Approved by: Henry Ford Health System Executive Administration

# 1.0 Philosophy/Purpose:

Supercedes: none

1.1 Henry Ford Health System is devoted to quality and safety of our patients and we have determined a need to set up a policy to track and monitor equipment and supplies into our system through consignment or loan.

## 2.0 Scope:

- 2.1 This policy is applicable for Henry Ford Hospital, Henry Ford Medical Group and all of its locations, Henry Ford Wyandotte Hospital, Henry Ford Bi-County Hospital, Henry Ford West Bloomfield Hospital Behavioral Health Services and Community Care Services.
- 2.2 This policy directly applies to vendors and manufacturer representatives that provide or wish to provide medical/surgical supplies and equipment on loan or consignment for patient care and non-patient care purposes.

## 3.0 Responsibility:

- 3.1 Application of this policy and ongoing monitoring is the responsibility of the consignee or user department and the Supply Chain Management.
- 3.2 HFHS employees are responsible for adhering to this policy.

### 4.0 Policy:

- 4.1 This Policy Statement has been created to:
  - 4.1.1 Manage Inventory and ownership for consigned or loaned products at HFHS.
  - 4.1.2 To establish a guideline for products consigned and/or loaned.
  - 4.1.3 To establish a process for inventory control.
  - 4.1.4 To establish quality and safety controls for consigned/loaned products used in patient care.

#### 5.0 Requirement/Procedure:

5.1 General Guidance:

- 5.1.1 All new incoming consignment and loaned equipment, instruments, and other products will be inventoried by the vendor and HFHS and confirmed on the appropriate count sheet.
- 5.1.2 Prior to vendor removing a tray or instruments from HFHS, the Sales Representative and HFHS will inventory the outgoing items against the original count for accuracy.
- 5.1.3 Vendors are not permitted to open trays, packs or sets without the prior approval and assistance of HFHS.
- 5.1.4 HFHS and vendor will inspect products during the arrival process.

#### 5.2 Consignment Items:

- 5.2.1 All items to be consigned must have a completed, signed Agreement on file in the Supply Chain Management department.
- 5.2.2 The delivery of the consigned and loaned equipment, instruments and other products should take place at the time appointed by the facility.

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- 5.2.4 All new incoming trays and instruments will be inventoried by the vendor and facility and confirmed on the vendor provided count sheet.
- 5.2.5 Prior to vendor removing consignment and loaned equipment, Instruments and other consignment products from the facility, the Sales Representative and HFHS will inventory the outgoing consignment and loaned equipment, instruments, and other consignment products against the original vendor provided count sheet for accuracy.
- 5.2.6 Vendors are not permitted to move or inventory trays, packs, instruments, or sets without the prior approval and assistance of HFHS.
- 5.2.7 Any additions or deletions to the consigned items, or request for removal of the tray must be in writing and presented to Supply Chain Management prior to implementation.
- 5.3 Consignment Implants:
  - 5.3.1 All items to be consigned must have a completed, signed Agreement on file in the Supply Chain Management department.
  - 5.3.2 Any product supplied by the vendor on the day of the surgical or interventional procedure must have prior approval for use. The standard form signed by Supply Chain Management must be submitted.
  - 5.3.3 Any changes to the consigned item or request for removal of implant must be in writing signed by Vendor and an authorized Henry Ford Health System representative.
  - 5.3.4 Upon the use of an implant, the identification labels will be presented to the facility and documented in the patient's medical record.
    - 5.3.4.1 Circulator is to document for the implant log the critical information and send the information to their materials management processor who then creates a requisition for purchase.
    - 5.3.4.2 The serial and/or lot numbers are noted on the purchase requisition for purchase. The patient's medical record number must be presented with purchase request.
  - 5.3.5 Vendor is responsible for shipment of replacements into inventory.
  - 5.3.6 Vendor is responsible for items opened by the vendor and discarded, unless otherwise agreed upon.
  - 5.3.7 Periodic inventory by Vendor and HFHS will take place for consigned products and the Vendor and HFHS will sign the inventory in agreement.
  - 5.3.8 Vendor is responsible for supply amount and expiration dates.
- 5.4 Loaner Instrument sets:
  - 5.4.1 Loaner instrument set, if shipped, require a no-charge purchase order number prior to shipping. HFHS does not pay loaner or rental fees.
  - 5.4.2 HFHS does not pay for freight associated with the shipping of loaner equipment unless prior approval is obtained.
  - 5.4.3 Prior to the return of the set vendor is to review with HFHS the components of the set to verify that all items are accounted for.

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5.4.4 The sales representative will provide information on cleaning and processing techniques for the instruments. HFHS will not accept contaminated, broken or defective instruments.

### 6.0 Compliance Monitors:

- 6.1 Staff Responsibilities
  - 6.1.1 All staff are responsible for assuring that all employees comply with this policy for patient quality and safety.
  - 6.1.2 Department leaders and chairs are responsible for the enforcement of the policy.
  - 6.1.3 Supply Chain Management Compliance department is responsible for monitoring compliance of policy.

#### 6.2 Compliance

- 6.2.1 The area of Vendor Compliance & Management within the department of Supply Chain Management will investigate any reported violations of this policy.
- 6.2.2 Staff found not to be in compliance with this policy will be reported to their supervisor for action

### 7.0 Definitions:

- 7.1 *Vendor* is any representative of a manufacturer or company who visits for the purpose of soliciting, marketing, or distributing products or information regarding the use of medications, products, equipment and/or services.
- 7.2 Supply Chain Management is Henry Ford Hospital's purchasing department.
- 7.3 *Consignment* indicates that the vendor will leave equipment, instruments and other products with Henry Ford Health System without transferring ownership or cost to Henry Ford Health System.
- 7.4 Loaned Instruments indicate that the Vendor has agreed to provide an instrument, set or sets of instruments to HFHS for a specific period of time to be used by HFHS staff.

#### 1.0 References:

1.1 Please refer to the following additional Supply Chain Management policies:

Approval Requirements and Authorization Levels Policy Business Associate Agreement Policy Emergency Orders Policy New Product Introduction Policy Product Recalls (RASMAS) Policy Supplier Diversity Policy Supply Chain Management Policy Vendor Policy and Procedures