

SUBJECT/TITLE: STATEMENT OF VENDOR POLICY

PURPOSE: At University of Iowa Hospitals and Clinics (UIHC), we are proactive in protecting the privacy of our patients to facilitate compliance with all government and University health and safety regulations and policies. Although we recognize the value of having sales representatives interact with our staff, we also have high expectations that all vendors will comply with UIHC Vendor Policy and with rules and additional guidelines established by individual departments and units. The detailing of products and services at the UIHC by Medical/Surgical/Pharmaceutical Representatives is a granted privilege, not a right.

A. Policy

Registration and daily badges at UIHC are required for all Medical/Surgical/Pharmaceutical Representatives from medical, surgical, medical device, and pharmaceutical companies. This policy applies to all Medical/Surgical/Pharmaceutical Representatives (e.g., distributors, information specialists, managers, scientific liaisons, medical affairs specialists, and tissue/bone representatives) selling products or services or providing information to UIHC staff that are involved in patient care activities (e.g., staff that provide patient care to inpatient care areas, clinics, O.R 's and invasive labs). All Medical/Surgical/Pharmaceutical Representatives from medical, surgical, medical device and pharmaceutical companies must be registered with RepTrax web-based community and compliant with credentials and policies.

Annual UIHC registration and badges may be required for vendors who provide service, repairs or rental deliveries or installations. Internal University, freight forwarders (e.g. UPS), floral and food delivery services and consultants of professional services are excluded. Construction vendors have a separate policy based within Safety and Security policies.

All Medical/Surgical/Pharmaceutical Representatives must be registered with the Purchasing Department to obtain a University of Iowa Vendor ID prior to engaging in any promotion or information activities - hereafter called “detailing” - involving their company’s products and services at UIHC.

A Business Associate Agreement is not required for all vendors; however, it is required for all vendors who will be present for a patient procedure, will have direct patient contact, or access to any patient information in order to provide their services to UIHC. It is the company’s responsibility to have a signed Business Associate Agreement on file. Please contact the

University of Iowa Hospitals and Clinics Compliance Office 319-384-8282 to make sure your company has one on file, and if not, to begin the process.

NOTE: Detailing privileges are not transferable from one company representative to another.

1. All Medical/Surgical/Pharmaceutical Representatives are required to register and comply with UIHC requirements via RepTrax web-based community *prior* to engaging in any promotion or informational activities involving their company's products and services at UIHC.
2. Members of the Procurement Services Department staff are available to meet with Medical/Surgical/Pharmaceutical Representatives by appointment during the hours of 7 AM to 5 PM, Monday through Friday, with the exception of University holidays.
3. Pharmaceutical company representatives will need to register during their first visit in the Department of Pharmaceutical Care's Pharmacy Purchasing Office (Room B17 GH), 319-384-5185 Pharmaceutical Sales Representative information record. Thereafter, pharmaceutical company representatives only need to report to Procurement Services for their badge for each scheduled visit. Appointments with Pharmacy staff are scheduled through the Pharmacy Administrative Office (319-356-2577)
4. Communicable Disease Screening: To protect patients, staff and vendors from transmission of communicable disease within our organization, vendors must be free of potentially transmissible communicable diseases and have had no recent exposure to these diseases. Before pursuing any appointments with UIHC staff, all vendors are reminded that compliance with hand hygiene and respiratory etiquette is required while in the UIHC.
5. Medical/Surgical/Pharmaceutical Representatives need to follow all hospital policies and procedures when detailing as a representative of their company while visiting here at the UIHC.

B. Identification Badge Check-in

1. **All** Medical/Surgical/Pharmaceutical Representatives with credentials approved on RepTrax must check in and receive a vendor badge at the Procurement Services Department, Room 3057-1 SRF, upon **each** visit. The office is open 7 AM to 5 PM, Monday through Friday, except University holidays. This badge must be worn at all times while conducting detailing activities or visiting in UIHC. Badges are one-time use and do not need to be returned. For questions call Procurement Services at 319-384-9800.
2. One time guests accompanying a registered vendor (e.g. regional sales manager) will need a vendor badge as well.
3. All visits, for whatever purpose, must be prearranged with the department, physician, or staff member prior to arrival at the UIHC.
4. Normal street clothes are required. Vendors are not allowed to wear personal scrubs when visiting UIHC. If scrubs are necessary for procedures, UIHC will issue white scrubs and shoe covers.

C. Access, Sales or Service Calls

All new products must have information on file in Procurement Services Department or Department of Pharmaceutical Care prior to detailing to any staff within UIHC. A completed vendor form must be delivered with all new requests for non-pharmaceutical products to be reviewed and evaluated for purchase at UIHC. Forms can be found at: <http://www.uihealthcare.com/depts/procurementservices/index.html> Failure to comply with this policy will result in reprimands as outlined in Section G, “Enforcement of Hospital Policy”.

Be advised that hospital administration has a product review process mandated by our governing board. This process involves product evaluation, economic evaluation, training and inventory matters, etc.

We appreciate the working relationship you have with our faculty and the work which is done on your part to bring in products on a rapid basis. However, you must obtain written prior approval from one of our products committee for items to be considered payable. Unless you’ve obtained prior approval from us for items to be purchased, we will consider them to be in a no-charge trial basis status

Likewise, you must obtain prior approval for items to be trialed as well. This gives us an opportunity to consider staff education needs, as well as perform the due diligence associated with our current products and contracts.

Marketing or discussing any non formulary products with Physicians or staff at UI Healthcare is strictly prohibited. Should there be an incidence of non compliance , we will reserve the right to suspend the vendor and company from UIHC.

With appropriate permission of the Products Committee, vendors may inform physicians or staff of new products.

Our physicians are not authorized to act as agents to amend or renegotiate these provisions.

1. Meetings with UIHC staff will occur at the request of the staff member by appointment only. Verification of the scheduled appointment may be completed to insure compliance with hospital policy. A “Do Not Call” list of staff will be available and sales representatives are not to call or e-mail these staff members.
2. Meeting places are restricted to staff offices, conference rooms in nonpatient care areas, or areas of UIHC open to the general public.
3. Medical/Surgical/Pharmaceutical Representatives must leave the visited area immediately upon completion of an appointment.
4. Medical/Surgical/Pharmaceutical Representatives are not permitted in inpatient care areas, outpatient clinics, or pharmacy dispensing areas in order to protect patient privacy (except as allowed within guidelines outlined in the supplements to this policy).
5. Loitering in UIHC corridors, cafeterias, and other areas in an attempt to facilitate a nonscheduled meeting with a UIHC staff member is prohibited.

6. UIHC telephones may not be routinely used; public telephones are available throughout the facilities. The use of cell phones is restricted in all patient critical care areas defined as Intensive Care Units, Intermediate Care Units, Emergency Treatment Center, Operating Rooms, Diagnostic and Radiological Imaging Rooms, Birthing Rooms and Neuro-Diagnostic areas. In all other areas throughout the UIHC, cell phone use is restricted to areas greater than three feet from patient equipment.
7. Overhead hospital paging systems are off limits to vendors. Other paging is limited to request by the specific UIHC staff member only.
8. Departmental mailboxes and University campus mail systems are off limits to all vendors. Commercial mail services may be used to disseminate information to UIHC staff.
9. Vendors are required to pick up after meetings, in-services or displays. Leaving materials, empty boxes or information after meetings will be considered an infraction of the vendor policy.
10. Vendors are not to leave unsolicited promotional/boxes/information in any hospital location.
11. Vendors who need parking, may park in Ramp 3. Valet parking is restricted to use by our patients and their visitors.

D. New Products

1. All new products and pharmaceuticals are subject to review by the Product Review and Standardization Committee or the Pharmacy and Therapeutics Subcommittee. A formal process has been established for documentation of product evaluations. The Procurement Services Department staff or Department of Pharmaceutical Care will provide assistance with the required documents.
 - a. A vendor form must be submitted for each new non-pharmaceutical product to be evaluated. **Vendors will not be paid for product use if prior approval has not been documented within Procurement Services or the Department of Pharmaceutical Care.**
 - b. No products should be left in any area of UIHC without prior approval of the Product Review and Standardization Committee.
 - c. Vendors leaving products without permission from Procurement Services will be subject to discipline under Section F, "Enforcement of Hospital Policy". **Items whose approval has not been previously documented within Procurement Services or the Department of Pharmaceutical Care will not be paid for.**
 - d. Procurement Services will help make arrangements with vendors when their products will be needed for evaluation or trial.
 - e. UIHC staff is required to submit a New Product Request form which includes requirements to sign a Conflict of Interest Statement before any product can be reviewed for trial or purchase.
2. We require that vendors not pressure UIHC staff during a negotiation or request for quotation process. The best way to expedite the process is to be prompt in returning calls and providing proposals and information as needed.
3. If the medical/surgical product merits further investigation or evaluation, it will be referred to the appropriate Department Director, Clinical Manager, Procurement Services Staff member or Value Analysis Facilitator. In the event of a trial where product is required to determine its merit, the supplier or manufacturer will, at no charge, provide an

adequate supply to make a fair determination. For pharmaceutical products see additional Pharmacy requirements.

4. All reusable items need to be cleaned and sterilized by the Central Sterilizing Services Department (CSS) prior to use; cleaning and sterilizing instructions must be presented to CSS with all products, by at least 7 PM (Main OR) or 4 PM (ASC) the night before surgery in order to be cleaned and sterilized properly. See Supplements for the CSS OR policy on loaner instrumentation.
5. Additional Pharmacy and Therapeutics Subcommittee and Department of Pharmaceutical Care Requirements:
 - a. Industry-supplied drug samples, drug-containing devices, and vouchers may not be distributed to patients at UI Health Care.
 - b. UI Health Care faculty, staff, and trainees may not seek or accept industry-supplied drug samples for personal or family use.
 - c. Drug coupons are not permitted to be given to patients at UIHC.
 - d. In order to meet patient educational needs, the Pharmacy and Therapeutics Subcommittee may approve industry-provided drug-related educational devices and/or written educational materials. These approved industry-provided drug-related educational devices will not contain active drugs and may be kept in specified clinics for patient teaching of drug administration.
 - e. Detailing of protocol, restricted, and non-stock drugs is limited to attending physicians and pharmacists. A list of protocol and restricted drugs is posted in the Pharmacy Purchasing Office.
 - f. Only UIHC and company-approved materials and not independently created or reproduced items, may be distributed to health care professionals or trainees within UIHC.
 - g. Distribution of written promotional information regarding protocol, restricted, and non-stock drugs at journal clubs is not permitted. Restricted drugs are defined as those drugs on the formulary whose use are limited to a specific clinical service(s).
6. Additional Tissue Bank requirements:
(See Supplement E for detail) All implantable material containing human cells must have prior approval through the Surgical Services Product Evaluation, Standardization and Review work group prior to use (except for sperm, oocytes, and vascular organs).
 - a. Vendors must stop at the Tissue Bank before they accompany tissue to the OR. This will allow the tissue to be accessioned into the inventory.
 - b. Vendors of tissue not accessioned in the Tissue Bank before implantation will not be paid for tissue.

E. Attendance at Hospital Meetings

1. Attendance at meetings that are not open to the general public, including patient care conferences/tumor boards where protected health information is disclosed, is not permitted.
2. Attendance at Grand Rounds, Departmental meetings, Product Review and Standardization meetings, etc., is allowed by written invitation of conference leader or organizer only.

F. Enforcement of Hospital Policy

These policies and regulations for Medical/Surgical/Pharmaceutical Representatives are to be followed rigidly. Any infraction may affect the entire company's representation at UIHC. All UIHC staff will assist in monitoring the level of compliance and will report violations to the Procurement Services Department or the UIHC Compliance Helpline at (319)384-8190. Upon notification of a potential policy violation, Procurement Services, Pharmaceutical Services and/or the Joint Office for Compliance will investigate the matter to determine if a violation has occurred, and upon confirming a violation, will determine the seriousness of the infraction. In order to complete its investigation, UIHC may contact the vendor and may require the company representative(s) involved in the matter to be interviewed at UIHC regarding the details surrounding the incident. Based on the seriousness of the infraction and the information obtained during the investigation, the resultant action may include a verbal reinforcement of the UIHC Statement of Vendor Policy or the disciplinary actions outlined below. A serious infraction which includes, but is not limited to, a violation of a HIPAA or JCAHO standards (or other accrediting organization requirements) may result in a higher level of disciplinary action.

Failure to comply with these policies may result in the following actions:

1. **First infraction:** A face-to-face meeting, a note in the file and possibly a letter of reprimand, loss of detailing and display privileges for one week or more.
2. **Second infraction:** A face-to-face meeting which includes a letter of reprimand with a copy being sent to the representative's immediate supervisor, and the company's possible loss of detailing and display privileges for one month or up to six months depending on severity of the infraction.
3. **Third infraction:** A face-to-face meeting which includes a letter of reprimand with a copy being sent to the representative's immediate supervisor, and the company's loss of detailing and display privileges to be defined and determined at the meeting or no further access depending on the severity of the infraction.

NOTE: The representative of record is responsible for any violation of policies by any representative from his/her company. Disciplinary actions will be documented in the company's file in Procurement Services.

G. Declaration of Patient Information Confidentiality

UIHC is legally required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of the health care information of all patients treated at our institution.

Your visit to UIHC may include contact with patients and/or viewing of computer-stored patient information and/or information from patient medical records. Under no circumstances may this information be discussed with anyone, unless otherwise required by law. Unless a specific exception exists under the law, you are prohibited by State and Federal law from making any disclosure of this information.

State and federal law protects the confidentiality of patient information that you may view during the course of your visit to UIHC. **State and federal law prohibits you from making any disclosure of this information.**

Your signature on the Declaration of Patient Information Confidentiality is required. Understand that a violation of this can result in serious administrative action.

H. RepTrax Credential Requirements

1. All vendors will be required to join the RepTrax community which will assist us in managing vendor credentials.
2. If you will be attending a surgical procedure or will be visiting areas such as the operating rooms, invasive labs, procedure areas, clinics or other patient care areas you will need to provide evidence within RepTrax of a Business Associate Agreement, MMR – Measles, Mumps and Rubella vaccination and annual tuberculosis status. You will also need to provide certification and training for Evidence of Employer Product/Service Competency.
3. All vendors will need to review all policies and documents provided online via RepTrax and must pass the review test with a score of 90% or higher.

I. Conflict of Interest/Conflict of Commitment

To reinforce our commitment to upholding the highest possible ethical standards and to foster greater transparency, University of Iowa Health Care has implemented a revised Conflict of Interest/Conflict of Commitment policy. The policy is available at <http://www.uihealthcare.com/about/conflictinterest/index.html>

Definitions

"Conflict of Interest" (COI) involves a situation in which faculty, staff, or student employees have financial or other personal considerations that may compromise, or have the appearance of compromising, their professional judgment or integrity in teaching, clinical care, conducting or reporting research, or performing other University obligations. (Adapted from UI Operations Manual; <http://www.uiowa.edu/~our/opmanual/ii/18.htm>)

"Conflict of Commitment" (COC) occurs when an employee engages in an outside activity that interferes, or appears to interfere, with fulfillment of the employee's obligations to the University, even if the outside activity is valuable to the University or contributes to the employee's professional development and competence. (From UI Operations Manual; <http://www.uiowa.edu/~our/opmanual/ii/18.htm>).

"Industry" is defined as any person or company seeking to do or doing business with University of Iowa Health Care, including any pharmaceutical, medical device, medical publishing, or medical equipment companies.

J. CORRESPONDING POLICIES AND SUPPLEMENTS:

Supplement A – Vendor Representatives Presence in Areas Where Procedures are Performed

Supplement B – Home Care Company and Nursing Facility Representatives

Supplement C – Department of Central Sterilization Services/Special Department Procedures

Supplement D - Department of Central Sterilization Services/Special Department Procedures for
ASC

Supplement E – Tissue Bank Policy for Vendor Delivery of Tissue to the Operating Rooms

Supplement F – Medical/Surgical/Pharmaceutical Representatives, Approval of Presence in the
Perioperative Division

Supplement G –Medical/Surgical/Pharmaceutical Approval of Presence in the Perioperative
Division

Date created: 06/05/2005

Source: Value Analysis Program and Procurement Services

Date approved: 06/05/2005

Date effective: 06/05/2005

Date revised: 6/06; 9/06, 11/06, 5/07, 1/08, 6/08, 1/10

Date Reviewed: 6/06; 9/06, 11/06, 5/07, 1/08, 6/08, 8/09

Supplement A

Vendor Representatives Presence in Areas Where Procedures are Performed

PURPOSE:

- To ensure that only authorized company representatives access the procedure areas;
- To maintain confidentiality of patients' protected health information;
- To provide accurate, timely communication between physicians, ambulatory care managers and the Medical/Surgical/Pharmaceutical Representatives.

POLICY:

1. Approval for presence in procedure areas may be granted if the following required criteria are met:
 - a. The representative's employer company has a current, signed business associate agreement in the Joint Office of Compliance, AND
 - b. There is a clinical need OR
 - c. If there is documentation (b) above but there is no signed business associate agreement, the physicians must obtain written patient consent for the representative to be present during the procedure.
2. Representatives shall sign in and obtain authorization to be present in the hospital at the UIHC Procurement Services Department office prior to coming to the procedure care areas.
 - a. UIHC personnel will verify that the company has a current business associate agreement, and provide a dated badge, white scrubs, and shoe covers if needed.

- b. If the representative will need access before 7:00 A.M., he/she must obtain a badge the day before surgery.
3. Representatives shall not have access to procedure schedules.
4. Representatives shall sign in with the procedure room designee before entering the patient care area. Multiple representatives from the same company must each sign in separately. Representatives shall leave the area immediately upon completion of authorized work.
5. Representatives may be present only for which approval has been granted with a maximum of two per company per procedure. Additional approval must be obtained for exceptions.
 - a. Representatives may not scrub in or open sterile supplies.
 - b. Representatives may detail only the products for which a clinical need has been identified.
 - c. Sterile products must be supplied in a manner consistent with UIHC Infection Control Policies.
6. Emergent Cases. In the event of an emergent case the procedure area designee will obtain information from the physician regarding a need for a representative. Information can then be reported to Procurement Services after the case.
7. Trials of equipment, instruments, and supplies requiring presence of a representative follow established vendor policy procedure. All new products require a completed vendor form and staff request form prior to trialing. Failure to follow this policy will result in enforcement of Hospital Vendor Policy.

PROCEDURE:

(Physicians)

Prior to the day of surgery, indicate to the procedure area designee that the presence of a representative is a clinical need, the name of the company and indicate if scrubs are needed.

(Representative)

1. Check in, obtain a badge and white scrubs and shoe covers.
2. After changing into surgical attire, sign in with the designated procedure staff person.
3. Introduce yourself to the designee in a procedure area and identify the physicians with whom you will be working.

(Procedure Area Designee)

1. Verify that the clinical need for the representative is indicated.
2. Tell the representative the location of the procedure suite.
3. Verify that the representative is wearing the appropriate badge.

(Representative)

1. Go to the assigned procedure suite.
2. Identify yourself to the procedure room nurse.

(Representative)

1. Sign out with the designated staff person upon completion of authorized work.
2. Change into street clothes, leaving white scrubs in the changing room.
3. Failure to leave the area at the end of the case will be a violation of the Vendor Policy.

Supplement B

Home Care Company and Nursing Facility Representatives

The Department of Social Service is very interested in home care, durable medical equipment, and community facility programs and services as they assist patients and families in making arrangements for any needed continuing care following discharge from the hospital.

Community home care/DME/hospice/facility representatives are encouraged to provide written resource information that can be shared with all Social Service staff via our Outlook mailing list. email rosemary-wilhelm@uiowa.edu the information to be shared.

Medical/Surgical/Pharmaceutical Representatives who wish to detail products and services and discuss the level of care and/or types of equipment/services offered with UIHC Department of Social Service staff must follow the procedures outlined in the UIHC Vendor Policy.

Community home care/DME/hospice/facility representatives are permitted in patient care areas only in the following circumstances:

- a) The company/facility representative has scheduled an appointment through Social Service to meet with a UIHC patient and/or family member for the purpose of providing discharge in-service and information, or
- b) The company/facility representative has scheduled an appointment through Social Service to meet with a UIHC patient and/or family for the purpose of evaluating the patient for possible transfer to their company/facility.

If you have questions regarding this matter, please contact Kusum Pradhan, Social, Patient and Family Services at (319) 356-7664.

Supplement C

Department of Central Sterilization Special Department Procedures

PURPOSE

To provide instructions for handling loaner instruments brought to UIHC from outside sources.

POLICY

To process surgical instruments and implants acquired from an outside source (e.g., consignment, rented, borrowed) in a timely manner, prior to patient use. Loaner instruments are defined as instruments, implants, or trays the vendors provide to the UIHC on a temporary basis for a specific case. These instruments are either shipped in via a carrier (UPS, FedEx, etc.) or brought in by a sales representative.

PROCEDURES

(Representatives and Operating Room Shared Responsibility)

1. Loaner instruments must be sent into the UIHC prior to the day of surgery. Trays will be brought into the UIHC will be taken to room 6521 JPP and Mary Goldammer or Pam Wetjen will be notified.

(Representatives' Responsibility)

The sales representative will perform the following tasks in order to prepare these items for surgery:

1. Room 5202 JPP will be used by the vendor representative for unpacking and inspecting all loaner instruments, storage of shipping materials, completing the necessary processing instructions (see representatives directions below), and preparing the instruments for shipment after the case has been completed.
2. In Room 5202 JPP will be a plastic bin of packaging supplies. In this gray bin are items you will need to prepare the trays for surgery.
3. Remove a metal disc, which is labeled as "Sales Rep Loaner Inst tray-XX" and place one of these tags into **each** tray or set. This tag will be used by CSS for tracking and identification of the tray or set.
4. Complete the Sales Rep/Loaner Tray form (please print). This form must accompany the trays each time instrument sets are processed. This form provides basic information that allows CSS to track and process trays together.
 - a. Fill out all pertinent Vendor/Rep Information.
 - b. Indicate 'Requesting Surgeon, Today's Date (date trays are delivered to CSS), Procedure Information' with date, time and location.
 - c. List each tray individually. Fill in corresponding ID number from metal disc. Indicate if tray contains implants.
 - d. Attach cleaning and sterilization instructions.
 - e. Circle correct sterilization method.
 - f. Complete sterilization parameters as indicated in the manufacturer's instructions.
 - g. Using an autoclavable pen, copy the name that you want the OR to call your tray and the ID number onto a SPM label that is in the gray bin, tear off label at perforation.
 - h. Attach SPM labels (to be used for identification after the tray or set is wrapped), sterilization and cleaning instructions to the Sales Rep/Loaner Tray Form with a paper clip. Each instrument tray or set **must** include complete cleaning and sterilization instructions each time you bring the tray in for processing. Failure to provide cleaning and sterilization instructions will result in delays in processing. No exceptions will be made to this policy. Cleaning and sterilization instructions can be faxed to (319) 356-0484. You will need to go to room 0806 JPP in Central Sterilizing Services to obtain the fax and attach it to the form.
 - i. If the tray contains an implant, the sales representative will need to pull an implant sticker and place it with the SPM labels and tell us which tray contains the implant by putting an

“I” on the Sales Rep/Loaner Tray Form. This will alert the Central Sterilizing staff to the fact that the sterilization load must contain a biological. This is a JCAHO requirement.

5. The vendor representative will deliver the loaner instrument trays or sets, the completed Sales Rep/Loaner Tray Form, the SPM labels, and the cleaning and sterilization instructions to Central Sterilizing Services’ (CSS) decontamination area, which is located off elevator G in the lower level. On the wall outside the room is a buzzer, which should be pushed in order to get someone to come to the door. The room number is 0327 JCP and the main telephone number is 356-2534. This must be done before 7 PM of the day before the scheduled date of the case. Items that must be gas sterilized must be delivered to CSS prior to 2 PM the day before the case is scheduled due to the long sterilization cycle time. If these timeframes cannot be met, the sales representative will have to contact the OR for instructions on what they need to do to get these items processed.

(CSS Responsibility)

*When the loaner instruments are delivered to the **decontamination** area, the CSS staff will:*

1. Scan each tray to decontamination.
2. Retain cleaning instructions and pass all remaining paperwork (log sheet, sterilization info and labels) to the assembly area.
3. Wash instruments per manufacturer’s instructions.
4. Save the cleaning instructions to use upon receipt of trays after surgery.

*When the loaner instruments are received in the **set assembly** area the CSS staff will:*

1. Scan each tray prep/receive.
2. When tray is completely dry, scan pp/pk and wrap tray as you would any other tray.
3. Attach the handwritten SPM label and the corresponding identification label prepared by the sales rep to the tray
4. Send all paperwork (Sales Rep/Loaner Tray form and sterilization instructions) to sterilizer area with the trays.

*When the loaner instruments are received in the **sterilization** area the CSS staff will:*

1. Review the sterilization instructions and if nothing unusual is found proceed with normal sterilization process. If there are special instructions for sterilization, follow special sterilization instructions; if in doubt, contact a CST III.
2. Scan tray into the sterilizer, if tray contains an implant a biological must be run.
3. After completion of sterilization process, CSS tech will place cool trays on the cart that has been placed in the sterilizer area for this purpose. Autoclave operator will need to make sure that the staff setting up the case carts are aware of the loaner trays so that these trays can be added to the case cart before it is set up. A copy of the Sales Rep/Loaner Tray form will be placed on top of the case cart. If case cart is already in the OR then trays will need to be sent up with a note telling core staff which room and cart to place the trays on. The Sales Rep/Loaner Tray form will be only way of knowing that these trays are needed on a case cart.
4. Scan trays to the appropriate case cart. Send yellow copy of form with trays; file white copy in the sterilizer file drawer. The pink copy goes with the daily sterilizer records.

(Sales Representative/Operating Room Nursing Responsibility)

1. After the surgical procedure nursing staff will place all loaner instruments into the correct loaner pan and set them on the dirty case cart that will be sent to decontamination. These instruments will need to be sorted by the CSS staff and cleaned as appropriate with special attention placed on the reamers.
2. Trays and implants that were not opened will be returned by the sales representative/nursing staff to the Sales Rep room 6521 JPP after the case.

(CSS Responsibility)

When the loaner instruments are received in the decontamination area the CSS staff will:

1. Scan the loaner trays into decontamination.
2. Place all loaner trays to the side, process all other trays as normal.
3. When time allows, accumulate all loaner trays and clean following the cleaning instructions that were saved from previous day.
4. After decontamination, accumulate all trays on a cart in the instrument assembly area. A nursing assistant from the OR will come down at some point each evening probably after 11 PM to pick up these trays and transport them to the loaner instrument storage room, 6521 JCP in the OR. They will then return the cart to CSS.

(Vendor Responsibility)

Within 24 hours after the completion of the case the vendor representative will:

1. Remove identifying tags from the tray and return tags to appropriate receptacle.
2. Missing items will need to be located by the vendor representative. The vendor representative will contact a CST III or the in-charge person if a CST III is not here, before going into the CSS department to locate any missing loaner instruments.
3. It will be your responsibility to have the loaner instruments removed from the UIHC in 24 hours, unless the same instruments are needed for a case scheduled for the next day. If they are needed, the same process as shown above will need to be followed.
4. Sterile trays are not to be stored in 6521 JCP. If trays are not used on the case scheduled for, open and discard wrapper. Room 6521 JCP is not a sterile area and should not be considered as such.

Sales Rep/ Loaner Tray Form (sample)

Vendor Name _____
 Representative Name _____
 Phone Number _____
 Requesting Surgeon _____
 Today's Date _____
 Procedure Date/Time _____
 Location of Procedure (circle one) MOR ASC Rm # _____

Tray/Inst/Item Name	Tag #	Implant

Sterilization Instructions
 Attach Manufacturer's Instructions to this form
 Method (circle one) Steam Gas Sterrad
 Exposure Time _____ (Example- 5 min)
 Exhaust Time _____ (Example- 30 min)

Temperature _____

NOTE: All items on this form MUST have identical sterilization parameters

Receipt in CSS

Date _____ Time _____ Name _____

Sterilized By _____

Attach Load Sticker Here _____

Returned to Area: Date _____ Location _____ Initials _____

Supplement D

Department of Central Sterilization Services Special Department Procedures for ASC

PURPOSE

To provide instructions for handling loaner instruments brought to UIHC from outside sources.

POLICY

To process surgical instruments and implants acquired from an outside source (e.g., consignment, rented, borrowed) in a timely manner, prior to patient use. Loaner instruments are defined as instruments, implants, or trays the vendors provide to the UIHC on a temporary basis for a specific case. These instruments are either shipped in via a carrier (UPS, FedEx, etc.) or brought in by a sales representative.

PROCEDURES

(Representatives and Operating Room Shared Responsibility)

Loaner instruments must be sent into the UIHC prior to the day of surgery. The trays will be taken to vendor room 41013 PFP and Diane Williamson or O.R. charge nurse will be notified.

(Representatives Responsibility: The Sales Representative will perform the following tasks in order to prepare these items for surgery.)

1. Room 41013 PFP will be used by the vendor representative for unpacking and inspecting all loaner instruments, storage of shipping materials, completing the necessary processing instructions (see representatives directions below) and preparing the instruments for shipment after the case has been completed.
2. In Room 4100-Z nursing charge desk, will be a counter with necessary packaging supplies to prepare the trays for surgery.
3. Remove a metal disc, which is labeled as “ASC Sales Rep Loaner Inst tray-XX” and place one of these tags into **each** tray or set. This tag will be used by CSS for tracking and identification of the tray or set.
4. Complete the Sales Rep/Loaner Tray three-part form (please print). This form must accompany the trays each time instrument sets are processed. This form provides basic information that allows CSS to track and process trays together.
 - a. Fill out all pertinent Vendor/Rep Information.
 - b. Indicate Requesting Surgeon, Today’s Date (date trays are delivered to CSS), Procedure Information with date, time and location.
 - c. List each tray individually. Fill in corresponding ID# from metal disc. Indicate if tray contains implants.
 - d. Attach cleaning and sterilization instructions.
 - e. Circle correct sterilization method.
 - f. Complete sterilization parameters as indicated in the manufacturer’s instructions.
 - g. Using an autoclavable pen, copy the name that you want the OR to call your tray and the ID number onto a SPM label that is in the gray bin, tear off label at perforation.

- h. Attach SPM labels (to be used for identification after the tray or set is wrapped), sterilization and cleaning instructions to the Sales Rep/Loaner Tray Form with a paper clip. Each instrument tray or set **must** include complete cleaning and sterilization instructions each time you bring the tray in for processing. Failure to provide cleaning and sterilization instructions will result in delays in processing. No exceptions will be made to this policy. Cleaning and sterilization instructions can be faxed to 319-356-4430. You can ask for the Charge Nurse to obtain the fax for you and then attach it to the form.
 - i. If the tray contains an implant, the sales representative will need to pull an implant sticker and place it with the SPM labels and tell us which tray contains the implant by putting an 'I' on the Sales Rep/Loaner Tray Form. This will alert the Central Sterilizing staff to the fact that the sterilization load must contain a biological. This is a JCAHO requirement.
5. The vendor representative will deliver the loaner instrument trays or sets, the completed Sales Rep/Loaner Tray Form, the SPM labels, and the cleaning and sterilization instructions to ASC Central Sterilizing Services' (CSS) decontamination area, which is located back hallway of ASC area. On the wall outside the room is a phone, which should be used in order to get someone to come to the door. The room number is 41233 PFP and our main telephone number is 356-7925 or 356-8366. This must be done before 4 PM of the day before the scheduled date of the case. Items that must be gas sterilized must be delivered to ASC CSS prior to Noon the day before the case is scheduled due to the long sterilization cycle time. If these time frames cannot be met the sales representative will have to contact the OR for instructions on what they need to do to get these items processed.

Supplement E

TISSUE BANK: ORDERING, RECEIVING, AND RETURNING HUMAN TISSUE

PURPOSE: Human tissue is an essential, expensive, and often unique product required for some surgical procedures. Tissue must be traceable from source to implantation in order to allow look back to occur if it is found to be defective or infected. This policy outlines the method by which tissue will be requested from the Tissue Bank for a specific case, received in the operating room on the day of surgery, and returned to the Tissue Bank if it is unused.

POLICY:

- A. All implantable material containing human cells passes through the Tissue Bank prior to use (except for sperm, oocytes, and vascular organs).
 - 1. Sales representatives may not bring tissue to the OR, except for corneas in emergent cases. All tissue must be ordered through the tissue bank from the distributor. Sales representatives may pick up tissue from the tissue bank for transport to the OR.
 - 2. Vendors of tissue not accessioned in the tissue bank before implantation will not be paid for the tissue.

- B.** The surgical team alerts the Tissue Bank of their need by placing an order on the IPR A- 1a form.
1. Tissue orders should be placed preferably one week and at least two working days prior to an elective surgery.
 - a) Tissue orders with specific parameters (e.g., exact dimensions) may require additional time for procurement and thus orders should be placed as soon as possible once the need for the tissue has been identified.
 2. Tissue orders required on a semi-emergent or emergent basis will be placed at the earliest possible opportunity by calling the Tissue Bank at 6-3709.
 3. Tissue bank personnel will advise as to the availability of requested tissue, either from the bank or from a vendor if not in stock.
 4. If the order is unclear or requires specific measurements to be determined prior to ordering, Tissue Bank personnel will contact the surgeon to provide clarification.
- C.** Tissue currently in the inventory of the Tissue Bank is placed on reserve for the specific patient.
- D.** Tissue not currently in inventory that is sized for a specific patient is ordered from a list of qualified vendors by Tissue Bank personnel, using the specifications listed on the IPR A-1a form as a guideline.
1. Tissue Bank personnel contact qualified vendors from the current vendor list to obtain specification sheets on suitable candidate tissue and send these to the surgical team for review and final selection of the tissue.
 2. Tissues are ordered after the Tissue Bank receives notification from the surgeon of final approval.
 - a) If the surgeon prefers for the Tissue Bank to obtain the tissue from a particular vendor, that may be noted on the A-1a.
- E.** Tissue Bank personnel notify the surgeon if requested tissue is not available or is backordered.
- F.** Unusual tissue requests (as detailed below) require that the surgeon obtain approval from the Surgical Product Evaluation, Standardization, and Review Work Group prior to placing the order with the Tissue Bank. This process is initiated by submitting an O.R./ASC Staff Product Request Form to this Work Group. Tissues that require approval include:
1. Tissue from non-qualified vendors
 2. Tissue for which equivalent tissue could be purchased from another vendor for less expense
 3. Tissue that closely approximates current inventory
 4. Non-FDA approved tissue. Institutional Review Board (IRB) approval must be obtained prior to evaluation by the Product Evaluation, Standardization, and Review Work Group.

Supplement F

Medical Surgical Company Representatives, Approval of presence in the Perioperative Division.

PURPOSE:

- To ensure that only authorized company representatives access the perioperative patient care areas
- To maintain confidentiality of patients' protected health information
- To provide accurate, timely communication between surgeons, perioperative nursing, and the company representatives.

POLICY:

- A. Approval for presence in perioperative patient care areas may be granted, if the following required criteria are met:
1. The representative's employer company has a current, signed business associate agreement in the Joint Office of Compliance, AND
 2. There is documentation of a clinical need provided by the surgeon on the Patient Information Card (PIC), OR
 3. If there is documentation on the PIC described in (b) above but there is no signed business associate agreement, the surgeon must obtain written patient consent for the representative to be present during the procedure.
- B. Representatives shall receive and agree to the "Statement of Vendor Policy".
- C. Representatives shall sign in and obtain authorization to be present in UIHC at the UIHC Procurement Services Department office prior to coming to the perioperative care areas.
1. Check the Operating Room schedule to validate that a clinical need is indicated on the PIC.
 2. UIHC will verify that the company has a current business associate agreement, and provide a dated badge, white scrubs, and shoe covers for the representative.
 3. The vendor ID badge may be picked up after 7:00 A.M. The office is open Monday through Friday except holidays. This badge must be worn at all times while conducting detailing activities in UIHC. For exceptions call Procurement Services 319-384-9800.
- D. Representatives shall not have access to surgery schedules.
Necessary information (e.g. OR #) is available from the Control Desk.
- E. Representatives shall sign in with the Control Desk Supervisor before entering the patient care area. Multiple representatives from the same company must each sign in separately. Representatives shall sign out with the charge nurse and UIHC Procurement Services Department upon completion of authorized work. If after 4:30 pm, the Representative will sign out with charge nurse, the badges are one time use only and must be properly disposed of daily.

- F.** Representatives may be present only in the operating room or area for which approval has been granted. No more than two vendors will be allowed in an operating room at one time. Special exceptions must be communicated to nursing leadership for that service and approved by the Medical Director of the Operating Room.
1. Representatives may not manipulate or operate equipment other than which they are detailing.
 2. Representatives may not sterilize instruments, remove items from a sterilizer, or open sterile supplies.
 3. Representatives may not scrub in for surgery.
 4. Representatives may detail only the product(s) for which a clinical need has been identified
 5. Sterile products must be shipped directly from the manufacturer or distributor, and are not brought in by the representative.
 6. Representatives may not use cell phones in the Operating Room suite.
- G.** Emergent Cases. In the event of an emergent case the nurse manager will obtain information from the surgeon regarding a need for a representative and indicate the need, if there is one, on the PIC.
- H.** Trials of equipment, instruments, and supplies requiring presence of a representative follow established procedure. The discipline needing the support (i.e. nursing or surgeons) will indicate the need on the PIC following established procedure. Communication of the need for a representative should occur between the surgeons and nursing.

PROCEDURE:

- A.** (Surgeon)
1. Prior to the day of surgery, indicate on the Patient Identification Card (PIC) if the presence of a representative is a clinical need, and if so, the name of the company.
 - a. The letter “V” will appear on the surgery schedule after the surgical team to indicate that a representative (vendor) will be present during the procedure.
- B.** (Representative), these are required steps or administrative action will become necessary
1. Check in with UIHC Procurement Services Department and obtain a badge and white scrubs.
 2. Additional information and restrictions for representatives detailing products within UIHC are available from Financial Services [Statement of Vendor Policy](#).
 3. After changing into surgical attire, sign in with the charge nurse.
 4. Introduce yourself to the charge nurse and identify the surgeon with whom you will be working.
- C.** (Control Desk Supervisor)

1. Verify that the clinical need for the representative is indicated on the surgery schedule.
 - a. If there is no “V” indicated on the surgery schedule or Patient Information Card (PIC), the representative is not permitted in the perioperative area. Notify the nurse manager or designee.
 2. Tell the representative the number of the assigned operating room.
 3. Weekly, give the representative sign in sheet(s) to the Administrative Assistant.
- D.** (Representative)
1. Go to the assigned operating room.
 2. Identify yourself to the circulating nurse.
- E.** (Circulating Nurse)
1. Verify that the representative is wearing the appropriate badge and that the surgery schedule has “V” indicated for the procedure.
- F.** (Representative)
1. Sign out with the charge nurse upon completion of authorized work, properly dispose of vendor badge.
 2. Change into street clothes.

Supplement G

Medical Surgical Company Representatives, Approval of presence in the ASC Perioperative Division.

PURPOSE:

- To ensure that only authorized company representatives access the ASC perioperative patient care areas
- To maintain confidentiality of patients’ protected health information
- To provide accurate, timely communication between surgeons, perioperative nursing, and the company representatives.

POLICY:

- A.** Approval for presence in ASC perioperative patient care areas may be granted, if the following required criteria are met:
1. The representative’s employer company has a current, signed business associate agreement in the Joint Office of Compliance, AND
 2. There is documentation of a clinical need provided by the surgeon on the Patient Information Card (PIC), OR
 3. If there is documentation on the PIC described in (b) above but there is no signed business associate agreement, the surgeon must obtain written patient consent for the representative to be present during the procedure.
- B.** Representatives shall receive and agree to the “Statement of Vendor Policy”.

- C.** Representatives shall sign in and obtain authorization to be present in UIHC at the UIHC Procurement Services Department office prior to coming to the perioperative care areas.
1. Check the Operating Room schedule to validate that a clinical need is indicated on the PIC.
 2. UIHC Procurement Services Department personnel will verify that the company has a current business associate agreement, and provide a dated badge and white scrubs for the representative.
 3. The vendor ID badge may be picked up after 7:00 A.M. The office is open Monday through Friday except holidays. This badge must be worn at all times while conducting detailing activities in UIHC. For exceptions call Procurement Services 319-384-9800.
- D.** Representatives shall not have access to surgery schedules.
Necessary information (e.g. OR #) is available from the charge nurse.
- E.** Representatives shall sign in with the charge nurse before entering the patient care area. Multiple representatives from the same company must each sign in separately. Representatives shall sign out with the charge nurse and UIHC Procurement Services Department upon completion of authorized work. If after 4:30 pm, the Representative will sign out with charge nurse, the badgers are one time use only and must be properly disposed of daily.
- F.** Representatives may be present only in the operating room or area for which approval has been granted.
1. Representatives may not manipulate or operate equipment other than which they are detailing.
 2. Representatives may not sterilize instruments, remove items from a sterilizer, or open sterile supplies.
 3. Representatives may not scrub in for surgery.
 4. Representatives may detail only the product(s) for which a clinical need has been identified
 5. Sterile products must be shipped directly from the manufacturer or distributor, and are not brought in by the representative.
- G.** Emergent Cases. In the event of an emergent case the nurse manager will obtain information from the surgeon regarding a need for a representative and indicate the need, if there is one, on the PIC.
- H.** Trials of equipment, instruments, and supplies requiring presence of a representative follow established procedure. The discipline needing the support (i.e. nursing or surgeons) will indicate the need on the PIC following established procedure. Communication of the need for a representative should occur between the surgeons and nursing.

PROCEDURE:

A. (Surgeon)

1. Prior to the day of surgery, indicate on the Patient Identification Card (PIC) if the presence of a representative is a clinical need, and if so, the name of the company.
 - a. The letter “V” will appear on the surgery schedule after the surgical team to indicate that a representative (vendor) will be present during the procedure.

B. (Representative), these are required steps or administrative action will become necessary

1. Check in with UIHC Procurement Services Department and obtain a badge and white scrubs.
2. Additional information and restrictions for representatives detailing products within UIHC are available from Financial Services [Statement of Vendor Policy](#).
3. After changing into surgical attire, sign in with the charge nurse.
4. Introduce yourself to the charge nurse and identify the surgeon with whom you will be working.

C. (Charge Nurse)

1. Verify that the clinical need for the representative is indicated on the surgery schedule.
 - a. If there is no “V” indicated on the surgery schedule or Patient Information Card (PIC), the representative is not permitted in the perioperative area. Notify the nurse manager or designee.
2. Tell the representative the number of the assigned operating room.
3. Weekly, give the representative sign in sheet(s) to the Administrative Assistant.

D. (Representative)

1. Go to the assigned operating room.
2. Identify yourself to the circulating nurse.

E. (Circulating Nurse)

1. Verify that the representative is wearing the appropriate badge and that the surgery schedule has “V” indicated for the procedure.

F. (Representative)

1. Sign out with the charge nurse upon completion of authorized work, properly dispose of vendor badge.
2. Change into street clothes.

End of Vendor Policy