



Any Surgery Center

POLICIES AND PROCEDURES

TITLE: Product Evaluation and Selection for Patient Care

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PURPOSE: To provide guidelines for the evaluation and selection of products and equipment used for peri-operative patient care.

GUIDELINES:

1. Products to be evaluated for use in the patient care setting should be safe, meet identified needs, and promote quality patient care.
 - a. Product evaluation and selection is based on a collaborative approach.
 - b. The role of the Clinical Director includes initiating, coordinating and/or participating in the clinical evaluation of a product.
 - c. Materials Specialist, Clinical Engineering, and manufacturer representatives should be resources for information concerning new or existing products to meet identified clinical needs.
2. A mechanism for product standardization evaluation should be implemented through a committee with clearly defined responsibility and authority.
 - a. The objective of this group is to facilitate the acquisition of standardized, quality, cost-effective products to promote quality patient care.
3. Product evaluation is based on objective criteria specific to the product, its function, and its use in the practice setting.
 - a. Evaluation criteria includes, but are not limited to:
 - performance
 - efficiency
 - cost, only after quality standards are met
 - safety
 - standardization
 - b. Products to be evaluated have an evaluation tool designed with criteria specific to the product.
 - c. The individual using the product should complete the evaluation tool or be interviewed immediately after trial.

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- d. Baseline clinical acceptability of a product is determined on comparison to the pre-set standard or desired level of performance.
4. A trial clinical evaluation is conducted prior to selection of a product.
 - a. Trial evaluations should be initiated because of an identified need or concern.
 - b. Literature should be reviewed and products screened prior to conducting a clinical evaluation.
 - c. The Executive Director, or designee should be notified in a timely manner when a specific trial is requested and will arrange an appropriate trial with the manufacturing representative. Unauthorized trials will not be permitted.
 - d. All clinical areas that are affected (in a substantial way) should be represented in the trial evaluation.
 - e. Limits should be placed on the scope of the clinical trial, including, but not limited to:
 - the number of products to be evaluated
 - time span
 - the number of clinical units involved
 - f. Instruction and demonstration of a product for all involved personnel should be conducted before a clinical trial evaluation is begun.