isi clinical sales representative (csr). The csr was present during the surgical procedure. According to the csr, the event occurred towards the end of the da vinci si surgical procedure. At the time the event occurred, pneumoperitoneum was lost from tubing placed through a laparoscopic assist port. Due to loss of insufflation, the surgical staff lost vision of the operative field. After insufflation was lost, a serosal tear was noticed on the patient's bowel. Although the bowel was not perforated, a gyn surgeon made the decision to apply sutures to the bowel injury as a precaution. The csr stated that the da vinci surgical procedure was completed and there were no reports of post-operative complications. The csr stated that no malfunction of the da vinci si system, an instrument, or an accessory occurred during the surgical procedure.

Manufacturer Narrative: Based on the information provided, the manufacturer has not determined the root cause for the intra-operative complication experienced by the patient. The company has reviewed the system logs for the site with a procedure date of (b)(6) 2013. No system errors were found to have occurred during the surgical procedure. This complaint is being reported due to the following conclusion: the patient sustained a bowel injury while undergoing a robotic ovarian cystectomy procedure and sutures were applied to the injury as a precaution. However, there is no indication that a malfunction of the robotic system, an instrument, or an accessory occurred during the surgical procedure.

MAUDE Report 1554085

Event Date: 10/29/2009	Event Type: Injury	Patient Outcome: Required Intervention, Hospitalization
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Event Description: It was reported that while beginning a robotic abdominal penical dissection procedure, the image was not aligned appropriately through the high resolution stereo viewer (hrsV). The company clinical sales rep (csr) present during the procedure advised an tech support engineer that the site will perform an emergency power off and call back for more troubleshooting assistance. Approximately 30 minutes later the csr called to report that during retraction of the pt's bowel, the pt's accessory vessel was cut or torn. The procedure was converted to traditional open surgical techniques to repair the affected vessel. The pt also experienced excessive bleeding, requiring the pt to undergo a blood transfusion. A monopolar curved scissors instrument, a fenestrated bipolar instrument and traditional laparoscopic instruments were used during the procedure, however, it is indeterminable as to if these instruments may have caused the damage to the pt's vessel.

Manufacturer Narrative: The company clinical sales rep followed up with the surgeon to verify the pt's status. The surgeon reported that the damage to the pt's vessel extended the pt's hospitalization, however, the pt was discharged from the hosp after 5 days and has not returned to the hosp due to any post operative complications. The camera head was returned to the manufacturer for failure analysis. Engineering evaluation found that the camera head stage was loose. Engineering concluded that the stage was loose due to physical impact. As of (b)(6), 2009, there have been no reported recurrences of the issue at this hosp.

MAUDE Report 1669451

Event Date: 04/21/2010	Event Type: Injury	Patient Outcome: Required Intervention, Hospitalization
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Event Description: Urologist called to report problems with robotic equipment. The urologist had to convert the robotic prostatectomy case to open when the system stopped working. The next week, the surgeon had two robotic prostatectomies. During the first case there were 10 alarms with the error #20013, that said press fault override button. Despite this problem the first case went as planned without any other issues. During the second case the same problem with the fault alarm occurred three times; on the third time the fault did not override. The manufacturer was contacted using the da Vinci help number. We were instructed to undock the robot completely and power down. I was instructed to check some connections on the console, which were fine. Then we turned on the robot and started again. We had another fault that we could not override, so i called the company again, had the surgeon press the emergency stop button and then fault override. This was to release the instruments' grasps on the tissue. At that time there was a bleeder that hadn't fully gotten under control because the robot was frozen. There were three more faults before we had another irrecoverable fault. The surgeon decided to completely undock the robot and convert to an open case. A sales rep came to do a system check on the robot, and it should have been ready to perform today. After speaking with three representatives from the da Vinci company, i was told it was most likely a component (sensor) in the arm that was not working correctly. We were also having trouble with the brightness of the light, but we changed the light cord and the picture was normal. There was some problem with our harmonic as well, but we opened a new instrument and it continued to work. The surgeon complained that one of the eyes was blinking on and off. Manufacturer technician is servicing the equipment shortly. ===== health professional's impression=====equipment problems
1. Lighting was 1/2 the intensity 2. One eye was blinking off/on 3. Problem with green arm surgeon feels that the machine keeps getting bandaid fixes; poor equipment maintainance. The case yesterday the red arm would not work, light bulb changed, but still blinding on and off. Our facility contracts directly with manufacturer for maintainance with service agreements. ===== manufacturer response for robot, da vinci@=====manufacturer was on site for maintainance; i'm waiting for a report. Our facility contracts with the manufacturer for them to provide the maintainance on this piece of equipment.

Manufacturer Narrative: N/A

MAUDE Report 3502026

Event Date: 11/25/2013	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported by the site that during a robotic procedure the prograsp forceps that was attached to arm 3 of the patient side cart (psc) stopped responding and would not open while it was grasping tissue. The site attempted to unlock the forceps using an emergency release wrench; however, the screw thread needed to unlock the instrument with the emergency release wrench was reportedly missing on the proximal end of the instrument. The surgical staff had to tear off the instrument that was grasping the tissue. It was reported that the patient's tissue tore and due to the alleged issue with the prograsp forceps, it increased surgery time and bleeding risk.

Manufacturer Narrative: The instrument has not been returned for evaluation; therefore, the root cause of the customer reported failure mode cannot be determined. The manufacturer has not received any new information as of date of this report. A follow-up report will be submitted if additional information is received. The company has reviewed the system logs for the site with a procedure date of (b)(6) 2013 and no system errors were found to have occurred during the reported surgical procedure. This complaint is being reported due to the following conclusion: the instrument did not function as intended and tore the patient's tissue.

MAUDE Report 3502026

Event Date: 11/25/2013	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported by the site that during a robotic procedure the prograsp forceps that was attached to arm 3 of the patient side cart (psc) stopped responding and would not open while it was grasping tissue. The site attempted to unlock the forceps using an emergency release wrench; however, the screw thread needed to unlock the instrument with the emergency release wrench was reportedly missing on the proximal end of the instrument. The surgical staff had to tear off the instrument that was grasping the tissue. It was reported that the patient's tissue tore and due to the alleged issue with the prograsp forceps, it increased surgery time and bleeding risk.

Manufacturer Narrative: The instrument has not been returned for evaluation; therefore, the root cause of the customer reported failure mode cannot be determined. The manufacturer has not received any new information as of date of this report. A follow-up report will be submitted if additional information is received. The company has reviewed the system logs for the site with a procedure date of (b)(6) 2013 and no system errors were found to have occurred during the reported surgical procedure. This complaint is being reported due to the following conclusion: the instrument did not function as intended and tore the patient's tissue.

MAUDE Report 2853531

Event Date: 10/30/2012	Event Type: Injury	Patient Outcome: N/A
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Event Description: On (b)(6) 2012, clinical sales representative received information from the customer to inform that during a robotic myomectomy procedure, while the surgeon was re-docking the system, the surgical staff forgot to install the mcs tip cover on the monopolar curved scissors instrument. The patient had a bowel burn and a general surgeon was called in to remove the burn piece of colon out.

Manufacturer Narrative: On (b)(4) 2012, the manufacturer contacted the initial reporter clinical sales representative, csr indicated that she was not present during the case, but according to the information provided to her by the customer, the nurse forgot to install the monopolar curved scissors (mcs) tip cover on the mcs monopolar curved scissors instrument. According to the information provided to the clinical sales representative, this was a onetime incident, the surgeon and the surgical staff at this account is an experienced robotic team. Clinical sales representative had contacted the company coordinator to initiate a training section with the surgical team to ensure that this incident does not re-occur. The myomectomy procedure was completed with the robotic system and the patient status is stable.

MAUDE Report 2632716

Event Date: 04/19/2012	Event Type: Injury	Patient Outcome: N/A
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Event Description: "pt in operating room for robotic laparoscopic hysterectomy; surgeon documented grossly enlarged uterus with multiple fibroids. As surgeon was bivalving the uterus, he saw a flash of blood coming from the left side of the pt and immediately recognized vascular injury. The robot was immediately undocked and procedure was converted to open procedure. The vascular surgeon responded immediately to repair the pt's left external iliac artery, which he described as "charred" due to the cautery injury. Operating room staff reported small tear in the plastic that covered the metal end of the monopolar scissor. The pt was stabilized after surgical repair and administration of blood products and transferred to the intensive care unit post-operatively. She remains stable and was transferred to the surgical unit the following day. The pt was discharged home (b)(6) 2012".

Manufacturer Narrative: The mcs instrument was returned and evaluated. Per the customer reported complaint (with the following clarification) " the defect was a tube extension dislodged from the main tube". The entire tube extension wall is circumferentially broken at the base of the axial keys. As a result, the tube extension can be rotated 360 degrees. The surface of the reinforcement tube extension exhibited burnt molded material, indicating unintended arcing may have occurred. Engineering concluded that the dislodged tube at the distal end is likely due to overloading at the distal end which led to a path for unintended arching. The mcs tip cover accessory was not returned. On (b)(4) 2012, isi contacted risk mgr, (b)(6) at (b)(6) and she indicated that the pt had a large uterus which required that the surgeon cut the pt's uterus in half to allow for removal. She indicated that the surgeon did not observe arcing from the instrument however; there was an excessive amount of smoke in the surgical area when the injury to the pt occurred. Since she stated that a vascular surgeon was immediately called to repair the affected vessel and during repair of the vessel, the vascular surgeon noted that it exhibited charring, thus it was determined that an arcing event had occurred. Per (b)(6), the surgeon did not observe that the mcs instrument broke during the surgical procedure, however, examination of the tip cover accessory by the surgical staff found that it had a hole; however, she does not know the status of the tip cover accessory. (b)(6) indicated that the pt is recovering well and has not returned to the hospital due to experiencing any post-operative complications. The instruments and accessories user manual specifically states: general precautions and warnings: handle instruments with care. Avoid mechanical shock or stress that can cause damage to the instruments. Do not use an instrument to clean debris from another instrument intraoperatively. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip. This mdr is being submitted for retrospective activity performed relating to field action number 2955842-051613-005 to investigate micro-cracks on the monopolar curved scissors instrument. These types of micro-cracks will not lead to mechanical failure of the instrument; however, there is a potential for insulation failure after reprocessing, resulting in a pathway for electrosurgical energy to leak to tissue and potentially cause unintended injuries. The location of theses micro-cracks is confined to 2 cm of the distal end of the instrument shaft. This instrument was inspected as part of this retrospective activity and found to contain cracks on the instrument main tube.

MAUDE Report 2184632

Event Date: 05/10/2011	Event Type: Malfunction	Patient Outcome: N/A
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Event Description: It was reported that during a robotic prostatectomy procedure, the site observed arcing coming from the tip cover accessory installed on the monopolar curved scissors (mcs) instrument. The surgical staff observed burns that were local into fatty tissue in the bladder region. The tip cover accessory was changed to successfully complete the surgery. The site reported that the patient was not injured beyond the local charring at the level of the distal tip and that the burns did not require any added intervention. The patient was reported as recovering normally and no follow up visit was required as result of burns.

Manufacturer Narrative: The tip cover accessory was returned and evaluated. Per the customer reported complaint engineering found the tip cover to have multiple holes burned through the silicone. The silicone exhibits localized melting around the hole which is indicative that an arcing event occurred. The hole sizes are roughly .015 and. 050, and are located. 220 and. 330 above the silicone to sleeve interface. The tip cover also has various mechanical tears and scratches in the general vicinity of the holes. The site also returned a video of the procedure where various collisions between silicone part of tip cover and other instruments can be observed prior to arcing. Evidence not conclusive, however, the instrument collisions with the tip cover accessory have likely contributed to the arcing event. No other damage was found. The endowrist instruments instructions for use (ifu) specifically states: general precautions and warnings to handle instruments with care. Avoid mechanical shock or stress that can cause damage to the instruments. Do not use an instrument to clean debris from another instrument intraoperatively. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip. The monopolar curved scissors instrument instructions for use. Inspect the tip cover accessory periodically during use. If any damage or tears are observed, replace the tip cover accessory with a new one.

MAUDE Report 2925864

Event Date: 12/23/2012	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported that during a robotic axillary lymph node dissection procedure, arcing from the mcs tip cover accessory installed on the monopolar curved scissors instrument occurred, causing damage to the patient's iliac vein. The affected vessel was repaired and the planned surgical procedure was completed.

Manufacturer Narrative: The tip cover accessory and monopolar curved scissors instrument were not returned to the manufacturer for evaluation; however, a video recording of the surgical procedure was received and reviewed by the manufacturer. Review of the procedure video showed that the back side of the mcs tip cover accessory installed on the mcs instrument collided and pushed against the wrist area of the cadiere grasper instrument that was installed on the 3 patient side manipulator (psm) arm located on the patient side cart. Review of the video recording showed that there were several scrape marks on the back side of the tip cover, due to colliding and rubbing against the pulley/cables on the cadiere grasper instrument. The video recording showed that arcing from the tip cover accessory occurred twice during the surgical procedure; however, the first instance of arcing was not observed by the surgeon. The second instance of arcing was observed and the site removed and replaced the tip cover accessory. Based on the video recording findings, intuitive surgical has determined that the arcng was the result of the tip cover making contact with the cadiere grasper instrument during the surgical procedure. The instruments and accessories user manual specifically states: general precautions and warnings o handle instruments with care. Avoid mechanical shock or stress that can cause damage to the instruments. Do not use an instrument to clean debris from another instrument intraoperatively. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip.

MAUDE Report 2637842

Event Date: 04/30/2012	Event Type: Malfunction	Patient Outcome: N/A
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Event Description: It was reported to that during a robotic hysterectomy procedure, a char was observed on the monopolar curved scissors instrument when it was removed from the patient. The distal tip of the instrument was also observed to be melted and have a crack. The planned surgical procedure was completed and no patient harm, adverse outcome or injury was reported. The company received a med watch report indicating that at approximately 0900 circulator and scrub noticed an electrical burning odor while the surgeon was using monopolar scissor 311 and notified surgeon. Assistant removed trocar with arm attached and discovered scissor arm damaged and melted. Case converted to laparoscopic. Tissue on uterus charred. Case was a robotic assist hyst.

Manufacturer Narrative: Engineering evaluation found that the tip cover has a .030 x. 050 oval shaped hole in the silicone. The hole is located. 500 above the silicone to sleeve interface. The silicone exhibits localized melting around the hole, indicative of arcing. With tip cover installed on mcs instrument the hole position is near grip cable and distal clevis ear. Engineering evaluation of the mcs instrument found that the main tube was found broken located slightly below the proximal clevis. The broken main tube can be rotated 360 degrees; however, it still remains intact with the instrument. The broken area shows signs of arcing due to localized melting. Engineering concluded that the damage was likely due to excessive side loading or other type of misuse. The instrument also passed electrical continuity testing. Engineering evaluation of the mcs instrument also found black char marks on the blade tips. The surface of the blades exhibit burnt material, indicative that unintended arcing occurred. Tube reinforcement ring also shows peeling off of surface material. The risk management at medical center (b)(6), provided the following details: - the monopolar curved scissors (mcs) instrument and mcs tip cover were inspected prior to use and there was no damage found. - the monopolar curved scissors instrument made contact with another instrument used during the surgical procedure. - the cannula was inspected prior to use. - the esu generator used during the surgical procedure was a valley lab, force, fx and the settings were coag 90, cut 90. Functional testing of the system found that it functioned within specification. The members of the surgical staff present during the surgical procedure indicated that the patient involved had a tight anatomy and that the surgical staff observed that the mcs instrument exhibited excessive torquing. Based on the additional information provided by the site, the regional fse manager has concluded that excessive torquing of the mcs instrument caused the instrument to break, which allowed energy to escape and arc to the patient's uterus, which was being removed.

MAUDE Report 875685

Event Date: 06/04/2007	Event Type: Injury	Patient Outcome: Required Intervention
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Event Description: It was reported that during the prostatectomy procedure, the surgeon noticed that the patient's iliac vein was bleeding. The monopolar curved scissors instrument was removed and a hole on the tip cover accessory was observed. The planned surgical procedure was completed, however, the case was lengthened by thirty minutes as the surgeon had to repair the bleeding iliac vein. No patient harm, adverse outcome or injury was reported.

Manufacturer Narrative: The instrument was not returned, however, the tip cover accessory used with the instrument was returned and evaluated. Engineering evaluation found a hole in the silicone around 1/16" in diameter at the proximal end of the tip cover. The hole does not appear to come from a puncture, as material is missing from the outer surface of the silicone overmold. A video of the procedure was returned. During review of the video, it was noticed that the tip cover accessory was pressing on the tissue, when the iliac vein began to bleed. It may have been possible that the cautery activation with the tip cover pressing on the tissue caused energy to transfer from the instrument, through the silicon, and to the iliac vein, causing the bleeding experienced by the patient. Engineering also observed a tear on the distal end of the tip cover that was not likely caused by heat. The silicone is thinner at the proximal end (where the hole is) than at the distal end (where the tear is), making it more susceptible to being damaged.

MAUDE Report 1617090

Event Date:	01/19/2010	Event Type:	Malfunction	Patient Outcome:	N/A
<p>Event Description: During a robotic prostatectomy procedure the console surgeon observed arcing coming from the monopolar curved scissors (mcs) tip cover accessory that was installed on a mcs instrument. The arcing caused a burn to the patient's bowel and although the surgical staff determined that the burn was not significant, the console surgeon repaired the burn as a precaution. (b)(6) reported that no post-operative complications have been experienced by the patient. (b)(6) also mentioned that the <u>valley lab force fx esu fulgrate setting was set to 50w during the time of the event.</u></p>					

Manufacturer Narrative: The instruments and accessories user manual specifically states: - warning: do not exceed the 3kv peak limit. Doing so may result in electrical arcs and alternate site burns. - warning: use the lowest power setting possible for the minimum time necessary to achieve the desired effect. - warning: never increase the power settings without first checking both the active electrode and the patient return electrode and their connections. Use the active electrode or forceps only for the minimum time necessary to achieve the desired surgical effect in order to minimize the possibility of burns. - warning: excessive power levels may result in instrument malfunction and possible patient or user injury. Reduce power setting if any of the following effects are observed: excessive arcing, excessive tissue charring, excessive overheating of end effector (e. G. , end effector glowing red). The instruments and accessories user manual also indicates the corresponding maximum esu power settings to stay below the 3kv limit are as follows for the valleylab force fx esu: coag desiccate mode - max power setting is 120 watts coag fulgrate mode - max power setting is 38 watts coag spray mode - max power setting is 25 watts.

MAUDE Report 1961862

Event Date:	12/17/2010	Event Type:	Injury	Patient Outcome:	Other
<p>Event Description: It was reported that approximately 2 hours during a robotic rectopexy procedure, <u>while an instrument change was in progress, the surgeon removed his hands from the master tool manipulators (mtm); however; left his head in the surgeon side stereo viewer.</u> This caused the instrument being exchanged in the guided tool change mode, to move slightly forward and bump the patient's colon. Slight bleeding of the patient's colon occurred; however, no repair, blood transfusion or intervention was necessary. The planned procedure was completed and no adverse outcome was reported.</p>					

Manufacturer Narrative: The investigation conducted by field service engineering concluded that mtm movement experienced by the customer was associated with use error. The master tool manipulator refers to the master controllers which provide the means for the surgeon to control the instruments and endoscope inside the patient from the surgeon's side console. One mtm is assigned to the surgeon's left hand (mtml) and one to his right (mtmr). The guided tool change is an efficient and safe method for instrument insertion, providing assistance to the patient side cart operator by guiding the instrument into the patient. The system was found to be within specification, however, gravity calibration was performed on the mtms as a precaution. On (b)(6) 2010, additional training was conducted with the surgeon to ensure that in future cases, he will remove his head from the surgeon side viewer when his hands are not engaged on the mtms. The system user manual specifically states: note: for guided tool change, the surgeon should remove their head from the stereo viewer to take all instruments out of following before removing and installing an instrument. As of january 13, 2011, there have been no reported recurrences of the issue at this hospital.

MAUDE Report 1570678

Event Date:	11/19/2009	Event Type:	Other	Patient Outcome:	N/A
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Event Description: It was reported that during a robotic hysterectomy procedure, the surgical staff experienced difficulty moving the endoscopic camera manipulator (ecm) and observed the right master tool manipulator (mtmr) drifting when it was released. The drift caused the associated patient side manipulator (psm) to move and resulted in a puncture to the patient's uterus from the instrument installed on the psm. The patient's uterus was scheduled to be removed as part of this procedure. The site undocked the system from the patient and restarted the system, however, the mtmr was reported as still drifting. The surgeon made the decision to convert to traditional laparoscopic surgical techniques to complete the planned procedure.

Manufacturer Narrative: The investigation conducted by field service engineering (fse) consisted of reviewing system error logs and performing functional tests. The fse's review of the logs did not reveal any system errors and the system functioned as intended with no issues. Since this event, an isi clinical sales representative provided additional training to the console surgeon on december 10, 2009, and again on december 17, 2009. During training, it was determined that the event was caused by the surgeon removing his hands from the mtm's without removing his head from the surgeon console's head sensor. The system's psms are designed to follow the movements of the mtms during normal use, however, once the surgeon's head is removed from the head sensor, the psms are no longer in the following mode, resulting in no movement of the psms. As of december 16, 2009, the hospital has continued to use the system with no reported recurrences of the reported issue.

MAUDE Report 2147492

Event Date: 05/31/2011	Event Type: Injury	Patient Outcome: Required Intervention
<p>Event Description: It was reported from a facility in europe that during a robotic hysterectomy procedure and while performing para-aortic lymph node dissection, the surgeon positioned the right master tool manipulator (mtmr) toward the uppermost boundary of his available mtm workspace. The surgeon removed his fingers from the mtmr while his head was in the surgeon console viewer (contrary to a warning in the labeling), and the instrument associated with the mtmr dropped down in an uncontrolled manner, and cut the patient's abdominal aorta. The planned surgical procedure was converted to traditional open surgery and the patient's aorta was repaired by placement of a stent. The planned hysterectomy procedure was also completed. As of the date of this report, the patient is reported to be recovering with no complications and was discharged from the hospital a week after the operation. The master tool manipulator (mtmr) was returned to isi for evaluation. The link 1 cover was removed to verify the spring guide failure. When the cover was removed to inspect the damaged spring guide it was noted that the counterbalance spring was pushing against the inside of the exterior cover. When the cover was replaced to take force measurements, it was necessary to compress the spring slightly to tighten the cover mounting screw. The joint 2 (shoulder) spring guide end flange was observed to have cracked away from the rest of the spring guide tube. The end flange remains attached to the tube by a small thickness of material at the end of a visible tear in the plastic. The fracture initiates at a high stress location near a mounting screw head. The spring extension resulting from the crack was measured with the cover removed to be approximately 1. 0 inch +/- . 1 inch. Visual inspection of the mtmr did not reveal any other anomalies, aside from the cracked spring guide, that would account for loss in gravity compensation. The root cause of the spring guide failure was a stress concentration in the spring guide where the flange intersects the thin wall of the tube in a sharp corner, combined with cyclic loading of the spring guide due to mtm motion. The stress concentration resulted in a crack that initiated at the high stress location and then slowly propagated due to cyclic loading as the force from the spring varied during use of the mtm. Stress was induced in the fracture location by tensile loading on the guide from spring compression. Stress near the end-flange on the spring guide restraining the joint 2 counterbalance spring was increased by the clamp force from the screw head that mounts the guide to the mtm. The reduction in gravity compensation on this mtmr is due to cracking near the joint 2 (shoulder) spring guide end flange. The spring tube contains stress concentrations that are inherent to the part geometry and cyclic loading can cause cracking and gradual tearing of the plastic part. The separation of the end flange from the tube and resulting reduction in gravity compensation is likely to have occurred over the course of several months. Intuitive surgical initiated a corrective action, 2955842-070111-002 c, issued 7/1/2011, in relation to this spring counterbalance subsystem failure of the master tool manipulator that occurred at (b)(4) hospital. Correction of affected systems has been performed using reinforcing caps for the retention component to correct the problem with the mtm subsystem. Affected mtm spring guides were inspected by field service engineers and those spring guides having no cracks or gaps less than or equal to 0. 156 inches were retrofitted with reinforcing caps in the field. Mtms containing spring guides with gaps larger than 0. 156 inches were returned through the rma process and spring guides were replaced prior to reinforcing cap installation. All affected systems have been retrofitted with the reinforcing caps. In addition, reemphasis of warnings listed in the approved user manual labeling provided with each system warning: once in following, the surgeon console operator must not remove his or her hands from the masters until removing his or her head from the surgeon console viewer - thereby taking the system out of following mode. Failure to do so may result in uncontrolled movement of the masters, resulting in serious harm to the patient. Has been provided to all affected sites.</p> <p>Manufacturer Narrative: The master tool manipulator refers to the master controller which provides the means for the surgeon to control the instruments inside the patient from the surgeon's side console. One mtm is assigned to the surgeon's left hand (mtml) and one to his right (mtmr). The instruments follow the motions of the mtms to conduct the procedure, which is referred to as following mode. As a safety feature, when the surgeon removes his head from the viewer portion of the surgeon console, the instruments freeze in position. An investigation was conducted by a local isi field service engineer (fse) following the event. The fse was unable to reproduce the reported event; however, the <u>fse did observe that the mtmr spring guide component had failed</u>. The system was repaired by replacing the affected mtmr, and the original mtmr was returned for analysis. The spring guide component that was found to be damaged contains two springs, which are part of the gravity compensation strategy for the shoulder and elbow joints of the mtm, which are joints that support the mtm handles that the surgeon grasps with his or her fingers. The spring guide secures the springs in place such that motion of the joint compresses the springs, partially counteracting the force of gravity. The spring counterbalance is supplemented by a motorized</p>		

gravity compensation algorithm. For the comfort and precision of the surgeon, the spring and motor compensation is to reduce the apparent weight of the robotic arm as perceived by the surgeon. It is believed that in instances where the spring guide component has failed, the gravity compensation system can be compromised, resulting in a maximum imbalance of 0.6 lbs. Thus, if contrary to the below warning included in the product labeling, the surgeon releases his grip on an mtm while his or her head is in the viewer, this component failure may cause the mtm and its associated instrument, to move in an uncontrolled manner. If the surgeon complies with the label warning below, no uncontrolled motion should occur. The da vinci si user manual warning states: warning: once in following, the surgeon console operator must not remove his or her hands from the masters until removing his or her head from the surgeon console viewer - thereby taking the system out of following mode. Failure to do so may result in uncontrolled movement of the masters, resulting in serious harm to the patient. A corrective action is underway to install metal reinforcing caps for the retention component in the mtms on all is3000 systems to prevent the failure of the spring guide component. Additional information concerning the corrective action is provided with the fedex copy of this report. (b)(4).

MAUDE Report 2644122

Event Date: 06/13/2012	Event Type: Injury	Patient Outcome: Required Intervention
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Event Description: It was reported that during a robotic hysterectomy procedure, using dual surgeon side consoles (ssc) the surgeon working from ssc 1 experienced resistance while manipulating the master tool manipulators (mtm) and when the surgeon let go of the mtms on the ssc1 the patient's abdominal wall was damaged. The site contacted isi technical support engineering (tse) for trouble-shooting assistance. With the assistance of the tse, the site switched from dual ssc setup to single ssc setup to proceed with the planned surgical procedure. Resistance on the ssc 2 mtms was not experienced by the surgeon. The tse asked the initial reporter if the surgeon working from ssc1 had removed head from the high resolution stereo viewer (hrsv) prior to releasing the his hands from the mtms; however, the surgical staff was unable to provide this information. Review of the site's system log by the tse found recoverable system error code 23002 occurred on the mtmr at the time of the customer's report. The planned surgical procedure was completed.

Manufacturer Narrative: The field investigation conducted by the fse concerning this event was unable to replicate the issue experienced by the site. However, after manipulating the mtm on ssc1 the fse was able to induce the recoverable system error code 23002 and concluded that the system error code was related to the mtmr; however, he did not note any resistance on the mtmr or the patient side manipulators. The master tool manipulator refers to the master controllers which provide the means for the surgeon to control the instruments and endoscope inside the patient from the surgeon's side console. One mtm is assigned to the surgeon's left hand (mtml) and one to his right (mtmr). The reported resistance from the surgeon and the 23002 are both consistent with an inaccurate calibration, since the gravity compensation algorithm on the master relies on an accurate measurement of the arm position. Gravity compensation is provided for the comfort of the surgeon and is not intended to allow them to release their grip on the master while in following. As a precaution, the fse calibrated the mtms on ssc 1. The patient injury most likely occurred as a result of the surgeon's removal of his hands from the mtms prior to removal of his head from the high resolution stereo viewer. The da vinci si user manual warning(s) specifically states: once in following, the surgeon console operator must not remove is or her hands from the masters until removing his or her head from the surgeon console viewer-thereby taking the system out of following mode. Failure to do so may result in uncontrolled movement of the masters, resulting in serious harm to the patient. The previous calibration of the mtm occurred on june 12, 2012 during a routine preventative maintenance (pm) on the site's system. The fse reported issues with his laptop while calibrating the master tool manipulator (mtms) on ssc 1. With the assistance of isi dvstat support, it was determined that the fse's laptop had malfunctioned and the calibration files were restored to site's system. A sine cycle and test drive of the system was performed by the fse found that the system performed within specification.

MAUDE Report 966367

Event Date: 10/20/2006	Event Type: Other	Patient Outcome: N/A
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Event Description: During a laparoscopic assisted vaginal hysterectomy, the surgeon placed the maryland bipolar shears on the pt's abdomen. He inadvertently stepped on the foot pedal, causing a 2 mm superficial burn to the pt's abdomen. A contributing factor was that the gyn laparoscopic pack was not available; this pack contains an instrument pouch which would have held the shears. The or was also out of the alternative instrument pouch.

Manufacturer Narrative: The instrument was not returned for evaluation. The info provided indicates that, the surgeon inadvertently stepped on the cautery foot pedal while the instrument was lying dormant on the pt's abdomen. Based on this info, it has been determined that the pt cautery burn was caused by user error.

MAUDE Report 1016400

Event Date: 02/22/2008	Event Type: Other	Patient Outcome: Other
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Event Description: It was reported that towards the end of a robotic myomectomy procedure, while the surgeon was attempting to cauterize tissue in the patient's abdomen, he noticed sparking coming from an area around the uterus. Upon further inspection, the surgeon located a burn mark on the patient's uterus. The surgeon immediately stopped using and the monopolar curved scissors instrument (mcs) and the mcs tip cover accessory was inspected, at that time, a hole in the mcs tip cover was noticed. The mcs tip cover was replaced and the planned procedure was completed with approximately a 15 minute delay. No additional patient harm, adverse outcome or injury was reported.

Manufacturer Narrative: The msc tip cover accessory was returned and evaluated. Per the customer reported complaint, engineering observed four distinct holes in the silicone. Three holes are spaced relatively close together on one side of the silicone, and the fourth hole is roughly 90 degrees from the other holes. The holes range in size from. 010" to. 030" and are. 150" to. 315" above the silicone to sleeve interface. Localized melting of silicone suggests failure is due to multiple arcing events through the sleeve. Also observed were a couple of scratches on the inside surface of the silicone near the three holes. Arcing may be due to prolonged cautery in combination with damage in silicone. Engineering believes it is possible instrument collisions may have damaged the silicone on the inner or outer surface, weakening the electrical insulating capacity and creating a path for energy to escape. No other damage was found. The endowrist instruments instructions for use (ifu) specifically states: general precautions and warnings. Handle instruments with care. Avoid mechanical shock or stress that can cause damage to the instruments. Do not use an instrument to clean debris from another instrument intraoperatively. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument.

MAUDE Report 2494890

Event Date: 02/16/2012	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported that during a da vinci s coronary artery bypass graft (cabg) procedure, arcing from the micro bipolar forceps instrument was observed when the surgeon was not applying cautery energy. The site contacted isi technical support engineering (tse) for troubleshooting assistance, however, the site declined support, as the surgeon did not have time to trouble shoot the issue with the tse. The planned surgical procedure was completed and no patient harm adverse outcome or injury was reported.

Manufacturer Narrative: On (b)(6) 2012, intuitive surgical received uf/importer report (b)(4) from the fda. The event details are provided below: event description: patient for a cabg with a da vinci robot. Surgeon attempted to use the da vinci bipolar forceps, but they did not work. Circulator checked the electrosurgical unit (esu and noted that ground pad (return electrode for esu was not plugged in. Ground pad connected. Surgeon stated there was no noise and the foot pedal was not depressed, but as soon as the surgeon touched the diaphragm with the bipolar forceps, the machine buzzed and the diaphragm had a small burn. Circulator checked the esu and noted that the forceps cable was plugged into two of the three monopolar 2 sockets. Bipolar was plugged into bipolar sockets, machine functioned normally throughout the rest of the case. Patient had two (2) ground pads on, unsure which was the actual lot number involved in event. Based on the additional information provided in the site's u/f report (b)(4) indicating that the patient's diaphragm was burned, on (b)(6) 2012, isi contacted risk manager, (b)(6) to advise that during isi's initial investigation into the reported event, it was reported by the site's da vinci coordinator, (b)(6) initial reporter) that no patient harm, adverse outcome or injury occurred. (b)(6) indicated that contrary to the initial information provided, a burn to the patient's diaphragm occurred, however, no repair of the affected area was required, the planned surgical procedure was completed, and there was no report that the patient experienced any post-operative complications. She does not know if the patient has had to return to the hospital due to any post-operative complications related to the reported event. As indicated in isi's initial medwatch report submitted to the fda on (b)(4) 2012, isi's investigation into the reported event found that the issue experienced by the site was due to improper connection of the micro bipolar forceps instrument to the electrical surgical unit (esu). The instruments and accessories user manual specifically states: general precautions and warnings o please refer to the individual esu manufacturer's operator's manual for operating instructions. Set the esu to bipolar output. Set the power as low a possible to achieve adequate hemostasis - do not use bipolar instruments with a monopolar source output as this may cause damage to the instrument and harm to the patient or medical personnel system functional testing performed by the fse found that the system functioned within specification. The investigation conducted by field service engineering (fse) found that the issue experienced by the site was due to improper connection of the micro bipolar forceps instrument to the electrical surgical unit (esu). The hospital's biomedical department indicated to the fse that during the surgical procedure, the micro bipolar forceps instrument was found to be incorrectly plugged into the monopolar connection output on the electrical surgical unit (esu). The site immediately resolved the issue by connecting the instrument to the bipolar connection site output on the esu as indicated in our ifu. The instruments and accessories user manual specifically states: general precautions and warnings o please refer to the individual esu manufacturer's operator's manual for operating instructions. Set the esu to bipolar output. Set the power as low a possible to achieve adequate hemostatsis o do not use bipolar instruments with a monopolar source output as this may cause damage to the instrument and harm to the patient or medical personnel system functional testing performed by the fse found that the system functioned within specification. On (b)(4) 2012, isi followed up with the initial reporter at university of medical center and he confirmed that no patient harm, adverse outcome or injury occurred. The patient tolerated the planned surgical procedure well and has not returned to the hospital due to any post operative complications. As of (b)(4) 2012, there have been no reported recurrences of the issue at this hospital.

MAUDE Report 3293519

Event Date: 07/17/2013	Event Type: Malfunction	Patient Outcome: N/A
<p>Event Description: It was reported that during a robotic hysterectomy procedure, the surgical staff encountered an error 23017 system fault. At the time the error occurred, the surgeon was reportedly cauterizing. <u>The surgeon claimed that she let go of the foot pedal and the master tool manipulator (mtm) moved on its own causing the instrument to burn the patient's uterus.</u> The surgical staff was able to override the error message and the surgical procedure was completed. The initial reporter of this complaint, a nurse, indicated that there was no harm or injury to the patient since the uterus was removed.</p> <p>Manufacturer Narrative: The fse reviewed the system logs for the site and found the error 23017 pointing to the right mtm. The master tool manipulator refers to the master controllers which provide the means for the surgeon to control the instruments and endoscope inside the patient from the surgeon's side console. One mtm is assigned to the surgeon's left hand (mtml) and one to his right (mtmr). The fse resolved the reported error 23017 issue by replacing the right mtm. The fse also indicated that the surgeon eye piece on the high resolution stereo viewer (hrsv) needed replacement for an unspecified reason. The fse replaced the surgeon eye piece. The fse tested the system and verified that the system was ready for use. The mtm was returned to isi and evaluated. During the first power up of the mtm, an error code of 23017 for axis 1 was triggered. Engineering restarted the mtm three more times and was unable to replicate the error. Engineering also sine cycled the arm for 4 hours and the mtm did not trigger any 23017 errors. Engineering also check all motor cables and connections and no issues were found. When the right mtm triggers 23017 fault the following is triggered: right mtm disengages with psm and turns off all amps and the left mtm soft locks. If energy is activated via foot pedal, activation stops; however, if the foot pedal is pressed again, energy will be activated. All psms will soft lock during a 23017 fault. Energy would have stopped immediately at the time of the 23017 fault. In the system logs there is nowhere to verify if the surgeon stepped on the pedal again to activate the energy. Isi reviewed the system logs for this site with this error 23017 and the system worked as intended during the fault. The right mtm turning the amps off correlates with the reporter's claim of the mtm moving. Any psm motion that may have occurred after the fault is not driven by the affected right mtm. If the instrument was in motion at the time of the fault, there is some possible tip motion as the arm quickly 'coasts to a stop'. At this time there is no information on how far the instrument moved in order to contact the uterus. Engineering evaluation indicated that the mtm triggered several error codes of 23 and 30 which indicated a wheel communication issue. Engineering found an intermittent and faulty connection on the motor power connector and main communication error of the main harness leading to the embedded serializer (esmb) printed circuit assembly (pca). On august 13, 2013, isi contacted the surgeon who performed the reported surgical procedure. She indicated that the surgical procedure was not recorded and the error 23017 occurred approximately half way through the hysterectomy procedure. According to surgeon, the right mtm moved on its own towards the posterior of the console while her fingers were within the velcro loops. She claimed that the mtm movement ripped the velcro loops from her fingers. She also indicated that she was cauterizing with a monopolar curved scissors (mcs) instrument installed on the right patient side manipulator (psm) and her head was within the hrsv when the right mtm moved on its own. The psm is an instrument arm located on the patient side cart (psc) that provides sterile interface for the endowrist instrument. She could not recall if the mcs instrument was colliding with another instrument or anatomy when the mtm moved on its own. <u>When the right mtm moved, she removed her foot from the foot pedal. However, the surgeon claimed that the mcs instrument burned the patient's uterus when the mtm moved on its own.</u> Since the right mtm moved to the back of the console and was out of reach, the surgeon indicated that she had to go below the console to re-grab the right mtm. After contacting an isi technical support engineer (tse) for assistance, the surgical staff was able to override the error 23017 message. The surgeon indicated that she was able to complete the da vinci si hysterectomy procedure with no further issues. She denied that the patient sustained any intra-operative or post-operative complications. The surgeon indicated that she has had no recurrences of the reported error message or mtm issue since the event occurred. As of the date of this report, there have been no reported reoccurrences of the reported issue by the site. Based on the information provided, this complaint is being reported due to the following conclusion: the surgeon claimed that at the time an error 23017 system fault occurred, she let go of the foot pedal and the instrument tip moved at the time of the fault to come into contact with the uterus and cause damage. However, at this time, there is no indication that the patient sustained a serious injury due to the reported issue. This report does not admit that the report or information submitted under this report constitutes an admission that the device, intuitive surgical or intuitive surgical employees, caused or contributed to the reportable event.</p>		

MAUDE Report 2970427

Event Date: 01/21/2013	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported that during a robotic hysterectomy procedure, the fenestrated bipolar forceps instrument activated without the surgeon activating cautery energy from the foot pedal on the surgeon side cart. No patient harm was reported.

Manufacturer Narrative: The instrument was returned and evaluated. Engineering was unable to confirm the customer reported failure mode. The instrument passed recognition and engagement testing when tested on an isi in-house is3000 system. The instrument moved intuitively with a full range of motion in all directions, the grips opened and closed properly and performed cautery function with no trouble found. On (b)(6) 2013, isi contacted the isi clinical sales representative that was present during the surgical procedure. The csr indicated that approximately 30 - 40 minutes into the surgical procedure, while the surgeon was grasping tissue that was being dissected for removal, the surgeon observed energy coming from the fenestrated bipolar forceps instrument without any activation of cautery energy from the foot pedal on the surgeon side cart (ssc). The csr indicated that the site performed troubleshooting of the issue and when the surgeon attempted to grasp tissue a 2nd time, the issue recurred. The csr indicated energy activated a 3rd time from the instrument when the surgeon demonstrated to him what had occurred during troubleshooting. The csr indicated that the fenestrated bipolar forceps instrument was immediately replaced and the issue was resolved. The csr indicated that a valley lab force triad electrical surgical unit (esu) and a valley lab disposable esu cable were used in conjunction with the fenestrated bipolar forceps instrument. The csr indicated that it is unknown if the site inspected the esu prior to use; however, the site did inspect the esu during troubleshooting and found that the esu cable was installed properly. The csr indicated that the settings on the ssc were correct and that the surgical procedure was not recorded. The csr indicated that the surgical procedure was completed and there was no impact to the patient, except to the tissue being removed as part of the surgical procedure. The csr also indicated that there was no report by the surgeon that the patient experienced any post-surgical complications as a result of the reported event. On (b)(6) 2013, the site's da vinci si surgical system was evaluated by an isi field service engineer. The fse was unable to replicate the failure mode experienced by the site as inspection of the site's surgical system found that it functioned within specifications. As of (b)(6) 2013, there have been no reported recurrences of the issue at this hospital.

MAUDE Report 2567858

Event Date: 04/09/2012	Event Type: Death	Patient Outcome: Death
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Event Description: It was reported that approximately 45 minutes into a da vinci si procedure when the assistant at the patient side cart (psc) performed a tool change to switch the instruments in the patient side manipulator (psm) arms, the patient's aorta was punctured. The surgeon made the decision to convert to traditional open surgical techniques to complete the planned surgical procedure. The patient was reported to be in stable condition right after the open surgical procedure, however, the patient expired the following day. The site has been contacted for additional information, however, no additional information has been forthcoming.

Manufacturer Narrative: The isi clinical sales representative followed up with the assistant rn and the rn indicated that the patient side assistant had not received training by the site on how to perform a guided tool change. Based on the information provided, the puncturing of the patient aorta is the result of an incorrect instrument change. The surgeon had requested that instruments located on the patient side manipulators (psm) arms be swapped, such that the instrument on psm arm 1 would be switched with the instrument located on psm arm 2. It is not clear whether the assistant nurse used a guided tool change to safely change instruments or whether the nurse used the arm clutch to insert the instrument manually. It is unclear whether any malfunction of the system occurred and the exact mechanism which resulted in puncturing of the aorta. The site has been contacted for additional information and once this information has been received, a follow up report will be sent to the fda. The da vinci si instructions for use (ifu) specifically states: warning: the instrument may not be immediately visible when being moved from the cannula into the patient. Use appropriate caution when manually inserting instruments into the patient.

MAUDE Report 1891889

Event Date: 08/26/2010	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported that prior to starting a da vinci si hysterectomy procedure, the site received a vision system error. The isi representative on site began to troubleshoot and found the left eye on the surgeon side console was not working. The surgeon and or staff were notified of the system status; however, the surgeon decided to perform the case with one eye working in 2d vision. During the procedure the patient's ureteral was injured and a urologist was called in to perform the repair and place a stent. At this time the case was converted to traditional open surgical techniques to repair the patient's ureteral and complete the planned procedure. The patient was required to stay in the hospital an additional 24-48 hours due to the open incision as well as the stent removal. On (b)(4) 2010, intuitive surgical received maude event report (b)(4) for this event.

Manufacturer Narrative: The investigation conducted by field service engineering found the camera cable had a bad left eye channel. The camera cable connects the camera to the system's vision cart, which then transmits the image to the surgeon side console. The system was repaired by replacing the defective camera cable. As of november 4, 2010, there have been no reported recurrences of the issue at this hospital.

MAUDE Report 1760256

Report Date: 06/17/2010	Event Type: Injury	Patient Outcome: Disability
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Event Description: It was reported that during a da vinci s prostatectomy procedure performed on (b)(6) 2008, the surgeon experienced interference in the left eye image viewed from the surgeon's console. The surgeon switched the image from 3-dimensional (3-d) to 2-dimensional (2-d) to proceed with the procedure. The planned surgical procedure was successfully completed and no patient harm, adverse outcome or injury was reported. The customer-reported-event does not in itself constitute a reportable event, however, on june 17, 2010, isi received a legal summons and complaint filed by the patient, alleging that due to the amount of time added by completing the surgery in 2-d (the surgery lasted over 8 hours) the patient sustained a severe and permanent right leg injury, specifically right calf compartment syndrome. The complaint further alleges that the patient has undergone numerous and extensive medical procedures, including surgery and therapy.

Manufacturer Narrative: The investigation conducted by the field service engineer concluded that the vision issue experienced by the customer was associated with a faulty camera cable. The camera cable connects the camera to the system's vision cart, which then transmits the image to the surgeon's console. The system was repaired by replacing the affected camera cable. The camera cable was returned to the original equipment manufacturer (oem) for evaluation. The oem observed that the left channel of the camera cable had a loose connection, thus causing the vision issue experienced by the customer. The da vinci s surgical system user's manual explicitly states that, environmental or equipment failures may cause the da vinci s system to become unavailable. The surgical team should always have backup equipment and instrumentation available, and be prepared to convert to alternative surgical techniques.

MAUDE Report 3206001

Report Date: 06/04/2013	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported that during a da vinci s mitral valve repair procedure, the instrument installed on patient side manipulator (psm) arm 1 was not rotating. With the assistance of an intuitive surgical, inc. (isi) technical support engineer (tse) the site installed different instruments and reseated the sterile adapter, however, the issue persisted. The site indicated that the surgeon encountered the issue every time he changed psms. The site advised the tse that they were continuing with the case. Approximately 1 hour later, the site called isi back for technical support assistance. The site indicated to the tse that the system was not working correctly and that the psm was shaking. The site declined to troubleshoot the issue with the tse, as they were in the middle of the procedure. The site requested that the tse dispatch an isi field service engineer to evaluate the system.

Manufacturer Narrative: During the field investigation performed by the intuitive surgical, inc. (isi) field service engineer (fse), the fse learned that the surgeon made the decision to convert the planned surgical procedure to open, due to the patient's heart having been punctured. The fse was also told by the site's nurse manager that a power fluctuation or loss occurred during the surgical procedure. However, the nurse manager indicated that it is unknown if the power issue contributed to the issue experienced by the site. The fse was unable to replicate shaking on patient side manipulator (psm) 1 during functional testing of the system using test instruments. Isi contacted the initial reporter and she indicated that the psm was not shaking, as initially reported, but while retracting tissue, the force of the was not as strong as normal and the patient's tissue was slipping. Isi engineering also the site's system logs and confirmed that the system lost ac power during the surgical procedure and the ac power was restored after 2 minutes. No other system error codes were generated that would have caused or contributed to the issue experienced by the site. During evaluation of the site's system, the fse found that the friction was high for axis 4 on psm 1 and the friction was high for axis 1 on psm 2. Psm 1 and psm 2 were replaced to repair the system. Psm 1 and psm 2 were returned for evaluation. Engineering evaluation found that psm 1 failed friction testing for axis 1 and axis 2. The harmonic drives for axis 1 and 2 were replaced to repair psm 1. Engineering evaluation of psm 2 found that axis 4 failed friction testing. The upper pulleys for link 5 and 6 were sliding off the bearing, adding unwanted friction. The pulley assemblies were replaced to repair psm 2. Engineering was unable to replicate the issue experienced by the site, as psm 2 passed software testing, and normal mode testing using isi in-house test sterile adapters and instruments. The psm's cannula mount was found to be current and within specification. As a precaution, an embedded serializer for the instrument interface (esii) board was replaced. On (b)(6) 2013, isi contacted the surgeon who performed the surgical procedure. The surgeon indicated that he was performing a left dynamic atrial retraction using an atrial retractor instrument when the puncture to the patient's heart occurred. The surgeon indicated that it was his belief that the damage to the patient's heart was due to a malfunction of the psm. The surgeon also believes that the malfunction of the psm occurred as a result of wear and tear to the system over time. The surgeon indicated that the surgical staff should have inspected the system prior to his use of the system to ensure that it was functioning properly. The surgeon indicated that the patient tolerated the open procedure well and was discharged from the hospital. The patient is recovering well and has not returned to the hospital due to experiencing any post-surgical complications as a result of the reported event. This complaint is being reported due to the patient sustained an injury during a da vinci s mitral valve repair procedure.

MAUDE Report 2476271

Report Date:	02/02/2012	Event Type:	Injury	Patient Outcome:	Required Intervention
<p>Event Description: It was reported that during a da vinci hysterectomy procedure, after the bipolar cord was connected to the electrosurgical unit, energy was released from the bipolar instrument. As a result, an injury to the patient's bowel occurred. The bowel damage was secured by suture and the planned surgical procedure was completed. No additional harm was reported.</p> <p>Manufacturer Narrative: The hospital has been contacted multiple times for further details and information concerning this incident. To date, no response has been received. As a result, the root cause of the reported event cannot be determined. A follow-up medwatch report will be submitted if additional information is received. On (b)(6) 2012, the hospital provided intuitive surgical a copy of medwatch uf/importer report (b)(4), which contained the following information: clinical engineering analysis: when connecting the bipolar cord to the esu, apparently the nurse inadvertently plugged the cord into the monopolar jack instead of the bipolar jack. Since the tips of the bipolar forceps were closed, this triggered the monopolar cut mode of the esu and it began delivering energy. Staff noticed the esu tone and smoke visible on the video display and immediately shut off the power to the esu. The monopolar jack on the esu has three holes. Connecting the two outer holes will activate the cut mode, as this is how the normal pencil switch works. The disposable bipolar cord has individual banana plugs on the machine end, which makes it possible to plug into the wrong jack. If the machine end had a single molded connector, the spacing of bipolar pins would prevent plugging into a monopolar jack. Per the additional information provided above, intuitive surgical concluded that the issue experienced by the hospital was due to improper connection of the bipolar instrument to the electrosurgical unit (esu). The instruments and accessories user manual specifically states: caution: please refer to the individual esu manufacturer's operator's manuals for operating instructions. Set the esu to bipolar output. Set the power as low as possible to achieve adequate hemostasis. Warning: do not use bipolar instruments with a monopolar source output as this may cause damage to the instrument and harm to the patient or medical personnel.</p>					

MAUDE Report 2494890

Report Date: 02/16/2012	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported that during a da vinci s coronary artery bypass graft (cabg) procedure, arcing from the micro bipolar forceps instrument was observed when the surgeon was not applying cautery energy. The site contacted isi technical support engineering (tse) for troubleshooting assistance, however, the site declined support, as the surgeon did not have time to trouble shoot the issue with the tse. The planned surgical procedure was completed and no patient harm adverse outcome or injury was reported.

Manufacturer Narrative: On (b)(6) 2012, intuitive surgical received uf/importer report (b)(4) from the fda. The event details are provided below: event description: patient for a cabg with a da vinci robot. Surgeon attempted to use the da vinci bipolar forceps, but they did not work. Circulator checked the electrosurgical unit (esu and noted that ground pad (return electrode for esu was not plugged in. Ground pad connected. Surgeon stated there was no noise and the foot pedal was not depressed, but as soon as the surgeon touched the diaphragm with the bipolar forceps, the machine buzzed and the diaphragm had a small burn. Circulator checked the esu and noted that the forceps cable was plugged into two of the three monopolar 2 sockets. Bipolar was plugged into bipolar sockets, machine functioned normally throughout the rest of the case. Patient had two (2) ground pads on, unsure which was the actual lot number involved in event. Based on the additional information provided in the site's u/f report (b)(4) indicating that the patient's diaphragm was burned, on (b)(6) 2012, isi contacted risk manager, (b)(6) to advise that during isi's initial investigation into the reported event, it was reported by the site's da vinci coordinator, (b)(6) initial reporter) that no patient harm, adverse outcome or injury occurred. (b)(6) indicated that contrary to the initial information provided, a burn to the patient's diaphragm occurred, however, no repair of the affected area was required, the planned surgical procedure was completed, and there was no report that the patient experienced any post-operative complications. She does not know if the patient has had to return to the hospital due to any post-operative complications related to the reported event. As indicated in isi's initial medwatch report submitted to the fda on (b)(4) 2012, isi's investigation into the reported event found that the issue experienced by the site was due to improper connection of the micro bipolar forceps instrument to the electrical surgical unit (esu). The instruments and accessories user manual specifically states: general precautions and warnings o please refer to the individual esu manufacturer's operator's manual for operating instructions. Set the esu to bipolar output. Set the power as low a possible to achieve adequate hemostasis - do not use bipolar instruments with a monopolar source output as this may cause damage to the instrument and harm to the patient or medical personnel system functional testing performed by the fse found that the system functioned within specification.

The investigation conducted by field service engineering (fse) found that the issue experienced by the site was due to improper connection of the micro bipolar forceps instrument to the electrical surgical unit (esu). The hospital's biomedical department indicated to the fse that during the surgical procedure, the micro bipolar forceps instrument was found to be incorrectly plugged into the monopolar connection output on the electrical surgical unit (esu). The site immediately resolved the issue by connecting the instrument to the bipolar connection site output on the esu as indicated in our ifu. The instruments and accessories user manual specifically states: general precautions and warnings o please refer to the individual esu manufacturer's operator's manual for operating instructions. Set the esu to bipolar output. Set the power as low a possible to achieve adequate hemostatsis o do not use bipolar instruments with a monopolar source output as this may cause damage to the instrument and harm to the patient or medical personnel system functional testing performed by the fse found that the system functioned within specification. On (b)(4) 2012, isi followed up with the initial reporter at university of medical center and he confirmed that no patient harm, adverse outcome or injury occurred. The patient tolerated the planned surgical procedure well and has not returned to the hospital due to any post operative complications. As of (b)(4) 2012, there have been no reported recurrences of the issue at this hospital.

MAUDE Report 3024317

Report Date: 02/11/2013	Event Type: Injury	Patient Outcome: Other
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Event Description: It was reported that during a da vinci si prostatectomy procedure, when the surgeon activated bipolar cautery energy from the footpedal on the surgeon side cart, cautery energy from the monopolar curved scissors (mcs) instrument was activated causing a burn to the patient's bowel.

Manufacturer Narrative: On (b)(4) 2013 an inspection of the site's da vinci si system conducted by an isi field service engineer (fse) was unable to replicate the cautery issue experienced by the site. Functional testing performed on the site's system by the fse found that the site's da vinci si surgical system functioned within specification. On (b)(4) 2013 isi contacted the isi clinical sales representative (csr) who reported this event. The csr indicated that she met with the operating room director and operating room scrub technician at the site on (b)(4) 2013 and the operating room scrub technician indicated to her that automatic activation of cautery energy was due to the surgical staff had incorrectly connected the electrical surgical unit (esu) cables into the improper receptacles on the esu. The scrub technician indicated that the esu connections were corrected, and the issue was resolved. The planned surgical procedure was completed. A general surgeon at the hospital was consulted to access the damage to the patient's bowel burn. The general surgeon's assessment of the burn to the patient's bowel determined that no repair of the affected area was required. On (b)(4) 2013, isi contacted the surgeon who performed the surgical procedure. The surgeon indicated that while he was retracting the patient's bowel using the maryland bipolar forceps instrument, he heard the alarm from the esu and immediately stopped using the maryland bipolar forceps instrument. The surgeon indicated that he had not touched the footpedal and that the instrument activated when he had not pressed the footpedal. The surgeon indicated that the patient sustained a small burn injury to the sigmoid colon and that he attempted to consult with a general surgeon concerning the patient's injury; however, there was no general surgeon available at that time. The surgeon indicated that he assessed the damage to the patient's bowel and he determined that the damage did not require any repair. The surgeon indicated that the patient remained in the hospital an additional day for monitoring and that the patient was discharged from the hospital. The surgeon indicated that the patient is recovering well and has not returned to the hospital due to experiencing any post-surgical complications as a result of the reported event. Intuitive surgical's instruments and accessories user manual precautions and warnings indicate: caution: please refer to the individual esu manufacturer's user manual for operating instructions. Warning: do not use monopolar instruments with a bipolar source output as this may cause damage to the instrument and harm to the patient or medical personnel. This report does not admit that the report or information submitted under this report constitutes an admission that the device, intuitive surgical or intuitive surgical employees, caused or contributed to the reportable event.

MAUDE Report 3473388

Report Date: 10/18/2013	Event Type: Injury	Patient Outcome: Required Intervention
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Event Description: On (b)(6) 2013, the user facility contacted an intuitive surgical, inc. (isi) clinical sales representative (csr) during a da vinci myomectomy procedure and requested her to come in because multiple instruments kept breaking. When the csr arrived, she noted that the port placement was incorrect for the type of surgical procedure and the vision was obscured, not allowing the instrument tips to be viewed. The csr stated that the surgeon was resistant to her recommendations but finally agreed to move the camera port for a better view of the instruments. According to the csr, the surgeon repeatedly over rotated the master tool manipulator (mtm) and kept losing view of the instrument's tips. The master tool manipulator refers to the master controllers which provide the means for the surgeon to control the instruments and endoscope inside the patient from the surgeon side console. The instruments were being pushed against the myoma with enough force that it was causing the

instruments to break. The csr stated she witnessed the instrument cables breaking on a maryland bipolar instrument. The csr observed that the view of the monopolar curved scissors (mcs) instrument tips was lost and the surgeon was engaging the mcs instrument as if he was cutting tissue and the patient sustained a possible artery nick in the right pelvic side wall. The da vinci procedure was then converted to an open surgical procedure. The csr was unable to obtain information regarding the broken instruments that were used prior to her arrival. The following day, an isi field service engineer (fse) went onsite and did not find any issues with the da vinci system and verified that the da vinci system was ready for use. On (b)(6) 2013, the user facility reported damage to 4 different instruments that were used during this reported event. On (b)(6) 2013, isi spoke with the csr. The csr stated that the patient's right external iliac vein was transected. She was unable to provide additional information regarding the injury and details regarding the reason why the surgeon converted the procedure to an open surgical procedure. She also stated that the surgeon had not performed any da vinci surgeries between (b)(6) 2012 and (b)(6) 2013. The csr reported that she had offered the surgeon supplemental training sessions prior to the procedure but they were not undertaken. On (b)(6) 2013, an isi clinical consultant spoke with the bed-side assistant surgeon to the da vinci surgeon performing the case. He confirmed that the patient's right iliac vein was lacerated and the procedure was converted to an open surgical procedure to repair the injury. He confirmed that the da vinci surgeon had difficulty operating with the da vinci system. He recalled there was over rotation of the master tool manipulator (mtm) and some degree of frustration in keeping all instrumentation in view. It was then that injury occurred, although his attention at the exact moment of the damage was on a different part of the screen. He did not think that the injury happened out of view of the camera.

Manufacturer Narrative: On (b)(6) 2013, the user facility reported damage to 4 different instruments that were used during this reported event. Review of the system log confirmed that the reported instruments were 4 of the 5 instruments that were used during the reported da vinci procedure. The 4 instruments involved with the reported event have been returned to isi and evaluated. Failure analysis investigations noted the following findings: instrument 1: monopolar curved scissors (mcs) (part 420179, lot m14130619-891): findings: tube extension was found broken and was missing a piece at the distal end. Instrument 2: monopolar curved scissors (part 420179, lot m14130619-047): findings: tube extension was found broken and was missing a piece at the distal end. Instrument 3: permanent cautery spatula (part 420184-06 , lot m10120523-783): findings: broken ceramic sleeve, heavy biodebris and black burnt or char marks residing around the spatula, and an uneven piece of the ceramic sleeve was missing, exposing the shaft of the spatula. There was also a derailed yaw cable at the instrument's wrist and both pitch cables were broken. Please reference mdr with patient identifier (b)(6). Instrument 4: maryland bipolar forceps (part 420172-07 , lot m10130819): findings: broken pitch cable at the proximal clevis hub. Please reference mdr with patient identifier 700108065. Investigation noted that the damage found on the 2 mcs instruments and permanent cautery spatula are likely due to misuse or mishandling. The instruments & accessories instructions for use (ifu) specifically states: handle instruments with care. Avoid mechanical shock or stress that can cause damage to the instruments. Based on the provided information, isi has not determined the root cause of the intra-surgical complications experienced by the patient. If additional information is received a follow up medwatch report will be submitted to the fda. This complaint is being reported due to the following conclusion: the patient sustained an injury during a da vinci surgical procedure and the procedure was converted to an open surgical procedure.

MAUDE Report 2963870

Report Date: 01/16/2013	Event Type: Injury	Patient Outcome: Required Intervention, Life Threatening
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Event Description: It was reported that during a da vinci si splenectomy procedure, the surgeon nicked the patient's splenic vein, causing bleeding from the vessel. The surgeon successfully occluded the patient's splenic vein utilizing the da vinci vessel sealer instrument; however, the surgeon made the decision to repair the vessel using open surgical techniques, as it was his decision that damage to the patient's vessel could not be repaired using the da vinci si surgical system. The surgeon attempted to release the vessel sealer instrument from the patient's vessel using the emergency release tool; however, the surgeon was unable to release the instrument. Since the surgeon was unable to release the instrument using the emergency release tool, he pulled the instrument from the patient's vessel, thus causing additional damage to the patient's vessel. Reportedly, the additional damage to the patient's vessel was a small tear.

Manufacturer Narrative: On (b)(4) 2013, additional information regarding the event was provided by the isi representative who initially reported this event. The isi representative indicated that he was not present during the surgical procedure and that it is unknown why the surgeon did not release the vessel sealer instrument utilizing the master tool manipulators (mtm) on the surgeon side cart. The isi representative indicated the site reported to him that no malfunction of the da vinci si surgical system, instruments and/or accessories occurred during the surgical procedure that caused the injuries to the patient's vessel. The isi representative indicated that the site reported to him that the system was not in an error state when the surgeon attempted to release the instrument from the patient's vessel at the patient side cart and that the surgeon removed the vessel sealer instrument from the patient's vessel after converting the procedure to open. The isi representative indicated that he advised the site that the surgeon could have released the jaws of the instrument from the patient's vessel using the mtms on surgeon side console since the system was not in an error state or if the system had been in an error, the jaw on the instrument could have been opened by manipulating the thumbwheel located on the housing of the instrument. The csr indicated that the site made the decision not to return the vessel sealer instrument to isi for failure analysis, since no malfunction of the instrument occurred. The master tool manipulator (mtm) refers to the master controllers which provide the means for the surgeon to control the instruments and endoscope inside the patient from the surgeon's side console. One mtm is assigned to the surgeon's left hand (mtml) and one to his right (mtmr). The thumbwheel is located on the side of the vessel sealer housing and allows the user to manually open and close the instrument jaws for intraoperative cleaning and emergency grip release. The csr indicated that he has re-trained the site on how to properly release and remove the vessel sealer instrument should this type of event recur. The endowrist one vessel sealer system user manual specifically states: general precautions and warnings - in case of system failure while the instrument is grasping tissue, open the instrument jaws by turning the thumbwheel in the direction of the arrow to release the tissue. Once the tissue is released, close the jaws (in this case, it is ok to close the jaws on an exposed blade). Squeeze the release levers and carefully withdraw the instrument. - after removal of the instrument during a system or instrument failure, use caution when opening the jaws using the thumbwheel, to avoid potential injury due to an exposed cutting blade. Based on the information provided, it was determined that the da vinci si surgical system did not malfunction in a way that would cause nor contribute to the patient injuries. As of (b)(4) 2013, there have been no reported recurrences of the issue at this hospital.