6-2017

Reuse of reprocessed single use devices: Summary

Children's Mercy Kansas City

Office of Evidence Based Practice – Specific Care Question: Use of Reprocessed Single Use Devices (SUDs)

Specific Care Question :

Are reprocessed, single-use devices (SUDs) safe and efficacious to use? (For definitions see Table 1)

Question Originator:
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Clinical Bottom Line:

Under the Medical Device User Fee and Modernization Act (MDUFMA, 2002), the use of reprocessed SUDs is allowed, when the ensuing regulations are followed (links to the regulations are included in this CAT, see page 20).
Many institutions use reprocessed single use devices and have incurred significant savings. There are few studies that compare new single use devices to reprocessed single use devices for outcomes like infection and adverse events. It is noted that some adverse events that may be important to the patient such as prolonging operative time are not captured in the literature at all. The medical literature does not contain evidence to guide the decision on using reprocessed SUDs. However, medical and nursing professional associations have varying views on the use of reprocessed SUDs. If use of the reprocessed SUDs increases, extensive education related their use will be necessary to provide a foundation for the success of their use.

Plain Language Summary from the Office of Evidence Based Practice:
This review is about reprocessed SUDs. SUDs are not "reusable" devices. See Table 1 for definitions.
Under MDUFMA (2002), certain medical devices that have been labeled "single use" can be reprocessed and reused. MDUFMA does not apply to devices that are labeled "reusable." To follow MDUFMA, third-party reprocessors clean, refurbish, sterilize, repackage and re-sell SUDs. The company that reprocesses the device must assure that (a) the reprocessed device has the same reliability as a new device, (b) the package clearly states that it is a reprocessed SUD, and (c) accepts that it is considered the Original Equipment Manufacturer (OEM) of the device. The Food and Drug Administration (FDA) must keep a list of SUDs that may be reprocessed, and determine which devices need pre-approval to be reprocessed before they are sold to hospitals. Finally, the FDA must assure that when hospitals, medical providers, or patients report adverse events they are able to include if the device was a reprocessed SUD. Examples of SUDs include:

- Surgical Saw Blades
- Surgical Drills
- Laparoscopy Scissors
- Orthodontic (metal) Braces
- Electrophysiology Catheters
- Electrosurgical Electrodes and Pencils
- Respiratory Therapy and Anesthesia Breathing Circuits
- Endotracheal Tubes
- Balloon Angioplasty (PTCA) Catheters

Very little research compares reprocessed SUDs to new medical devices for the outcomes of infection, visual defects, or adverse events.

Our confidence in the estimate of the effect is very low. Six studies are included that either show no difference, or if a difference is seen, the studies contradict each other over which type of device is better, new or reprocessed. The studies also do not evaluate the same type of devices. For example, one study (Mues, 2010) evaluates devices used in general surgery, while others (Ledonia, 2014) evaluate devices used in orthopedic surgery. Further research is likely to change our confidence in these findings.

Finally, position papers of medical professional societies vary over the acceptance of the use of reprocessed SUDs (see Table 2).

Table 1. ***Definitions***

Term	Definitions from MDUFMA (2002)
Single-use device -(SUD)	A device that is intended for one use, or on a single patient during a single procedure and then disposed
Reprocessed single use device (Reprocessed SUD)-	A. An original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The reprocessed single use device is the same as a new or predicate device. B. A SUD that meets the definition above, shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device. Therefore, if a manufacturer calls the device "recycled" it must still follow the regulations for a reprocessed SUD.
Original device	A new, unused single-use device. The term "predicate device" is sometimes used.
Critical reprocessed SUD	A reprocessed SUD that is intended to contact normal sterile tissue or body spaces during use.
Semi critical reprocessed SUD	A reprocessed SUD that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.
Classification of device recalls	Recalls are classified into a numerical designation (I, II, or III) by the FDA to indicate the relative degree of health hazard presented by the product being recalled. A. Class I - a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. B. Class II - a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

	C. Class III - a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
Reusable devices	Devices that health care providers can reprocess and reuse on multiple patients (FDA, 2015). Examples of reusable medical devices: Surgical instruments such as clamps and forceps Endoscopes, examples doudenoscopes, colonoscopies and bronchoscopes Graspers and scissors Non critical devices such as stethoscopes and blood pressure cuffs

Review of the Literature

Initially, SUDs were marketed to reduce infection and to be convenient. However, the cost of both using a new device and disposal of the device each time a SUD was needed, led to the reprocessing SUDs. Reprocessing includes cleaning, sterilizing, and refurbishing (if necessary) the medical device (Noble, 2013). If a hospital reprocesses SUDs, they must comply with the FDA's medical device requirements that apply to manufacturers. Therefore the usual path hospitals take is to use third party reprocessors (FDA, 2003). Reprocessors must comply with the MDUFMA (2002). To be compliant with the law, the reprocessed single use device must:

- Be "substantially equivalent" to the predicate device.
- Be labeled to show "prominently and conspicuously" that the medical device is a reprocessed SUD.
- Submit premarket and approval applications (510(k)), that are as rigorous as original device manufacturers (OEMs) provide.
- The third-party reprocessor will be considered "manufacturers" and will be regulated in the same manner (GAO, 2000; Rutala, Weber, & HICPAC, 2008).

In addition, the FDA must:

- Maintain a list of devices that must undergo premarket approval for reprocessing.
- Determine which devices are low and moderate, and high risk devices (FDA, 2003), and determine which devices should be subject to enhanced requirements.
- Provide validation data on the maximum number of times a SUD can be safely reprocessed.
- Modify the MedSun, the adverse event reporting program to facilitate the reporting of SUDs, the reprocessor, and if the device had been reused.

Since SUDs became available, medical professional organizations have developed guidance and or position papers regarding their use (see Table 2).

- The Centers for Disease Control and Prevention (CDC) acknowledges that regulations on the reuse of SUDs are emerging. Their guidance echoes that sterilization and disinfection guidelines must be strictly followed. They ask healthcare workers to monitor the FDA sites and be aware of the latest information.

- The Association for Professionals in Infection Control and Epidemiology (APIC, 2007) supports the FDA's requirements for the reuse of single-use devices meeting criteria for reprocessing.
- The Association of periOperative Registered Nurses (AORN, 2017) states that devices labeled as single-use should not be reprocessed for reuse unless the FDA guidelines can be met.
- In 2012 The American College of Obstetricians and Gynecologists Committee's released an Opinion Statement on reprocessed SUDs to educate its members on the use of reprocessed SUDs. It neither recommends using or not using reprocessed SUDs, although it acknowledges the regulations that surround the use of SUDs (Committee on Gynecologic Practice 2012).
- Finally, the Society of Gastroenterology Nurses and Associates (SGNA, 2015) takes the position that reprocessed SUDs should not be used citing the absence of evidence on the safety and efficacy of such devices in the endoscopy setting. (This statement does not include reusable devices such as endoscopes.)

The literature search yielded six studies that answered the question (Horwitz, Schagel, & Higgins, 2007; Ledonio et al., 2014; Loftus, 2015; Maben-Tenney, 2012; Mues et al., 2010; Sung et al., 2008). A meta-analysis could not be performed as the types of devices and surgeries varied. Only one randomized control trial (Sung et al., 2008) was identified in the selected studies. Data, when appropriate, are displayed in forest plots for four outcomes (infection, visual defects, ability to distinguish new and reprocessed SUDs, and blade sharpness (see Figures 1-3).

Infection. Sung et al. (2008) reported on 96 subjects who sustained a fracture, and external fixation was selected as the initial treatment. Subjects were randomized into new or reprocessed external fixation devices. For the outcome, pin infection, the odds of pin infection are 78% less in the SUD arm, however it is statistically insignificant, as the confidence interval crosses 1, *OR* = 0.78, 95% CI [0.35, 1.74]. A power analysis showed 1600 subjects were required to detect a difference, and only 96 subjects were included in this study (see Figure 1), further weakening the estimate of the effect. The results of this study are uncertain.

Visual Defects. Two studies (Loftus, 2015; Mues et al., 2010) are included. The methods of detecting defects varied between the studies. In Loftus (2015) a device was defective if any member of the surgical team determined the device was not functioning correctly. In Mues et al. (2010) the devices were examined using a digital microscope (10, 20, 40 x magnification). Overall, there is no difference in the odds of the defect rate between reprocessed vs. new SUDs, *OR* = 1.51, 95% CI [0.98, 2.31] However, (Loftus, (2015) reported reprocessed devices had significantly less defects, while the other study (Mues et al., 2010) identified the new devices had less defects.

Ability to Distinguish New and Reprocessed Devices. Ledonio et al. (2014) integrated reprocessed arthroscopic shavers into competency training of orthopedic surgeons to see if they were able to identify the reprocessed shavers. In this study, that included thirty-nine surgical training events on bovine cadaveric knees, the odds that surgeons were not able to distinguish between the new and reprocessed instruments was *OR* = 0.61, 95% CI [0.15, 2.49] (see Figure 2).

Blade Sharpness

Ledonio et al. (2014) also reported on blade sharpness by reporting the blade slope test for reprocessed and new arthroscopic shavers, the mean difference of the blades sharpness was not significantly different, MD = -0.01, 95% CI [-0.13, 0.11] (see Figure 3).

Cost

Horwitz et al. (2007) report that for a single trauma center, 474 external fixation rods, clamps or posts were used for orthopedic procedures. Seventy-six percent of the devices passed both visual inspection and mechanical testing after the first reprocessing, and those devices (n=35) which underwent a second reprocessing, 83% (n=29) passed visual and mechanical inspection. Further, they reported a limit of three re-certifications per item. The average cost per item was 68% of a new item.

Acceptance of SUDs

Maben-Tenney (2012) is included as a descriptive review of survey results of nursing students (*N* = 174). Concerns the students expressed include: a.) Increased risk for hospital infection (74%), b.) Risk associated with reusing something labeled as single use, c.) Uncertainty if the devices could be adequately sterilized, and d.) Uncomfortable with the processes used for sanitation. Although this is very low quality evidence, it points to the various groups that will require education if reprocessed SUDs are utilized.

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Search Strategy and Results:

Search: ("Disposable Equipment"[Mesh] AND (reuse[tiab] OR preprocessing[tiab)) OR ((Equipment Reuse[Mesh] OR "equipment reuse"[tw] OR "reusable equipment"[tw]) AND ("single-use"[tw] OR "single use"[tw] OR "Safety"[Mesh] OR "Safety-Based Medical Device Withdrawals"[Mesh] OR "Equipment Safety"[Mesh] OR "Risk Management"[Mesh] OR "Patient Safety"[Mesh] OR "Safety Management"[Mesh] OR "Infection Control"[Mesh] OR "Cross Infection"[Mesh] OR "Disease Transmission, Infectious"[Mesh] OR "Disease Reservoirs"[Mesh] OR "Risk"[Mesh] OR "Risk Assessment"[Mesh] OR "Cost-Benefit Analysis"[Mesh])) AND (Meta-Analysis[ptyp] OR Multicenter Study[ptyp] OR Randomized Controlled Trial[ptyp] OR systematic[sb]) AND (("2002/01/01"[PDAT] : "2017/12/31"[PDAT]) AND English[lang]) 87 results 16 selected for closer reading, 6 included in this review

Included in this review:

Government Publications:

Medical Device User Fee and Modernization Act, 2002 (MDUFMA, 2002)

Food & Drug Administration (FDA)

2000 Enforcement priorities (Health, 2000)

2003 (Health, 2003) FAQs

Government Accounting Office (GAO)

2008 Reprocessed Single-Use Medical Devices: FDA Oversight has Increased and Available Information Does Not Indicate That Use Presents an Elevated Health Risk (GAO, 2008)

Position Papers and Guidance from professional organizations

APIC 2007 (APIC, 2007)

AORN 2017 (AORN, 2017)

Gyn Practice 2012

Reuse of Single Use Critical Medial Devices (SGNA, 2015)

PubMed and Ancestry Search

15 articles were identified. After close reading ten articles were excluded.

Not included in this review with rationale for exclusion:

Reference	Reason for Exclusion
Brann & Capone (2013)	Narrative review
Buleon et al. (2013)	Plastic single use laryngoscope vs Metal laryngoscope, both single use and reusable
Jacobs, Polisena, Hailey, & Lafferty (2008)	Uncertain if reprocessed in-house or third party vendor
Manatakis & Georgopoulos (2014)	Does not answer the question. It is a cost comparison only
Nelson (2006)	Narrative review
Shuman & Chenoweth (2012)	Narrative review
Slater (2009)	Does not answer the question. It is a cost comparison only
Siu, Hill, & MacCormick (2017)	Does not answer the question. Compares reusable vs single-use surgical instruments, not reprocessed SUDs
Vockley (2016)	Narrative review

Method Used for Appraisal and Synthesis:

The Cochrane Collaborative computer program, Review Manager (RevMan 5.3.5), was used to synthesize the six included studies. Unable to use GRADEpro GDT (Guideline Development Tool) for this review.

Updated: May 2 2017

Included Studies:

Total Number: 6

Blinded: 0

Non-blinded: 6

Quality Assessment of Included Studies:

Bias risk assessment factors: There was high risk of bias from all the included studies. Only one study was a randomized control trial and it was significantly underpowered.

Foundation of bias risk: Five of the six included studies were not randomized control trials. The cohort studies did not have large effect sizes,

Number of Independent reviewers: 2

In case of discrepancy: NA

GRADE Analysis:

Unable to GRADE

Number of independent reviewers: 2

In case of disagreement: N/A

Tables:

Table 2. ***Positions of Professional Organizations***

Organization	Position
CDC (Rutala et al., 2008)	"The reuse of single-use medical devices continues to be an evolving area of regulations. For this reason, healthcare workers should refer to the FDA for the latest guidance."
Association for Professionals in Infection Control and Epidemiology (APIC, 2007)	• Reprocessing single-use devices can be safe and cost-effective. • The U.S. Food and Drug Administration has established regulation for reprocessing single-use devices. • The U.S. Centers for Medicare & Medicaid Services recommends that hospitals use a third-party reprocessor wen deciding to preprocess single-use devices • Reprocessing single-use devices is an acceptable practice in many countries
Association of perioperative Registered Nurses (AORN, 2017)	"Devices labeled as single-use should not be reprocessed unless the FDA guidelines for reprocessing of single-use devices can be met."
Society of Gastroenterology Nurses and Associates, Inc. (SGNA, 2015)	"In the absence of substantial scientific evidence to prove the safety and effectiveness of reprocessed critical medical devices in the endoscopy setting, SGNA maintains the position that critical medical devices originally manufactured and labeled for single use should not be reused.

Tables 3. ***Characteristics of included studies:***

Horwitz et al., 2007

Methods	Non randomized, ex *vivo* study
Participants	**Setting:** Single level-I trauma center All Hoffmann-II external fixation components that had been remove during the study period • **Group 1:** 474 external fixation rods, clamps, and posts sent for recertification **Inclusion Criteria:** • Clamps, posts, and external fixation rods. **Exclusion Criteria:** • Internally implanted components (half-pins) • components made of carbon fiber Agreed that each component should be recertified three times, Components met the FDA standards, and were considered to be an "original product"
Interventions	None

Outcomes	After first use of the instrument in the study period, the external fixation rod, clamp, or post was sent to the manufacturer for • visual inspection • mechanical testing
Notes	Of the 474 rods, clamps, and posts sent for recertification **Primary outcome(s):** • 360 components (76%) passed the first inspection and testing. **Secondary outcome(s)** • 35 components that had already been recertified once were sent for a second recertification. Twenty-nine or 83% of them passed the second recertification. **Reason(s) for failure:** • did not meet mechanical standards • visual inspection revealed defects **Cost analysis:** with a limit of three recertification events, the average cost per item was 68% of that of a new item.

Ledonio et al., 2014

Methods	ex vivo clinic study
Participants	Analysis of reprocessed arthroscopic shavers **Randomized into study: 39 shavers** • **Group 1:** 13 New shavers • **Group 2:** 13 Reprocessed sharpened reprocessed shavers • **Group 3:** 13 Reprocessed shavers, not sharpened because they passed the inspection criteria for sharp blades **Power Analysis**: Post-hoc power analysis performed, and power was not met.
Interventions	**1**. An evaluation of the clinical performance of new and reprocessed shavers using cadaveric knees • Shaver performance was evaluated during arthroscopy on cadaveric knees with typical medial and lateral portals and super lateral outflow portals. • Meniscal tears were created using scissors or blades. • Clinical competences of the shavers were assessed by having 3 orthopedic surgeons (C.G.T.L., E.A.A., J.E.A.), who were blinded to the shaver status, perform arthroscopy of the knee. Evaluation form of the shavers • new

	• reprocessed • indeterminate If the shaver could not perform the procedure, failure mode was selected from a) shaver was not sharp b) shaver did not effectively work in the hand piece c) observed metal shavings d) any other failure noted **2.** An examination of the engineering performance of blade sharpness using bovine reconstituted tissue cylinders to measure the sharpness of selected orthopedic shavers. • Dulled shaver blades showed the steepest negative slope (-4.39 Hz), indicating that after penetrating approximately 4 mm into a 25-mm tissue cylinder, the blades had stopped turning. • Rejected blades had the next steepest negative slope (-0.50 Hz), indicating that their rotational speed had decreased by over half after penetrating approximately 20 mm into the tissue cylinder. • New blades, reprocessed blades classified as acceptable after inspection, or reprocessed-sharpened blades exhibited essentially identical behavior and showed almost no decrease in rotational speed after traversing a 25-mm tissue cylinder (-0.01 Hz). • The initial rotational speed for all treatments was 48 Hz
Outcomes	Primary outcome: • Physician ability to detect if shaver is refurbished (Surgeons tested on cadaver knees) Secondary outcome: • Sharpness (cadaveric test)
Notes	The success rate in identifying reprocessed shavers was 42% (11 of 26), demonstrating that the ability to detect a reprocessed shaver is no better than chance, with a non-inferior margin of 10% (P=.0328). The observed proportion of reprocessed shavers classified as reprocessed (42%) was less than the observed proportion of new shavers classified as reprocessed (54%).

Loftus, 2015

Methods	Retrospective study
Participants	**Setting:** USA: health care system in large metropolitan area, January 2013-July 2013 **Equipment compared:** N=3112 (all devices were purchased for vessel sealing and dividing in open/laparotic surgical procedures) OEM ultrasound diathermy devices (US OEM) n=680 RP (repurposed) ultrasound diathermy devices (US RP) n=1036 OEM bipolar diathermy devices (BD OEM) n=713

	RP bipolar diathermy devices (BD RP) n=683 **Inclusion criteria:** a device was considered defective if any member of the surgical team determined that device was not functioning in a manner consistent with the device's intended purpose.
Interventions	**How devices were obtained:** collected from the operating rooms of 19 acute care facilities **How devices were reprocessed:** reprocessed by an external vendor approved by the FDA (510(k) approval). The reprocessed devices were the same as the original manufactured device.
Outcomes	Defect rate in devices (number of defects divided by the number of devices purchased).

Maben-Tenney, 2012

Methods	Cohort study - exploratory, descriptive review of voluntary survey results from nursing students
Participants	**Participants:** Nursing students enrolled in nursing research courses **Setting:** University of Central Florida **Completed Study:** N = 157 **Gender:** Male: 8.9% **Age (mean)**: 32.1 yrs. **Inclusion criteria:** at least 18 yrs. of age, undergraduate nursing student, currently enrolled in nursing research course at UCF **Exclusion criteria:** student in Master's program at UCF **Power analysis:** not needed **Covariates:** recycling habits, age, gender, academic program, and environmental consciousness
Interventions	Survey invitations were emailed to nursing students by their instructors. Survey participation was voluntary and students were given 1 extra credit point for completion. Surveys were accessed through SurveyMonkey and consisted of various types of questions including Likert scale, yes/no, and open-ended responses.
Outcomes	• Attitudes toward use of reprocessed medical device • Likelihood of using reprocessed devices in future practice • Concerns/barriers to use of reprocessed devices

Notes	Results (SA=strongly agree; A=agree; U=uncertain; D=Disagree; SD = strongly disagree):
	• Attitudes toward use of reprocessed medical devices
	  ○ single-use medical devices should be used only once: SA=52.5%; A=29.1%; U=0.8%, D=5.7%; SD=1.9%
	  ○ single-use medical devices can be reused if properly sterilized: SA=10.1%; A=18.4%; U=19.6%, D=27.2%; SD=24.7%

	○ reusing single-use medical devices contributes to hospital-acquired infections: SA=35.4%; A=38.6%; U=18.4%, D=7%; SD=0.6% • Likelihood of using reprocessed devices in future practice ○ would consider reusing single-use devices that have penetrated skin if sterilized before reuse: SA=4.4%; A=10.4%; U=13.3%, D=31%; SD=40.5% ▪ participants who recycle at home were significantly more likely to consider reuse in this situation: p=0.018 ○ would consider reusing single-use devices that have come into contact with mucous membranes but have not penetrated the skin if sterilized before reuse: SA=6.3%; A=18.4%; U=13.3%, D=26.6%; SD=35.4% ○ would consider reusing single-use devices that have only been in contact with intact skin if sterilized before reuse: SA=19%; A=37.3%; U=14.6%, D=12.7%; SD=16.5% • Concerns expressed by students included ○ perceived increased risk of hospital-acquired infection ○ risks associated with reusing something labeled for single-use ○ uncomfortable with sanitation process for single-use devices ○ uncertainty as to whether devices could be adequately sterilized • Limitations ○ study used a convenience sample which may not be representative of health-care providers in general ○ some demographic groups were underrepresented again limiting generalizability

Mues et al., 2010

Methods	Prospective Randomized Single-Blinded
Participants	**Setting:** laboratory **Randomized into study: N=527** • **Group 1:** New Trocars (Ethicon Endo-surgery)=199 • **Group 2:** Reprocessed Trocars (Ascent Health Solutions Inc.)= 328 **Completed Study: N=527** • **Group 1:** New Trocars (Ethicon Endo-surgery)=199 • **Group 2:** Reprocessed Trocars (Ascent Health Solutions Inc.)= 328 **Inclusion Criteria:** • Two dilating bladed trocars (Endopath Xcel D5LT-5 mm and D12LT-12 mm, Ethicon Endosurgery) • 1 bladeless trocar (Endopath Xcel B5LT- 5mm, Ethicon Endosurgery) • The blade mechanism on new and reprocessed trocars was tested only on D5LT trocars that did not undergo force testing.

Interventions	• **Evaluation For Visible Damage and Force Testing: D5LT, B5LT, D12LT**
	  ○ New Trocars=132
	  ○ Reprocessed trocars=259
	  ○ New and reprocessed trocars were initially examined using a digital microscope (10, 20, 40 x magnification) (Keyence Corporation) to document discernable imperfections including deep scratches, nicks, cracking, denting in the shaft of the trocar or obturator, or any visible damage. Both the trocar itself (housing unit and shaft) and the obturator (housing unit and shaft) were evaluated separately
	  ○ Force testing each trocar insertion and removal through the porcine abdominal wall. Trocars were inserted in the typical manner by creating a skin incision through the dermis (5mm incision of smaller trocars and 12mm incision for larger trocars). Force measured in pounds of force using a button load cell contained within a handle nest tensometer
	• **Shield Response Test: D5LT**
	  ○ New Trocars=31
	  ○ Reprocessed=33
	  ○ Blade measurements determined the time (seconds) necessary for the trocar shield to eclipse the blade (shield cover time) and the time for the shield to fully lock after complete insertion of the trocar (shield response time)
	  ○ Utilized shield response test fixture which locked the trocar in a horizontal position while the blade shield was manually retracted and locked into place. The shield was then released and the shield cover time and shield response time were captured using a high-speed camera system
	• **Leak Test: D12LT**
	  ○ New Trocars=36
	  ○ Reprocessed trocars=36
	  ○ Trocars were placed in an airflow tester that was set to test leakage at a pressure of 17mmHg. Both new and refurbished trocars were tested initially with the trocar ports empty and then with 2 different diameter (4.7mm and 12.9mm) metal probes traversing the seal to simulate small and large laparoscopic instrument insertion. Tested the seal durability of each trocar by passing a standard, hand-held right-angle clamp through the trocar exactly 20 times. The airflow tester digitally captured the quantity of leakage.

Outcomes	Primary Outcomes: Force Test: Discernable imperfections and performance in both in vitro and porcine in vivo mechanical testing Shield testing - using a shield response test fixture, which locked the trocar in the horizontal position with the blade shield was manually retracted and locked into place • Shield Response Test- captured using a high speed camera system ○ time (sec) for the trocar shield to eclipse the blade (shield cover time) AND

	○ time (sec) for the shield to fully lock after complete insertion of the trocar (shield response time) Leak test: Seal durability
Notes	• Can only use the visible inspection data for forest plot • For other outcomes, the shield cover time and the **shield response time** were significantly faster in the reprocessed trocars than the new trocars. However, the mean difference was 0.6 and 0.8 milliseconds respectively. • For the f**orce to insert and remove** the trocar, the new D12LT trocars required more force to remove than the reprocessed trocars, there was no difference in the force to insert. For the other trocars, D5LT and B5LT, there was not significant difference in the force to either insert or remove reprocessed vs. new trocars. • For the **leak test**,(n=36) there was significant difference in leak rates, with when probes of small diameter were inserted, leak rate was greater ○ After insertion of a 4.7 mm probe (n=36) ▪ Leak rate of new trocars- 89.3 ml/min ▪ Leak rate of reprocessed trocars- 169.0 ml/min ○ After insertion of a 12.9mm probe (n=36) ▪ Leak rate of new trocars- 26.4 ml/min ▪ Leak rate of reprocessed trocars- 43.4 ml/min

Sung et al., 2008

Methods	RCT
Participants	**Setting:** Single-center study, Boston, MA **Randomized into study:** N=96 • **Group 1:** New Frame: 50 • **Group 2:** Reused frame: 46 **Completed Study:** N=96 • **Group 1:** New Frame: 50 • **Group 2:** Reused frame: 46 **Gender, males:** • **Group 1:** 52% • **Group 2:** 52% **Age, years (mean):** • **Group 1:** 42 y • **Group 2:** 45 y

	Inclusion Criteria: • Age 18 years or older • Able to give consent • Function independently • Live locally • Sustained a fracture of the humorous, distal radius, wrist, femur, tibia, or ankle for which external fixation was the chosen initial treatment. (fractures were Orthopedic Trauma Association type A or C with significant shortening and metaphysealdiaphyseal dissociation) **Exclusion Criteria:** • patients younger than 18 years • prisoners or transients • those who had a history of alcohol or drug abuse in the 12 months prior to injury **Power Analysis:** Power analysis was performed, 1600 patients would be needed to show a significant difference in the occurrence of infection. Power was not met, only 96 patients were enrolled.
Interventions	• **Group 1:** New external fixation device • **Group 2:** Refurbished external fixation device that has undergone decontamination and inspection Refurbished by external vendor. Frame constructs were the same in both groups in the study. The distal radius construct used was a bridging external fixator with distal two pins (3 mm) in the second metacarpal and two proximal pins (3 mm) in the shaft of the radius. The tibial plateau construct was a spanning external fixator with two pins (5 mm) in the distal femur and two pins (5 mm) in the mid-shaft of the tibia. The pilon construct is a frame with foot inclusion: two proximal tibial pins (5 mm), a calcaneal transfixion pin (6 mm), and a single pin (3 mm) into each of the fifth and first metatarsal bases. All pin sets were placed at the outer extent of a multiple pin clamp, thus the spread of the pins was the same for each frame for all of the treated injuries. No independent pin-to-bar connectors were used. All pins were maximally tightened as is done in standard clinical practice.
Outcomes	**Primary outcome(s):** • complications of pin tract infections **Secondary outcome(s)** • Loss of fixation, or loosening of components.
Notes	The authors did not meet the power analysis requirement The commentary at the end of the study also points out that there is increased liability to the physician for using the refurbished part as the manufacturer would not indemnify the institution or surgeon after the part is refurbished.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Use of medical record number to determine group selection
Allocation concealment (selection bias)	Low risk	The medical record number was designated for the patient before orthopedic evaluation, so it would prevent the surgeon or assessor from altering group selection.
Blinding of participants and personnel (performance bias)	Unclear risk	Participants were blinded, but surgeons and outcome evaluators would be able to see a small etching on the device.
Blinding of outcome assessment (detection bias)	Unclear risk	Outcome assessors would find device etching, but the outcomes are not subjective and unlikely to be effected even if the group assignment was known
Incomplete outcome data (attrition bias)	Unclear risk	ITT, all of the patients that were randomized and consented were reported.
Selective reporting (reporting bias)	Unclear risk	All outcomes were reported
Other bias	High risk	Did not have enough participants to meet power analysis. With a considerable amount of attention focused on using refurbished parts to control costs, there may be a bias to present these parts as a reasonable alternative when the lack of participants in the study prevented the research from concluding the statistical significance.

Figures:

Figure 1. Reprocessed SUD vs. New, Outcome: Infection

Study or Subgroup	Reprocessed Events	Reprocessed Total	New Events	New Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Sung 2008	23	50	24	46	100.0%	0.78 [0.35, 1.74]
Total (95% CI)		**50**		**46**	**100.0%**	**0.78 [0.35, 1.74]**
Total events	23		24			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.60 (P = 0.55)

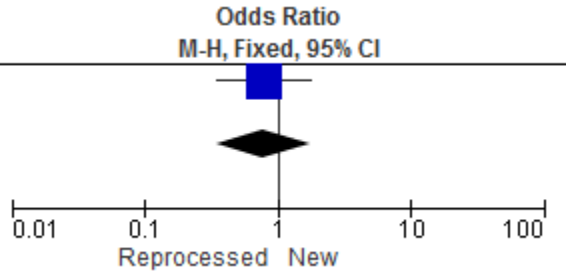


Figure 2. Reprocessed SUD vs. New, Outcome: Ability to discern if device (orthopedic surgical blade) was reprocessed

Study or Subgroup	Reprocessed Events	Reprocessed Total	New Events	New Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Ledonio 2014	11	26	4	13	100.0%	1.65 [0.40, 6.77]
Total (95% CI)		**26**		**13**	**100.0%**	**1.65 [0.40, 6.77]**
Total events	11		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.70 (P = 0.49)

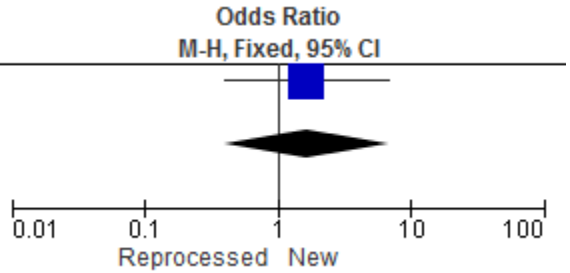
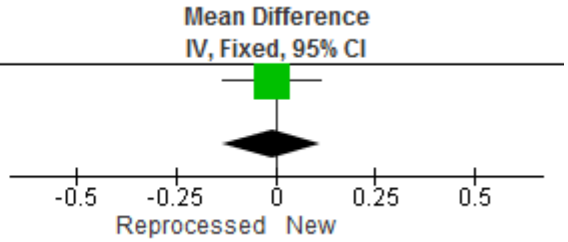


Figure 3. Reprocessed SUD vs. New, Outcome: Blade Slope test of sharpness (Lower is better)

	Reprocessed			New				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Ledonio 2014	-0.11	0.18	27	-0.1	0.16	9	100.0%	-0.01 [-0.13, 0.11]
Total (95% CI)			**27**			**9**	**100.0%**	**-0.01 [-0.13, 0.11]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.16 (P = 0.88)



References:

Association of periOperative Registered Nurses (AORN). (2017). AORN Guidance Statement: Resue of Single-Use Devices. In AORN, *2017 Guidelines for Periperataive Practice*. Denver CO: AORN, Inc.

Association for Professionals in Infection Control and Epidemiology (APIC). (2007). Reprocessing of single use medical devices. In *Association for professionals in infection control and epidemiology*.

Brann, H., & Capone, A. (2013). A tale of two SUD reprocessing programs: How two similar health systems can achieve very different savings results in teh EP lab. *EP Lab Digest*. Retrieved from http://www.eplabdigest.com/archive

Buleon, C., Parienti, J. J., Lesage, A., Grandin, W., Pouliquen, E., Flais, F., . . . Hanouz, J. L. (2013). Comparison of plastic and metallic single-use and metallic reusable laryngoscope blades: a randomised controlled trial. *Eur J Anaesthesiol, 30*(4), 163-169. doi:10.1097/EJA.0b013e32835c1cdb

Horwitz, D. S., Schagel, K. L. S., & Higgins, T. F. (2007). The economic impact of reporcessing external fixation components. *The Journal of Bone and Joint Surgery, Incorporated, 89*, 2132. doi:10.2106/JBJS.F.01409

Jacobs, P., Polisena, J., Hailey, D., & Lafferty, S. (2008). Economic analysis of reprocessing single-use medical devices: a systematic literature review. *Infect Control Hosp Epidemiol, 29*(4), 297-301. doi:10.1086/529587

Ledonio, C. G., Arendt, E. A., Adams, J. E., Matz, J., Boers, A., Miller, K., & Lester, B. R. (2014). Reprocessed arthroscopic shavers: evaluation of sharpness and function in a cadaver model. *Orthopedics, 37*(1), e1-9.

Loftus, T. (2015). A Comparison of the Defect Rate Between Original Equipment Manufacturer and Reprocessed Single-Use Bipolar and Ultrasound Diathermy Devices. *Journal of Medical Devices, 9*.

Maben-Tenney, L. (2012). Nursing attitudes toward the use of reprocessed single-use medical devices. *HIM 1990-2015, 1337*.

Manatakis, D. K., & Georgopoulos, N. (2014). Reducing the Cost of Laparoscopy: Reusable versus Disposable Laparoscopic Instruments. *Minim Invasive Surg, 2014*, 408171. doi:10.1155/2014/408171

Medical Device User Fee and Modernization Act of 2002, 21 U.S.C, Pub. L. No. 107-250 § 301 (2002).

Mues, A. C., Haramis, G., Casazza, C., Okhunov, Z., Badani, K. K., & Landman, J. (2010). Prospective randomized single-blinded in vitro and ex vivo evaluation of new and reprocessed laparoscopic trocars. *The American College of Surgeons, 221*(6). doi:10.1016/j.jamcollsurg.2010.08.003

Nelson, R. (2006). Reprocessed single-use devices--safe or not? *Am J Nurs, 106*(4), 25-26.

Noble, M. (2013). Interventions to Allow the REuse of Single-use Devices: Brief REview (NEW) *Making Health Care Safer II: An Updated Critical Analysis of the Evidence of Patient Safety Practices. Comparative Effectiveness Review No. 2011.* (pp. 117-121). Rockville MD: Agency of Health Care Research and Quality.

Rutala, W. A., Weber, D. J., & (HICPAC), H. I. C. P. A. C. (2008). *Guideline for disinfection and sterilization in heatlhcare facilities, 2008*.

Society of Gastroenteroloby Nurses and Associates (SGNA). (2015). *Reuse of Single-Use Critical Medical Devices*. Retrieved from https://www.sgna.org/Portals/0/Single%20use%20devices_FINAL.pdf

Shuman, E. K., & Chenoweth, C. E. (2012). Reuse of medical devices: implications for infection control. *Infect Dis Clin North Am, 26*(1), 165-172. doi:10.1016/j.idc.2011.09.010

Siu, J., Hill, A. G., & MacCormick, A. D. (2017). Systematic review of reusable versus disposable laparoscopic instruments: costs and safety. *ANZ J Surg, 87*(1-2), 28-33. doi:10.1111/ans.13856

Sung, J. K., Levin, R., Siegel, J., Einhorn, T. A., Creevy, W. R., & Tornetta, P., 3rd. (2008). Reuse of external fixation components: a randomized trial. *J Orthop Trauma, 22*(2), 126-130; discussion 130-121. doi:10.1097/BOT.0b013e318162e55c

U.S. Food and Drug Aministration. (2000, 08/06/2009). *Reuse of single use devices*. Retrieved from https://www.fda.gov/newsevents/testimony/ucm115002.htm

U.S. Government Accountablility Office. (2000). *Medical Devices: Reprocessing and reuse of devices labeled single -use*. Retrieved from https://www.gao.gov/products/T-HEHS-00-143

U.S. Government Accountablility Office. (2008). *Reprocessed single-ue medical devices FDA oversight has increased, and available information does not indicate that use presents an elevated health risk.*. Retrieved from https://www.gao.gov/products/GAO-08-147

U.S. Food and Drug Aministration. (2000). Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals. Retrieved from https://www.fda.gov/ohrms/dockets/98fr/000053g2.pdf

U.S. Food and Drug Aministration. (2001). *Frequently Asked Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors: Final Guidance for Industry and Staff*. Retrieved from https://www.fda.gov/RegulatoryInformation/Guidances/ucm070864.htm

U.S. Food and Drug Aministration. (2003). *Frequently Asked Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors: Three Additional Questions.* Retrieved from https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070908.pdf

Vockley, M. (2016). The Servicing of Medical Devices: In Need of Repair, Regulation, or Redemption? *Biomed Instrum Technol, 50*(5), 316-328. doi:10.2345/0899-8205-50.5.316

FDA. (2003). Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notificatin; Requirements for Submission of Validation Data *78 Fed. Reg. 03-10413 (April 20, 2003).*