Welch Allyn®

Advancing Frontline Care™

Rigid Reusable & Single use Sigmoidoscopes, Anoscopes, and Accessories

Cleaning, Disinfection, and Sterilization Instructions

Mat'l 103251 Ver. B

(This document is made from 713512 Version B).

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The CE mark on these products indicates that they are in conformity with the provisions of Council Directive 93/42/EEC.

EC REP

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ENGLISH

Intended Use

The Welch Allyn Rigid Reusable & Single Use Sigmoidoscopes and Anoscopes are used to illuminate and facilitate the examination of the rectal and anal cavity. The instrument also provides a means of entry for surgical instruments into the rectal and anal cavity.

Endoscopes and the insufflation system are categorized as semi-critical devices requiring high level disinfection and the illumination system is categorized as a non-critical device requiring low-level disinfection according to the Multi-society guideline for reprocessing flexible gastrointestinal endoscopes published by Gastrointestinal Endoscopy (volume 58, No. 1, 2003) and simultaneously in Infection Control and Hospital Epidemiology. Optional higher level processes have been included in these instructions.

Refer to ASTM F1518-00, Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera, for additional guidance on reprocessing of these devices/accessories. Although this standard is for flexible endoscopes, it contains information that can be applied to rigid endoscopes as well.

Caution U.S. federal law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner. This device should only be used by trained personnel.

Caution Perform reprocessing immediately after each use.

Caution Consult your facility's procedures and the reprocessing agents manufacturer's instructions for the agents reuse, recommended Personal Protective Equipment and other safety precautions such as ventilation, etc.

Caution Examine surfaces of all components for wear or damage after cleaning, disinfection, and/or sterilization.

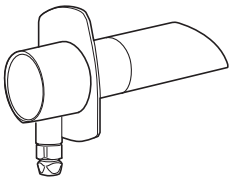
Caution For cleaning and/or disinfection, use brushes appropriate for the size of the endoscope channel parts, connectors, and orifices (e.g. bristles should contact all surfaces). Cleaning/disinfection tools (brushes, etc.) should be single use or thoroughly cleaned, disinfected, and/or sterilized between uses.

Caution Unless otherwise specified, perform all reprocessing procedures at ambient (room) temperature.

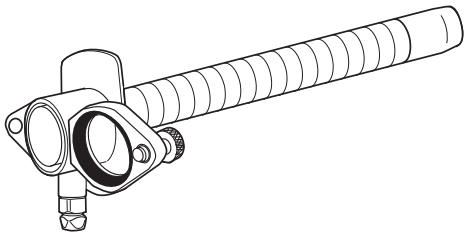
Caution Clean and disinfect all devices or accessories per these instructions prior to returning to Welch Allyn (e.g. for repair and service).

Caution Users are responsible to qualify any deviations from these procedures.

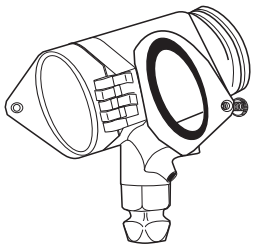
Rigid Sigmoidoscopes, Anoscopes, and Light Carrier



37023



32820



36019

Anoscope Part Numbers:	
37019	38614
37023	38619
37027	38622
38108	38900
38114	39614
38119	39619
38122	39622

Sigmoidoscope Part Numbers:	
32010	32820
32020	32830
32410	33220
32420	33620
32810	33830

Light Carrier Part Numbers:
36019
38700

Suction Tube* Part Numbers:
30130
30140

*Suction Tubes not illustrated

Note For all steps, remove obturator for separate cleaning and open viewing window.

Caution Welch Allyn recommends the use of the Single Use Insufflation Bulb Filter (REF 30210) for all applicable endoscopic procedures. The filter does not eliminate the need to properly process the insufflation bulb with each use, but restricts internal contamination and aspiration of fluids.

Cleaning

1. Prepare an enzymatic detergent formulated for endoscopic instruments according to the manufacturer's instructions.These instructions were validated using ENZOL®/ CIDEZYME®.
2. Submerge the item in the cleaning solution.
3. Using a soft bristle brush, scrub the item submerged in the cleaning solution for a minimum of 5 minutes then rinse with sterile water for 5 minutes.

High Level Disinfection

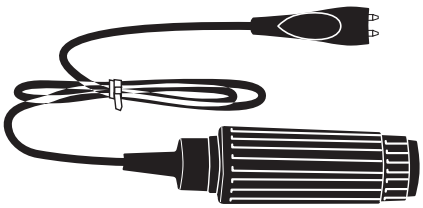
1. Follow the Cleaning instructions above.
2. Using CIDEX® OPA (0.55% OPA, 14-day maximum reuse), soak the item for a minimum of 12 minutes.
3. Perform 3 sequential rinses of the item for a minimum of 5 minutes each with sterile water.

4. Allow the item to dry for 24 hours or until no moisture remains in the device. Any moisture in the device could occlude the insufflation bulb filter.

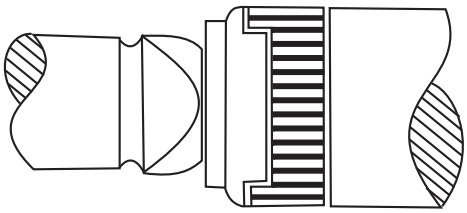
Sterilization

1. Follow the Cleaning instructions above.
2. Perform one autoclave cycle that includes 6 minutes at 270° F (132° C) and a cool down period of at least 15 minutes. These instructions were validated using a gravity autoclave. Validate any other sterilization equipment and load configurations.

Light Handle Assembly and Handle Adapter



Part Numbers 73210 and 73211 (including 07800-U lamp)



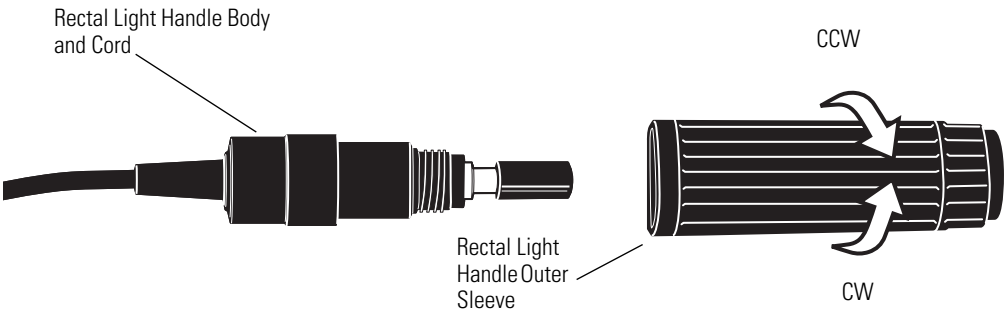
Part Number 73500 (including 03100-U lamp)

WARNING Allow the lamp to cool for at least 5 minutes before handling.

Note Leave the lamp installed while reprocessing 73210, 73211 and 73500.

Assembly and Disassembly Instructions for 73210 and 73211

1. Disconnect the light handle from the power supply cord and the device.
2. Unscrew the outer sleeve of the handle by turning it counterclockwise.



3. Follow one of the reprocessing methods described below.

Caution Do not immerse the rectal light handle body and cord in any solution. Doing so may damage the rectal light handle body and cord and void the warranty.

4. After performing a reprocessing procedure, wipe the lamp with a soft, dry, lint free cloth.
5. Re-attach the clean sleeve to the handle by screwing in a clockwise direction.
6. Re-connect the power supply cord to the light handle and verify that the unit works by plugging it in. If the lamp fails to illuminate follow the troubleshooting instructions located in light handle manual (REF 700791) supplied with your handle.

Cleaning (73210, 73211 and 73500)

1. Prepare an enzymatic detergent formulated for endoscopic instruments according to the manufacturer's instructions.These instructions were validated using ENZOL/ CIDEZYME.
2. Submerge the rectal light handle outer sleeve in the cleaning solution.
3. Using a soft bristle brush, scrub the item submerged in the cleaning solution for a minimum of 5 minutes then rinse with sterile water for 5 minutes.
4. Wet the rectal light handle body and cord with the cleaning solution.
5. Using a soft bristle brush, scrub the cord with the cleaning solution for a minimum of 5 minutes then rinse the cord with sterile water for 5 minutes.

Intermediate Level Disinfection (73210, 73211 and 73500)

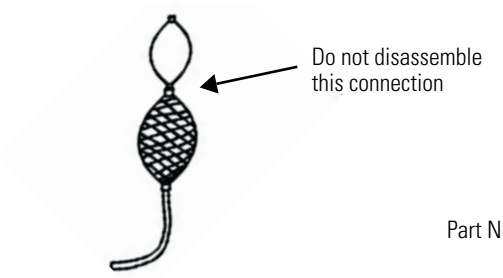
1. Follow the Cleaning instructions above.
2. Using CaviWipes™, wipe all item surfaces and keep wet with CaviWipe solution for a minimum of 5 minutes.
3. Allow the item surface to dry for a minimum of 10 minutes.

Sterilization (73211 ONLY)

Caution Autoclaving the light handle may reduce the product's functional life.

1. Follow the Cleaning instructions above.
2. Perform one autoclave cycle that includes 6 minutes at 270° F (132° C) and a cool down period of at least 15 minutes. These instructions were validated using a gravity autoclave. Validate any other sterilization equipment and load configurations.

Insufflation System



Part Number: 30200

Caution Welch Allyn recommends the use of the Single Use Insufflation Bulb Filter (REF 30210) for all applicable endoscopic procedures. The filter does not eliminate the need to properly process the insufflation bulb with each use, but restricts internal contamination and aspiration of fluids.

Caution Do not disassemble the insufflation bulb.

Caution The insufflation bulb may discolor after disinfection or sterilization without effecting performance.

Caution Do not autoclave insufflation system. Damage will occur.

Cleaning

1. Prepare an enzymatic detergent formulated for endoscopic instruments according to the manufacturer's instructions.These instructions were validated using ENZOL/ CIDEZYME.
2. Submerge the item in the cleaning solution.
3. Using a soft bristle brush, scrub the item submerged in the cleaning solution for a minimum of 5 minutes then rinse with sterile water for 5 minutes.
4. Using a 60 cc syringe, deliver 60 cc of the cleaning solution to the inside of the bulb through the hose-end.
5. Lightly agitate the solution inside of the bulb for a minimum of 5 minutes.
6. Empty the cleaning solution from the bulb.
7. Using a 60 cc syringe, deliver 60 cc of sterile water into the bulb through the hose-end.
8. Lightly agitate the water inside of the bulb for a minimum of 5 minutes.
9. Empty the rinse water from the bulb, and repeat rinse with sterile water 5 more times.
10. The bulb must be dried sufficiently. Any moisture inside the device could occlude the insufflation bulb filter (if used) or dilute disinfection or sterilization agents. One way to achieve this is to hang the bulb with the tube down for a minimum of 24 hours.

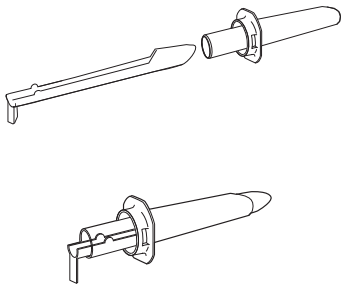
High Level Disinfection

1. Follow steps 1 through 9 of the Cleaning instructions.
2. Using CIDEX OPA (0.55% OPA, 14-day maximum reuse), soak the item for a minimum of 12 minutes.
3. Perform 3 sequential rinses of the bulb for a minimum of 5 minutes each with sterile water.
4. Using a clean 60 cc syringe, deliver 60 cc of the CIDEX OPA solution to the inside of the bulb through the hose-end.
5. Lightly agitate the solution inside of the bulb for a minimum of 12 minutes.
6. Empty the solution from the bulb.
7. Using a clean 60 cc syringe, deliver 60 cc of sterile water into the bulb through the hose-end.
8. Lightly agitate the water inside of the bulb for a minimum of 5 minutes.
9. Empty the rinse water from the bulb, and repeat rinse with sterile water 5 more times.
10. The bulb must be dried sufficiently. Any moisture inside the device could occlude the insufflation bulb filter (if used) or dilute disinfection or sterilization agents. One way to achieve this is to hang the bulb with the tube down for a minimum of 24 hours.

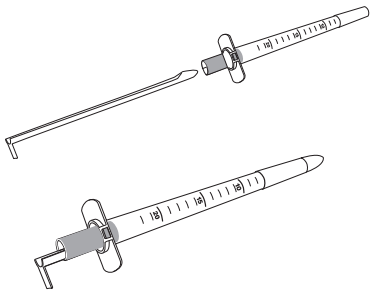
Sterilization

1. Follow steps 1 through 10 of the Cleaning instructions.
2. Sterilize using a STERRAD® 100S for one 55 minute cycle. Validate any other sterilization equipment and load configurations.

Single Use Sigmoidoscopes and Anoscopes



53110



53130

Single Use Anoscope Part Numbers:	Single Use Sigmoidoscope Part Numbers:
53110	53130
53110-B	53130-B
53110-JP	53130-F
	53130-JP

Caution Welch Allyn recommends the use of the Single Use Insufflation Bulb Filter (REF 30210) for all applicable endoscopic procedures. The filter does not eliminate the need to properly process the insufflation bulb with each use, but restricts internal contamination and aspiration of fluids.

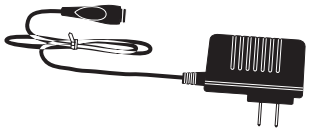
Caution Sterilization process is not valid for 53130-L and 53130-LF. These single use devices are lubricated and cannot be sterilized.

Caution These devices are not reusable, but can be sterilized one time prior to single use.

Sterilization

1. Remove the device from the plastic bag before sterilizing.
2. Sterilize using a STERRAD 100S for one 55 minute cycle. Validate any other sterilization equipment.

Power Supply



Part Numbers:
73305, 73322, 73324, 73326

Caution Do not immerse the power supply in any solution or sterilize. Doing so may damage the power supply and void the warranty.

Caution The power supply can only be wiped with a soft, dry, lint free cloth or scrubbed with a dry brush.

The following cleaning instructions apply to the Power Cord ONLY:

1. Disconnect the power supply cord from the light handle.
2. Disconnect the power supply from its wall receptacle.

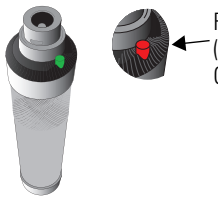
Cleaning the Power Cord

1. Prepare an enzymatic detergent formulated for endoscopic instruments according to the manufacturer's instructions. These instructions were validated using ENZOL/ CIDEZYME.
2. Wet the cord with the cleaning solution.
3. Using a soft bristle brush, scrub the cord with the cleaning solution for a minimum of 5 minutes then rinse the cord with sterile water for 5 minutes.

Intermediate Level Disinfection of the Power Cord

1. Follow the Cleaning instructions above.
2. Using CaviWipes, wipe the cord and keep wet with CaviWipe solution for a minimum of 5 minutes.
3. Allow the cord surface to dry for a minimum of 10 minutes.

Rechargeable Handle



Part Number 71000-A

Cleaning

Caution Do not saturate the rheostat area. Excess solution entering the assembly may damageinternal components in the handle.

1. Using CaviWipes, wipe the surface to remove all gross debris.
2. Using a soft bristle brush, scrub the handle for a minimum of 5 minutes then repeat wipe with a second CaviWipe.
3. Allow the handle surface to dry for a minimum of 10 minutes.

Intermediate Level Disinfection

1. Follow the Cleaning instructions above.
2. Using CaviWipes, wipe the handle and keep wet with CaviWipe solution for a minimum of 5 minutes.
3. Allow the handle surface to dry for a minimum of 10 minutes.