

**Save and Safe(ty)  
in the Therapeutic Endoscopy**

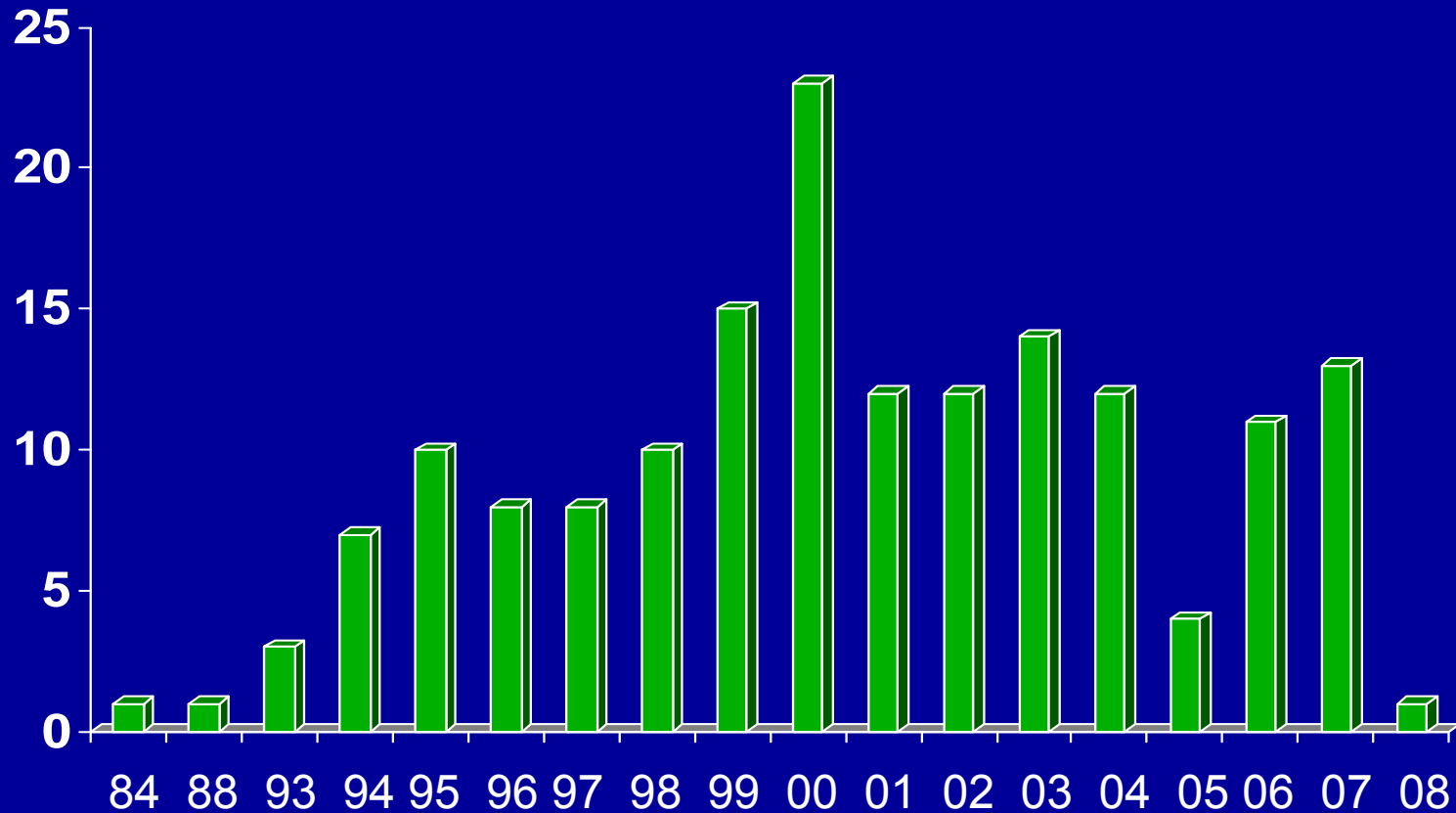
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Prince of Songkla University**

***The speaker declares no any  
conflict of interest, and has  
nothing to be disclosed..***

# Scope of Contents

- Pros and cons of reuse
- Reprocessing process
- Awareness regarding the reuse
- Sharing our experience
- Overview of organizing the “reuse” system

## No. of published articles



**Pub-Med Search: “ Reuse + Endoscopy”**

# Reuse

“The repeated use or multiple use of any medical device including devices intended for reuse or single-use, with **reprocessing** between uses.”

FDA definition

Type of devices	Cost/ procedure	Cross contamination	Liability
<b>SUDs</b>	<b>++++</b>	<b>no</b>	<b>Less likely</b>
<b>Reusable</b>	<b>++ - +++</b>	<b>Potential</b>	<b>Yes</b>
<b>Reuse of SUDs</b>	<b>+</b>	<b>Potential</b>	<b>Yes</b>



**This Product Contains No Detectable Latex.**  
本製品は検出可能なラテックスを含有し

**STERILE** **EO**

**Sterilized with ethylene oxide gas**  
エチレンオキサイド滅菌済



**For single use only. Do not reuse.**

1回限りの使用。再使用しないこと。



**Consult instructions for use.**

取扱説明書を参照。

**NUMBER OF WIRES: 4**

**BASKET SIZE: 3.0 CM. X 6.0 CM.**

**CATHETER: 7 FR./220 CM.**

**COMPATIBLE W/SOEHENDRA LITHOTRIPTOR**

**MINIMUM ACCESSORY CHANNEL: 2.8 MM.**

**DISPOSABLE - SINGLE USE ONLY**

**U.S. PATENT 5,330,482**

# Practices of Reuse of SUDs

- “already used”
- “opened-but-unused”
- “expired”



# Reuse of Endoscopic Accessories

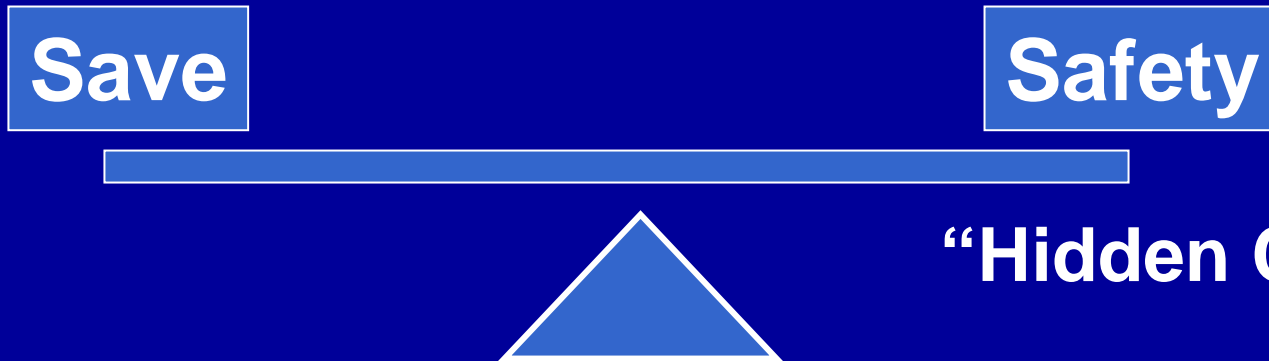
**Cost reduction**  
**Environmental burden**

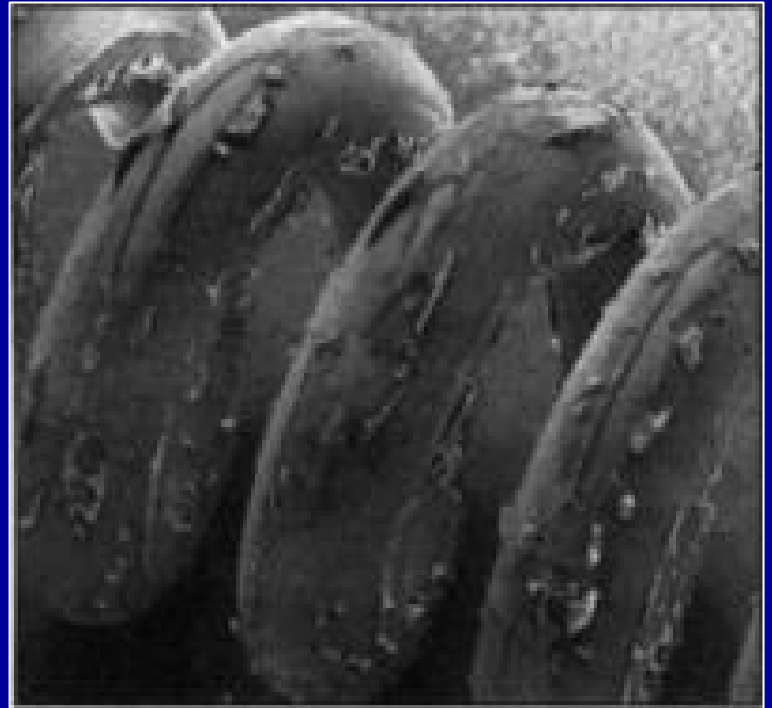
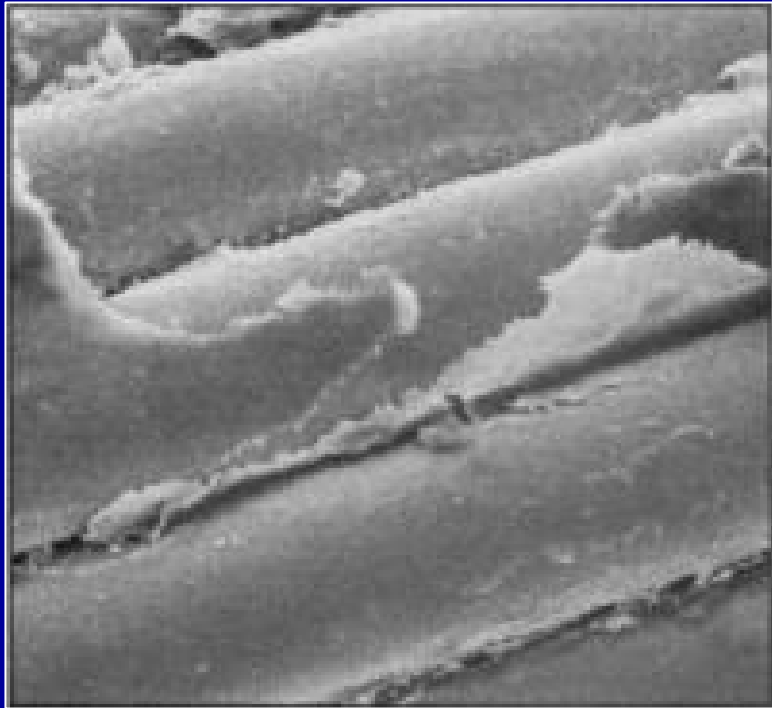
**Save**

**Sterility**  
**Functionality**  
**Liability issue**  
**Ethic**

**Safety**

**“Hidden Cost”**





# FDA Classification of Medical Devices

Class	Safety and effectiveness	Pre-market
I	<ul style="list-style-type: none"><li>- Met by general controls,</li><li>- Not life supporting/life-sustaining</li></ul>	Notification
II	<ul style="list-style-type: none"><li>- Need special controls (guideline, registration, post-market surveillance)</li></ul>	Notification
III	<ul style="list-style-type: none"><li>- Life supporting/life-sustaining</li><li>- Potential risk of illness or injury</li></ul>	Approval

<b>Medical Device</b>	<b>Definition: Making contact with</b>	<b>Level of disinfection</b>
<b>Non-critical</b>	<b>Intact skin</b>	<b>Low</b>
<b>Semi-critical</b>	<b>Mucous membrane, Nonintact skin</b>	<b>High</b>
<b>Critical</b>	<b>Penetrate skin, Invade sterile parts of the body</b>	<b>Sterilization</b>

## Spaulding Classification

## Level of Disinfection

## Destroyed Microorganisms

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**Critical:**

**Sterilization**

**All (?but Prions)**

**Semi-critical:**

**High-level disinfection**

**All vegetative organisms, mycobacterium, fungal spore, Viruses, **Not all bacterial spore****

**Non-critical:**

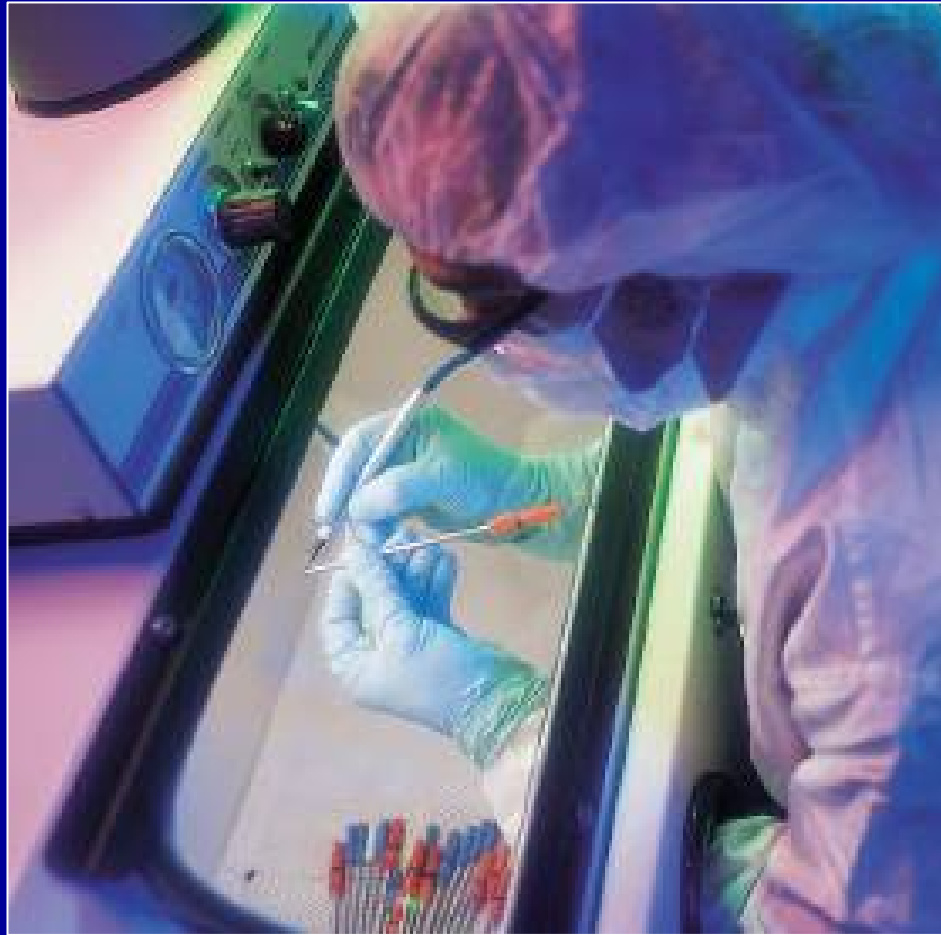
**Low-level disinfection**

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Guidance for Industry and for FDA Staff

**Enforcement Priorities for  
Single-Use Devices Reprocessed  
by Third Parties and Hospitals**

Document issued on: August 14, 2000



**Association of Medical Device Reprocessors (AMDR)**

DENTAL BURS AND BLADES, REPROCESSED

ENT BUR, REPROCESSED

ENT BUR, REPROCESSED

STONE RETRIEVAL BASKET

BIOPSY FORCEPS

STONE RETRIEVAL BASKET

TROCAR

BIOPSY FORCEPS, HOT

ENDOSCOPIC ELECTRODES

HOSPITAL BED PATIENT MONITORING ALA

PRESSURE BAG

CARDIOVASCULAR SURGICAL SAW BLADE



	<b>Accessories (N)</b>	<b>Type</b>	<b>Numbers of reuses</b>	<b>Infect. Compli.</b>
Kozarex 1997	Sphincterotomes (10) (Vitro)	SUDs	Mean $\geq 4$	None
Cohen J. 1997	Papillotomes (25) Retrieval basket (15)	Reusable	9.8 / 8 12.9 / 13	NM
Wilcox 1998	Sphincterotome (80)	SUDs	Median 3	NM
Lee RM. 1999	Double channel sphincterotome (20)	Reusable	Mean 3.1	None
Kozarex 1999	Sphincterotome <b>APC probes (10) (Vitro)</b>	SUDs <b>SUDs</b>	Mean 3.4 <b>All 10 testing</b>	None <b>None</b>
Kozarex 2001	Double channel sphincterotome (10)	Reusable	Mean 11	None
Prat F. 2004	Sphincterotome (30) Retrieval basket (20)	Reusable	Median 10 Median 10	None

# Steps in Re-processing

- **Immediately enzymatic soaked**
- **30-min ultrasonic cleaning**
- **tap-water rinse**
- **Lubrication**
- **Sterilization**

# Transmission of Infection during GI Endoscopy

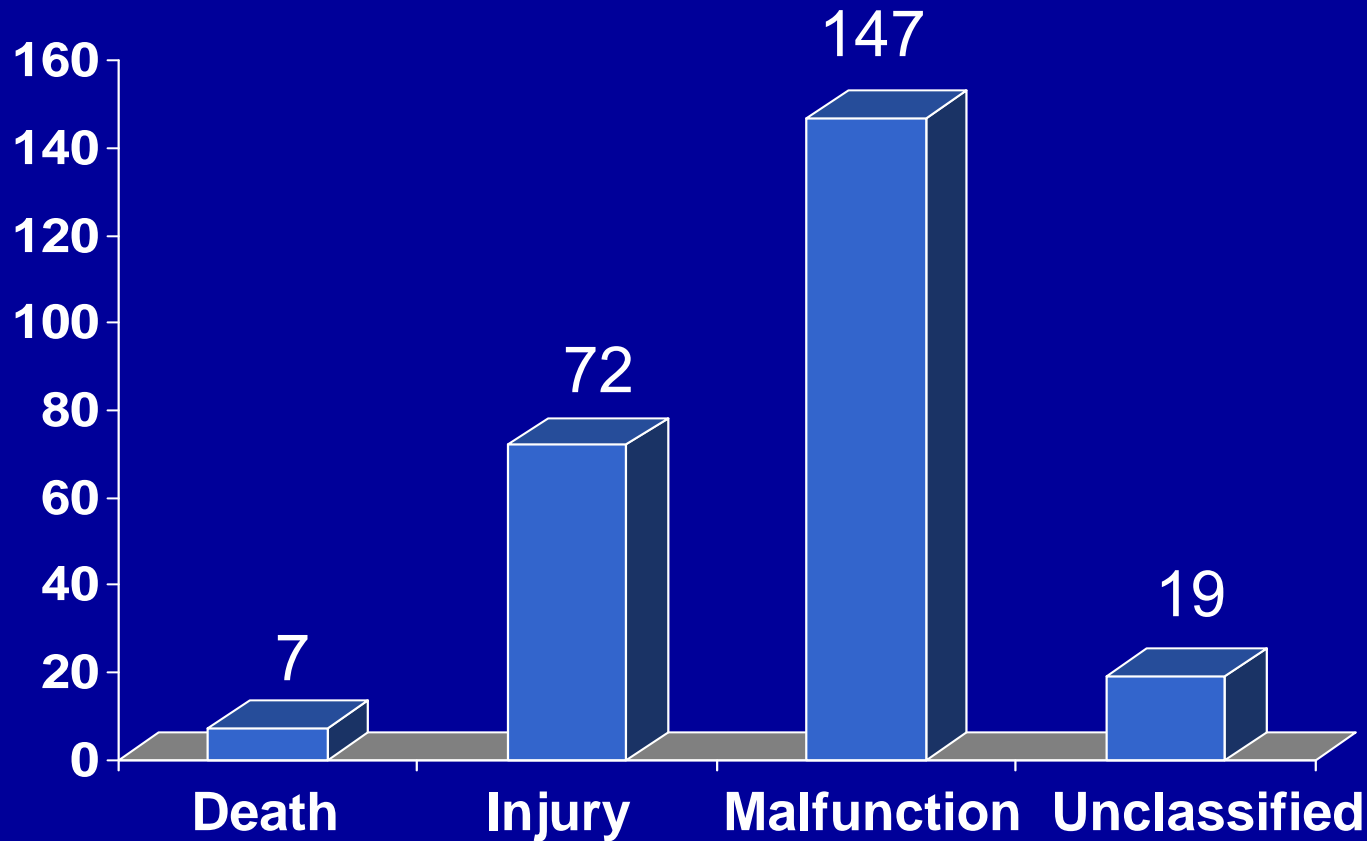
Organisms	Number of Reported Cases
<b>P. aeruginosa</b>	<b>216</b>
<b>Salmonella</b>	<b>84</b>
<b>H. pylori</b>	<b>12</b>
<b>Hepatitis C</b>	<b>8 + 6</b>
<b>Hepatitis B</b>	<b>5</b>
<b>Strongyloides</b>	<b>4</b>
<b>Misc</b>	<b>5</b>

MMWR 2008;57:513-7

ASGE guideline. Gastrointest Endosc 2008;67:781-90

Nelson DB, et al. World J Gastroenterol 2006;12:3953-64

## Reported Cases



## FDA's Medical Device Reporting System 1996-1999

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>

# The Washington Post

## GOOD BLINDSPOT? The Rise of Medical Professions

Health care is hot. You've probably noticed that just in the last few years, the medical profession has become a hot topic. The profession is now being hailed as the most important of all professions. The profession is now being hailed as the most important of all professions. The profession is now being hailed as the most important of all professions.



## U.S. Won't Join in Binding Climate Talks

Administration Agrees to Separate Dialogue

WASHINGTON — The United States will not join in binding climate talks, the administration has agreed to separate dialogue. The administration has agreed to separate dialogue. The administration has agreed to separate dialogue.

## In Iraq, Bush Pushed For Deadline Democracy

Timeline Didn't Guarantee Oil, But Peace

WASHINGTON — President George W. Bush pushed for a deadline for democracy in Iraq, but the timeline did not guarantee oil, but peace. The timeline did not guarantee oil, but peace. The timeline did not guarantee oil, but peace.



## Hospitals Save Money, But Safety Is Questioned

A study of hospital care in the United States has found that hospitals are saving money, but safety is being questioned. The study found that hospitals are saving money, but safety is being questioned. The study found that hospitals are saving money, but safety is being questioned.



## Gentle Senator, Presidential Hospital Empowered U.S. Antiwar Movement

WASHINGTON — A gentle senator, a presidential hospital, and a powerful antiwar movement. The gentle senator, a presidential hospital, and a powerful antiwar movement. The gentle senator, a presidential hospital, and a powerful antiwar movement.

INSIDE  
It's Time for Children  
Richard Rogers, Staff and Board  
Time to Light the Way?  
It's Time to Stand Up to the Secretary  
Marianne Post (with Photo) (2)

Richard Pryor, 1944-2005  
With Humor and Anger On Race Issues, Comic Inspired a Generation  
A History of the  
The Great

**Hospitals Save Money, But Safety Is Questioned**

*Alec Klein  
Washington Post Staff Writer  
December 11, 2005; Page A1  
Section: Financial*

# **Survey of Accessory Reprocessing Practices in Asia-Pacific Region (138 centers)**

<b>Accessories</b>	<b>% reuse</b>
<b>Biopsy forceps</b>	<b>99</b>
<b>Mechanical lithotripter</b>	<b>95</b>
<b>Dormia basket</b>	<b>90</b>
<b>Balloon stone extractor</b>	<b>82</b>
<b>Biliary guidewire</b>	<b>82</b>
<b>ERCP cannula</b>	<b>81</b>
<b>Sphincterotome</b>	<b>73</b>
<b>Sclerotherapy needle</b>	<b>69</b>

# Cost Analysis of the Reused Accessories

- Initial purchase price.....1
- Reprocessing cost.....2

Per-Procedure Cost:

$$\frac{1 + 2 (\# \text{ uses} - 1)}{\# \text{ uses}}$$

**Number of uses =**

**Reusable device cost**

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**Disposable device cost - reprocessing cost**

**Reusable biopsy forcep = 100 USD**

**Disposable biopsy forcep = 10 USD**

**Number of uses =  $\frac{100}{10 - 8}$**

**= 50**

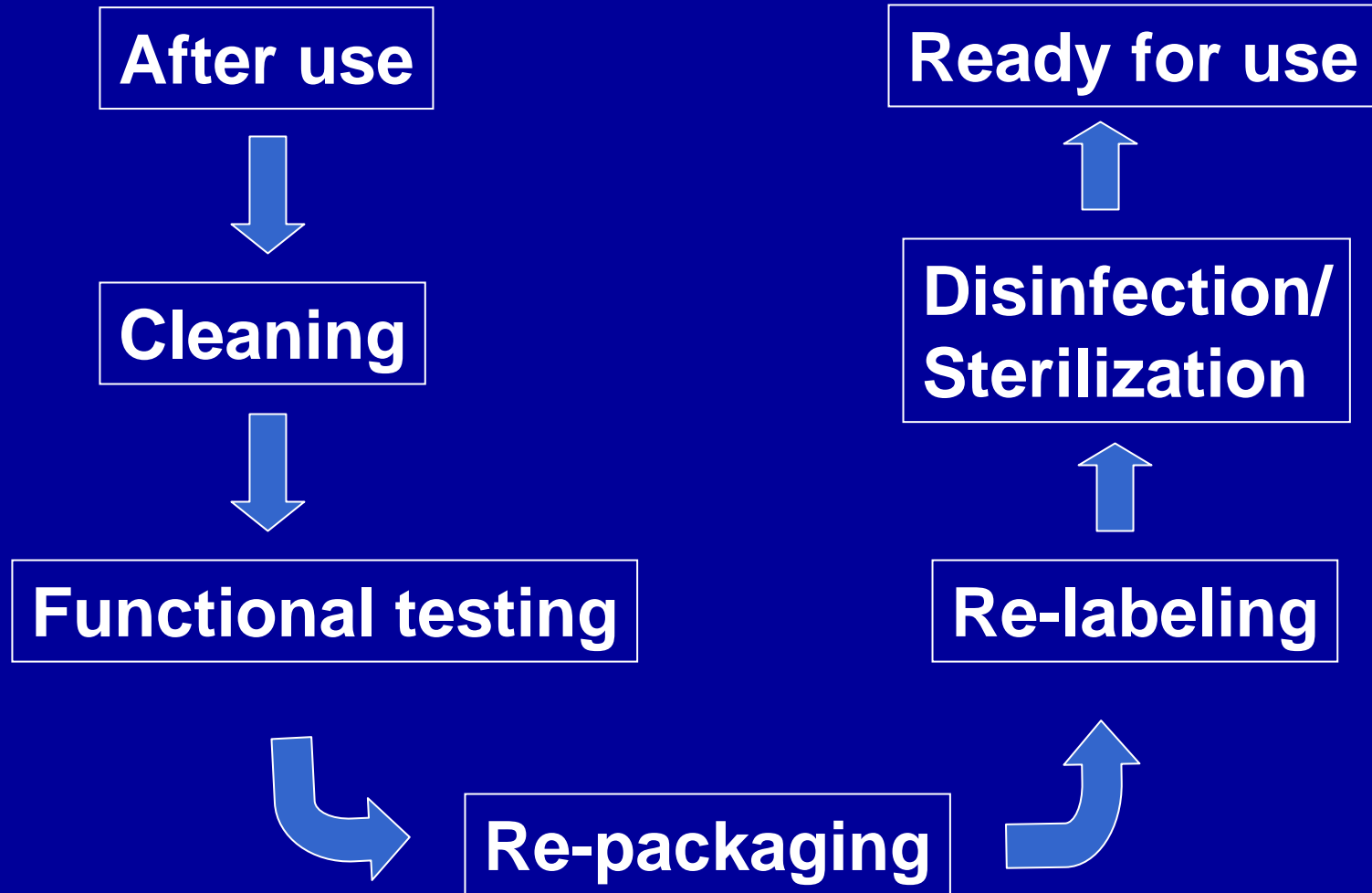


# Reprocessing Cost/Device at NKC

Items	Cost (Bath)
Central supply fee	15
Technician wage	60
Gown, goggles	12
Gloves, mask, cover shoes	7
Ultrasonic cleaner	75
Enzymatic/disinfectant	33
Brush	-
Package	10
<b>Total</b>	<b>212</b>

# Reprocessing Process

# Standard Reprocessing Process

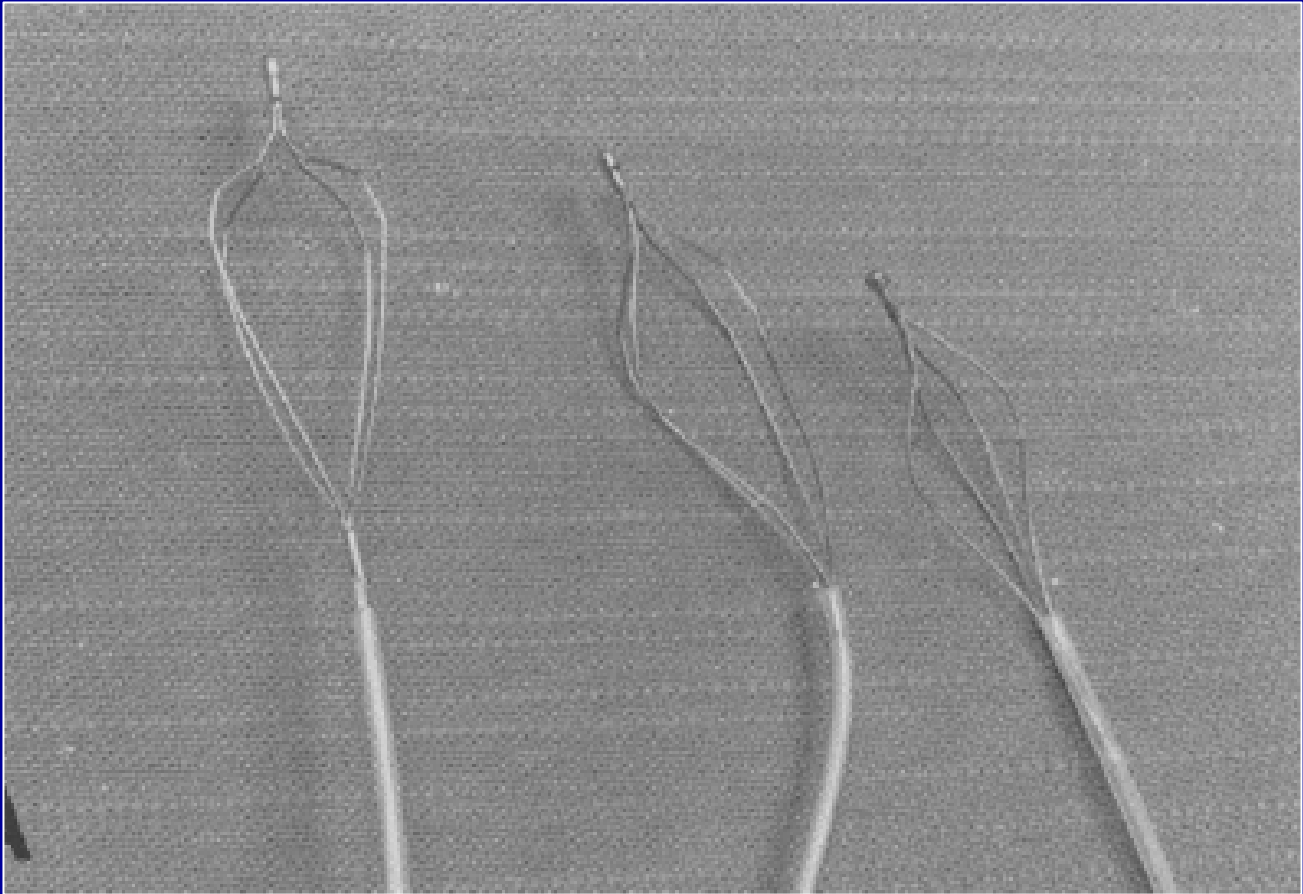


# Considerations for Reprocessing and Reuse of a Device

- Is a device can be **cleaned**?
- Is the **sterility** of post-reprocessing can be demonstrated? Sterility
  - Assurance Level (SAL)
  - Individual device testing
- Is the **integrity and functionality** of the device maintained?

# Functionality of Accessories

<b>Sphincterotomes</b>	<ul style="list-style-type: none"><li>• <b>Straight cutting wire</b></li><li>• <b>Patent lumen(s)</b></li><li>• <b>No leakage when flush</b></li><li>• <b>Effective bending at the tip</b></li><li>• <b>Intact electrical integrity</b></li></ul>
<b>Retrieval Basket</b>	<ul style="list-style-type: none"><li>• <b>Widely unfold wire</b></li><li>• <b>Smooth motion of the basket into the sheath when retracted</b></li></ul>



# A Prospective Study 323 ERCPs in Jan.-Sep. 2006, at NKC

301	22
Reuse	New accessories

Complete records

205	15
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**Success rate**

**Complications: in-patient f/u,  
F/u calls in day 1, 7**

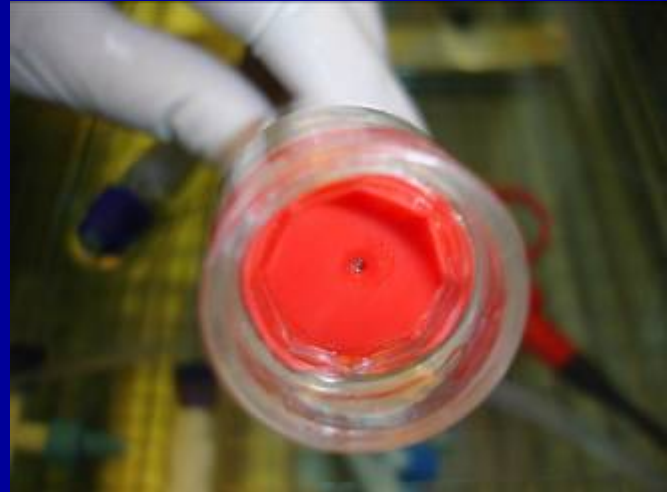
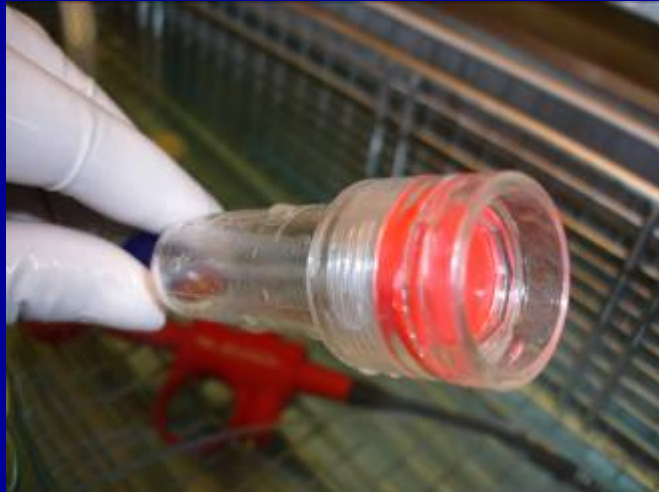
**Reusable numbers**

# Steps of Reprocessing at NKC

- Rinsing/Manual cleaning
- Ultrasonic cleaning with enzymatic detergent x 8 min.
- Inspection/rinsing
- Disinfection
- Alcohol flushing and drying (forced air)
- Package/Labeling
- Sterilization (EO. Gas)











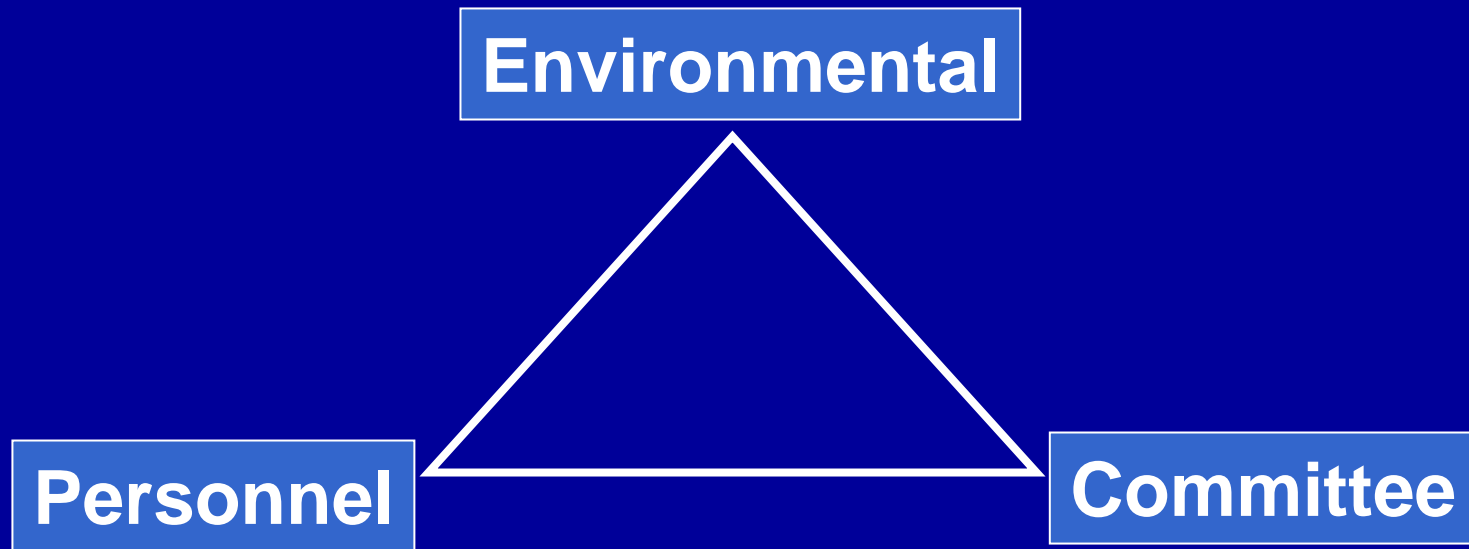




<b>Accessory</b>	<b>Number discarded</b>	<b>Times of Use</b>	
		<b>Mean</b>	<b>Median (range)</b>
<b>ERCP cannula</b>	<b>6</b>	<b>4.8</b>	<b>5 (2-7)</b>
<b>Precut needle knife</b>	<b>2</b>	<b>3</b>	<b>3 (1-5)</b>
<b>Sphincterotome</b>	<b>6</b>	<b>2.5</b>	<b>2 (1-5)</b>
<b>Stone retrieval balloon</b>	<b>26</b>	<b>3.4</b>	<b>3 (1-8)</b>
<b>Guide wire 0.035</b>	<b>42</b>	<b>3.6</b>	<b>3.5 (1-9)</b>
<b>Oasis stent introducer</b>	<b>8</b>	<b>5.8</b>	<b>6 (1-14)</b>
<b>Dormia basket</b>	<b>4</b>	<b>2.2</b>	<b>1.5 (1-5)</b>

<b>Outcomes</b>	<b>New accessory</b>	<b>Reused accessory</b>
<b>Success rate</b>	<b>100%</b>	<b>90%</b>
<b>Fever (?)</b>	<b>20%</b>	<b>17.6%</b>
<b>ERCP-pancreatitis</b>	<b>0%</b>	<b>5.8%</b>

**Ventilation, isolated unit**  
**Blood and body fluid control**  
**Clean area**



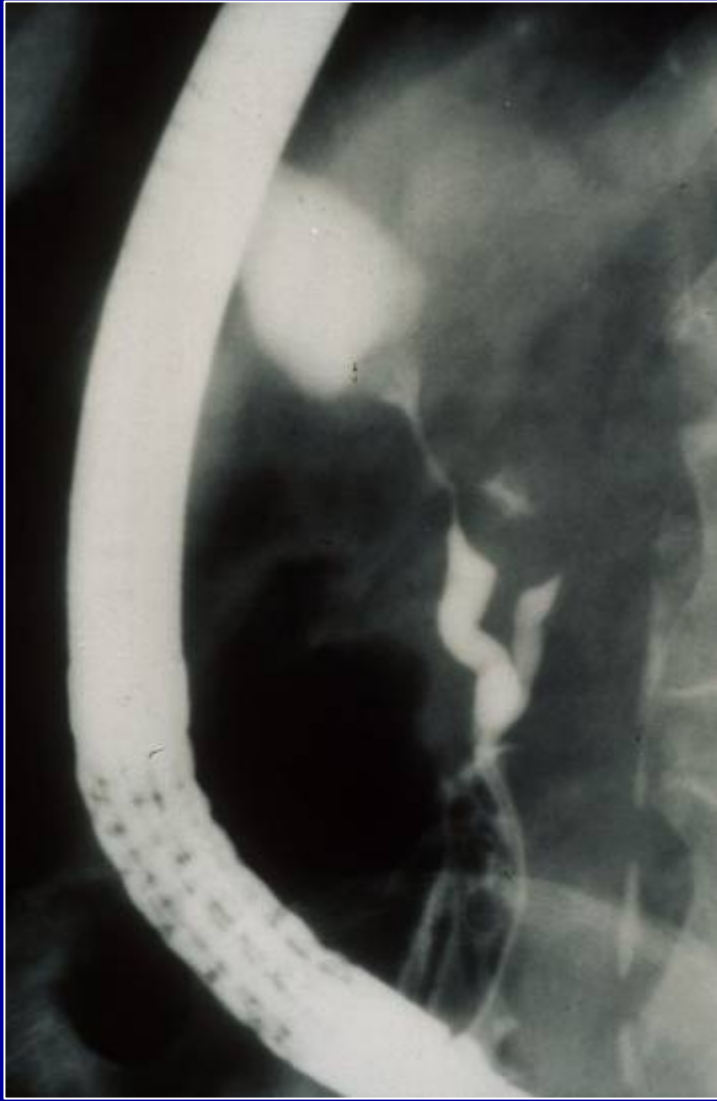
**Safety first**  
**Universal precaution**  
**Vaccination**  
**Training program**

**Establishing guideline**  
**Surveillance program**



# Endoscopists' Perspective

- **Pretest the accessories**
- **Low threshold for discarding the accessories**
- **Have the “back-up” accessories in hands**
- **Start with the new accessory in selected cases**
- **Beware of procedure-related complications ..esp. infections**



# Administration Perspectives

- A committee
- List of items of reusable SUDs
  - Cost impact vs quality/safety
- Established written guidelines for each step of reprocessing
- Quality assurance
  - Internal control, adherence
- Training programs for personnel
- Liability issues (?)

# Conclusion

- Sterility and functionality are the main concerns
- Requirements:
  - Good attitudes
  - A dedicated committee
  - Well-written reprocessing steps
  - A well-planned organization including regular surveillance



# Sticking to the Standard Practice Guideline is Crucial:

- A proper endoscope reprocessing process
- Good practice in drug/iv. fluid handling

Single use drug vial

Disposable syringe

Almost all (cross contamination) reports had involved *inadequate* reprocessing process

There are no published reports of transmission when strict to the guideline

**Thank you**