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
- 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)

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**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

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**THIRD PARTY REPROCESSORS**
- Arjo ReNu
- Cardinal Health
- Innovative Health
- Medline ReNewal
- NEScientific
- Stryker
- Suretek Medical

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**CHALLENGES**

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| Complex regulatory issues | - Work with third party reprocessors who have been validated by the FDA & assume liability
| Clinician concerns regarding safety | - Read Instructions for Use (IFU’s) for reprocessed SUD’s; may have limitations
| 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

**SOLUTIONS**

**THIRD PARTY REPROCESSORS**
- 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 *

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**USEFUL RESOURCES**
- Association of Medical Device Reprocessors (AMDR)
- ASC Quality Collaborative Reprocessing Toolkit

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