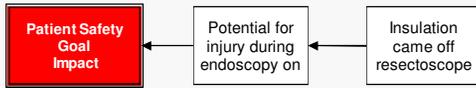


1 Problem

Step 1. Define the Problem		
What	Problem(s)	Resectoscope fell apart during procedure on 2-month old
When	Date	September 2011
	Different, unusual, unique	Age of patient?
	Task being performed	Endoscopy
Impact to the Goals	Patient Safety	Potential injury from medical device
	Property, Equip, Mils	Potential lawsuit
	Labor, Time	Time to repeat procedure correctly

2 Analysis

Basic Level Cause Map - Start with simple Why questions.



Basic Cause-and-Effect

After defining the problem and the impact to the organization's goals, the next step is to build a Cause Map by asking why an event occurred. The Cause Map visually depicts what led to the young patient being exposed to harm.

In this case the patient was exposed to danger because the insulation slipped off a resectoscope in the middle of a procedure.

RESECTOSCOPE ASSEMBLY

Cause Map

A 2-month old was undergoing a cystoscopy to incise a ureterocele in the bladder. During the endoscopic procedure, a resectoscope was used to remove the unwanted tissue. However, during the operation part of the resectoscope slipped off, exposing a hook-shaped internal piece of the instrument. Fortunately the patient was not injured; however the potential for injury was very real. How did the medical instrument come apart?

Cause Mapping is a Root Cause Analysis method that captures basic cause-and-effect relationships supported with evidence.

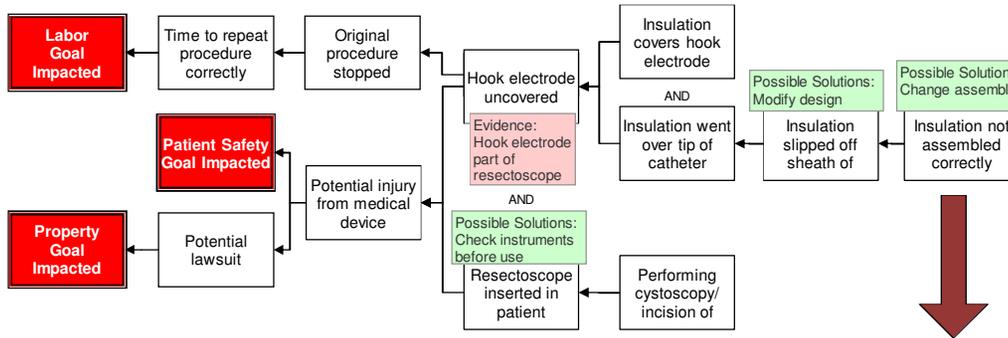
CAUSE MAPPING

Problem Solving • Incident Investigation • Root Cause Analysis

- Step 1 Problem** - What's the Problem?
- Step 2 Analysis** - Why did it happen?
- Step 3 Solutions** - What will be done?



More Detailed Cause Map - Add detail as information becomes available.



More Detailed Cause-and-Effect

Reviewing the complete Cause Map, it turns out that the resectoscope was incorrectly assembled. The third step in an incident investigation is to develop a set of solutions. Remembering that all causes are necessary to produce an effect, the investigation team can brainstorm solutions to eliminate or counteract contributing causes. In this case, three possible solutions were developed. It is possible that the resectoscope could be designed differently so that the insulation would not be able to slip. While this is a reasonable long term solution, it would not immediately remedy the problem. Another solution would be to verify that the instrument is in working order before using on a patient. This may have occurred, but it should be included until ruled out as a potential solution. A final idea is to revise the assembly procedures for the resectoscope. This is in fact what the FDA recommended.

The FDA recommends that the manufacturer's assembly procedures always be carefully followed. A process map is another helpful tool to determine where something went wrong. The organization can build a process map depicting the ideal sequence of events, then compare that with what actually occurred. The problem may not be in the instructions; the instructions might be perfect! However, if someone doesn't follow those instructions correctly, the process isn't going to reach the desired outcome.

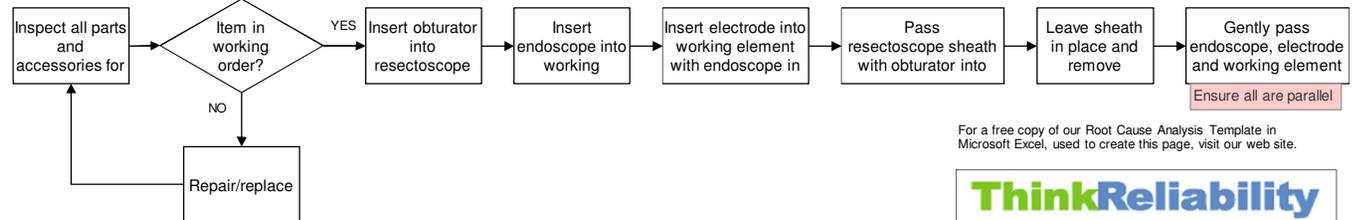
At this point, the investigation team might go back to the Cause Map to elaborate on the why the resectoscope was incorrectly assembled. This might generate new solutions and changes to the ideal process map. Through this iterative process, an optimum solution can be found.

This event was reported as part of the FDA's MedWatch program. The FDA encourages health professionals to voluntarily report problems on medical devices. For more information on the MedWatch program, please visit their website.

4 Process Map

3 Solutions

No.	Action Item	Cause
1	Modify design	Insulation slipped off sheath of resectoscope
2	Change assembly procedure	Insulation not assembled correctly
3	Check instruments before use	Resectoscope inserted in patient



For a free copy of our Root Cause Analysis Template in Microsoft Excel, used to create this page, visit our web site.

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