



DirectVision[®] Guide

REPROCESSING INSTRUCTIONS

**CLEANING & STERILIZING
INSTRUCTIONS**

General Warnings, Cautions and Notes

Warning: Read these instructions thoroughly before cleaning and/or sterilizing the product. Failure to follow these instructions may cause damage to the product or harm to the patient and/or user.

Warning: Always inspect the DirectVision® Guide before performing a cleaning and/or sterilization procedure. Reject a visual guide that has burrs, sharp edges, cracked or disconnected jacket and/or strain relief(s), or is kinked.

Warning: Only clean or sterilize the DirectVision® Guide as specified in this manual. Failure to follow the instructions provided in this manual could result in infection or damage to the DirectVision® Guide.

Caution: Ultrasonic cleaning should not be used to clean the DirectVision® Guide.

Caution: The cleaning and sterilizing methods presented in this document are validated. Any deviation is not validated and is not recommended.

Caution: To prevent damage to the DirectVision® Guide always handle with care. Do not drop, crush, cut, or bend any portion of the visual guide beyond a 2" radius.

Caution: Machine washing is not recommended. It increases likelihood of damage to the DirectVision® Guide.

Caution: When cleaning the DirectVision® Guide, use a soft sponge and/or soft bristle brush to clean surfaces and crevices.

Caution: Inspect the DirectVision® Guide for damage following each use.

Caution: The DirectVision® Guide should never be exposed to temperatures greater than 55° C (131° F). It can cause damage.

Caution: Never place heavy objects on the DirectVision® Guide.

Caution: The DirectVision® Guide must be disposed of according to local regulations, ordinances and hospital practices.

Note: The cleaning and sterilization procedure can affect performance of the DirectVision® Guide. If a DirectVision® Guide ceases to provide adequate illumination or a clear image of the urethra, discontinue use of that DirectVision® Guide.

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Device Name	Cleaning Solutions	Disinfecting Solution	Sterilization Environment		
			Sterilization System or Method	Cycle(s)/Parameters	Tray or Pouch
DirectVision® Guide	Enzol™	---	ASP Sterrad 100s	Full Cycle	APTIMAX® Instrument Tray (13835) or equivalent
			ASP Sterrad 200	Full Cycle	APTIMAX® Instrument Tray (13835) or equivalent
			ASP Sterrad 100 NX	Duo Cycle	APTIMAX® Instrument Tray (13835) or equivalent
			Steris Amsco V Pro-1	Lumen Cycle	Steris Tray (VP0003) or equivalent
			Steris Amsco V Pro-1Plus	Lumen Cycle	Steris Tray (VP0003) or equivalent
				Non-Lumen Cycle	
			Steris Amsco V-Pro maX	Lumen Cycle	Steris Tray (VP0003) or equivalent
Non-Lumen Cycle					
Steris System 1E	Flexible Cycle	Steris Tray (VP0003) or equivalent			
			Standard Operating Cycle	Steris C1140E, C1200E, or C1220E	

Table 1: Recommended Cleaning and Sterilizing Conditions for the DirectVision® Guide

Cleaning Procedure

1. Prior to cleaning, disassemble the DirectVision® Guide from camera handpiece.
2. Prepare an enzymatic detergent, such as Enzol™ (1 oz detergent/gallon water), using warm tap water and following the manufacturer's instructions.
3. **Note:** The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
4. Immerse the DirectVision® Guide in an enzymatic solution for at least one minute.
5. **Warning:** During cleaning, immerse the DirectVision® Guide in an enzymatic solution for at least 1 minute while cleaning or patient infection may result.
6. Soak a clean soft cloth in the detergent and wipe entire DirectVision® Guide to remove any visible evidence of soil or debris.
7. Using a soft bristled brush (such as M-16 BRUSH-DBL END), scrub the DirectVision® Guide for a minimum of 30 seconds, paying particular attention to the visual guide coupler's two lenses.
8. Use only a soft cloth to clean the tip of the DirectVision® Guide lens.



9. Remove the DirectVision® Guide from the detergent and wipe with a clean soft cloth that is dipped in ambient sterile water to remove any evidence of detergent.
10. Dry the DirectVision® Guide with a clean soft cloth. Use filtered pressurized air (no more than 40psi) to dry crevices and hard to reach areas.
11. Visually examine each DirectVision® Guide to ensure cleanliness.

Sterilization Recommendations

During reprocessing ensure the following:

1. Comply with labeling and instructions for use for the STERRAD®, Steris Amsco® V-PRO®, or Steris System 1E system and parameters (listed in Table 1).
2. Use only the recommended cycles listed in Table 1 for respective sterilization systems listed in *Table 1*.
3. Use only recommended trays listed in Table 1 for respective sterilization systems listed in *Table 1*.

Sterilizing Procedure

1. The DirectVision® Guide is sterilized with vapor hydrogen peroxide sterilization. See *Table 1* for recommended sterilization systems and conditions.
2. **Warning:** To ensure proper sterilization of the DirectVision® Guide, follow the sterilization procedure provided by the manufacturer for the respective system listed in *Table 1*. Failure to follow the sterilization procedure defined by the manufacturer could result in infection or damage to the DirectVision® Guide.
3. **Warning:** Use of sterilization systems or conditions not listed in *Table 1* may result in shortened useful life for the DirectVision® Guide.
4. **Warning:** Always sterilize the DirectVision® Guide in a tray/container listed in *Table 1*. Failure to use the correct container could result in patient infection or damage to the DirectVision® Guide.
5. **Warning:** To minimize the risk of patient infection, the DirectVision® Guide must be sterilized prior to the first use and after every subsequent use.

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6. **Warning:** Clean the DirectVision® Guide immediately after use to prevent incrustation. Failing to do so could compromise future sterility and possibly cause damage to the visual guide.

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