Name of Policy:	**Medical Device Implant Tracking**	
Policy Number:	3364-124-13	
Department:	Nursing Service/Operating Room	
Approving Officer:	Director of Surgical Services	
Responsible Agent:	Chief Nursing Officer/CNO	**Effective Date:** 6/1/2024
Scope:	Operating Room (OR)/Perioperative Services	Initial Effective Date: April 1, 1981

_____ New policy proposal	_____ Minor/technical revision of existing policy
_____ Major revision of existing policy	**X** Reaffirmation of existing policy

(A) Policy Statement

In accordance with federal regulations (Food and Drug Administration – Code of Federal Regulations Title 21, Volume 8, Part 821, updated April 8, 2021) the policy of the Operating Room will be to:
1: Assist device manufacturers in obtaining the information they are required by federal regulation to obtain in order to track medical device implantation in patients.
2. Document the available Unique Device Identifier (UDI) information in the patient's medical record.

(B) Purpose of Policy

To provide an ongoing record of information pertinent to medical devices implanted in patients for future reference as needed in case of recall, and to appropriately document care received by the patient while in the operating room.

(C) Background

The Safe Medical Devices Act of 1990 and the Food and Drug Administration Modernization Act of 1997 requires that manufacturers track certain devices when the agency orders them to do so. Tracking is intended to facilitate notification and recall in the event a device presents a serious risk to health that requires prompt attention.

(D) Definitions

Medical Device Implant
For purposes of this policy, an implanted device is any device that is identified by the Food and Drug Administration as a device subject to tracking as well as any other device that is implanted into a patient that is intended to remain in the patient for 30 days or longer. This is not intended for a device used only for temporary purposes or intended for explantation in 1 year or less.

Unique Device Identifier (UID)
Information used to identify medical devices may include:

a) Manufacturer
b) Model # / Catalog #
c) Lot # / Serial #
d) Item description
e) Expiration date
f) Other identification codes as assigned by the manufacturer
g) Identification stickers which include the above information are commonly supplied by device manufacturers and included in device packaging.

(E) Procedure

The circulating nurse will be responsible for documenting the available implant UDI in the medical record as well as the case resource map at the time of the procedure.
The surgical billing department will be responsible for final verification of implanted devices used with the manufacturer and for final documentation in the electronic record.

Medical Record Documentation by the Circulating Nurse
The (UDI) information for the implanted medical device must be documented in the medical record at the time of surgery by any of the methods described below:

1. Affixing a manufacturer supplied sticker with the required information onto a progress note in the patient's paper record.
2. Documenting the required information directly into the patient's electronic medical record.
3. Documenting into the patient's paper record by writing the information onto a progress note.
4. Attaching a patient sticker to a "common set sheet" which identifies the implants used and including it in the patient's medical record.

Additional considerations:
When the implanted device packaging does not include a sticker with implant identification information, the product catalog number and/or a description of the implant may be substituted. The information may be found on the "common set sheet" or supplied by the vendor. The medical record implant documentation should occur prior to the circulating nurse handing off care of the patient to the next phase of care.

Resource Map Documentation
In addition to documentation in the medical record, the UDI information for the implanted medical device must be documented on the patient's resource map by any of the methodologies described above.

Final Documentation
The final verification of implanted devices used is the responsibility of the surgical billing department. The surgical billing staff will validate the correct UD information with the manufacturer and assure the correct information resides in the electronic medical record.

Device Manufacturer Responsibilities
The operating room staff will assist the manufacturer's representative in collecting the patient and UDI information they are required to obtain according to the Safe Medical Devices Act of 1990 and the Food and Drug Administration Modernization Act of 1997.

Any questions or issues should be directed to the Director of Surgical Services or their designee.

Approved by:	**Review/Revision Date:**
/s/ Michelle Mallet RN, MSN, CNOR, Director of Surgical Services — Date /s/ Kurt Kless, MSN, MBA, RN, NE-BC Chief Nursing Officer — Date Review: Policy& Standard Committee, 5/2021, 6/2024 Revision completed by: Heidi Pitzen BBA, MSN, RN, CNOR Perioperative Educator	1982 7/2005 1983 8/2008 1984 1/2009 1985 8/2012 1986 4.1.2016 1987 4/2018 1988 5/1/2018 1989 5/1/2021 9/1990 6/1/2024 1993 6/1996 7/2002 **Next Review Date:** 6/1/2027
Policies Superseded by This Policy: 4-13	

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