	The Johns Hopkins Hospital INTERDISCIPLINARY CLINICAL PRACTICE MANUAL	<i>Policy Number</i>	IFC-004
		<i>Effective Date</i>	7/2000
	<i>Subject</i> REUSE OF DISPOSABLE OR SINGLE-USE PATIENT -CARE ITEMS	<i>Page</i>	1 of 5
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POLICY


Reuse of single-use or disposable patient care items may be permitted if the users either obtain written instructions from the manufacturer or provide documentation showing that the reuse will not compromise patient safety or device effectiveness and integrity or follow guidelines when using a third-party re-processor of medical devices. All expenses related to reuse must be thoroughly analyzed to ensure the cost-effectiveness of reprocessing the item. The process to prepare each item for reuse must be reviewed and approved by Hospital Epidemiology and Infection Control, Clinical Engineering Services, and Central Sterile Processing prior to final review by the Risk Management Committee of the Medical Board.

Definitions

Material Risks	Risk which a reasonable person would want to know about an item or product before giving consent to undergo a procedure or treatment using that item or product.
Reprocessing	The cleaning, repackaging, and sterilization (or disinfection) of an item that was either (a) used on a patient or (b) not used on a patient, but has had its packaging breached.
Reuse	The use of an item, labeled by the manufacturer as a single-use or disposable patient-care item, that has been cleaned and disinfected or sterilized after its original use on a patient.
Third Party Re-processing	Reprocessing services provided by an outside company which may include reesterilization of open but unused single-use medical products (e.g. sutures), products whose sterility expiration dates have passed and re-processing of single-use items for re-use.


REFERENCES

Reichert, M. Reuse of single-use devices. Nur Clin N Am 28:3. 697-709.
 ECRI. Reusing Disposable Products. October, 1992. 1-10.

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RESPONSIBILITIES

Clinical Department	Identify item and develop proposal for possible reuse. Review documentation provided by third party reprocessor regarding policies, procedures and practices. Determine and document cost justification (Form A - sample attached). If cost-effective, submit financial data as well as product information and re-processing procedure to: <ul style="list-style-type: none"> A) Hospital Epidemiology and Infection Control B) Central Sterile Processing C) Clinical Engineering
Hospital Epidemiology and Infection Control	Review reuse proposal. Review documentation provided by third party reprocessor regarding policies, procedures and practices Assist in the microbiological evaluation of items for potential reprocessing/reuse to determine if sterilization/ disinfection can be achieved. Submit proposal to the Hospital Epidemiology and Infection Control Committee.
Central Sterile Processing or any area that reprocesses patient-care items.	Assist clinical department in determining how to sterilize each item. Reprocess items marked single-use or disposable only with Risk Management Committee approval. Clinical Engineering, Applied Physics Laboratory or other testing department. Review documentation provided by third party reprocessor regarding policies, procedures and practices Assess whether the item can safely be used after reprocessing.
Risk Management Committee of the Medical Board	Review and approve request. Convene Task Force if necessary to review proposal.

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PROCEDURES

1. Clinical Department Administrator, Functional Unit Administrator or Designee

- a. Prepare a cost analysis for reuse of the item. Include estimated one-time costs associated with item and process evaluation, as well as ongoing costs associated with personnel, repackaging materials, sterilization costs, data base management, etc. (Complete Form A.) When using a third party processor, obtain information regarding registration, business practices, other clients/products serviced, polices and procedures, insurance information, etc. (Form C)

If cost analysis indicates that reprocessing of this item may be cost-effective, proceed to 1b.

- b. Submit in written format a method for completing each of the following components/steps to support the reuse of a disposable or single-use patient-care item. Each component/step must be measurable or observable so that it may be consistently repeated. Each component/step must be accompanied by documentation to support the following items:
 - i) A method for cleaning, disinfecting, repackaging, and reprocessing the item as described by the manufacturer. If the manufacturer does not produce this information, consult Central Sterile Processing or Hospital Epidemiology and Infection Control for assistance in creating an appropriate method. Clinical Engineering Services should be consulted about the physical characteristics of the item and any special consideration that should be given. Included in this document must be a method for testing any electrical or moveable components of the item prior to reprocessing.
 - ii) Measurement data to indicate how much, if any, chemical residual (e.g., ethylene oxide) is expected to remain on the reprocessed item. Further documentation must compare these data with the acceptable residual levels described in federal and/or state regulations. This toxicology screen can be performed by an outside laboratory, but if so, the results must be reviewed and approved by Central Sterile Processing.
 - iii) A data-base system to maintain a product inventory and also track each reprocessed item during its useful life. The data base must contain information on how many times an individual item can be reprocessed and reused, and how many times each item actually has been reprocessed and reused. The data base also must provide documentation that the appropriate reprocessing procedure for each item had been completed prior to each use. The final item for the data base should be documentation of when the item was finally discarded and why (completed maximum cycles, failed testing procedures, etc.)
 - iv) A surveillance strategy to monitor patients for adverse outcomes.
 - v) A statement regarding the material risks, if any, to the patient from the reuse of the item. If there is such a material risk, an appropriate consent document must also be provided.
 - vi) A billing schedule to describe the method for patient billing throughout the useful life of the item.
- c. Provide supporting documentation for the written proposal.
 - i) A document which attests that an item can be effectively cleaned and reprocessed. If written documentation cannot be obtained from the manufacturer, then provide a statement

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by Hospital Epidemiology and Infection Control and the Director of Central Sterile Processing.

- ii) A document from an outside laboratory or Hospital Epidemiology and Infection Control which approves the effectiveness of the cleaning and terilization/disinfection procedure. If the item is evaluated at an outside laboratory, Hospital Epidemiology and Infection Control must review and approve the evaluation process.
- iii) A document from the manufacturer which attests that the item can withstand reprocessing and reuse without loss of structural, mechanical, or chemical integrity. If this document cannot be obtained from the manufacturer, then provide a statement by Clinical Engineering Services, the Applied Physics Laboratory, or similar facility.
- iv) A document from the manufacturer which describes the maximum number of reuse cycles the item can safely tolerate. If the manufacturer cannot provide this information, then provide a statement from Clinical Engineering Services, the Applied Physics Laboratory, or the clinical department.
- v) A document which outlines how the department will verify if reused instruments are associated with adverse events and how patients who are treated with reused instruments will be tracked.
- vi) If no scientific evidence or documentation is available to support any of the steps in the proposed process, a document summarizing past experience that has resulted in this process being created, along with a proposal on how concurrent data will be collected, may be acceptable.


d. Submit the proposal to the Risk Management Committee

2. Risk Management Committee

- a. Reviews clinical department proposal or third party processor. Recommends approval or denial. The committee may convene a task force which may include representatives from Central Sterile Processing, Hospital Epidemiology and Infection Control, Clinical Engineering Services, and the involved clinical department. If approved, the department proposal or third party contract may be initiated by the requesting department; Medical Board approval is not required.

3. Central Sterile Supply

- a. Assign an item number for each item that is reprocessed.
- b. Visually inspect each item for soil and structural or physical damage which would make the item unsuitable for reuse.
- c. Clean and sterilize each item as per recommended method.
- d. Maintain a pool of individuals specifically trained to process items for reuse.

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SPONSORS

Hospital Epidemiology and Infection Control
The Risk Management Committee of the Medical Board

COMMUNICATION/EDUCATION

Policy No. IFC-004, Reuse of Disposable or Single-Use Patient-Care Items, will be communicated to the appropriate JHHS personnel via the following channels:

1. Hospital Epidemiology and Infection Control will present the policy at the Management Forum Meeting.
2. The Risk Manager will present the policy at the Risk Management Seminars for physicians.
3. Departmental Physician Advisors will present the policy to their respective departmental Performance Improvement Committees.
4. A copy of the policy will be distributed to all policy manual holders within each clinical department. The department leadership is charged with communicating policy contents to unit personnel.
5. Important aspects of the policy will be printed in Hospital publications.
6. Department management will be responsible for orienting and training staff to the policy.
7. The Policy Management Office will distribute policy revisions to all manual holders with instructions on updating their manuals.

REVIEW CYCLE

3 years

APPROVAL

Medical Board

6/27/00
Date

Vice President, Medical Affairs

Date

FORM A
COST JUSTIFICATION

A. ITEMS COST - UTILIZING SINGLE USE	
1. Cost of initial item	\$
2. Projected volume/year	
Total cost per year (volume x initial cost)	\$
B. COST OF REUSE	
1. Labor for each employee involved in processing (including benefits)	\$
2. Administrative cost for developing protocol and procedure and quality assurance program*	\$
3. Training cost for preparation and presenting educational sessions	\$
4. Processing costs	\$
5. Equipment costs	\$
6. Outside laboratory test(s) costs*	\$
7. Cost reused item (initial item divided by number of times reused)	\$
8. Maintenance of files on complaints	\$
9. Total cost of reuse program per year	\$

* ONE TIME COSTS

FORM B

REUSE PROTOCOL STEPS CHECKLIST

STEPS	√
1. Check with the manufacturer if the item can be reprocessed.	
- If yes, provide manufacturer documentation.	
- If no, go on to number 2.	
2. Develop a method of cleaning, disinfecting, repackaging, and reprocessing item. (Attachment)	
3. Develop a system for tracking individual items. (Attachment)	
4. Develop a mechanism by which expired items will be identified and discarded. (Attachment)	
5. Documentation from an outside laboratory or the Department of Hospital Epidemiology and Infection Control that can that can validate the sterility of the item. (Attachment)	
6. Documentation attesting to the capability of the item to withstand reuse. (Attachment)	
7. Outside laboratory documentation. (attachment)	
8. Written assurance on the number of cycles an item can withstand.	

Form C

Third Party Reprocessing Company Audit Tool

ITEM	YES	NO	COMMENTS
1. Is company registered with FDA?			
If yes, under what classification?			
If registered, registration number?			
Has the company been inspected for compliance With GMPs? (document outcome)			
Any warning letters as form 483s from FDA?			
2. How long has the company been in business?			
3. Is the company a member of, or associated with, any industry oversight organization?			
Document membership number or attach copy of certification.			
4. Attach list of devices handled by company and services offered.			
5. Is sterilization performed at facility? If not, document name of sterilization company and FDA registration.			
6. Attach documentation of how sterilizers are commissioned and certified.			
Include policy and procedure on verification of efficacy of sterilization process, e.g., spore strips, biological/chemical indicators, etc			
7. Attach policy and procedures:			
a. Procedure for cleaning and reprocessing specific to each type of device.			
Include device testing such as biological and functional tests and tests that demonstrate that the device is not adversely affected by processing steps.			
b. Method of tracking each device it reprocesses.			

ITEM	YES	NO	COMMENTS
8. Attach documentation of company's quality assurance program.			
9. Will company provide the following reports with each shipment: <ul style="list-style-type: none"> a. Name and quantity of devices received b. Name and quantity of devices rejected and reason c. Name and quantity of devices reprocessed d. Charges of each device reprocessed 			
10. Attach policy and procedure assuring that the sending unit will receive its own devices back (rather than those from another health care organization).			
11. Attach copy of liability insurance coverage (Note: \$1 million per occurrence, \$2 million aggregate as a minimum are industry standards). <ul style="list-style-type: none"> a. Is JHH named as additional insured on the policy? b. Will JHH receive 30 days notice of termination of coverage or changes in limits? 			