

Name of Policy: Safe Medical Device Act Compliance			
Policy Number: 3364-124-25			
Approving Officer: Chief Executive Officer			
Responsible Agent: Chief Nursing Officer			
Scope: The University of Toledo Medical Center Operating Room (OR)/Perioperative Services		Effective date: 12/2025	
		Original effective date: June 1993	
Key words: Safe Medical Device Act, Operating Room, Safety Guidelines, Tagged Equipment, Procedure			
	New policy proposal		Minor/technical revision of existing policy
	Major revision of existing policy	X	Reaffirmation of existing policy

- (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 the [Safe Medical Device Act](#).
- (C) Procedure

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.

After decontamination, the device/product will either be sent to the appropriate technology support department or technology support will be notified, and the device/product will be checked in the OR.

<p>Approved by:</p> <p>/s/</p> <hr/> <p>Daniel Barbee, MBA, BSN, RN, FACHE Chief Executive Officer</p> <p>12/19/2025</p> <hr/> <p>Date</p> <p>/s/</p> <hr/> <p>Kurt Kless, MSN, MBA, RN, NE-BC Chief Nursing Officer</p> <p>12/18/2025</p> <hr/> <p>Date</p> <p><i>Review/Revision Completed by: Operating Room Management</i></p>	<p>Policies Superseded by this Policy:</p> <ul style="list-style-type: none">• 4-25 <p>Initial effective date: June 1993</p> <p>Review/Revision Date:</p> <p>June 1996 February 1999 July 2002 July 2005 June 10, 2008 January 8, 2009 October 10, 2014 February 1, 2016 August 1, 2019 December 1, 2022 December 2025</p> <p>Next review date: 12/2028</p>
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