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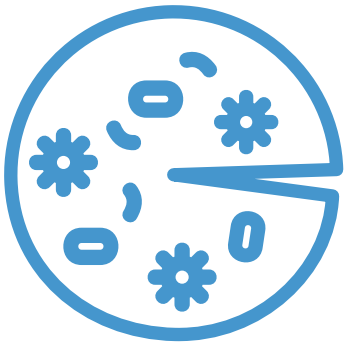
It’s Well Past Time for an Instrument Sterilization Wake-Up Call

Instrument Sterilization Wake-Up Call

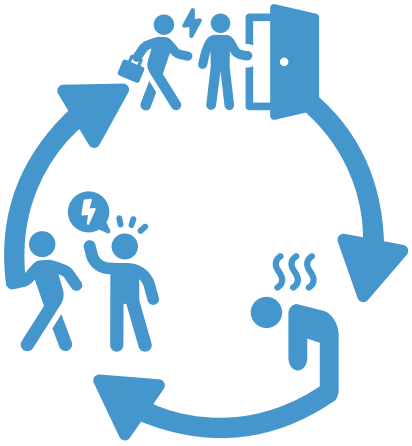
Many surgeons assume that their sterile processing department is generally reliable and effective. The data, however, does not support that assumption—rather, it reveals unexpected and unacceptable rates of morbidity, mortality, and resulting costs caused by improperly sterilized surgical instruments. **Many will be shocked to learn that 51% of hospitals and 43% of ambulatory surgery centers fail Joint Commission spot inspections on instrument sterilization.** [1] These same compliance inspections identi-fied that an astounding 74% "of all Immediate Threat to Life (ITL) deficiencies . . . were related to improperly sterilized equipment." [1]

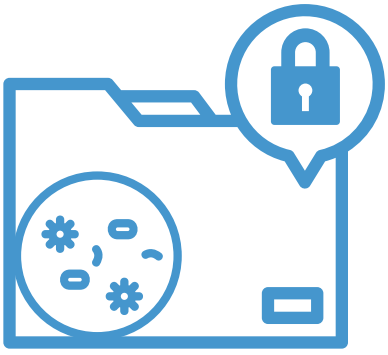
Fixing a facility's sterile processing deficiencies, however, can be a difficult nut to crack. Despite significant academic attention, endless working groups, and high-level management focus on surgical instrument sterilization, the Joint Commission reports that the rate of improperly sterilized equipment has been rising steadily for over a decade [2], and that the rate of SSIs caused by multiple antibiotic-resistant strains has increased from only 12% in the year 2000 to over 54% today. [3]



Part of the cause of this SSI crisis is that the design of reusable surgical instruments often makes them impossible to reliably sterilize. **In one study by the University of Michigan Medical Center, out of 350 reusable surgical instruments—each carefully cleaned and sterilized in exact accordance with manufacturer recommendations—342 (98%) still retained sufficient blood, bone, and tissue to spread infection.[4] Dr. Daniel Schwartz, former Chief Medical Officer of CMS, stated that most surgical instrument designs are simply "impossible to clean."[4]**

Another challenge in improving sterile processing department performance is the training, pay, and management of staff. Most SPD staff are paid less than fast food workers, have little formal training, and in most cases require no certification. As one former hospital SPD director explained, management's mentality toward SPD staff is driving increasing failures: "fire someone . . . replace . . . run them into the ground, blame them, repeat." [5] Investigations often reveal startling candor from surgeons. **"We are drowning in the OR due to our Sterile Processing Department and we are putting patients at risk frequently," said the Chief of Surgery at the Detroit Children's Hospital.** [5]





As a result, there is an increasing sense of futility among both surgeons and management. "Who has the will to solve this problem that has not been solved in the 11 years I have been here?" commented DCH's Chief of Surgery. [5] This sense of futility, as well as significant financial incentives and "pay-for-performance" metrics, drive deceptively low reporting rates of sterilization failures. Most hospitals refuse to release data on SSIs and sterilization failures, and there is no federal law, and virtually no state laws, that mandate public disclosure of this data. [10]

One alarming study by HHS found that 86% of instruments identified in the OR as improperly sterilized were never internally reported. [6] "Not a week goes by when I couldn't file a formal complaint," one frustrated surgeon commented on the condition of anonymity, "But why bang your head against the wall?" [7] It is clear that "there is a culture of secrecy" surrounding instrument sterilization failures, noted Jahan Azizi, a clinical engineer and nationally renowned expert on instrument cleaning.[8] As a result of these pervasive failures and under-reporting, it is no surprise that improperly cleaned and sterilized surgical instruments are by far the greatest cause of avoidable SSIs.

Despite this alarming reality, as a medical community we continue to plow forward with new twists on the same initiatives that have so consistently failed in the past, such as mandating 'improved SPD training,' encouraging a 'change in culture,' or applying 'Lean methodology.' **More than 30,000 Americans die per year from SSIs, and our healthcare system reliably presents the same inadequate explanation that 'operations and procedures are consistent with industry standards and best practices.'** The reality, however, is that these 'standards' are no longer the actual best practice. Sterilization failures and the resulting morbidity, mortality, and cost can now be dramatically reduced with the adoption of an increasing range of single-use, sterile, pre-packaged (SSP) implants and instruments (including the Sure Retractor, www.suresystem.com, the first and only SSP surgical retractor).

The second part of this series will address the significant reduction in infections made possible by single-use, sterile, pre-packaged instruments. Patients deserve reliably sterile surgical instruments, and our healthcare system can now provide them. **The adoption of SSP instruments will not only reduce morbidity, mortality, and cost, but it will inevitably become the surgical best practice against which patient outcomes —and liability—will be measured.**

1. https://bulletin.facs.org/2017/08/improper-sterilization-and-high-level-disinfection-of-equipment-challenges-organizations/
2. https://betsylehmancenterma.gov/news/improperly-sterilized-equipment-a-growing-problem
3. Young PY, Khadaroo RG. Surgical site infections. Surg Clin North Am. 2014 Dec; 94(6):1245-64.
4. https://publicintegrity.org/health/filthy-surgical-instruments-the-hidden-threat-in-americas-operating-rooms/
5. https://www.detroitnews.com/story/news/spe -ial-rports/2016/08/25/dirty-instruments-plague-dmc-surgeries/89303582/
6. https://www.detroitnews.com/story/news/special-reports/2016/08/25/hospital-records-kept-public/89383334/
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8. https://www.detroitnews.com/story/news/special-reports/2016/08/25/hospital-records-kept-public/89383334/