**Name of Policy:** Safe Medical Device Act Compliance  
**Policy Number:** 3364-124-25  
**Department:** Nursing Service/Operating Room  
**Approving Officer:** Nurse Manager Operating Room  
**Responsible Agent:** Chief Nursing Officer/CNO  
**Scope:** Operating Room/Perioperative Services  

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**Effective Date:** 4/1/2016  
**Initial Effective Date:** 6/1993

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<table>
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<tr>
<th>New policy proposal</th>
<th>Major revision of existing policy</th>
<th>Minor/technical revision of existing policy</th>
<th>Reaffirmation of existing policy</th>
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(A) **Policy Statement**

Use of any medical device in the Operating Room (OR) will adhere to internal and external safety guidelines.

(B) **Purpose of Policy**

To comply with Safe Medical Device Act.

(C) **Procedure**

1. If a medical device/product is found to be defective, the device/product will be removed from service and decontaminated. It will then be tagged with a description of the defect.

2. After decontamination, the device/product will either be sent to the Technology Support Department or they will be notified and the device/product will be checked in the OR.

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**Approved by:**

<table>
<thead>
<tr>
<th><strong>C. Powlesland BSN, RN.</strong></th>
<th>4/26/16</th>
<th>Date</th>
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<tbody>
<tr>
<td>Nurse Manager Operating Room</td>
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<tr>
<th><strong>Monecca Smith, MSN, RN.</strong></th>
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<td>Chief Nursing Officer/CNO</td>
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**Review/Revision Date:**

- 6/96  
- 2/99  
- 7/2002  
- 7/2005  
- 6/10/2008  
- 1/8/2009  
- 10/10/2014  
- 4.1.2016

**Next Review Date:** 4/2019

**Policies Superseded by This Policy:** 4-25

*It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.*