**Problem**

<table>
<thead>
<tr>
<th>Step 1. Define the Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What</strong></td>
</tr>
<tr>
<td><strong>When</strong></td>
</tr>
<tr>
<td><strong>Impact to the Goals</strong></td>
</tr>
</tbody>
</table>

**Problem(s)**
Resectoscope Assembly

**Date**
August 4, 2011

**Endoscopy**

**Problem**
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 off?

**Analysis**

**Basic Level Cause Map** - Start with simple Why questions.

<table>
<thead>
<tr>
<th>Patient Safety Impact</th>
<th>Potential for injury during endoscopy on resectoscope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulation came off resectoscope</td>
<td></td>
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</table>

**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.

**Solutions**

<table>
<thead>
<tr>
<th>No.</th>
<th>Action Item</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Modify design</td>
<td>Insulation slipped off sheath of resectoscope</td>
</tr>
<tr>
<td>2</td>
<td>Change assembly procedure</td>
<td>Insulation not assembled correctly</td>
</tr>
<tr>
<td>3</td>
<td>Check instruments before use</td>
<td>Resectoscope inserted in patient</td>
</tr>
</tbody>
</table>

**Process Map**

1. Inspect all parts and accessories for:
   - Item in working order?
   - YES: Insert obturator into resectoscope
   - NO: Repair/replace

2. Insert electrode into working element with endoscope in:
   - Pass resectoscope sheath with obturator into
   - Leave sheath in place and remove

**Cause Mapping**

**Problem**
What’s the Problem?

**Analysis**
Why did it happen?

**Solutions**
What will be done?

**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.

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**Inspection Questions**

1. Inspect all parts and accessories for:
   - Item in working order?
   - YES: Insert obturator into resectoscope
   - NO: Repair/replace

2. Insert electrode into working element with endoscope in:
   - Pass resectoscope sheath with obturator into
   - Leave sheath in place and remove

**Process Map**

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