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Designing to Ensure the Quality of Instrument Processing Regardless of the Approach

In the face of newly recognized pathogens and well-known microorganisms becoming resistant to treatment modalities, there is growing pressure to reduce healthcare-associated infections (HAIs) and surgical site infections (SSIs). A key infection prevention practice for reducing the likelihood of an infection is proper processing of medical instruments.

This Midmark white paper takes a look at what architects, designers and healthcare providers need to know to ensure the quality of the instrument processing (IP) area regardless of whether an in-house or centralized approach is taken.

Growing pressure to reduce infections

Healthcare-associated infections (HAIs) and surgical site infections (SSIs) have long been recognized as a major patient safety challenge, especially in acute care environments. However, as more procedures transition to outpatient environments, such as ambulatory surgery centers (ASCs) and physician offices, the urgency to prevent infections in these environments is intensifying. In fact, recent projections indicate that surgical volumes in ambulatory settings are expected to increase by 25% in ASCs and 18% in hospital outpatient departments and physician offices over the next decade.

A key infection prevention practice for reducing the likelihood of an infection is proper reprocessing of medical instruments. However, there are a number of challenges that in some ways are making it a more difficult and complex endeavor to ensure safe, efficient and compliant reprocessing of medical instruments.

- **Staffing shortages** mean many ambulatory facilities operate with lean teams and instrument processing (IP) is often not staffed by dedicated, trained professionals. Instead, responsibilities may fall to medical assistants or other staff who juggle multiple roles and responsibilities. This can lead to errors in the process, staff burnout, especially when workloads are high, and patient safety concerns.
- An ongoing **increase in procedure volume** is occurring in ambulatory care facilities. Many medical procedures that were once performed exclusively in hospitals are now being done safely and effectively in outpatient settings, including physician practices and ASCs. As case volume grows, turnaround time expectations tighten, putting additional pressure on already stretched staff and systems.
- Another major challenge involves **regulatory compliance**. There are relevant regulations, standards and best practices from organizations such as the Occupational Health and Safety Administration (OSHA), The Joint Commission, the Association for the Advancement of Medical Instrumentation (AAMI) and the Centers for Disease Control and Prevention (CDC). For ambulatory care facilities without dedicated compliance teams, keeping up with these evolving requirements can be difficult and resource-intensive.

OSHA® The Joint Commission AAMI CDC Centers for Disease Control and Prevention

- **Space and infrastructure limitations** can also be an issue. Unlike most acute care facilities, many ambulatory care facilities were not designed to accommodate dedicated IP areas. This can result in suboptimal workflows, such as limited storage and inadequate separation between dirty and clean areas, which can compromise efficiency and increase the risk of contamination.
- **Finally, there is the challenge of education and training.** Proper IP requires detailed knowledge of manufacturer's instructions for use (IFUs), sterilization methods and infection prevention principles. In ambulatory settings, ongoing training may be inconsistent due to time constraints, budget limitations or lack of access to specialized educators.

Two primary approaches to instrument processing

When it comes to establishing a sterile processing strategy, there are two primary approaches that most ambulatory care facilities consider: centralized sterile processing and in-house (on-site) processing. Each model offers distinct advantages and disadvantages that must be carefully evaluated based on the needs capabilities and design of the ambulatory care facility.

Centralized processing involves outsourcing IP to an external facility within a larger healthcare system's central sterile processing department. Instruments are transported offsite for cleaning, sterilization and return. Central facilities often employ highly-trained technicians and standardized procedures. They offer scalability for those ambulatory facilities experiencing growth or fluctuating instrument volume, while also reducing the on-site space, staffing and administrative burden.

However, there are some drawbacks to ambulatory facilities outsourcing their IP. Transporting instruments introduces delays and requires precise coordination, while service disruptions or quality issues may be outside the direct control of the practice. A larger instrument inventory may be required to compensate for off-site processing cycles.

In-house processing refers to reprocessing instruments within the ambulatory facility itself. Ideally, the space should be a separate and distinct, centrally located area designed specifically for IP, including sterilization. This separation allows easier control and management of the process and helps ensure safety and an efficient workflow. An IP area should not share space with a laboratory or staff breakroom, or be located in the facility's storage room.

In-house processing enables direct oversight of the process and allows for faster turnaround times, as well as any needed adjustments. Additionally, it eliminates the need for a larger instrument inventory. It can also provide more seamless coordination and workflows with clinical staff and procedures. Conversely, it may require upfront spending on facility space modifications and equipment, as well as dedicated personnel. Maintaining compliance requires ongoing education, audits and documentation.

Instrument Processing Workflow

Regardless of the model utilized, and the size and shape of the IP area, there are five critical steps, based on guidelines from the Centers for Disease Control and Prevention (CDC), that can help standardize IP workflow. Utilizing these five steps to standardize IP workflow can make it easier to manage the process and maintain the standards needed for providing a safe healthcare experience.

1. Receiving + Cleaning + Decontamination
Reusable instruments, supplies and equipment should be placed in appropriate containers at the point of use to prevent percutaneous exposure incidents (PEIs) during transportation to the IP area. All items should be received, cleaned and disinfected in one section of the processing environment. It's important to ensure that all instruments, supplies and equipment are thoroughly cleaned of organic debris prior to sterilization or sterilization will be ineffective.

**To ensure best practices, make sure to remove gross soil at the point of use in the exam room. This should be done prior to practicing the five steps within the dedicated sterilization space.*

2. Preparation + Packaging
This area should be at least four feet from the previous section or have a barrier to prevent contaminants from entering the space as items are inspected, assembled into sets or trays, and wrapped or packaged for sterilization.

3. Sterilization
This area should include sterilizer(s) and related supplies with adequate space for loading, unloading and cooling down of instruments and other supplies. Thought should be given to the size and type of sterilizer(s) that will need to fit into the configuration of the IP space.

4. Monitoring/Sterility Assurance
This area needs to be configured to support the documentation and recording of mechanical, chemical and/or biological monitoring utilized to help ensure the efficacy of the sterilization process. Monitored results and records should be accessible and stored long enough to comply with federal, state and local regulations.

5. Storage
The storage area should be covered and contain space for both sterile and disposable items. Supplies and instruments should not be stored under sinks or in other locations where they might become wet or damaged, or the packaging could be compromised.

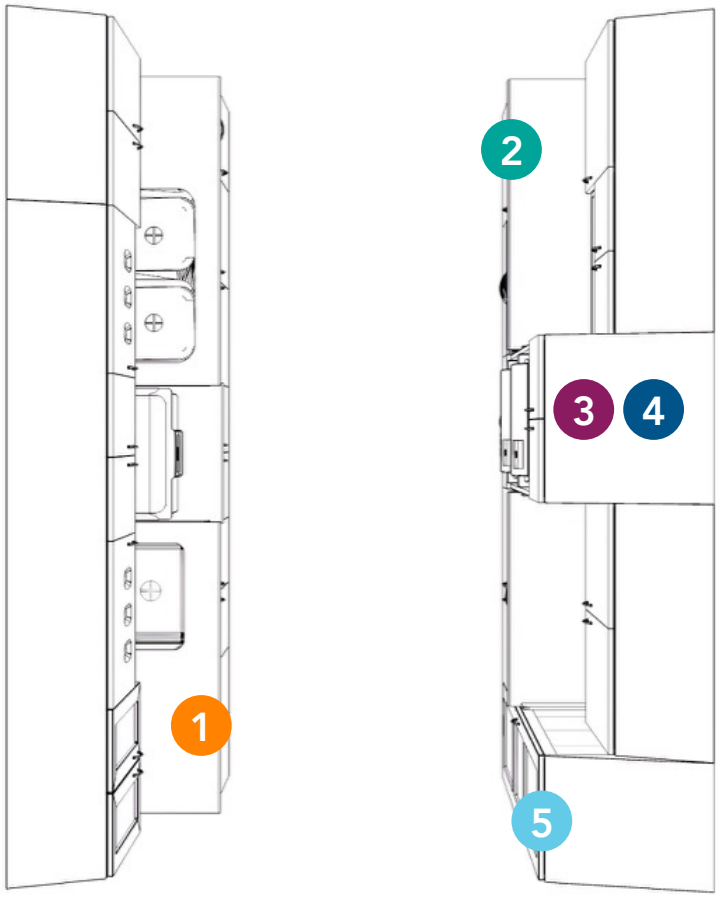
The right cabinetry strengthens instrument processing

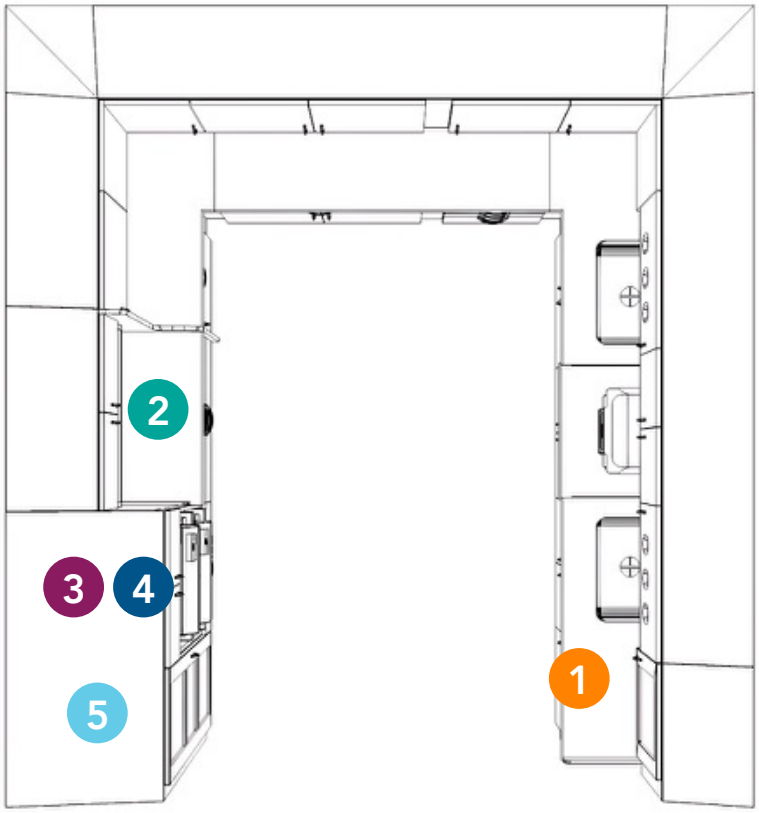
Along with these five critical steps, the cabinetry used in the space can further strengthen and standardize IP. Modular cabinetry created specifically for the medical environment, such as Synthesis® Cabinetry, can help ensure the workflow design of the IP area is organized efficiently. This makes it easier to control and manage the process and maintain safety standards. The right cabinetry configuration allows staff to follow the dirty-to-clean workflow as recommended by the CDC to help contain contamination and maximize the efficiency of the instrument cleaning and sterilizing process.

Cabinetry that is modular and configurable provides a variety of layout options that follow the 5-step workflow within the space available in the facility.

1. Galley

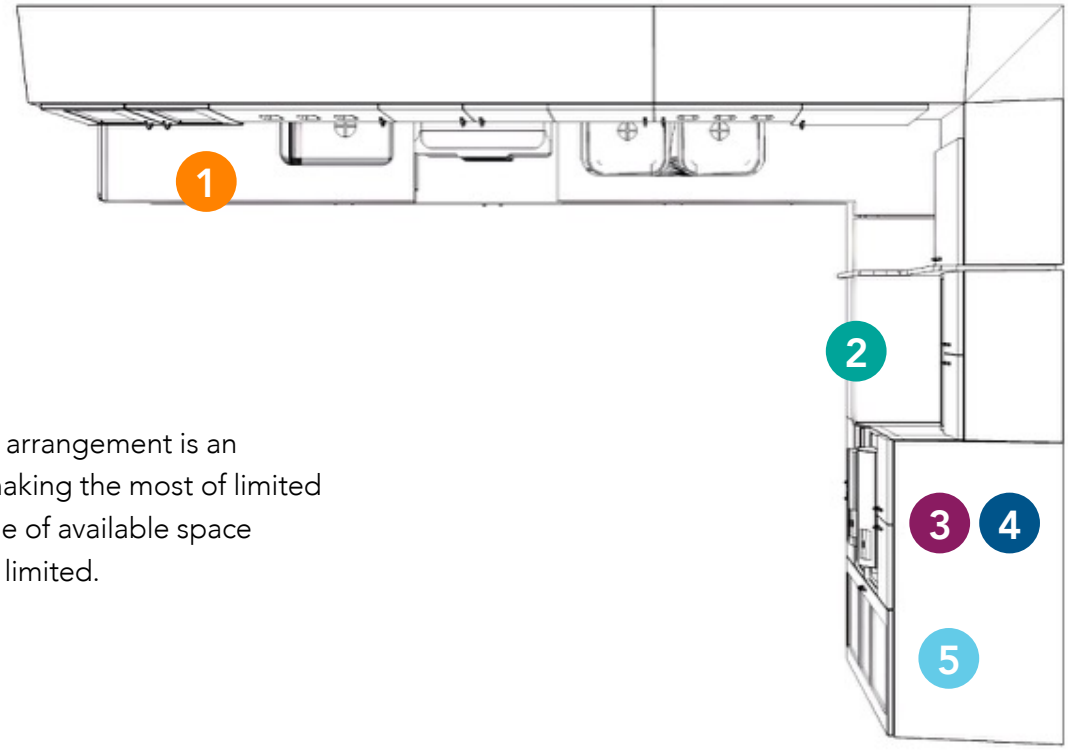
The galley layout consists of workspaces on two opposing walls with a single traffic lane between. This arrangement allows for easy access and efficient workflow, helping staff keep the process moving using a linear flow while keeping everything within reach.





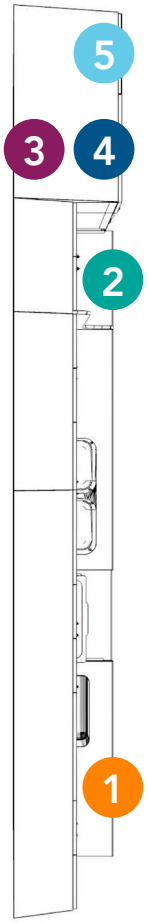
2. U-Shaped

A U-shaped workspace design provides space for multiple cleaners and sterilizers. Ample surface areas allow more staff in the room to multitask and maintain a bustling workflow.



3. L-Shaped

An L-shaped counter arrangement is an efficient design for making the most of limited space, maximizing use of available space where elbow room is limited.



4. Straight Line

The straight-line layout can help create an efficient, standardized 5-step IP workflow. The linear design creates a clear flow path from dirty to clean, minimizing the risk of cross-contamination.

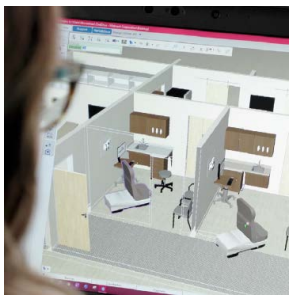
Important role of the equipment provider

Equipment providers can be a valuable resource for healthcare professionals, architects and designers when it comes to ensuring the quality of the IP area. A knowledgeable manufacturer that has broadened its offerings beyond equipment can bring a deeper understanding of how design, equipment and layout can position the IP space to maintain efficiency and quality standards.

At Midmark, in-house design consultation experts work directly with project architects, contractors and interior designers to help ensure facility design and room configurations align with equipment and furniture needs, as well as desired workflows and accessibility goals.

During the Midmark Live Design process, the design team makes sure design decisions align with clinical workflow and human needs, creating clinical environments that reflect real user needs rather than purely stylistic trends. The team often solves potential issues previously undetected and offers options and critical insight to help resolve the issues. The ultimate goal of the process is to create clinical spaces that perform on multiple levels simultaneously.

Midmark also has delivery setup and integration teams that can seamlessly connect equipment and technology within the clinical environment. Midmark Product Repair + Service Solutions helps ensure the medical equipment within the ambulatory space is functioning as intended so quality care can be provided. Led by professional clinical educators, Midmark Clinical Education offers flexible education options for healthcare staff, including continuing medical education courses on such topics as infection prevention and patient safety.



As pressure continues to grow to reduce HAIs and SSIs in the ambulatory care space, focus is falling on the IP area. While ambulatory facilities face a number of challenges in IP, including staffing shortages, increased procedure volume and spacing constraints, there are steps they can take to help ensure safe, efficient and compliant reprocessing of medical instruments.

Contact us to learn how Midmark can help establish and strengthen your IP workflow.

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