

CleanSpace Technology, the manufacturer, confirms that CleanSpace HALO components (except Filter & Bio Hood components) are tested to be compatible with the STERRAD[®] 100S and STERRAD[®] 100NX[™] sterilization systems.

Refer to [Washing, Disinfecting & Sterilisation Compatibility Guidelines](#) for a full list of CleanSpace HALO components compatible with this sterilisation process.

TESTING

Based upon the principles in ISO 14937:2000, [Advanced Sterilization Products \(ASP\)](#), has determined the STERRAD[®] 100NX[™] System, STANDARD cycle, can be used as the testing model for general medical devices.

Components were tested with the STERRAD[®] 100NX STANDARD cycle. [Advanced Sterilization Products \(ASP\)](#) has established that the STERRAD[®] 100NX[™] System, STANDARD and FLEX cycles, have the maximum cycle hydrogen peroxide concentration. Therefore, these cycles are used as testing cycles for component material compatibility and device functionality.

At the completion of testing CleanSpace HALO components were fully functional and material unaffected by the process. The Power Unit was tested to a nominal 50 cycles in accordance with testing procedures.

REPROCESSING

The Filter is not compatible with this type of reprocessing and must be removed from the Power Unit prior to reprocessing.

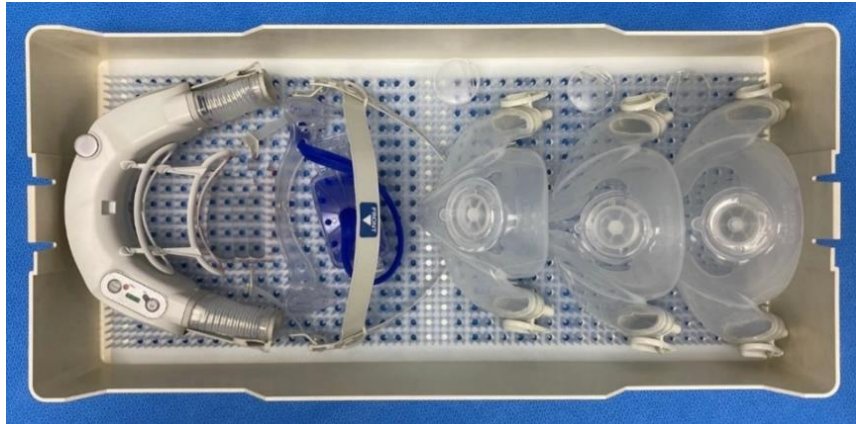
Prepare the Half Mask by removing the exhalation valve cap from the front of the mask in accordance with [CleanSpace HALO User Instructions](#). The valve cap should be placed together with the mask in the sterilization system (preferably contained within a basket).

Prepare the Power Unit by wiping clean prior to reprocessing with an approved cleaning wipe. Refer to [Compatible Cleaning & Disinfecting Agents](#) for approved cleaning agents.

Do NOT insert the cleaning and storage plug into the power unit for sterilisation. A clear airpath through the power unit must be maintained.

Prior to sterilizing, components must be thoroughly cleaned, rinsed, and dried in accordance with procedures contained within the CleanSpace HALO Instruction manual and as described by the manufacturer's instructions.

Preferably place power unit and components in a tray for reprocessing. An example is shown below.



Package components prior to sterilization as described in the manufacturer's instructions for the STERRAD Sterilization System. The use of a pouch is not recommended, however wrapping can be used for reprocessing. An example of wrapping is show below.



Reprocess components by following the manufacturer's instructions.

The following cycles are compatible with CleanSpace HALO components:

- STERRAD 100S: Short cycle (boosters not required)
- STERRAD NX: Standard or advanced cycle