Executive Summary

The following guide provides a decision tree for PEPFAR Implementing Partners to make informed decisions as to whether to use Reusable or Disposable VMMC Kits to support their campaigns. For the Reusable Kits, sophisticated equipment and skills in addition to a minimum disciplined infrastructure are required to ensure that Reusable Metal Instruments are correctly sterilized and managed for reuse to reduce the risk of health-care caused infections.

Infrastructure Requirements for Reusable MC Kits

Sites must meet the following minimum infrastructure requirements to be considered for the use of the VMMC **Reusable** MC Kits

Certain requirements that are shared for sites using **reusable** and those using **disposable** MC Kits have been excluded from this guidance document. Below is a list of requirements exclusive to sites using reusable MC kits which requires sterilization of metal / surgical instruments for reuse post-decontamination.

Public Utility Requirements

Power:

- The site requires a consistent electricity supply for at least 8 working hours per day to support autoclave use.
- In order to avoid any injury by electrical hazard, it is mandatory for the electrical outlet and the autoclave be grounded /earthed.

Water:

- The site must have a potable/clean water supply.
- The site must be able to supply enough water to support proper functioning of the autoclave. It is imperative to have the correct amount of water for proper operation of the autoclave.
- Water Quality: Water supplied to the autoclave should be distilled or de-mineralized and have less than the maximum acceptable level of contaminants indicated in the table below (refer to the manufacturer's operating manual):

Physical characteristics and acceptable contaminants levels in water, for autoclaves	
Evaporate residue	≤ 15 mg/l
Silica	≤ 2 mg/l
Iron	≤ 0.2mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Rest of heavy metals	≤ 0.1 mg/l
Chloride	≤ 3 mg/l
Phosphate	≤ 0.5 mg/l
Conductivity	≤ 50 µs/cm
pH	6.5 to 8
Appearance	Colorless, clean, without sediment
Hardness	≤ 0.1 mmol/l
Note: *Compliance with the above data should be tested in accordance with acknowledged analytical methods, by an authorized laboratory.*	
Attention: *Testing of the water quality is recommended at once a month. The use of water for autoclaves that does not comply with the table above may have severe impact on the working life of the autoclave and can invalidate the manufacturer's guarantee.*	

Physical Requirements

Wrapping Station:

- Minimum 2x2m enclosed location with concrete floors
- Access limited to only authorized personnel
- Well ventilated (window, A/C unit, fan) but dust-free
- Low relative humidity (less than 50%)
- Temperature controlled (18°C - 25°C)
- Wrapping table (washable and non-porous)
- Temporary storage area (open, metal or plastic shelves)

Sterilization Station:

- Minimum area to support the size of the autoclave as per manufacturer's installation requirements.
- Enclosed location with concrete floors
- Access limited to authorized personnel
- Well ventilated (A/C unit) but dust-free
- Low relative humidity (less than 50%)
- Temperature controlled (18°C - 25°C)
- Temporary storage area (open, metal or plastic shelves)
- Electrical outlet, properly configured for the autoclave power cord

- The sterilizer must be placed on a rigid and leveled surface (i.e. a table or the floor). The stand must be able to hold the load of the device and loaded material. Note: Make sure while placing the autoclave, to leave space around the machine to allow the door to fully open and to give the technician access to service the machine.

Storage Area for Sterile Stock:

- Minimum 2x2m enclosed location with concrete floors with a stock pool sufficient to meet demand
- Access controlled to authorized personnel
- Well ventilated (A/C unit) but dust-free
- Low relative humidity (less than 50%)
- Temperature controlled (18°C - 25°C)
- Shelving (open, metal or plastic) 250 mm above the floor and 440 mm from the ceiling
- Inventory management system based on the date of sterilization to assure stock rotation

Supplies / Products Requirements

- Sufficient chemical indicators (CIs) (ratio: 1 CI to 1 wrapped kit) and biological indicators (BIs) (one autoclaved BI + one control BI/ week) are routinely utilized to monitor and detect potential sterilization failures (Note: CIs should be Class 4 or 5; Biological indicators should contain 1 x10^6 spores of *Bacillus stearothermophilus*.)
- Sufficient chemical indicator tape utilized to secure each instrument pack and inform the user if the pack has been exposed to steam (Class 1 Chemical Indicator)
- Sufficient indicator tape to monitor sterility of each instrument pack.
- Adequate stock of reusable instruments to meet demand
- Adequate stock of wraps to meet demand
- On-site laundry facility for laundering reusable wraps
- Adequate supply of necessary Personal Protective Equipment (PPE) in accordance with autoclave/sterilizer manufacturer's directions.
- Non-porous, washable containers for holding decontaminated instruments prior to packing

Human Capacity Requirements

- Minimum of 2 staff members suitably trained and competent on:
  - Microbiology; operation of equipment; principles of cleaning, disinfection and sterilization; selection and packaging of instruments; preparation of textile material; wrapping, loading of autoclaves; control of processes; storage of sterile material; collection and distribution of material; documentation of cycle controls and indicator results, and use of PPE.
- Minimum of 1 staff member suitably trained and competent on proper maintenance of procured autoclave:
  - **Daily:** cleaning the door gasket
  - **Weekly:** cleaning tray holders & trays; cleaning & descaling the chamber, copper tubes & reservoir; oiling door pins & door-tightening bolts; cleaning outer parts of the autoclave; draining the water from the reservoir and replacing with fresh mineral-free or distilled water as per abovementioned water quality guidelines, etc.
  - **Periodical:** checking safety valve, air-trap jet, door gasket every 12 months, check and tighten piping joints once a year to prevent leakage, once a year check and tighten all screw connections in the control box, heaters and valves and instrumentation [must be done by a qualified electrician], once a year calibrate the pressure switch, etc.

Controls

- A quality management system, which includes M&E and incident management. A basic summary of monitoring requirements for autoclaves in general is shown in the table below, but depends entirely on the autoclave procured.

Process Recorder	Temperature Measurement	Chemical Monitoring	Other	Optional Monitoring
Every cycle	Every cycle	Every load and if required, every item	Vacuum-assisted or dynamic air removal autoclaves - weekly leak rate if autoclave fitted with an automatic air detector, otherwise daily Biological Indicator for emergency - non validated loads	Biological Indicators Process Challenge devices Electronic Data Loggers Internal Chemical Indicators

- Batch-control label system for wrapping and sterilization of reusable instruments and stock rotation.