

Product Commentary

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Reuse of Disposable Medical Devices: Historical and Current Aspects

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ABSTRACT

The "plastics revolution" of the last quarter century disrupted a hospital tradition. Since the 1890s, hospitals processed, packaged, and sterilized most of the medical-surgical items they needed in their own sterile supply departments—a "cottage industry" developed specifically for recycling. Only those consumable items that were too difficult, expensive, or inconvenient to reprocess were purchased from outside manufacturers as presterilized, single-use "disposables." Since the plastics revolution, however, the "disposables" started to displace the "reusables," and while claiming to be an economical innovation, have become a significant item in the budget. Some hospitals feel that if disposables save money, reusing the disposable several times will save more. The practice is spreading. The manufacturers, in turn, claim that hospitals do not have adequate quality assurance programs or skills to reprocess *their* items properly. The debate is further complicated by legal and ethical ramifications, as well as commercial and economic arguments. [Infect Control 1986; 7(10):508-513.]

HISTORICAL FOOTNOTES

In the beginning the hospitals themselves made and processed and sterilized nearly everything they needed or wanted for medical and surgical use. This is not surprising. The devices, techniques, instruments, and drugs that are part of today's aseptic surgical world were thought up

and introduced by the physicians and surgeons who worked in these hospitals. There were no independent research institutions; no FDA regulations; no JCAH inspections; and no human research committees. The doctors tinkered and experimented and innovated.¹ They saw Lister's success and improved upon it. In 1886, von Bergmann in Berlin learned how to steam his dressings, operating gowns, and surgical towels. They came out wet, but sterile. Just about the same time Kummell in Hamburg introduced the surgical "scrubbing up" technique. In 1890, Halstead at Johns Hopkins invented rubber gloves, and shortly thereafter, in 1892, Mikulicz at Breslau devised a gauze mask that covered the nose and mouth. These aseptic innovations were not considered ancillary to surgery; they were considered as critical as the operating procedure itself. The preparation of masks, gloves, gowns, and drapes, as well as the instruments and the saline and the disinfectants was a medical task best performed or at least supervised by the doctors, in the hospital itself.

At about the same time, in the last decade of the 19th century, the steam autoclave became commercially available.² It was invented in 1880 by Charles Chamberland working in Pasteur's laboratory, and its application to the aseptic ritual of surgery was quickly recognized. By 1890 "the first complete plant for pressure sterilization of surgical appliances," including a dressing sterilizer and a pair of water sterilizers, was installed at City Hospital in Rochester, NY. In 1892 a bigger and more elaborate system was purchased by Roosevelt Hospital in New York City. Thus began the in-hospital "cottage industry" known as "sterilization." Operating room nurses and aides were taught how to process and sterilize dressing materials, glassware, sutures, used rubber gloves and catheters, used surgical instruments, and hypodermic needles. The theory and practice of steam sterilization evolved from an art

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into a science. And by 1915, equipment processing and reprocessing became a fixed feature of any reasonably managed hospital. By the time of WWII, the processing-sterilizing departments of hospitals outgrew their parochial attachment to surgery. We entered an era of central supply and sterilization departments which invested hundreds of millions of dollars in mechanical equipment; hundreds of millions more in instruments, devices and fabrics that were processable in their equipment; and tens of thousands of trained workers (not necessarily with nursing or medical training) who operated these departments. The complexity and magnitude of the current in-hospital enterprise is illustrated in Tables 1 and 2.

It is interesting to note that concurrent with these developments, the hospital supply industry also developed and grew. On the one hand, there were the manufacturers of sterilizing equipment; on the other hand there was a burgeoning mixture of device manufacturers, surgical supply houses, and jobbers who sold the "raw" instruments, dressings, gloves, etc. to the hospital. And most germane to this discussion, we can document in the early 1890s the intent of at least one surgical supply house (Johnson & Johnson) to provide hospitals with medicated dressings, medicinal plasters and surgical ligatures *already packaged and already sterilized!*⁴

This fascinating glimpse into medical-bacteriological-sterilization history was provided by Gaughran at the first Kilmer Conference on Sterilization of Medical Products.⁴ Unfortunately, a retelling of the story is beyond the time and scope of this paper. It is only referred to in order to document the fact that the sterile disposable industry is as heavy with tradition as is the in-hospital sterilizing industry. The two enterprises have existed side by side for nearly a hundred years in a spirit of cooperation and friendly competition. Each had its profitable share of the pie and the boundaries were fairly well defined—mostly on economic grounds. There were many items that the "disposable" industry provided, even a century ago, that could be manufactured more conveniently in a factory than in the hospital. In particular, factories were the major sources of "consumables"—items that are literally used up in practice—such as bandages, medicated dressings, sutures, pharmaceuticals, and paper goods. Nearly everything else that could be sterilized in a steam autoclave was considered durable, to be processed and reprocessed in-house by non-unionized, underpaid workers employed by the hospital.

This is not to say that all has been sweetness and light for a hundred years. As long ago as 1897, Kilmer⁵ raised the specter of quality control in hospitals and doctors' offices. Kilmer described the doctors' offices as "filled with dust from pest laden households . . . tables, shelves, books and apparatus spattered with debris from urinal examinations, pus from foul sores, dried excretions from diseased skin, pathological tissue, clotted blood . . ." etc. He had similar things to say about "the hundreds of sources of contagion" and "particles rich in pyogenic and pathogenic bacteria" found in hospitals as well as the "favorable lodging and breeding place for organic life" in the pharmacist's laboratory. In contrast, he described the ultra-clean facilities and rigorous precautions employed by the

TABLE 1
MATERIALS COMMONLY STERILIZED IN
HOSPITAL STERILIZING FACILITIES²

Metals	Wood
Glass	Bristle fibers
Rubber	Oils
Water (and aqueous solutions)	Powders
Paper	Vaseline
Bristle fibers	Petrolatum gauze
Textiles	Pastics
cotton	polyvinyl chloride (PVC)
wool	polyethylene
linen	polyamide (nylon)
acrylic	Polytetrafluoroethylene (teflon)
canvas	polystyrene
leather	polymethylmethacrylate
cellulose	

manufacturer, "whose only calling is that of preparing surgical material" and whose personnel "have been schooled in the principles" of asepsis and sterilization.

On the other hand, hospitals that acquired experience and sophistication in the sterilization business sometimes wondered whether industrial sterilization standards were as high as their own. Not infrequently, hospital infection committees would demand from suppliers of disposables copies of *their* quality control protocols. There was always a subtle suspicion that "company secrets" could be used to mask short cuts in sterility monitoring—a suspicion that was fed by some rare but well publicized infectious outbreaks attributed to commercially supplied parenteral solutions and implantable lenses.

Now it seems that the suspicions have shifted again. During a 1982 AAMI conference, Bruch⁶ referred to "a double standard . . . evolving in the way device sterility assurance is assessed by industry in comparison to the procedures used by CSDs of hospitals." He was concerned that hospitals depend too much on empirical protocols and inadequate sterility monitoring procedures while industry approaches the problem with a greater degree of sophistication and science.

This may all be true, or it may be an unfair indictment of hospitals. There is no epidemiologic evidence that hospital sterilizing practices—in American hospitals today—are anything less than adequate. The overriding criteria for choosing one option over another were economics and convenience. For close to sixty years it is fair to say that patients benefited from the best of both possible worlds: the economics of hospital sterilized reusables and the convenience of industry sterilized disposables. And until now, the quality assurance of sterile material from both sources has been beyond suspicion.

BLURRING THE BOUNDARIES

The status quo described above began to disintegrate in the 1950s, during and because of the big "plastics" explosion. The hospital-supply industry learned how to fabricate, out of polyvinyls, polystyrenes, polycarbonates, and poly-everything else, the myriad of items and devices

TABLE 2
FLOW SHEET OF A CENTRAL STERILE SUPPLY DEPARTMENT IN 1965³

Source	Contaminated Articles From Wards				Laundry	Hospital Stores	Tap or Still	Commercial Manufacturer
Item	Syringes and Needles	Small Instruments	Special Instruments	Gloves and Tubing	Gowns and Drapes	Dressings	Bottled Water	Plastic Items Disposable Dressings
Process	1. Clean 2. Service (sharpen, lubricate, etc) 3. Inspect 4. Package				Package		None	
Sterilize	Hot Air Oven		Gas Sterilizer	Pre-Vacuum Steam Autoclave			Conventional Autoclave	None
Store	CSD Inventory							
Distribute	Different Departments							

they had originally made out of glass, metal, rubber, and woven textiles. Moreover, they learned how to sterilize these things with ethylene oxide or radiation—technologies which were not yet available in hospitals. Above all, they learned to make these items cheaply and efficiently.

The net result was a marketing revolution: the abundant availability of inexpensive but reliable syringes, fine gauge needles, gloves, tubing, catheters, etc, all pre-packaged, presterilized, and pre-labeled—"for single use only."

In the earlier years of the plastics explosion, hospitals were forced to discard these things after a single use, simply because they could not sterilize them again. They would melt in a traditional steam autoclave! Then many hospitals discovered that they were actually saving money by buying sterile disposables and discarding them after a single use instead of the old way of buying durables and reprocessing them in-house. The Puritan ethic of re-using and repairing something until it completely wore out was encountering the realities of cost-effectiveness economics.

A footnote on hospital economics might be in order at this point. It played as important a role in the reusable/disposable shift as any innovation of plastics technology, and despite our emphasis on sterility, safety, reliability, and ethics in this debate, economics is still at the heart of the controversy today.

Everyone knows about the astronomic rise in hospital costs during the last 20 years, and everyone has an hypothesis to account for it. Demography, malpractice, technology, inflation, greed, and Medicare extravagance all share the blame (or at least the indictment). But one factor is often overlooked: the elevation of salaries of hospital workers from disgracefully low to reasonable recompense for skill and effort. In truth, Americans have always perceived hospitals as some kind of charitable institution that should be staffed by volunteers, nuns, and martyrs. And if this is true for the nursing staff, how much more so for the central sterilizing department,

which somehow acquired the image of a place where charitable ladies meet to roll bandages. The point is that just about the time CSD workers started to achieve some small steps on the road to equity, the disposable market revolution was beginning to get underway. And both movements have gained momentum since leading to a lot of interactions and a lot of perturbations.

For example, by the beginning of the 1970s more than one third of American hospitals were equipped with ethylene oxide sterilizers and had the technical capability to sterilize plastics and other heat-sensitive devices. Also, by this time, the plastics manufacturers were fabricating many devices from heat resistant plastics, which were compatible with steam sterilization. Still many hospitals kept on switching to presterilized disposables because it was just too expensive to collect, clean, sharpen, lubricate, inspect, package, and sterilize the hundreds of items included. Labor intensive enterprises in the hospital were being phased out.

Those who remember the revolution remember nearly daily innovations and modifications of the old status quo. And it was not only sterilizable items that were involved. It seems like everything was changing at once. Anything that had been made of stainless steel or glass or rubber or woven cotton was replaced by a disposable. Disposable masks, caps, booties, gowns, drapes, bedpans, water pitchers, urinary bags, endotracheal tubes—the list seems endless. And all was justified in the name of economics.

As might be expected, it was not long before disposables and presterilized devices became a major hospital expense. And major hospital expenses always attract the attention of cost-conscious administrators, especially those who know how much equity the hospital has invested in sterilizing and laundry machinery. Why not try to resterilize some of the less critical disposables—like plastic bedpans and urinals and water pitchers and thermometers? After all, if a disposable is cheaper to buy than a durable, and it can be reprocessed without adding too much cost—the equipment and workers are already

TABLE 3
DISPOSABLE MEDICAL DEVICES REPORTED TO BE REUSED
(DESCENDING ORDER OF FREQUENCY)⁷

Hemodialyzers	(46%)	External pacemaker electrodes	(4%)	Ear syringes	(<1%)
Cardiovascular catheters and guidewires	(31%)	Arterial catheter needles	(2%)	Face tents	(<1%)
Respiratory therapy breathing circuits	(18%)	Aseptic irrigating syringes	(2%)	Gastric pH monitors	(<1%)
Biopsy needles	(17%)	Shunt connectors	(2%)	Hypodermic needles	(<1%)
Cautery devices	(16%)	Sterile skin scribes	(2%)	Javid tubes	(<1%)
Anesthesia breathing circuits	(14%)	Cholangiographic catheters	(1%)	Oxygen masks	(<1%)
Endotracheal tubes	(10%)	Esophageal stethoscopes	(1%)	Microscalpels	(<1%)
Suture staple removers	(9%)	Pacemakers	(1%)	Stone baskets	(<1%)
Syringes	(9%)	Pulmonary nebulizers	(1%)	Surgical gloves	(<1%)
Orthopedic appliances	(7%)	Skin staplers	(1%)	Surgical packs	(<1%)
Suction canisters	(7%)	Surgical sponges	(1%)	Tri adaptors	(<1%)
Tracheal tubes	(6%)	Urinary catheter plugs	(1%)	Tracheostomy tubes	(<1%)
Bovie cords	(5%)	Allen needles	(<1%)	Urethral stents	(<1%)
Esophageal thermometers	(4%)	Arterial embolectomy catheters	(<1%)	Urinary bags	(<1%)
		Condensing bottles	(<1%)		
		Operating room clamps	(<1%)		

here—why not save double: buy it cheap and don't throw it away?

It seems to me that reusing a disposable has an element of poetic justice ingrained, if one can become poetic about economics.

STUMBLING BLOCKS: HIGH TECHNOLOGY AND QUALITY ASSURANCE

The scenario described above sets the stage for today's debate about reusing disposables.⁷⁻⁹ The classic boundaries between disposables and reusables were blurred by the technological and economic revolutions of the last 25 years. It is difficult to decide exactly where—because of economic or medical reasons—a device should be considered a durable, a single use disposable, or a reusable disposable.

The real stumbling blocks enter the picture when we look at yet another feature of the technical-economic revolution of the last quarter century: the development of high-tech, very expensive disposables.

Bacteriologists who worked on the NASA program remember the problems we faced when asked to sterilize electronic circuits and servomotors. We became very sensitive to the dual restrictions of microbial sterility (about which we knew something) and functional reliability (about which we did not). We were impressed with the technical complexities and costs of these gadgets. There was to be *no* trade off between sterility and function. They *had* to work and they *had* to be sterile (or at least germ-free enough to meet NASA's treaty obligations to Planetary Quarantine).

Similar problems exist in hospitals today but are multiplied many-fold. The bioinstruments and invasive devices used today are as complex and sophisticated as anything we landed on the moon or Mars. But instead of exploring planets, human lives depend on their function. The pacemakers, dialyzers and insulin pumps have to work! And they must be sterile to minimize infection risk.

The manufacturers of these high-tech devices seem to

have solved the dual quality assurance problems of reliability and sterility. They are fabricated, tested, packaged, and sterilized in very sophisticated factories. The operations and products are closely monitored by the Bureau of Medical Devices of the FDA. Quite understandably, the manufacturer does not want anyone to "tamper with" or impair the device. He is willing to warranty safety and function only if he can control those qualities. Thus he warns the user that his responsibility is terminated once the device is removed from the original package. He certainly does not want to bear the legal or moral burden of negligence if a malfunction or an infection occurs after someone—not under his supervision—tests, processes, or sterilizes his device.

Thus, most of these high-tech items are supplied pre-packaged and presterilized, just like the less critical, less expensive disposables. And that leads to an identity crisis. These things do not really belong to the generic class that we generally think of as "disposables" or "consumables," like drainage bags and syringes and gloves. They are too critical and complicated and expensive. But because they are expensive and because hospitals know how to sterilize and reuse other disposables, they are tempted to try to reprocess these high-tech devices anyway.

THE REALITIES OF REPROCESSING

At the 1984 Georgetown University International Conference⁷ on the reuse of disposables, an informal survey of attendees revealed the widespread practice of reprocessing in American hospitals. Of the 204 respondents, 54% were affiliated with hospitals. More than 80% responded positively to a question dealing with reuse of disposables in their institution. Only 6% stated that their facilities either had a policy prohibiting reuse or did not reuse such devices.

A total of 44 different medical devices were identified as reused disposables (Table 3), with the most frequently cited being hemodialyzers, cardiovascular catheters and guidewires, respiratory therapy breathing circuits, biopsy

needles, and cautery devices.

Although the survey was informal and not representative (79% of the hospital-affiliated respondents were from the bigger and more sophisticated hospitals in the country), the prevalence of the practice is inarguable. It surely means that many hospitals are simply disregarding the suppliers' warnings. They feel confident that their own quality assurance programs provide their patients with the same safety and effectiveness warranties as do the manufacturers'—and they think they save money at the same time.

In the case of some of the devices listed, this may indeed be true. Or it may be of no consequence. Surgical sponges and skin scribes are not really critical performance items. If the hospital actually saves money by reusing them no one is going to criticize them too vigorously. On the other hand, some of the most frequently reused devices are the high-tech items we mentioned above, and the monetary savings achieved must be evaluated against the issues of safety, ethics, and even legality.

These are areas where good, hard data are difficult to assemble. The Health Industry Manufacturers Association (HIMA), who represent the suppliers of presterilized single-use items, has assembled a number of clinical case reports and court verdicts that predict dire consequences to anyone who transgresses against the command "Thou shalt not reuse a disposable."⁸ They describe, *inter alia*, a \$970,000 malpractice verdict against a physician and hospital who reprocessed an intravenous catheter which subsequently broke during use inside a patient; 27 bacteremia cases among patients treated with dialyzers that had been reused, even though they were labeled single-use; 18 cases of hepatitis B in a physician's office where a nurse reused single-use blood lancets for hemoglobin testing; and four bacteremia deaths caused by contaminated pressure monitoring domes originally sold presterilized for single-use only.

The litany assembled by HIMA may represent only examples of reuse tragedies or it may be the sum total of all the adverse consequences. And it does not report those operational failures and infections that occurred despite proper use of presterilized disposables. Regardless, the widespread reuse of disposables coupled with any probability of human suffering and death requires a serious evaluation of this activity by all concerned, including professional microbiologists.

But first we must distinguish the critical issues from certain semantic non-issues.

SEMANTIC AND OTHER OBFUSCATIONS

A real handicap to rational analysis lies in the very terms we use to describe our problem. What do we really mean by a "disposable"? Is it the same as a "consumable" or can it be a "durable" that has been labeled "single-use" by a manufacturer who makes a living by selling new devices? Is the criterion for a "single use" designation its cost, or its life expectancy, or its potential hazard after repeated use, or its impact on the manufacturer's legal liability, or lack of confidence in a hospital's quality assurance capability? Hopefully, it is more than another profit enhancing gimmick!

Indeed, what is meant by reuse? Two possible scenarios come to mind: In one case, the manufacturer's package is opened in surgery, but before the device can be used or implanted the circumstances change and the physician decides not to use it. Can the hospital repackaging it and sterilize it? In the other case the device is employed according to directions and it works well. Can the hospital clean it—like they do other complicated and expensive high-tech devices, eg, endoscopes—and wrap it and sterilize it? Do both of these scenarios fall under the same all encompassing category of reuse?

Undoubtedly, some of our problems have less to do with quality assurance or patient welfare than they do with images. "New" sounds neat; "reused" sounds cheap. "Cost control" by industry is praiseworthy; cost control by hospitals sounds stingy. What we need in this business is an objective, neutral vocabulary whose terms do not generate value judgments.

And while we are at it, we might have to neutralize the pseudoscientific-commercial advocacy that permeates the field of hospital supply. We have become so influenced by our own legends it is hard to distinguish between facts, fallacies, fads, and frauds. Sterilizing is not really that much of a technical mystery anymore. The probability of contaminating a sterile device after it has been opened in the operating room is orders of magnitude greater than the probability of an undetected autoclave failure. The sterile field really isn't bacteriologically sterile. And a lot of successful infection-free surgery is really done with instruments that have only been highly disinfected instead of legally sterilized.

These are the facts. If they are not consistent with our fantasy, so much the worse for our fantasy.

AN AGENDA OF ISSUES

The opponents of reuse of single use items present a coherent list of issues for consideration and debate.⁸ Their position on these issues is predicated on an assumption that the quality assurance programs of industry are more rigorous, consistent, and scientific than those in hospitals. Moreover, the manufacturers claim, if hospitals were to introduce proper quality control—with the technology, manpower, and statistical sampling involved—the cost of reprocessing would be so high that any economic advantages that currently exist would be rapidly dissipated. They may have a point. It's a testable hypothesis, but it has not been tested yet.

Notwithstanding these assumptions, these are the issues for discussion:

1. **Infection risk:** Is a device that is resterilized in a hospital as safe, from an infection control point of view, as the original device supplied by the manufacturer? Is the packaging as reliable? What are the maximum number of resterilizations permitted?
2. **Toxicity:** Is the resterilized device as safe, from a toxicological point of view, as the original device? Were the toxic residues that might accrue during cleaning, sterilizing, packaging, and storage removed? How is toxicological safety ascertained?
3. **Pyrogenity:** What assays were done and what stan-

dards were used to assure safety from a pyrogen point of view?

4. **Biocompatibility:** What tests were done and what standards were used to ascertain biocompatibility of devices that are implanted in or which have significant contact with body tissues and fluids?
5. **Functional reliability:** Does the reprocessed device function as well as the original device? What tests and standards were used in the hospital to evaluate functional effectiveness?
6. **Physical state:** What tests and standards were used to evaluate such physical properties as tensile strength, burst pressure, leak pressure, surface finish, and dimensional tolerances?
7. **Legal and liability issues:** Does the hospital carry liability insurance for reused items? Does reuse violate any federal or state or accreditation laws or regulations? If problems arise, who in the hospital is liable? Will the hospital subject itself to the regulations of the Bureau of Medical Devices?
8. **Economics:** Does the hospital actually save money by reprocessing? Should the hospital pocket the savings or return them to the patient (or the insurer)? Should the same charge be made for a reprocessed device as a new one? Will such cost savings ultimately be recaptured by payment reductions for third-party payments?
9. **Workplace hazards:** Is the hospital equipped to prevent infection and chemical hazards that are associated with reprocessing? Will there be any restrictions on the reuse of items previously used on patients with certain infections or diseases?
10. **Ethics:** Who in the hospital will get the reprocessed device and who will get the new one? Should patients be informed that they are being supplied with reused items? While the hospitals are gathering the information on safety and effectiveness (items 1 to 6, above), will the hospital inform the patients that they are part of a clinical trial? Will this be a random, controlled trial? Will all patients have an equal opportunity to participate? or to withdraw? Will the manufacturer be informed that his product is being tested?

THE BOTTOM LINE

The preceding agenda sounds formidable and frightening. It would be both arrogant and foolish to try to simplify the current controversy. But bacteriologists are known for their agar and petri dish empiricism. Let's try to use some of this empiricism to thread our way out of this jungle.

First of all, we must demystify the mysterious world of quality control. Table 4 shows the seven basic questions. It makes no difference whether you call the device a disposable, a durable reusable, or a reusable disposable. It makes no difference whether the job is done in a \$100 million clean room or a hospital CSD. These are the questions that must be answered. If we cannot answer them, we have no business in the medical device field—period.

Second, we must decide, a priori, that there are no

TABLE 4
QUESTIONS ABOUT THE
FINISHED PRODUCT³

What minimum level of sterility will be tolerated?
What maximum level of pyrogens will be tolerated?
What minimum level of device function (eg, electrical, mechanical, thermal) will be tolerated?
What is the sensitivity and specificity of the tests available to monitor these levels?
How many unsatisfactory devices will be tolerated (eg, per batch, per period of time)?
How many acceptable devices are you willing to reject to achieve the tolerance selected?
What is the life expectancy of the device in storage?

universal answers. The answers will differ from instrument to instrument, from device to device. They may even differ from patient to patient or case to case. It is even conceivable that different hospitals will answer differently. That is also permissible—if they are willing to live with the consequences.

Third, we must accept the reality that any polarization—toward 100% in-house sterilization or toward 100% single-use—is probably impractical. Each hospital will decide on its proper economic mix of disposables, durables, and reuse of disposables, depending on its size, its reprocessing capacity and its in-house quality assurance compatibility. In the long run manufacturers will recognize this. Marketplace pressures will encourage industry to produce some disposables that the hospital will not want to reuse and simultaneously, other disposables designed for limited reuse. We have already been successful with such items as hemodialyzers and cardiovascular catheters. There are no theoretical limitations to expanding this list.

But to do that, we need better data than we have. And a better insight into economics, law, ethics, toxicology, and quality assurance.

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