

A matter of reprocessing

Reusing SUDs to save money and the environment

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QUICK TAKE >>>

Though still a controversial topic, the trend of reprocessing single-use devices is gaining momentum in the health care industry. Not only are hospitals using reprocessing as a means to help the environment, they are also realizing the tremendous savings that can be reaped by implementing such a practice. It isn't an easy task and, though a few hospitals have chosen to implement a program on their own, many have turned to third-party reprocessors to do the work. Choosing one can be tricky and knowing what questions to ask can be crucial to the success of the practice and safety of your patients.

In today's health care environment, hospitals battle rising operating costs and shrinking bottom lines and many are implementing cost reduction initiatives in an effort to maintain financial sustainability. In light of this trend, reprocessing single-use devices (SUDs) is a hot topic in both clinical and non-clinical circles as a way to save money.

Thousands of hospitals across the United States already have turned to reprocessing as a safe, cost-effective strategy to reduce their supply expenditures. Some facilities chose to implement an initiative on their own, while others hired health care consultants.

Regardless of which approach a facility uses, the reprocessing team must develop a sound implementation methodology that addresses the concerns of the hospital stakeholders. Financially, it's relatively easy to assemble the numbers that demonstrate reprocessing can save a facility roughly 30 percent to 50 percent on various medical device equipment expenses. It is much more difficult and complicated, however, to develop a transparent mechanism to track the data and ensure a guarantee of this financial outcome.

In addition to proving financial value, a hospital must create a process that will achieve clinical staff satisfaction in the reuse of select medical devices.

A well planned and well executed implementation can be a financial bonus

for a facility, but a flawed implementation plan can increase both the amount spent on devices and staff dissatisfaction.

The true success or failure of a reprocessing initiative depends directly on the implementation strategy. To ensure a successful operation, hospitals planning to reprocess should follow several key guidelines when developing facility-appropriate policies.

Leader of the pack

Projects typically begin with the best intentions, especially when savings are at stake. But many projects veer off course due in part to the lack of a clearly identified project leader who is vested in and committed to the mission.

Because reprocessing impacts all areas of a hospital (e.g., clinical, financial and operational), it is imperative to the success of the overall project for a hospital to identify and empower an internal supporter.

An individual from finance or materials management would be the ideal candidate to lead the charge from an operational standpoint. But clinicians ultimately hold the key to the project's success and endurance.

This indicates that a clinical leader should be chosen from each key department to directly oversee device reprocessing. This leader also should collaborate with the overall project leader.

Keeping the right company

Different reprocessing companies offer different value propositions, which make them unique and allow them to perform services that might be beneficial to your hospital.

When evaluating different proposals from reprocessors, ask the following questions in the preliminary stages of your investigation:

- What kind of savings have you been able to achieve at institutions with similar bed size? Also, ask the vendor to provide validation through current client references.
- What type of implementation resources will your company offer? Does your program include hospital staff training? How frequently will the implementation contact change or will the same individual be assigned to my account?
- Do you comply with the FDA's Quality System Requirements and are you ISO-

certified? In particular, is the vendor ISO 9001 and 13485 certified? Ask the vendor to provide documentation to demonstrate this.

(The possession of ISO certification by the reprocessor means that the company will adhere to the same standards applied to some of the leading original equipment manufacturers (OEM)).

A "yes" answer here lends a degree of automatic credibility insofar as the production and testing process is concerned.

If the answer to any of these questions is "no" or "not sure," then it's prudent to continue the due-diligence process. A reputable reprocessor should be able to answer these questions immediately and provide credible data and documents.

All or none

The reprocessing of medical devices impacts many areas in the hospital. Because of this, any decision to move for-

ward with reprocessing must involve a cadre of people who represent each of the individual departments involved with the initiative.

Departmental representation and participation in the decision-making process is the cornerstone of a successful hospitalwide reprocessing implementation.

This group should include senior level hospital administration, supply chain managers, operating room and central sterile managers, and directors of the electrophysiology lab and endoscopy.

Interdepartmental discussions about the staff's comfort with the reprocessing implementation should take place.

Neither administration nor third-party consultants can force a reprocessing initiative on the hospital staff.

While the thought of prospective savings might encourage the finance and supply chain departments to embrace reprocessing, the initiative will never be fully executed without the support of the clinical and nonclinical end users.

If end-user support does not exist, chances are high that compliance will be low. After all, it is up to the clinical end-user to select the device item and determine whether to use the reprocessed item.

An end user who does not support the initiative can easily discard a medical device with the regulated medical waste rather than discard it in a reprocessing tube or tray.

Certainly, not all clinicians will initially feel comfortable using a reprocessed device—a stigma around the purchase and the reuse of SUDs still exists in some circles. To allow these individuals to voice concerns, the reprocessing team should create a forum as a first step toward an honest, objective inquiry into the merit of the initiative.

Reprocessing education

Follow up with hard, scientific evidence to educate staff of your continued commitment to quality health care.

Educating the hospital staff on the sci-



Photo by Alliance Medical Corporation

FEATURE 2 [cost control]

entific validation of reprocessing is vital to gain clinical and operational support.

The challenge is to overcome the negative associations attached to the idea of medical device reuse with factual evidence.

A plethora of scientific evidence exists to buttress the argument that reprocessing is safe and positively affects patient care.

For instance, according to a June 2000 Government Accountability Office report, experts at the CDC say they were not aware of any patient illnesses caused by the reuse of SUDs.

Also, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) codified reprocessing in federal law.

The FDA also requires reprocessors to submit extensive paperwork proving

that their methods of cleaning, sterilization, validation and functional performance testing renders an SUD safe and effective.

Staff are not always familiar with the aforementioned points. Therefore, introducing appropriate evidence is vital to dispelling the myth that reprocessing is unsafe or ineffective.

Before the start of the initiative, forecast your savings.

The standard rule of thumb is that the average facility will save approximately half of its OEM spend.

For example, if a new drill bit costs \$100, the same reprocessed drill bit can be purchased through a reprocessor for \$50.

At first glance, it seems easy to forecast savings for the year by multiplying the

savings per device by the number of items the hospital would use in a given year. The resulting number would represent the total dollars saved.

However, there are many factors not addressed by the simple arithmetic done above that need to be considered to gauge overall, total savings.

These factors include the hospital's ability to estimate the appropriate device compliance rate (usage) for various SUDs.

This is important because the compliance rate reflects hospital usage of a particular item and the number of times a specific item is reused.

The result of this calculation will have either a negative or positive effect on the procurement budget.

After implementing a reprocessing initiative, a hospital can usually expect to pay a higher price point across the OEM spectrum due to a lower number of OEM purchased items.

As such, an astute materials manager will then need to analyze the trade-off between a higher cost OEM device and lower cost reprocessed item.

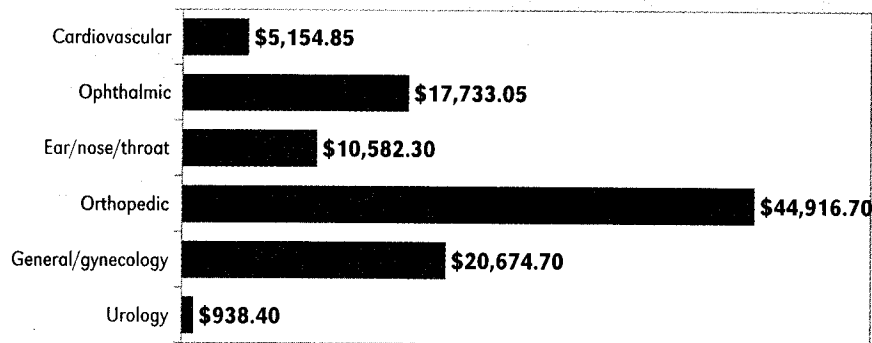
Furthermore, the manager also will need to evaluate which instruments should be carved out based on criteria, including previously negotiated agreements, low cost or clinical preference.

The exclusion of select items typically happens in an area such as the operating room, where many implant device manufacturers and hospitals have existing agreements that bundle such specific items as bits, burs and blades.

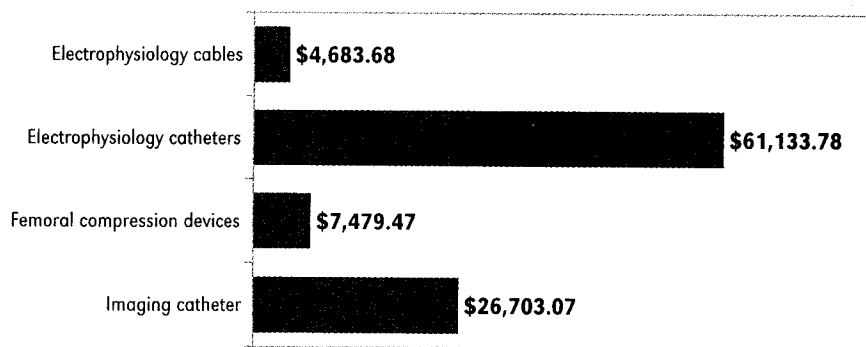
Since these items can be reprocessed, they are routinely placed into a cost-savings analysis, which might mistakenly inflate projected savings.

A savings analysis also should consist of information on the percentage of device items within a given category that are regularly rejected by the reprocessor, the number of pickups and deliveries per week the reprocessor is performing, the turnaround time for sterilization of the SUDs, the cost of shipping SUDs to and from a reprocess-

OR reprocessing savings by area



Average distribution of \$100K in EP reprocessing savings



Source: Nexera Consulting, 2005 (Data based on average OR savings of \$100K across 20 facilities)

sor, and the cost of labor associated with the change in practice across each of the departments.

A hospital may have secondary streams of savings to consider. For instance, a facility may gain supplementary savings through waste avoidance, e.g., the reduction of sharps, municipal solid and regulated medical waste.

These savings, though very small, should be quantified and entered into the financial forecasts.

Other considerations include items for donation as well as a continuous examination and evaluation of select items within the facility that are not being reprocessed but could be.

A master plan

Once all parties feel comfortable with the idea of reprocessing SUDs, it's time to implement the project plan.

The key to this step is creating a transparent process to address three fundamental operational items:

Item #1: The collection procedures and the management of those procedures

Hospital staff must be trained to properly collect SUDs. After reprocessing inservices are completed, hospital administration must support the staff in this new process, which means the overall project leader must monitor and continually reevaluate the collections process to rectify issues of noncompliance or operational mistakes.

To this end, the facility should hold weekly or biweekly initiative meetings during which the project leader, clinical leader and vendor provide updates.

Item #2: Operational use of reprocessed items and communication on their use
Having a reprocessed device checked into a storeroom does not equal success.

Rather, a reprocessed device must reach the floor and be pulled for use by staff to achieve savings.

To ensure reprocessed medical devices are used, senior management must allow the staff to engage in honest and candid feedback as to the quality and effectiveness of reprocessing.

At the end of the day, a successful reprocessing launch depends on both a hospital's and vendor's commitment to discuss and resolve operational problems of any sort, including taking corrective action within a timely manner.

Item #3: The development of an accurate financial tracking mechanism to monitor savings and continually assess any new opportunities.

Tracking the use of all OEM devices and reprocessed items throughout the facility is a necessary challenge.

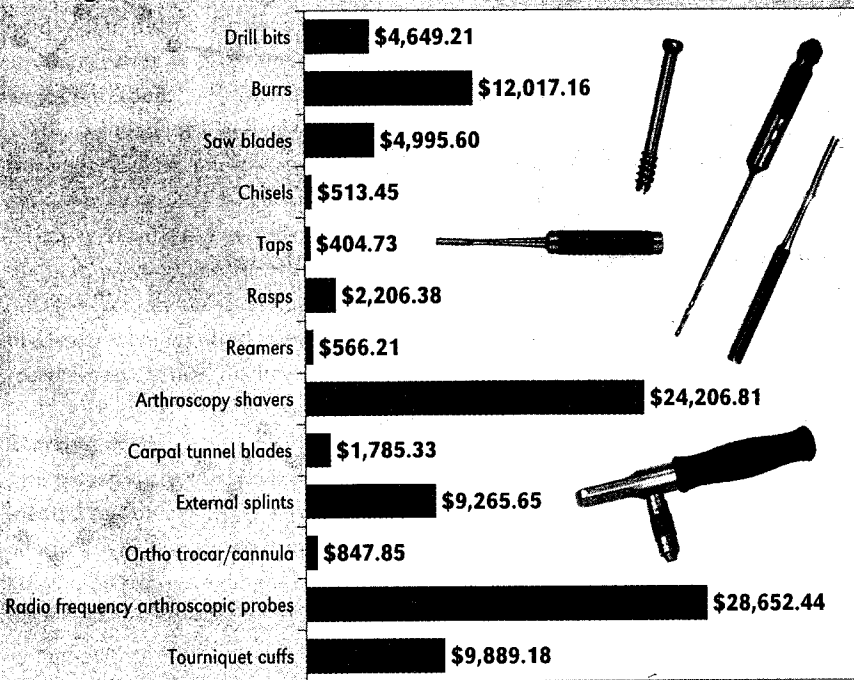
Analysis should be performed on a weekly to monthly basis to continually identify usage trends and communicate this information to the departments.

Equally as important is the development of a master item reprocessing list complete with OEM-reprocessing costs, manufacturer/hospital ID numbers, and departmental information. The list should be updated frequently.

Reprocessing SUDs offers hospitals an effective, cost-cutting strategy. Additional dollars achieved through savings from reprocessing can be used to fund new health care programs, pay existing debt and create initiatives to improve patient care. The bottom line is that when reprocessing is implemented correctly—with support from all hospital stakeholders—everyone, including patients, wins. **MMHC**

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Average distribution of \$100K in orthopedic reprocessing savings



Source: Nexera Consulting, 2005 (Data based on average savings of \$100K across 20 facilities)