Validation of instrument reprocessing methods for the Ipas manual vacuum aspiration devices

Bill Powell* | Nathalie Kapp

Technical Innovation and Evidence, Ipas, Chapel Hill, NC, USA

*Correspondence
Bill Powell, Ipas, Chapel Hill, NC, USA.
Email: powellb@ipas.org

Abstract

Objective: To validate recommended reprocessing methods for Ipas manual vacuum aspiration (MVA) devices.

Methods: All recommended reprocessing methods for Ipas MVA devices were tested for effectiveness in cleaning, achieving high-level disinfection (HLD) and/or sterilization, and any physical effects on instruments. Worst-case scenario testing was performed using artificial soil and microorganisms. Study protocols replicated standard steps for reprocessing. The specified method for reprocessing was performed 25 times on multiple devices, including controls. After runs 1, 2, 3, 15, and 25, devices and controls were analyzed for: microbial growth; residual soils; surface damage; and functionality.

Results: All samples were negative for microbial growth and residual soils. On inspection and functionality testing, no damage was observed for aspirators and cannulae except with STERRAD and Cidex OPA. Other methods of HLD and sterilization did not affect surfaces or functionality through 25 cycles.

Discussion: Ipas MVA devices were not negatively affected following validated instrument reprocessing methods for HLD or sterilization for up to 25 reuse cycles. STERRAD and Cidex OPA did not meet assessed standards and are therefore not recommended. Strict adherence to guidance is critical for effective reprocessing of instruments.

KEYWORDS
Device reuse; FDA regulation; Infection prevention; Instrument reprocessing; Manual vacuum aspiration; Medical devices

1 INTRODUCTION

Vacuum aspiration is a very safe procedure for uterine evacuation, with major complications requiring intervention (such as hemorrhage requiring transfusion or perforation necessitating repair) occurring in up to 0.1% of procedures. Ipas, a global non-profit that works to improve sexual and reproductive rights, is the original developer of the manual vacuum aspirator (MVA) device and has guided the manufacturing, distribution, training, use, and improvement of these devices for over 45 years.

MVA instruments consist of a manual vacuum aspirator that produces suction and holds tissue and blood that are removed during uterine evacuation procedures. Cannulae are attached to the aspirator and used to apply intrauterine suction to aspirate tissue. Aspirators and cannulae up to 12 mm are intended for uterine evacuation/aspiration for the following indications: treatment of incomplete abortion for uterine sizes up to 12 weeks since the last menstrual period; first-trimester abortion (also called menstrual regulation in some countries); and endometrial biopsy.
Manufacturers of reusable medical devices are responsible for providing labeling that includes instructions for reprocessing devices and accessories safely and preparing them for reuse, while following clinical practice guidelines and recommendations for infection control. Additionally, the Food and Drug Administration (FDA) requires manufacturers to validate how a device should be cleaned and disinfected or sterilized adequately for safe reuse over its intended period of use. Reflecting scientific advances in the complexity of reusable medical devices and reprocessing technology, recent regulatory changes by the FDA strengthened validation requirements, requiring new studies to update product documentation and recommendations for all reusable medical devices.3

In response, Ipas and WomanCare Global, a non-profit organization that manufactured and distributed Ipas MVA devices globally, commissioned studies in 2014 to update the validation of effectiveness of the recommended reprocessing methods to achieve high-level disinfection (HLD) and/or sterilization and to test their physical effect on the MVA instruments. This paper describes the validation processes, results, and the ensuing evidence-based recommendations for reprocessing the Ipas MVA devices, thus addressing questions regularly received from field staff, distributors, trainers, and users of the Ipas MVA devices.

1.1 | Why reprocessing is important

Microorganisms such as hepatitis B and C and HIV can contaminate instruments used during abortion procedures. If reusable instruments are not adequately cleaned and either high-level disinfected or sterilized, healthcare-associated infections can result. Healthcare workers must use appropriate methods of reprocessing and carefully follow all instrument reprocessing steps to remove microorganisms from contaminated instruments to prevent them from infecting other women during subsequent procedures.

Ipas MVA instruments have been designed for reuse wherever regulations permit. Although cannulae are labeled for single use in the United States and other high-resource countries, when properly reprocessed, cannulae are permitted for multiple use in many settings globally. The re-design of the Ipas MVA Plus Aspirator (Fig. 1) and Ipas EasyGrip Cannulae (Fig. 2) (Ipas, Chapel Hill, NC, USA) in the early 2000s was largely driven by considerations for infection prevention and to facilitate reprocessing with the same methods used for other medical devices, such as steam sterilization and boiling. The re-engineering incorporated these features: clear fluid path without ridges, or crevices, where fluids or materials get trapped; all surfaces accessible for direct cleaning; heat-tolerant plastics withstand reprocessing by boiling or steam autoclaving; and slick plastics prevent the adhesion of fluids or materials to the device or components during procedures.

The Ipas Single Valve (SV) aspirator (Fig. 3) (Ipas) is also reusable after proper reprocessing. However, because it is not made of heat-tolerant plastics, it cannot be boiled or autoclaved, but rather must be reprocessed with chemical soaks. The older Ipas Double Valve aspirator (Ipas), now only available in limited markets, and Karman Cannulae (Ipas) are single-use devices everywhere and must be disposed of after use (Fig. 4).

For decades, the MVA aspirators were considered “non-critical” devices per the Spaulding classification (Box 1) because they generally did not touch the patient during use, or if they did, it was only against intact skin. During that era, the MVA was commonly reused after soaking and cleaning but did not require either HLD or sterilization.

In 2006, the MVA was reclassified as a “semi-critical” device per the Spaulding classification for the following reason: when it is used, the cylinder fills with blood, creating the potential risk that some contaminants from a previous patient could be introduced to another woman if the MVA aspirator is not fully reprocessed (cleaned and HLD or sterilized) between each use and the contents of the aspirator

![Figure 1](image1.png) **Figure 1** Ipas Manual Vacuum Aspiration Plus Aspirator.

![Figure 2](image2.png) **Figure 2** Ipas EasyGrip cannulae.
are discharged into the uterus due to user error. While not known to have ever occurred, it is a theoretical risk. With this change, the guidance for reuse of the MVA aspirator additionally required either HLD or sterilization after soaking and cleaning to meet the instrument reprocessing requirements of semi-critical devices.6

The EasyGrip cannulae are reusable after reprocessing where regulations allow. These cannulae, classified as semi-critical devices, require full reprocessing between patients, including cleaning and HLD or sterilization, and must be high-level disinfected or sterile before intrauterine use.

2 | MATERIALS AND METHODS

Validation studies to assess the methods of reprocessing listed in Table 1 were conducted in 2014–2015 by an FDA-registered and compliant laboratory in Puerto Rico (Scienza Labs, Dorado, PR) with current ISO 9001:2008 certification (Ipas, reports on file). Each method was performed and assessed to determine whether the process removed organic and inorganic soil potentially adherent to the device surface and for disinfection/sterilization validation. The studies also tested whether the devices maintained functionality after reprocessing 25 times. Sampling for each device (MVA Plus aspirator, SV aspirator, 4-mm and 12-mm EasyGrip cannulae) included: cleaning studies, nine devices each (n=36); STERRAD (Advanced Sterilization Products, Irvine, CA, USA), 10 MVA Plus aspirators only (n=10); all other studies about reprocessing methods, 63 devices each (n=1386).

All studies were performed using worst-case scenario testing. For the Ipas EasyGrip cannula, the 4- and 12-mm sizes represented the cannula product family since they covered all applicable steps for reprocessing, materials/components, and intended uses for the product. The 4- and 12-mm cannulae are the smallest and the largest, respectively, of the cannula family and represent the extremes of sizes and difficulty cleaning. The 4-mm cannula has the smallest orifice, making the cleaning brush more difficult to use. The 12-mm cannula has the largest surface area and two apertures at the tip.

Both the MVA Plus and the SV aspirators were tested since they covered all applicable steps for reprocessing, materials/components, and intended uses for the product. These aspirators were selected for their multiple pieces, sizes, and complexity of cleaning. The SV is the smallest and simplest aspirator and the MVA Plus is the largest and has more pieces from which organic and inorganic material must be removed.

Guidelines recommend that simulated-use testing includes a representative inorganic and organic challenge that mimics actual in-use conditions.3,7,8 Artificial Test Soil (ATS) is appropriate for
TABLE 1 Methods of reprocessing tested.

| Methods                  | MVA Plus aspirator | SV aspirator | EasyGrip cannula |
|--------------------------|--------------------|--------------|------------------|
| Cleaning                 |                    |              |                  |
| Luminox detergent        | x                  | x            | x                |
| HLD                      |                    |              |                  |
| Boiling (20 min)         | x                  | NA           | x                |
| 0.5% chlorine soak (20 min) | x                | x            | x                |
| 2% glutaraldehyde soak (20 min) | x                | x            | x                |
| Sporox II (30 min)       | x                  | x            | x                |
| Cidex OPA (20 min)       | x                  | x            | x                |
| Sterilization            |                    |              |                  |
| Steam sterilization (autoclave) (30 min at 121°C [250°F] and 106 kPa [15 lb/in^2]) | x                  | NA           | x                |
| 2% glutaraldehyde soak (10 h) | x                | x            | x                |
| Sporox II (6 h)          | x                  | x            | x                |
| STERRAD 100s^ab (54 min) | x                  | NA           | NA               |

Abbreviations: HLD, high-level disinfection; MVA, manual vacuum aspiration; SV, Single Valve.

^Method already known to be incompatible for use with the SV aspirator.

^Method already known to be incompatible for use with the EasyGrip cannula.

evaluating efficacy of cleaning and for assessing “worst-case” soiling on efficacy of disinfection/sterilization with narrow lumen medical devices.⁹ We used ATS comprising organic contaminants remaining on surgical instruments after clinical use, including protein (~23 mg/mL), hemoglobin (~8 mg/mL), and carbohydrates (~6 mg/mL).¹⁰ The microorganisms added to the ATS for the validation of disinfection/sterilization included representative gram-positive and gram-negative bacteria, yeast, mold, and a spore-forming bacterium for robustness (Table 2).

TABLE 2 Microorganisms used for the validation of disinfection/sterilization.

| Microorganism | Description |
|---------------|-------------|
| *Pseudomonas aeruginosa* ATCC 9027 | Gram-negative bacilli related to water contamination |
| *Staphylococcus aureus* ATCC 6538 | Gram-positive cocci common in production areas and carried as normal human flora |
| *Salmoneella enterica* ATCC 14048 | Gram-negative bacilli common representative of coliform group typically used as an indicator of non-sanitary conditions |
| *Escherichia coli* ATCC 8739 | Gram-negative bacilli common representative of Coliform group typically used as an indicator of non-sanitary conditions |
| *Aspergillus brasiliensis* ATCC 16404 | Representative of molds or filamentous fungi |
| *Candida albicans* ATCC 10231 | Representative of yeast and part of the normal human flora |
| *Bacillus subtilis* ATCC 6633 | Gram-positive bacilli that can form protective spores, allowing the organisms to tolerate extreme environmental conditions |

All validation protocols were performed according to the standards/methods outlined by the FDA, Association for the Advancement of Medical Instrumentation and United States Pharmacopeia.³⁷⁸¹¹

The study protocols replicated standard steps for reprocessing: a decontamination soak; cleaning; HLD or sterilization; and then use or storage.² A 0.5% chlorine solution was used for the initial soak before cleaning for simulated-use testing due to potential damage of chlorine to instruments and because this is common practice in the field.

Physical cleaning reduces the bioburden and removes foreign substances (e.g., organic and inorganic materials) that may act as barriers and interfere with the effectiveness of the processes of disinfection and/or sterilization. The FDA recommends validation of the cleaning process but does not recommend microbial markers to test the effectiveness of the cleaning method.³

The cleaning studies using Luminox (Alconox, Inc., White Plains, NY, USA) were conducted under written and monitored protocols guiding instrument calibration, soaking, and cleaning. In each study, the cleaning method was performed 25 times. For runs 1, 2, 3, 15, and 25, the analysts performed device inoculation including positive and negative controls with the ATS soil before the soaking step. Following a 24-hour drying period, the devices were then soaked and cleaned per protocol.

All studies regarding HLD and sterilization were conducted under written and monitored protocols guiding calibration of instruments, soaking, cleaning, and application of the methods of disinfection or sterilization (Table 1). In each study, the specified method of reprocessing was performed 25 times on multiple devices. For runs 1, 2, 3, 15, and 25, the analysts performed inoculation of the device, including positive and negative controls with the ATS soil and microorganisms (Table 2), before the soaking step. Inoculum verification was performed to confirm an inoculum level of 10⁶ cfu/mL per microorganism. Following a 24-hour drying period, the devices were soaked, cleaned, and HLD or sterilized per protocol.
After runs 1, 2, 3, 15, and 25, the devices and the controls were analyzed for the following: any microorganism counts obtained from cultures plated from the test samples (except for cleaning studies); positive controls showing growth and negative controls showing no growth from cultures plated from the control samples (except for cleaning studies); protein, carbohydrate, and hemoglobin (ATS) residual test; visual observation and inspection with an eye loupe for surface damage; and functionality test for device operation, fit, measurements, and vacuum pressure (holding a pressure of a minimum of 22 mmHg for 30 minutes).

3 | RESULTS

The cleaning studies demonstrated that the tests for residual protein, carbohydrate, and hemoglobin from the ATS were negative for all devices (n=36). The studies also demonstrated that all devices maintained their full functionality after the cleaning process was performed 25 times.

All results of test samples obtained during the execution of the HLD and sterilization protocols were negative (n=1396), i.e., no growth of any microbes with any of the methods representing a 6-log$_{10}$ reduction of the microorganisms. Positive controls showed positive results and negative controls showed negative results. The tests for residual protein, carbohydrate, and hemoglobin were also negative for all methods.

On visual observation and inspection (n=1396), no surface damage was observed for the aspirators and cannulae except with STERRAD and Cidex OPA (ortho-pthalaldehyde) (Advanced Sterilization Products). With STERRAD, 4 of the 10 aspirators tested suffered surface damage with repeated cycles; insertion of the plunger into the aspirator barrels became increasingly difficult with additional cycles, and one aspirator failed the vacuum test. Cidex OPA caused the valve liners of the aspirator to change color from white to green; no other surface damage was observed and these devices passed the functionality tests. All other methods of HLD and sterilization did not affect functionality of the instruments through 25 reprocessing cycles.

4 | DISCUSSION

Results show that the Ipas MVA Plus and SV aspirators, and the EasyGrip cannulae, can be safely reused (where regulations permit).
following recommended methods and steps of instrument reprocessing. Current recommendations for reprocessing, based on the results of these validation studies, are summarized in Figure 5.

The methods of reprocessing validated for HLD are boiling or chemical soaks in either 0.5% chlorine, 2% glutaraldehyde, or Sporox II (7.5% hydrogen peroxide) (Sultan Healthcare, York, PA, USA). The validated methods for sterilization are steam (autoclave) or longer chemical soaks in 2% glutaraldehyde or Sporox II. The methods that failed to meet our standards were STERRAD, due to observed surface damage and functionality testing, and Cidex OPA, which produced color changes on valve liners.

It is critical that the steps for effective reprocessing of instruments are followed closely. Many studies have documented a lack of compliance with established guidelines for disinfection and sterilization and concerns have recently been raised about the reprocessing of medical instruments in low- and middle-income countries.4,13 Notably, recent technical guidance stresses the importance of adequate competency-based staff training, continuing education, and periodic evaluation of competency for staff performing reprocessing of instruments.4,14

The critical importance of disassembly and thorough physical cleaning before disinfection and sterilization should be consistently stressed.4,14–16 Disinfection studies using small lumen devices demonstrate that thorough manual cleaning results in a mean reduction of microbial load by $4 \log_{10}$ (99.99% kill rate) on the instruments.12 While our cleaning studies did not include microbial markers, in accordance with FDA guidance, the negative ATS residual tests demonstrated the ability to thoroughly clean these devices and provides assurance that reasonable soil challenges will not interfere with the subsequent processes of HLD or sterilization.17

Likewise, our results showing no growth from the microbial cultures following HLD are particularly important. Semi-critical instruments, which are only required to be HLD, represent the greatest risk for transmission of disease by virtue of the body cavities they enter.12 Although transmission of disease has never been documented with MVA devices, the risk exists. Thus, documenting achievement of HLD with all the recommended processes should provide reassurance to users.

Supporting this reassurance are the consecutive reductions achieved with adequate cleaning followed by HLD or sterilization. Cleaning significantly reduces microbial load and HLD results in the reduction of another $4 - 6 \log_{10}$ while sterilization can achieve a reduction of $12 \log_{10}$.17 The combination for cleaning and sterilization provides a large margin of safety and a substantial but narrower margin with cleaning and HLD. Strictly following the reprocessing protocols are key to achieving these margins of safety.

The limitation of our study involves the use of chlorine in the presoak step. At the time of these studies, Ipas’s guidance regarding instrument reprocessing included a “decontamination soak.” However, Ipas guidance, like that of WHO, noted that while a “0.5% chlorine solution can be used,” the primary purpose of this soak is to keep instruments wet until cleaning.2,11 The “Ipas Decontamination Statement” produced in 2003 and updated in 2014 stated that soaking in chlorine solution does not make instruments safe or safer to handle with bare hands and for this step, any solution, including tap water, could be used.12

Since the implementation of these studies, WHO and others have issued new guidance on infection prevention and reprocessing of instruments.4,14 One notable change is that “soaking of instruments in 0.5% chlorine solution or any other disinfectant before cleaning is not recommended.”14 This recommendation is based on potential damage to the instruments, inactivation of the chlorine by blood and body fluids, risks in subsequent transportation, and contribution to the development of antimicrobial resistance to disinfectants. As our studies included a chlorine presoak before disassembly and cleaning, we note the results would have been strengthened by conducting comparison studies using a presoak with water and/or enzymatic spray to assess comparative effectiveness. Nevertheless, in our collective agency experience, most low-income countries are still using chlorine presoaks; thus, our study reflects common practice. Users, however, should heed the clear guidance from WHO to avoid the use of chlorine for presoaking14 and that instruments should be presoaked, rinsed or sprayed with water or an enzymatic spray, and kept moist until cleaning.4,14–16 Given this recent guidance, the assertion that “Cleaning is the first and most essential step before any process of disinfection or sterilization can be carried out”14 and the margin of safety achieved by cleaning combined with HLD or sterilization as discussed above, it is likely our results would hold when water is used for presoaks rather than chlorine.

In conclusion, the results from this study support reuse of the Ipas MVA devices following the validated methods of instrument reprocessing with HLD or sterilization, which do not negatively affect the devices for up to 25 reuse cycles. The STERRAD and Cidex OPA methods did not meet the standards assessed in these studies and are therefore not recommended, which represents a change from earlier recommendations. Strict adherence to the reprocessing guidance is critical to achieve effective reprocessing of instruments.

**AUTHOR CONTRIBUTIONS**

BP and NK conceived the idea; BP drafted the manuscript and NK provided substantive revisions to the manuscript.

**ACKNOWLEDGMENTS**

The authors thank Wilberto Robles, True Overholt, Christopher Hamon, Joan Healy, and Kathryn Andersen.

**CONFLICTS OF INTEREST**

The authors have no conflicts of interest.

**REFERENCES**

1. White K, Carroll E, Grossman D. Complications from first-trimester aspiration abortion: a systematic review of the literature. *Contraception*. 2015;92:422–438.
2. Ipas. Woman-Centered, Comprehensive Abortion Care: Reference Manual. 2nd edn. Chapel Hill, NC: Ipas; 2013.
3. Food & Drug Administration. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Rockville, MD: FDA; 2015.
4. Curless MS, Ruparelia C, Thompson E, Trexler PA, eds. Infection Prevention and Control: Reference Manual for Health Care Facilities with Limited Resources. Baltimore, MD: Jhpiego; 2018.
5. Rutala WA, Weber DJ. Disinfection and sterilization: an overview. Am J Infect Control. 2013;41:S2–S5.
6. Ipas. Technical update: changes affecting MVA use: Ipas; 2006. Report No.: M-06-LET-003 Rev 1 5/2007.
7. Association for the Advancement of Medical Instrumentation. Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers. Arlington, VA: AAMI; 2010.
8. Association for the Advancement of Medical Instrumentation. A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices. Arlington, VA: AAMI; 2011.
9. Alfa M, DeGagne P, Olson N. Validation of ATS as an appropriate test soil. Zentr Steril. 2005;13:387–402.
10. Healthmark. Artificial Test Soil product brochure. Fraser, MI. http://www.artificialtestsoil.com/ATS.pdf. Accessed February 1, 2019.
11. United States Pharmacopeial Convention. Chapter 61: Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests. United States Pharmacopeia—National Formulary. Rockville, MD: USP-US; 2014.
12. Rutala WA, Weber DJ. New developments in reprocessing semicritical items. Am J Infect Control. 2013;41:S60–S66.
13. O’Hara NN, Patel KR, Caldwell A, Shone S, Bryce EA. Sterile reprocessing of surgical instruments in low- and middle-income countries: a multicenter pilot study. Am J Infect Control. 2015;43:1197–1200.
14. World Health Organization and Pan American Health Organization. Decontamination and Reprocessing of Medical Devices for Health-care Facilities. Geneva: WHO & PAHO; 2016.
15. Centers for Disease Control. Guideline for Disinfection and Sterilization in Healthcare Facilities. Atlanta, GA: CDC; 2008.
16. Rutala WA, Weber DJ. An overview of disinfection and sterilization. In: Rutala WA, ed. Disinfection, Sterilization and Antisepsis: Principles, Practices, Current Issues, New Research, and New Technologies. Washington, DC: Association for Professionals in Infection Control and Epidemiology (APIC); 2010: 12–48.
17. Alfa M, DeGagne P, Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. Am J Infect Control. 1999;27:392–401.