



Ramping up *Single Use Device (SUD)* Reprocessing

SINGLE USE DEVICE (SUD) = “intended for use on one patient during a single procedure” - FDA
(ex = *Ligasure* cautery, laparoscopic trocars, disposable bronchoscopes)

1970's:

Hospitals start reprocessing SUD's with their own sterilization equipment

1990's:

Hospitals shift toward 3rd party reprocessors

2002:

Medical Device User Fee and Modernization Act

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT

- Established FDA regulatory authority over 3rd party SUD reprocessors, assigning them liability
- Funded by annual 3rd party fees
- Designates devices to be reprocessed and frequency
- Requires labeling of reprocessed SUD's
- Repeatedly re-authorized (most recently in 2022)



Significant potential financial savings from reprocessing SUD's:

Both from collecting used devices for reprocessors AND buying reprocessed devices instead of new

1

IDENTIFY A TARGET PROCEDURAL SPACE

(e.g. OR pod, endoscopy suite)

2

DEFINE YOUR GOAL

Collect SUD's for reprocessing?
Buy reprocessed SUD's for use in your system?
Both?

3

SELECT SUD'S

Solicit input from both clinicians and your purchasing team

4

WORK WITH STAKEHOLDERS FOR APPROVAL AND IMPLEMENTATION

including clinicians, nursing, purchasing, infection control, environmental services, engineering

5

DRAFT HOSPITAL POLICY FOR NEW SUD WORKFLOW

Ensure compliance with Joint Commission Standard PCI 7.1

THIRD PARTY REPROCESSORS

- [Arjo ReNu](#)
- [Cardinal Health](#)
- [Innovative Health](#)
- [Medline ReNewal](#)
- [NEScientific](#)
- [Stryker](#)
- [Suretek Medical](#)

CHALLENGES



SOLUTIONS

Complex regulatory issues	- Work with third party reprocessors who have been validated by the FDA & assume liability - Read <i>Instructions for Use (IFU's)</i> for reprocessed SUD's; may have limitations
Clinician concerns regarding safety	- Provide education on FDA oversight - Collaborate with Infection Control team
Inhibitory riders on purchasing contracts preventing collection & purchase of reprocessed SUD's	- Evaluate contracts with purchasing team - Flag inhibitory language and negotiate to eliminate such terms in future contract negotiations

BENEFITS

- Participating facilities have preferential access to buy reprocessed SUD's when supply chain shortages limit access to new devices
- **20 million tons** diverted from medical waste in 2021 *
- More than **\$400 million** saved by hospitals and surgical centers reprocessing SUD's in 2021 *

USEFUL RESOURCES



Joint Commission White Paper on Reprocessing (2017)



*Association of Medical Device Reprocessors (AMDR)



ASC Quality Collaborative SUD Reprocessing Toolkit

