



Endoscope Cleaning and Sterilization Instructions

WARNINGS

- ▲ This section only applies to Endoscopes CardioFocus Part # 18-1447 (EU). Do not reprocess any other CardioFocus products.
- ▲ These instructions are validated only when the device is arranged within the package as prescribed. Any other configuration could result in inadequate sterilization.
- ▲ Wear appropriate protective equipment (gloves, eye protection, etc.) when reprocessing any medical device.
- ▲ The device must be cleaned prior to sterilization, or inadequate sterilization may result.
- ▲ Inspect the device for visible damage, such as kinks, prior to use. Do not use the device if it is damaged or the Endoscope image is not clear.
- ▲ Use only packaging approved for use in the STERRAD® NX, STERRAD® 100NX DUO cycle systems (including the STERRAD® ALLClear™ versions of each system) or STERRAD® 100S.

CAUTIONS

- △ The Endoscope is fragile and must be handled with care. To prevent damage (i.e. kinking), do not coil the Endoscope into a loop smaller than 6" (15 cm). Avoid Endoscope Ends contact with hard surfaces.
- △ Handle the Endoscope as if it has been contaminated with blood and follow appropriate hospital guidelines for handling.
- △ Do not use metallic brushes, scrub pads, or other abrasive cleaning aids when reprocessing the device. These can cause permanent damage.
- △ Do not use harsh chemicals (such as chlorine or caustic soda) or organic or ammoniated acids or solvents (such as acetone) when reprocessing the device. These could cause permanent damage to the endoscope.
- △ Do not clean more than three (3) Endoscopes in the same cleaning basin.

LIMITATIONS ON REPROCESSING

- These reprocessing instructions are provided in accordance with ANSI ST 81 and ISO 17664.
- While these instructions have been validated by the manufacturer as being capable of preparing the device for re-use, it remains the responsibility of the processor to ensure that the reprocessing (as actually performed, using equipment, materials, and personnel in the reprocessing facility) achieves the desired result. This normally requires validation and routine monitoring of the process.
- The Endoscope may be reprocessed up to ten (10) times.
- An Enclosed Tracking Card, 06-5124 can be found in each 18-1447 (EU) Endoscope Box.
- Refer to and fill out the Tracking Card for endoscope reprocessing status.
- Use only the STERRAD® Sterilization method specified for reprocessing. Other sterilization methods have not been validated and might significantly reduce the performance of the device or result in inadequate sterilization.
- Damage incurred by improper processing will not be covered by the warranty.



INSTRUCTIONS FOR REPROCESSING	
Point of use:	<ul style="list-style-type: none"> • Upon completion of the clinical procedure, carefully remove the Endoscope from the catheter.
	<ul style="list-style-type: none"> • Rinse the entire Endoscope under running water for at least one minute to remove major debris.
	<ul style="list-style-type: none"> • Wipe the Endoscope with a water dampened soft cloth.
	<ul style="list-style-type: none"> • Place the endoscope into a container and cover with a towel moistened with clean tap water.
Preparation for decontamination:	<ul style="list-style-type: none"> • Reprocess the device as soon as reasonably practical following use.
	<ul style="list-style-type: none"> • Cleaning should be performed before blood and debris are dry.
Cleaning - Manual:	<ul style="list-style-type: none"> • Prepare enzymatic detergent¹ in accordance with the manufacturer's instructions.
	<ul style="list-style-type: none"> • Submerge Endoscope (no more than 3) in a clean basin (minimum 8" x 8") with enzymatic detergent, making sure all surfaces are free of bubbles by gently agitating the device(s).
	<ul style="list-style-type: none"> • Soak the Endoscope (no more than 3) for a minimum of 5 minutes. Wipe the device with a soft clean cloth while submerged to remove visible soil and debris.
	<ul style="list-style-type: none"> • Submerge the Endoscope (no more than 3) in a basin of clean tap water for at least 1 minute.
	<ul style="list-style-type: none"> • Submerge Endoscope (no more than 3) in a clean basin (minimum 8" x 8") with a neutral pH detergent, making sure all surfaces are free of bubbles by gently agitating the device(s).
	<ul style="list-style-type: none"> • Soak the Endoscope (no more than 3) for at least 4 minutes. Wipe each device at least once with a soft clean cloth while submerged.
	<ul style="list-style-type: none"> • Submerge the Endoscope (no more than 3) in a basin of clean non-pyrogenic deionized water for at least 1 minute. Repeat two (2) additional times.
Drying:	<ul style="list-style-type: none"> • Clean the Endoscope ends with 70% isopropyl alcohol using a clean cotton tip, non-plastic applicator or a clean soft, lint-free cloth.
	<ul style="list-style-type: none"> • Dry the Endoscope with a soft, lint free cloth.
Maintenance, inspection, and testing:	<ul style="list-style-type: none"> • Visually verify, under fluorescent lighting, that the Endoscope and cloth are clean. If soil is visible, repeat cleaning.
	<ul style="list-style-type: none"> • Visually inspect the Endoscope fiber ends for any residue or hazing. Repeat cleaning if residue visible.
Packaging:	<ul style="list-style-type: none"> • Coil device in a coil no smaller than 6" (15 cm) and place in a pouch approved for STERRAD[®] NX, STERRAD[®] 100NX DUO cycle sterilization systems (including the STERRAD ALLClear[™] versions of each system) or STERRAD[®] 100S.

¹Enzol[®], a trademark of Advanced Sterilization Products, was used in the validation.



INSTRUCTIONS FOR REPROCESSING

Sterilization:	<p>▲ Warning: The following STERRAD® processes have been validated; however, the sterility assurance level for any given sterilization cycle is dependent on the actual conditions selected by the user and the correct calibration of the user’s sterilization equipment and instrumentation. Because these factors are not within the control of CardioFocus, Inc., the user is responsible for the sterility assurance level.</p>
	<p>▲ Warning: Sterilization is not a substitute for cleaning. The Endoscope must be thoroughly cleaned prior to sterilization.</p>
	<p>▲ Warning: The Endoscope is only validated for STERRAD® NX, STERRAD® 100NX DUO cycle sterilization (including the STERRAD® ALLClear™ version of each system) or STERRAD® 100S . Do not use any other sterilization methods.</p>
	<p>▲ Warning: The adequacy of any sterilization procedure must be tested. It is critical that appropriate process parameters be validated for each facility’s sterilization equipment and product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility.</p>
	<ul style="list-style-type: none"> • Sterilize the device within the pouch in accordance with the following STERRAD® NX or STERRAD® NX with ALLClear™ Technology sterilization parameters: <ul style="list-style-type: none"> ○ Standard 28 minute Cycle ○ No more than 3 endoscopes
	<ul style="list-style-type: none"> • Sterilize the device within the pouch in accordance with the following STERRAD® 100NX DUO cycle or STERRAD® 100NX DUO cycle with ALLClear™ Technology sterilization parameters: <ul style="list-style-type: none"> ○ DUO 60 minute Cycle ○ No more than 2 endoscopes
	<ul style="list-style-type: none"> • Sterilize the device within the pouch in accordance with the following STERRAD® 100S sterilization parameters: <ul style="list-style-type: none"> ○ 54 minute Cycle ○ No more than 3 endoscopes
	<ul style="list-style-type: none"> • Refer to and fill out Tracking Card for endoscope reprocessing status.
Storage:	<ul style="list-style-type: none"> • Between uses, store the device in a clean, dry environment.
	<ul style="list-style-type: none"> • To prevent damage, minimize contact between the device and other equipment.
	<p>▲ Warning: These storage guidelines are not provided as a means to maintain sterile devices within the tray.</p>



Approved Systems and Cycles

	Mode	Number of Endoscopes
STERRAD 100S	54-minute Cycle	≤ 3 endoscopes
STERRAD 100 NX / STERRAD 100 NX All Clear	DUO 60-minute Cycle	≤ 2 endoscopes
STERRAD NX / STERRAD NX All Clear	Standard 28-minute Cycle	≤ 3 endoscopes

