

Single Use Ureteroscopes

Fad or Here to Stay?

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LithoVue

(the 1st single use digital flexible ureteroscope in Canada)

How and why we got here

MDRAO Conference September 10-12, 2017
MEASURING SUCCESS:
QUALITY ASSURANCE IN MEDICAL DEVICE REPROCESSING



March 2017 Outpatient Surgery Magazine



The job recently got a lot more daunting with the publication of a study that found that rigorous, by-the-book cleaning of flexible endoscopes before disinfection doesn't ensure that scopes are free of contamination, particularly when the scopes have scratches and dents that could harbor blood, tissue and bacteria. The study, published in the February *American Journal of Infection Control* (osmag.net/C8WRex), raised the frightening possibility that you can't count on current reprocessing practices to consistently decontaminate your scopes — even if, and it's a mighty big if, your techs meticulously follow reprocessing guidelines and don't take shortcuts.

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The Danger *Within*

Confronting the Challenge of
Healthcare-Associated Infections

Amber Bauer



Hospitals are supposed to be places where people get better—not sicker. Yet healthcare-associated infections (HAIs) are a growing problem that not only increase patients' length of stay but also can threaten their lives.

Many initiatives have focused on promoting behaviors like handwashing to combat HAIs, but

what about the cleanliness of the ever-increasing number of medical devices with which patients come into contact on a daily basis? Following the recent outbreak of life-threatening infections linked to endoscopes, the entire healthcare community has a renewed focus on developing strategies to keep dirty devices from ever reaching patients.



Feb 2017 Study in the Journal Biomedical
Instrumentation & Technology

A highly skilled workforce is needed to sterilize and reprocess the increasing number of complicated instruments used in the healthcare environment.

In some hospitals, sterile processing departments are viewed by hospital executives as a cost center. If the goal is to cut costs, sterile processing personnel will not have the resources they need.

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APPLIED EPIDEMIOLOGY IN HEALTH CARE SETTINGS AND THE COMMUNITY

**The Effectiveness of Sterilization
for Flexible Ureteroscopes:
A Realworld Study**

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at
www.ajicjournal.org

Cori L. Ofstead MSPH, Otis L. Heymann BA, Mariah R. Quick MPH,
Ellen A. Johnson BAS, John E. Eiland MS, RN, and
Harry P. Wetzler MD, MSPH

Conclusions: Flexible ureteroscope reprocessing methods were insufficient and may have introduced contamination. The clinical implications of residual contamination and viable microbes found on sterilized ureteroscopes are unknown. Additional research is needed to evaluate the prevalence of suboptimal ureteroscope reprocessing, identify sources of contamination, and determine clinical implications of urinary tract exposure to reprocessing chemicals, organic residue, and bioburden. These findings reinforce the need for frequent audits of reprocessing practices and the routine use of cleaning verification tests and visual inspection as recommended in reprocessing guidelines.

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FLEXIBLE ENDOSCOPES Case Study



Device-Related Urinary Tract Infection Outbreak

Does your facility have a process for determining which endoscope was used for each patient?

Is there a process in place to evaluate the method used to reprocess endoscopes (for example, high-level disinfection versus sterilization)?

Do you follow the endoscope manufacturer's instructions for the selection and use of channel-cleaning brushes, including the correct size and type of brush?

A urology resident in an academic medical center reported seeing five patients with signs of urinary tract infections in the emergency department over one weekend. The previous week, the surgical resident had performed ureteroscopy procedures on these patients using a flexible ureteroscope. Urine cultures obtained from the five patients in the emergency department grew an identical bacterial organism, a gram-positive cocci.

The attending surgeon contacted the OR manager, the sterile processing department manager, and the infection preventionist responsible for the unit. The infection preventionist initiated an outbreak investigation and removed from service all ureteroscopes that could have been used on the five patients. The microbiology lab cultured the ureteroscopes internally and externally. The vendor for the endoscope processor examined the processor to ensure it was working correctly. The sterile processing manager observed the personnel responsible for cleaning and sterilizing ureteroscopes for correct cleaning methods and adherence to established cleaning protocols. She discovered that processing personnel were not using a clean channel brush for each endoscope.

The first culture results for the five ureteroscopes came back positive for the gram-positive bacteria. The microbiology lab repeated the cultures after the endoscopes were recleaned and


2016 Study in AORN Journal - The
 Association of periOperative Registered
 Nurses of American

TAKEAWAY

Manual cleaning is the most important step in reprocessing flexible endoscopes. The manufacturer's instructions should be followed in the selection and use of endoscope cleaning brushes. Either a single-use or a clean brush should be used for each endoscope reprocessed. Identifying which endoscope was used for each patient is a tracking mechanism that can be used in the event a device-related infection is suspected or a breach in the cleaning protocol is found.



2017 Study from the International Association of HealthCare Central Service Material Management

 Hot Topics

by Cori L. Ofstead, MSPH; Mariah R. Quick, MPH;
John E. Eiland, MS, RN; Steven J. Adams, RN, CRCST

A GLIMPSE AT THE TRUE COST OF REPROCESSING ENDOSCOPES: RESULTS OF A PILOT PROJECT

INTRODUCTION AND METHODS
In light of recent outbreaks of infection tied to contaminated flexible endoscopes, several national organizations have published more stringent reprocessing guidelines. The guidelines are intended to reduce the risk of infection and improve patient safety. Complying with these recommendations will require institutions to invest more resources into endoscope reprocessing.

The purpose of this pilot project was to explore the real-world impact of the new guidelines as it relates to reprocessing time and material costs. Our commitment to doing this research came from discussions with front-line personnel who are under fire to do more with less. The findings

are intended to empower managers and technicians, so they can attain the resources they need to ensure patient safety.

This article provides an initial glimpse at the cost of reprocessing endoscopes. The focus is on endoscopes that are reprocessed using high-level disinfection (HLD) rather than sterilization. The estimates presented here are not comprehensive, in part because they do not include the cost of purchasing or leasing flexible endoscopes.

We included 17 tables in order to be transparent about how costs were calculated. Our goal is to provide a stepping stone for others to collect data and share findings to expand our collective knowledge about the true cost of endoscope reprocessing.

www.iahccm.org REPRODUCED WITH PERMISSION FROM THE INTERNATIONAL ASSOCIATION OF HEALTHCARE CENTRAL SERVICE MATERIAL MANAGEMENT Communiqué

THE BOTTOM LINE

THERE ARE FOUR KEY TAKEAWAYS FROM THIS PILOT PROJECT:

1. Reprocessing one flexible endoscope requires approximately 76 minutes of hands-on staff time.
2. The cost of reprocessing one endoscope ranges from \$114.07 to \$280.71.
3. These findings likely underestimate the time and cost associated with endoscope reprocessing.
4. More research is needed to determine the true cost of endoscope reprocessing.



March 2012 - Infection Control Today

ICT **INFECTION
CONTROL
T O D A Y**
March 2012 \$39.00 US

 **VIRGO**
MEDICAL

SPECIAL REPORT

Best Practices for High-Level Disinfection and Sterilization of Endoscopes

By Kelly M. Pyrek

Conclusion

As we have seen, high-profile outbreaks have been associated with improper medical device reprocessing, and despite a preponderance of guidelines and recommended practices, sterile processing personnel are challenged by real-world conditions that impact practices significantly. Sterile processing personnel and infection preventionists must work together to ensure that proper reprocessing protocols are being followed, and healthcare institution leadership must ensure that these departments have the staff and resources necessary for a high-functioning reprocessing program.

reprocessing machines. The biggest challenge in this process is consistency in the repetition of all steps in a thorough sequential fashion. When this

Hence, the challenge of consistency of performance of all reprocessing steps is greater when procedures are performed after-hours in settings distant from the endoscopy suite, perhaps by personnel with varied concurrent demands and expectations.



Joint AUA/SUNA White
Paper on the

REPROCESSING OF FLEXIBLE CYSTOSCOPES

(2/8/14): The STERIS System 1E (SS1E) liquid chemical sterilant processing system has become available for reusable processing heat-sensitive devices and their accessories that cannot be processed using thermal methods (Page 10).

Additionally, new evidence indicates properly processed cystoscopes can now be stored 7-10 days before reprocessing is necessary (Page 12).

Edits made in 2014 to the original white paper are highlighted in yellow.

New References:

Rutala WA and Weber DL. New developments in reprocessing semicritical items. Am J Infect Control 2013;41:560-566.

Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011. Gastrointestinal Endoscopy 2011;73(6): 1075-84.

2009 WORKGROUP MEMBERS:

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Victor Senese, RN
Jennifer Bertsch, Staff



American
Urological
Association

Education & Research, Inc.

Multiple White papers,
Recommendations and
DFU's that are constantly
being updated
Combined with medical
devices that are
becoming more
sophisticated, intricate
and minimally invasive.

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So what your are options?



Changing the game in Flexible Ureteroscopy



MDRAO
Medical Device Reprocessing
Association of Ontario

LithoVue™ Single-Use Digital Flexible Ureteroscope



SUCCESS:
MEDICAL DEVICE REPROCESSING



LithoVue™

Technical Features



- 276° deflection in both directions
- 7.7F tip diameter
- 9.5F [$\leq 3.23\text{mm}$] outer diameter
- 3.6F ID working channel
- Working distance of 2mm–50mm
- Light source built into the handle
- Integrated camera head– no secondary external attachments required
- Mobile cart for portability- easily connectable to existing systems/monitors.
- All-in-one touchscreen PC
- Auto White balance



LithoVue Workstation

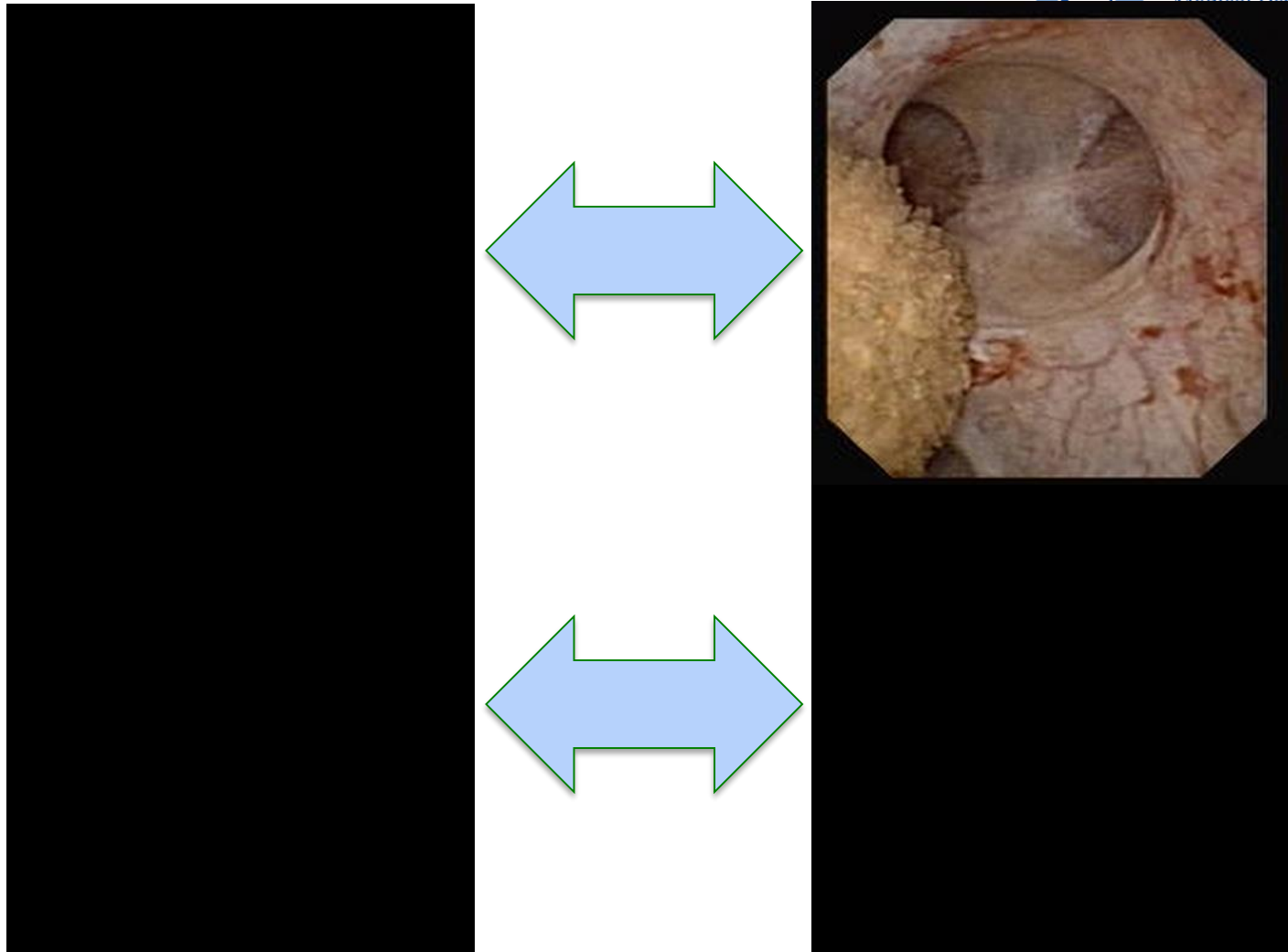
System Workstation



Single-Use Device



F-URS : NEW GENERATION



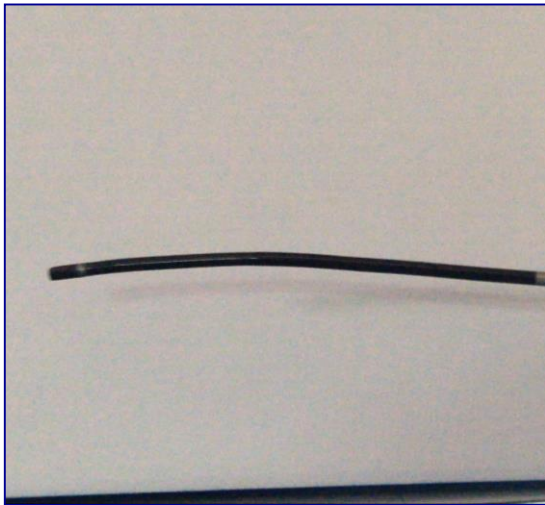
FiberOptic

September 10-12, 20
SUCCESS:

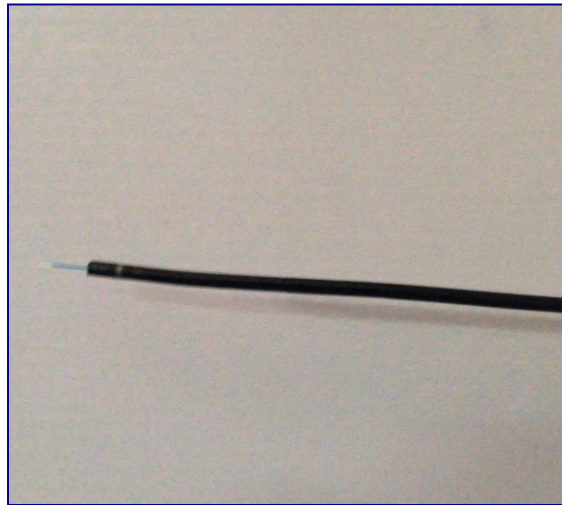
LithoVue



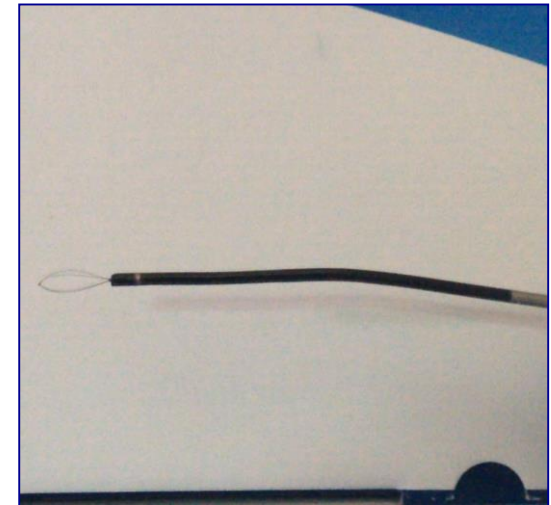
LITHOVUE & DEFLECTION



**EMPTY
WORKING
CHANNEL**



**LASER
WORKING
CHANNEL**



**BASKET
WORKING
CHANNEL**

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Key Technical Advantages

Of Single Use Option Vs. Current Reusable Scopes

	LithoVue	Current Fiberoptic Options	Current Digital Options
Image Quality	High quality digital image on par with current digitals (~62000 pixels)	10,000 – 17,000 “pixels”	60,000 – 63,000 pixels
Catheter Access (Tip Size)	7.7Fr (Smallest profile digital available for purchase)	4.9 – 7.5 Fr	8.4 – 9.9 Fr.
Catheter Access (OD)	9.5 Fr. OD	8.4 – 9.9 Fr. OD	8.5 – 9.9 Fr. OD
Capital Equipment	Medical Grade Touch PC only, eliminates need for current box on tower and separate light source	Tower Box and Light source box required	Tower box required
Monitor	No new monitors required. Tablet is the Monitor (can also integrate with existing monitors)	OR monitor utilized	OR monitor utilized
System Integration	Pole Cart vs. Existing tower	Tower or special cart required	Tower or special cart required
Portability	Equipment easily portable from OR to OR	Portable if only on a separate cart	Portable if only on a separate cart

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Recent AUA & EAU 35 + Publications



Category	Study	Author	Description	BSC Support required
Technical	LithoVue durability	Traxer, et al.	Study LithoVue in the K-box model for durability	Providing equipment post-WCE
Technical	LithoVue image performance	Bolton, et al.	Optical testing at The Austin in Melbourne	Providing equipment post-SIU
Clinical	DVAL performance	Wiseman, et al.	Summary of successful use in pigs by leading urologists	Coordination
Clinical	DVAL video abstract	Wiseman, et al.	Video showing experience in pigs	Coordination
Economic	Delays & Cancellations	EDGE	Frequency and duration of delays and cancellations using reusable scopes	Coordination
Economic	Staff Time	Matlaga, et al.	Documentation of process flow and duration of all steps required to manage scopes from OR to next OR	Coordination
Economic	Systematic review of literature	Matlaga, Eisner, BSC	Systematic review of 170 publications regarding costs associated with cost-per-use of reusable flexible urs	Abstract Development
Economic	Consequences of non-sterility	Stoller, et al	Documentation of efforts required to manage 1200 patient notifications after a sterility failure	Coordination

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LithoVue Evidence Spotlight: Image Quality Survey



Authors: Wilson Molina, Roger Sur, Mitch Abrahams, Michael Lipkin, Glenn Preminger, Thomas Knoll, Ben Chew, James Lingeman, Marshall Stoller, Ojas Shah, Thomas Chi, Bodo Knudsen, Brian Matlaga, Oliver Traxer, Francis Keeley, Brian Eisner

Methods: Dr. Eisner performed flexible ureteroscopy using saline irrigation on 3 ex-vivo porcine kidneys and images of 2-3 renal papilla per kidney were obtained using a MediCapture Device for 8 scopes.

The images were all rounded, blinded and printed on high-gloss paper and sent to the authors. The authors took a survey evaluating image quality on a scale of 1-5, with 5 being the best.

Results:

Ureteroscope	Scope Type	Mean Image Quality	Standard Deviation (SD)	p-value versus LithoVue
LithoVue	Digital	4.59	0.6	N/A
Storz Flex-X2	Fiber Optic	1.87	0.8	<0.001
Storz Flex-XC	Digital	4.25	0.8	<0.001
Olympus URF-P5	Fiber Optic	1.69	0.8	<0.001
Olympus URF-P6	Fiber Optic	3.08	1.0	<0.001
Olympus URF-V2	Digital	3.51	1.0	<0.001
Wolf Cobra	Fiber Optic	1.92	0.8	<0.001
Wolf Boa	Digital	4.53	0.7	0.6

LithoVue demonstrated statistically significant superior image quality to most commonly used digital and fiber optic scopes and similar image quality to the Wolf Boa

LithoVue™ Performance Data

Image and Performance Data



Characteristic	LithoVue	Flex-Xc	Cobra
Platform	Digital	Digital	Fiberoptic
Working Channel	3.6F	3.6F	Dual 3.3F
Resolution at 10mm (lines/mm)	7.13	8.00	4.00
Image Distortion	3.6%	22.6%	16.7%
Depth of Field (mm)	4.5	6.0	4.0
Field of View (mm)	15.75	10.5	14.25
Maximum Deflection	276°	263°	253°
Maximum Flow Rate (ml/min)	40.3	38.4	28.8

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Pain Points of using fURS program



System Impact & Pain points of a Flexible Ureteroscopy Program



SPD/Reprocessing:

- Lengthy, multi-step process to reprocess. 2+ hours.
- Highly technical cleaning process required
- Exposure to harmful chemicals.
- Mitigate infection/sterility risk on challenging device to clean.
- Off-hours reprocessing.

Purchasing & Materials Management

- Budgeting challenges due to variable costs.
- On-going requirement for new scopes at high capital cost.
- Management/ordering of ancillary equipment.

Nursing:

- Scope availability and necessity to juggle/delay cases.
- Dealing with poorly functioning scopes.
- Necessity to set-up FURS in non-standard room (ie. Cysto, Th #8).
- Handling concerns.
- Off-time availability of scopes (weekends and evenings).



System Impact & Pain points of a Flexible Ureteroscopy Program cont'd



Physician:

Lack of optimally functioning scope.

Delayed, postponed cases due to limited scope availability.

Diminished performance limiting outcome success in challenging cases.

Patient:

Effected by impacts on flow, scope availability and underperforming technology.

Potential cross contamination or infection risk

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Burden of Reprocessing

Reprocessing is a very cumbersome, labor intensive, and technical process.

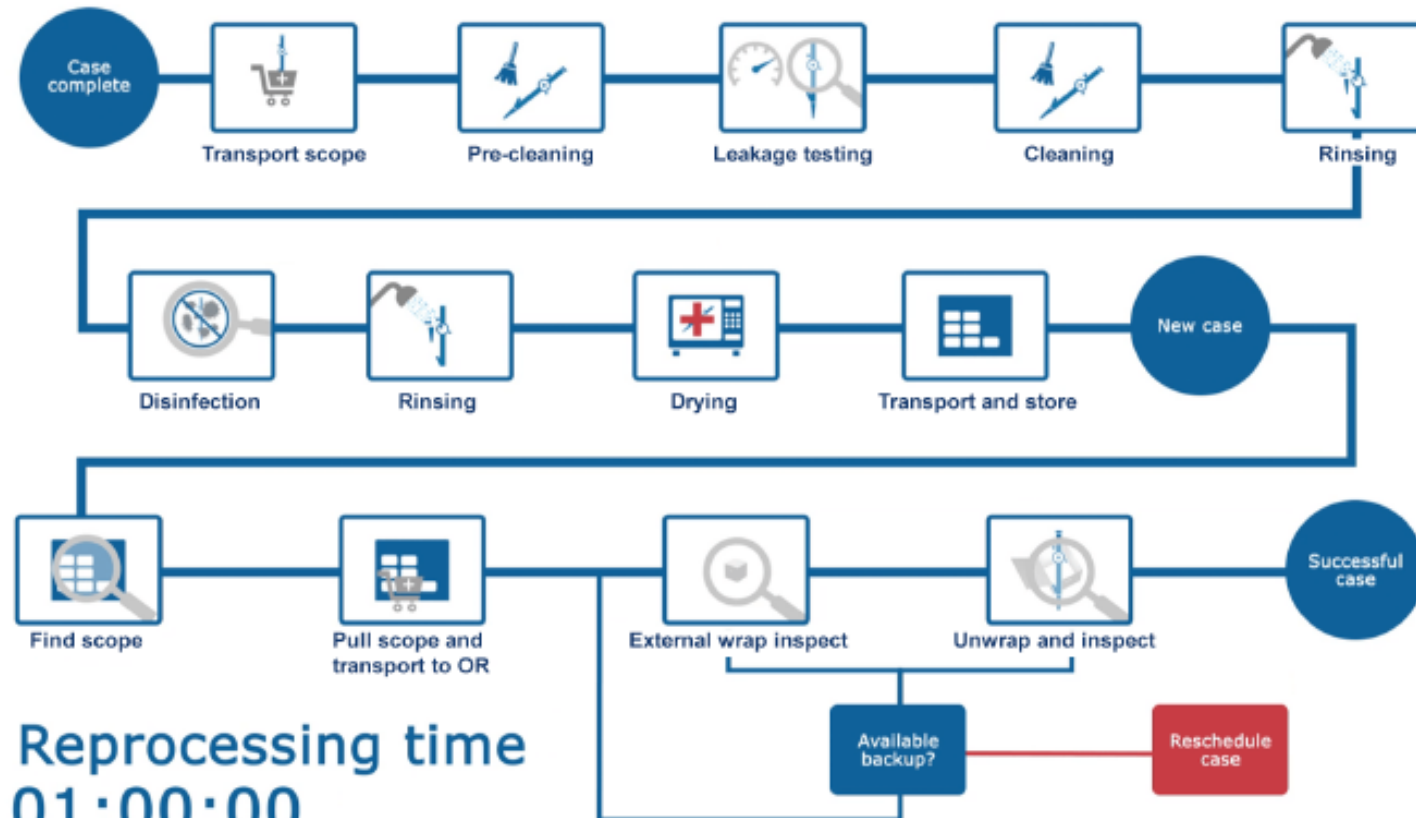
Steps in reprocessing:

Case complete
Transport
Pre-clean
Leakage Testing
Cleaning
Rinsing
Disinfection
Rinsing
Drying
Transport & Storage
New Case
Find scope
Pull scope and Transport
External Wrap Inspect
Unwrap and Inspect
Complete Case



The Burden of FURS Reprocessing

Reusable Ureteroscope



Eliminating Time, Resources Pain of Reprocessing

Single-Use Ureteroscope



Costs Associated with fURS



What is the real cost to run your FURS program?

The true economic impact of reusable digital scopes

How much does a typical hospital really spend to acquire, repair, sterilize, reprocess, prepare and manage ureteroscopes?

These numbers speak volumes about the true total cost of ownership.

Potential business costs per reprocessing incident:

\$1.79 to \$20.4 million¹¹

Purchase price for a digital flexible scope can exceed:

\$20,000^{9,10}

Repair cost per digital flexible scope after on average fewer than 12 uses can exceed:

\$6,000^{7,8}

Cost per procedural delay due to reprocessing:

\$830³⁻⁶

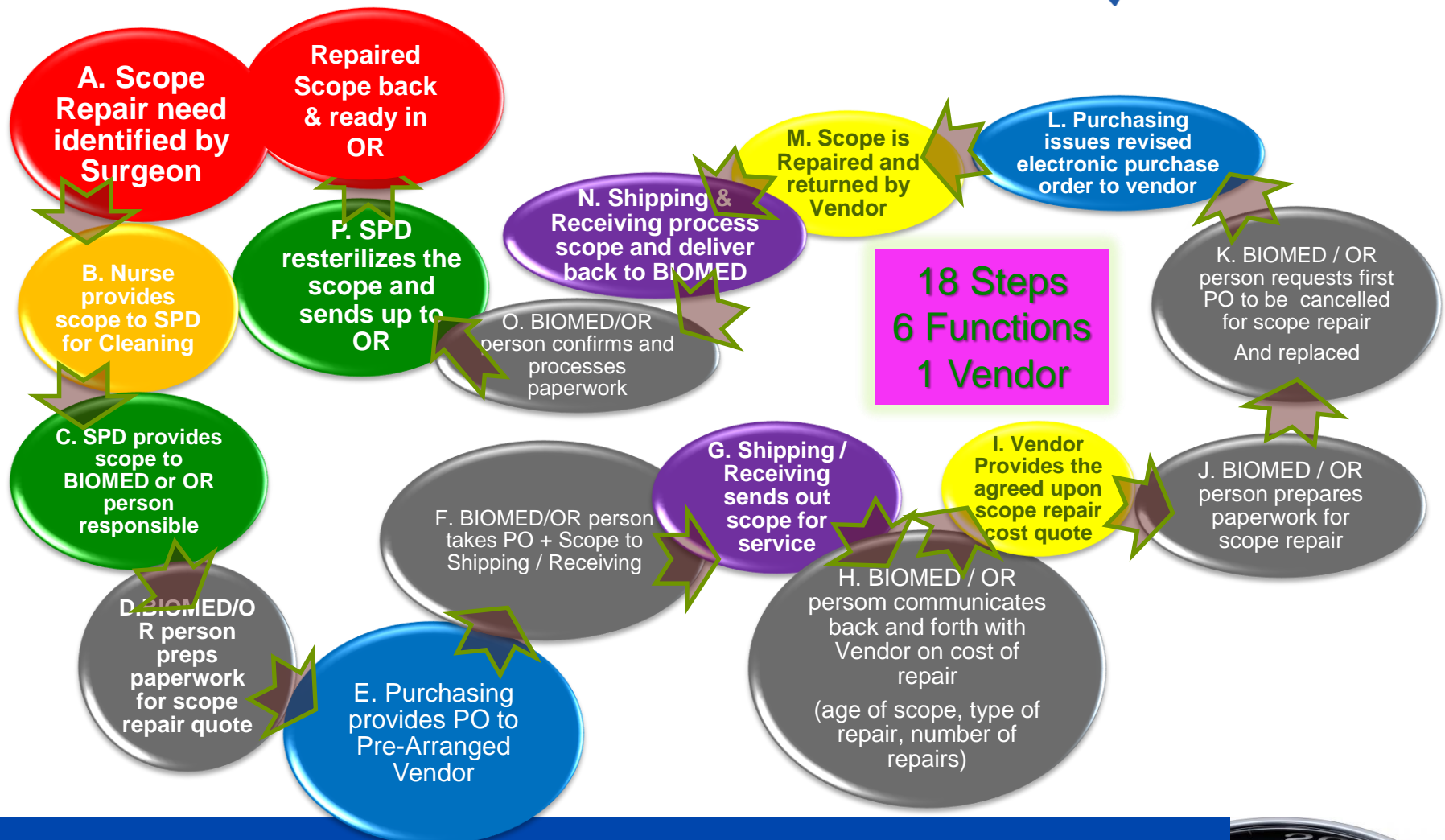
Cost savings using a digital flexible versus a fiber-optic scope:

\$780¹⁻⁴



Reprocessing labor time:
30-60 minutes¹²

The Scope Repair “Whirlwind”



LithoVue™:

Positive Impact in Hospitals



Nurses:

- Guaranteed scope availability.
- Ease of set-up in all rooms: no burdensome set-up in non-standard rooms.
- Eliminates handling concerns and pulling incorrect scope or finding missing parts.

Physicians:

- Rapid and simple set-up for quick transition during case.
- Optimally performing scope for every case.
- No concerns about “pushing” scope too hard, damaging while trying to complete cases.
- Eliminates risk/stress of damaging scope.

Purchasing & Materials Management:

- Able to accurately budget FURS program (eg predictability)
- Avoid large capital purchases.
- Avoid costly repairs.
- Reduced administrative requirements on FURS program

Patient:

- New scope every case.
- No scope related risk of infection.
- Physician operates with optimally performing scope



LithoVue™: Positive Impact for you



Sterile Processing Department:

- Eliminates 2+ hour scope reprocessing cycle.
- Minimize staff exposure to harmful cleaning chemicals.
- Eliminate weekend, evening coverage concerns
- Eliminates SPD staff being blamed for scope breakage and missing pieces
- Eliminate infection/sterility risk on challenging device to clean.
- One less complex instrument you have to clean, track and process
- Frees up SPD resources.

