KARL STORZ — ENDOSKOPE

en **Reprocessing Instructions**
Endoscopes with Suction Channel

KARL STORZ — ENDOSKOPE

ATTENTION:
USA CUSTOMERS: Please note the following content is not applicable to U.S. customers. U.S. instructions can be found here:
https://www.karlstorz.com/
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02-2026

CE 0123

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1 Scope

These reprocessing instructions apply to:

Product name	Item number
Broncho-Fiberscope 5.0 x 54	11001BN1
Broncho-Fiberscope 3.7 x 54	11002BD1
Broncho-Fiberscope 2.8 x 54	11003BC3
Broncho-Fiberscope 6.4 x 54	11004BC1
Broncho-Fiberscope 5.6 x 54	11009BC1
Flexible Video Cystoscope HD-VIEW	11272VH
Flexible Video Cystoscope HD-VIEW	11272VHU
Intubation Fiberscope 2.8 x 65	11301AA1
Intubation Fiberscope 5.2 x 65	11301BN1
Intubation Fiberscope 3.7 x 65	11302BD2
LIVE HD Video Bronchoscope 5.5/2.0	11910D
LIVE HD Video Bronchoscope 6.5/2.8	11910T

2 Target group

These reprocessing instructions are intended for personnel with technical knowledge and expertise in the reprocessing of medical devices.

3 General information

3.1 Read the reprocessing instructions

If the reprocessing instructions are not followed, patients, users, or third parties may be injured or the product may be damaged.

- Read the reprocessing instructions for the product and its components carefully and follow all the safety notes and warnings.

3.2 Read the reprocessing instructions for use

If the reprocessing instructions for use are not followed, patients, users, or third parties may be injured or the product may be damaged.

- Read and follow the “Cleaning, disinfection, care, and sterilization of KARL STORZ instruments” instructions for use (item no. 96216003).

The cleaning, disinfection, and sterilization procedures are explained in detail in the reprocessing instructions for use.

The reprocessing instructions for use can be downloaded from www.karlstorz.com.

3.3 Read the instructions for use for the reprocessing unit

If the instructions for use are not followed, patients, users, or third parties may be injured or the product may be damaged.

- Read the instructions for use for the reprocessing unit carefully and follow all the safety notes and warnings.
- Carry out reprocessing in accordance with the instructions for use for the reprocessing unit.

3.4 National laws and regulations

National laws and regulations must be observed in addition to the accompanying documentation.

3.5 Additional information on the product

Additional general information on the product can be requested and downloaded from www.karlstorz.com.

3.6 Definition of warnings

To prevent any injury to persons or damage to property, the warnings and safety notes in the instructions for use must be observed. The warnings use the following levels of danger:

⚠ WARNING

WARNING

Designates a possible imminent risk. If this is not avoided, it could lead to death or serious injuries.

⚠ CAUTION

CAUTION

Designates a possible imminent risk. If this is not avoided, it could lead to minor injuries.

NOTICE

NOTICE

Designates a possibly harmful situation. If this is not avoided, the products could be damaged.

4 Safety and warning

4.1 Non-sterile product

The product is not sterile when delivered. The use of non-sterile products poses a risk of infection for patients, users, and third parties.

- Reprocess the product in line with the reprocessing instructions before initial use and every subsequent use.

4.2 Contaminated products

During work on contaminated products, the guidelines for personal safety must be observed.

4.3 Working with process chemicals

Incorrect exposure time, concentration, life span, and range of action of chemicals can lead to a risk of infection for the patient, user, and third parties, as well as damage to the product.

- Note the information provided by the manufacturer of the chemicals and the microbiological range of action of the chemicals used.

4.4 Creutzfeldt-Jakob disease

Products that come into contact with the central nervous system and high-risk tissues can become contaminated by organic residue containing prions. Prions lead to infection with Creutzfeldt-Jakob disease.

If Creutzfeldt-Jakob disease has been diagnosed or is suspected:

- Do not continue to use the product.
- Dispose of the product properly; see the instructions for use.

4.5 Steam sterilization

Steam sterilization will damage the product.

- Do not autoclave the product.

5 Overview of processes

The effectiveness of the following reprocessing procedures has been verified for the product:

- Manual cleaning
- Manual disinfection
- Machine cleaning / chemical disinfection
- Hydrogen peroxide (H2O2) – ASP STERRAD
- Hydrogen peroxide (H2O2) – STERIS V-PRO

A detailed description of the processes is provided in the respective chapters in these instructions.

6 Materials for reprocessing

The reprocessing accessories used must be clean and functional.

Reprocessing instructions for cleaning adaptors can be downloaded from www.karlstorz.com.

The reprocessing accessories are listed below:

Application	Material
Bedside precleaning	
	Moist compresses, possibly disposable cloth
	Syringe
Leakage test	
	Leakage Tester, item no. 13242XL
Manual precleaning, manual cleaning	
Wiping the surfaces	Soft cloth
Brushing the surfaces	Brush, item no. 27652
Brushing the lumens	
11002BD1, 11003BC3, 11301AA1, 11302BD2	Brush(es), item no. 110931
11272VH, 11272VHU	Brush(es), item no. 110940
11001BN1, 11301BN1, 11910D	Brush(es), item no. 110941
11004BC1, 11009BC1, 11910T	Brush(es), item no. 110950
Connecting lumens for filling and rinsing	
11272VH, 11272VHU	Adaptor, item no. 11014RA, 11301CD1
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2	Adaptor, item no. 11301CD
11910D, 11910T	Adaptor, item no. 11910CD
Manual cleaning and disinfection	
Cleaning solution for manual cleaning	Mild enzymatic cleaning agent conforming to manufacturer's specifications (validated by KARL STORZ: CIDEZYME enzymatic cleaning solution from ASP (Advanced Sterilization Products) at 0.8% for 1 minute)
Disinfectant solution for manual disinfection	2% accelerated hydrogen peroxide solution conforming to manufacturer's specifications (validated by KARL STORZ: Revital-Ox RESERT from STERIS at 20°C for 8 minutes)
Automatic cleaning and disinfection	
Cleaning solution for manual cleaning	Mild alkaline cleaning agent conforming to manufacturer's specifications (validated by KARL STORZ: neodisher MediClean forte from Dr. Weigert at 1% for 5 minutes)

Application	Material
Cleaning solution for automatic cleaning	Cleaning agent conforming to manufacturer's specifications (validated by KARL STORZ: Olympus EndoDet at 0.6% for 3 minutes)
Disinfectant solution for chemical disinfection	Disinfectant conforming to manufacturer's specifications (validated by KARL STORZ: Olympus EndoDis, Olympus EndoAct at 1.2% for 5 minutes)
Machine cleaning / chemical disinfection	Device with suitable slide-in basket / instrument holder
Connecting lumens for filling and rinsing	
11272VH, 11272VHU	Adaptor, item no. 11014RA, 11301CD1
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2	Adaptor, item no. 11301CD
11910D, 11910T	Adaptor, item no. 11910CD
Manual drying and/or after-drying	Medical compressed air from compressed air gun Alternatively: syringe 60 cc
Packaging for sterilization	Standardized and approved packaging
Sterilization	Pressure Compensation Cap, item no. 11025E

Suitable reprocessing accessories are listed in the following catalog:

– HYGIENE – Care, Sterilization, Storage Techniques (item no. 96211004)

7 Bedside precleaning

1. Wipe the surfaces of the flexible endoscope with a moist compress or disposable cloth to remove gross debris.
2. Close the Luer-Lock connector with a Luer-Lock cap.
3. Immerse the distal tip of the flexible endoscope in a basin filled with water. Actuate the suction valve and suck at least 100 ml water through the channel using a connected syringe or suction pump.
4. Remove the Luer-Lock cap and rinse the working channel with a water-filled syringe (at least 100 ml).

ⓘ Reprocessing of the flexible endoscope should start within 2 hours of use to ensure the effectiveness of the reprocessing processes listed in the reprocessing instructions.

7.1 Transport to the reprocessing site

1. Right after using / bedside precleaning of the flexible endoscope, place it in a suitable dry transport container.
2. Transport the securely positioned flexible endoscope to the reprocessing site.

8 Leakage test

Phase 1: Performing the leakage test – dry

1. The connection tube of the leakage tester and the vent port on the flexible endoscope must be clean and dry. If there is any visible soiling, carefully remove it using a cloth with 70% isopropyl alcohol.
2. Connect the leakage tester connector to the vent port using the bayonet coupling.
3. Pump up the leakage tester to a pressure of 200 mmHg.
   - The deflection rubber on the distal end may expand in the process.
4. Use the control lever to move the distal tip all the way in each direction five times and then reduce the pressure by actuating the pressure release button until it reaches 160 mmHg.
   - When moving the distal tip, the pressure may drop by up to 10 mmHg.
   - If the pressure drops by more than 10 mmHg, pump up the leakage tester to 160 mmHg again.
5. Once the pressure has stabilized, wait at least 2 minutes and then check the leakage tester for pressure loss.
   - If the pressure drops, the flexible endoscope has a leak and must not be used, immersed in liquids, or reprocessed by machine. Fill out the repair form. Clean the flexible endoscope by wiping off any organic soiling and residue and label it as not disinfected. Contact KARL STORZ and send the flexible endoscope to KARL STORZ for repair. Line the transport container for the flexible endoscope with protective film, item no. 13990SFN.
   - If the pressure does not drop, the flexible endoscope does not have a leak and the leakage test in liquid can be performed.

Phase 2: Performing the leakage test – in liquid

NOTICE

Risk of damage!

Immersing the flexible endoscope with the pressure compensation cap fitted can damage the product.

▷ Remove the pressure compensation cap before immersing in liquid.

1. Place the flexible endoscope – with the leakage tester connected – in water at room temperature. Do not immerse the leakage tester.
2. Make sure that the flexible endoscope is fully immersed. If bubbles are visible on the surface of the flexible endoscope after immersing, use a syringe filled with water to remove them.
3. Fill the lumens with a water-filled syringe.
4. Leave the flexible endoscope in the liquid for 1 minute while angling the distal tip as follows:
   - ▶ Hold the distal tip in the neutral (straight) position for 15 seconds.
   - ▶ Move the distal tip all the way up and hold the position for 15 seconds.
   - ▶ Move the distal tip all the way down and hold the position for 15 seconds.
   - ▶ Return the distal tip to the neutral (straight) position and hold for 15 seconds.
5. Wait at least 2 minutes, check the leakage tester for pressure loss, and look out for bubbles forming on the surface of the endoscope or a constant stream of rising bubbles.
   - ▶ If the pressure drops, the flexible endoscope has a leak and must not be used, immersed in liquids, or reprocessed by machine. Fill out the repair form. Clean the flexible endoscope by wiping off any organic soiling and residue and label it as not disinfected. Contact KARL STORZ and send the flexible endoscope to KARL STORZ for repair. Line the transport container for the flexible endoscope with protective film, item no. 13990SFN.
   - ▶ Remove the flexible endoscope from the liquid and press the vent button on the leakage tester to reduce the pressure to 0.
6. Remove the leakage tester from the flexible endoscope and continue with the cleaning process.

9 Disassembly

Only applies to item no. 11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2

9.1 Removing the light inlet socket

1. Unscrew the larger adaptor from the light inlet socket.
2. Unscrew the smaller adaptor from the light inlet socket.

10 Cleaning and disinfection

For a complete list of the materials required for reprocessing, see *Materials for reprocessing* [p. 9]

10.1 Manual reprocessing

NOTICE

The product is not suitable for ultrasonic treatment.

NOTICE

Risk of damage!

Immersing the flexible endoscope with the pressure compensation cap fitted can damage the product.

▷ Remove the pressure compensation cap before immersing in liquid.

10.1.1 Manual cleaning

10.1.1.1 Cleaning solution

1. Completely immerse the flexible endoscope in the cleaning solution.
2. Connect the cleaning adaptor to the suction port. Close the working channel with a Luer-Lock cap.
3. Draw the cleaning solution up through the suction channel until the syringe is completely filled.
4. Dispose of the cleaning solution that has been drawn up in a separate sink or basin.
5. Remove the Luer-Lock cap from the working channel and connect a syringe.
6. Draw the cleaning solution up through the working channel until the syringe is completely filled.
7. Remove the syringe and cleaning adaptor.
8. Allow to take effect in accordance with the specifications of the chemicals manufacturer.
9. Wipe the surfaces:
   a) Fiberscopes: While immersed, wipe the sheath of the flexible endoscope thoroughly with a soft cloth at least once until there is no visible residue left.
   b) Videoendoscopes: While immersed, wipe the video cable and then the sheath of the flexible endoscope thoroughly with a soft cloth at least once until there is no visible residue left.
10. Use the surface brush to thoroughly clean the surface of the handle, including the operating buttons and the interfaces between the deflection lever and the handle.
11. Actuate moving parts, including the buttons, in the cleaning solution while brushing to make sure that all gaps are reached. Brush the entire handle surface at least once until there is no visible residue left.
12. Clean the suction channel at least once with the long lumen brush until no more residue can be seen on the brush head. To do this, insert the brush and push it through as far as possible. Carefully pull out the brush at the distal end while the sheath is straight.
13. Clean the working channel at least once with the long lumen brush until no more residue can be seen on the brush head. To do this, insert the brush and push it through as far as possible. Carefully pull out the brush at the distal end while the sheath is straight.
14. Connect the cleaning adaptor to the suction port. Close the working channel with a Luer-Lock cap.
15. Fill the syringe with 50 ml cleaning solution. Rinse the suction channel with the cleaning solution.
16. Then draw at least 50 ml cleaning solution through the suction channel and flush this back through the channel.
17. Repeat steps 15 and 16 with the working channel.
18. Remove the syringe from the Luer-Lock connector.
19. Remove the flexible endoscope from the cleaning solution.

20. Close the working channel with a Luer-Lock cap.
21. Fill the syringe with air and connect it to the adaptor. Flush the entire volume of air through the suction channel to expel the cleaning solution from the channel.
22. Repeat steps 20 and 21 with the working channel.
23. Remove the syringe and cleaning adaptor.
24. Dispose of the single-use cleaning accessories and use new accessories for rinsing.

10.1.1.2 Rinsing

1. Flush the flexible endoscope under running water for at least 1 minute.
2. Fill a sink or basin with enough water to completely immerse the flexible endoscope.
3. Completely immerse the flexible endoscope in the rinse water.
4. While immersed, wipe the entire surface of the flexible endoscope thoroughly with a soft cloth at least once.
5. Connect the cleaning adaptor to the suction port. Close the working channel with a Luer-Lock cap.
6. Fill the syringe with 50 ml water. Rinse the suction channel with water.
7. Then draw at least 50 ml water through the suction channel and flush this back through the channel.
8. Repeat steps 6 and 7 with the working channel.
9. Leave the flexible endoscope immersed for the time specified by the chemical manufacturer and repeat the rinsing process in line with the manufacturer's specifications.
10. Remove the flexible endoscope from the rinse water.
11. Close the working channel with a Luer-Lock cap.
12. Fill the syringe with air and connect it to the adaptor. Flush the entire volume of air through the suction channel to expel the water from the channel.
13. Repeat step 11 and 12 with the working channel.

10.1.1.3 Drying

1. Dry the surface using a soft, fresh cloth or medical-grade/HEPA-filtered compressed air.
2. Dry the channel for at least 10 minutes with pressure-controlled medical-grade or HEPA-filtered compressed air. If moisture is still visible after 10 minutes of drying time, extend the drying time until there is no visible moisture left.

10.1.2 Manual disinfection

10.1.2.1 Disinfectant solution

1. Prepare the disinfectant solution in line with the manufacturer's instructions. Make sure that the minimum concentration specifications are observed.
2. Completely immerse the flexible endoscope in the disinfectant solution.
3. Remove any air bubbles on the surfaces of the flexible endoscope. Bubbles can be removed using a syringe or by brushing them away with a gloved hand.
4. Actuate moving parts in the disinfectant solution to make sure that all gaps are filled with disinfectant solution.
    a) Videoendoscopes: Remove air bubbles from the operating buttons by pressing the buttons at least three times.
5. Connect the cleaning adaptor to the suction port. Close the working channel with a Luer-Lock cap.
6. Draw the disinfectant solution up through the suction channel until the syringe is completely filled.
7. Remove the Luer-Lock cap and connect a syringe.
8. Draw the disinfectant solution up through the working channel until the syringe is completely filled.
9. Remove the syringe and cleaning adaptor and leave in the cleaning solution.
10. Allow to take effect in accordance with the specifications of the chemicals manufacturer.
11. Once the contact time recommended by the manufacturer has elapsed, connect the cleaning adaptor to the suction port and close the working channel with a Luer-Lock cap.
12. Fill the syringe with air and connect it to the adaptor. Flush the entire volume of air through the suction channel to expel the disinfectant solution from the channel.
13. Repeat step 12 with the working channel.
14. Remove the syringe and cleaning adaptor.
15. Remove the flexible endoscope from the disinfectant solution.
    a) Videoendoscopes: Press each button at least three times after removing from the disinfectant solution.

10.1.2.2 Rinsing

1. Fill a sink with water at room temperature. Make sure there is enough liquid to completely immerse the flexible endoscope.
2. Completely immerse the flexible endoscope in the rinse water.
3. Remove any air bubbles on the surfaces of the flexible endoscope. Bubbles can be removed using a syringe or by brushing them away with a gloved hand.
4. Actuate moving parts in the rinse water to make sure that all gaps are filled with rinse water.
    a) Videoendoscopes: Remove air bubbles from the operating buttons by pressing the buttons at least three times.
5. Connect the cleaning adaptor to the suction port. Close the working channel with a Luer-Lock cap.
6. Fill the syringe with water. Rinse the suction channel with at least 100 ml water.
7. Repeat step 6 with the working channel.
8. Remove the syringe and cleaning adaptor.
9. Leave the product immersed for the time specified by the chemical manufacturer and repeat the rinsing process in line with the manufacturer's specifications.
10. Connect the cleaning adaptor to the suction port. Close the working channel with a Luer-Lock cap.
11. Fill the syringe with air and connect it to the adaptor. Flush the entire volume of air through the suction channel to expel the water from the channel.

12. Repeat step 11 with the working channel.
13. Remove the flexible endoscope from the rinse water and place on a clean/disinfected/sterile covered surface.

10.1.2.3 Drying

⚠ WARNING

Risk of infection due to residual liquid!

If products are not adequately dried following disinfection, the effectiveness of the validated reprocessing processes is not guaranteed.

▷ Use compressed air or a syringe filled with air to dry products fully following disinfection.

NOTICE

Excess pressure! Risk of damage!

Excess pressure may damage the product.

▷ Set the pressure to < 5 psi.

1. Dry the surface using a soft, fresh cloth or medical-grade/HEPA-filtered compressed air.
2. Dry the channel for at least 10 minutes with pressure-controlled medical-grade or HEPA-filtered compressed air. If moisture is still visible after 10 minutes of drying time, extend the drying time until there is no visible moisture left.

10.2 Machine reprocessing

NOTICE

The product is not suitable for ultrasonic treatment.

NOTICE

Risk of damage!

Immersing the flexible endoscope with the pressure compensation cap fitted can damage the product.

▷ Remove the pressure compensation cap before immersing in liquid.

10.2.1 Manual precleaning

10.2.1.1 Cleaning solution

1. Completely immerse the flexible endoscope in the cleaning solution.
2. Connect the cleaning adaptor to the suction port. Close the working channel with a Luer-Lock cap.
3. Draw the cleaning solution up through the suction channel until the syringe is completely filled.
4. Dispose of the cleaning solution that has been drawn up in a separate sink or basin.
5. Remove the Luer-Lock cap and connect a syringe.
6. Draw the cleaning solution up through the working channel until the syringe is completely filled.
7. Remove the syringe and cleaning adaptor.
8. Allow to take effect in accordance with the specifications of the chemicals manufacturer.
9. Wipe the surfaces:
   a) Fiberscopes: While immersed, wipe the sheath of the flexible endoscope thoroughly with a soft cloth at least once until there is no visible residue left.
   b) Videoendoscopes: While immersed, wipe the video cable and then the sheath of the flexible endoscope thoroughly with a soft cloth at least once until there is no visible residue left.
10. Use the surface brush to thoroughly clean the surface of the handle, including the operating buttons and the interfaces between the deflection lever and the handle.
11. Actuate moving parts, including the buttons, in the cleaning solution while brushing to make sure that all gaps are reached. Brush the entire handle surface at least once until there is no visible residue left.
12. Clean the suction channel at least once with the long lumen brush until no more residue can be seen on the brush head. To do this, insert the brush and push it through as far as possible. Carefully pull out the brush at the distal end while the sheath is straight.
13. Clean the working channel at least once with the long lumen brush until no more residue can be seen on the brush head. To do this, insert the brush and push it through as far as possible. Carefully pull out the brush at the distal end while the sheath is straight.
14. Remove the flexible endoscope from the cleaning solution.

10.2.1.2 Rinsing

1. Connect the cleaning adaptor to the suction port. Close the working channel with a Luer-Lock cap.
2. Fill the syringe with water and connect it to the adaptor. Rinse the suction channel twice with at least 100 ml water.
3. Repeat step 2 with the working channel.
4. Remove the syringe and cleaning adaptor.
5. Flush the flexible endoscope under running water for at least 1 minute.
6. Actuate each moving part ten times while rinsing.

10.2.2 Machine cleaning / chemical disinfection

A washer-disinfector for thermolabile products must be used for the flexible endoscope. The washer-disinfector must meet the requirements of standard ISO 15883.

1. Place the flexible endoscope in the slide-in basket and, if necessary, in the instrument holder.
2. Place disassembled small parts in a tray.
3. Connect the lumens of the flexible endoscope using the rinsing facilities of the slide-in basket.

The quantity of endotoxins in the final rinse water must not exceed a limit value of 8.0 EU*/ml.

* Endotoxin units

The parameters of the machine cleaning and disinfection process validated by KARL STORZ are specified as follows.

Phase	Water inflow	Temperature (°C)	Time (min:sec)
Prerinsing	Completely demineralized water	23	0:30
Cleaning	Completely demineralized water	35	3:00
Intermediate rinsing	Completely demineralized water	20	0:30
Disinfection	Completely demineralized water	35	5:00
Intermediate rinsing	Completely demineralized water	20	1:00
Final rinsing	Completely demineralized water	57	1:00
Drying	-	57	3:00

⚠ WARNING

Risk of infection due to residual liquid!

If products are not adequately dried following disinfection, the effectiveness of the validated reprocessing processes is not guaranteed.

▷ Use compressed air or a syringe filled with air to dry products fully following disinfection.

NOTICE

Excess pressure! Risk of damage!

Excess pressure may damage the product.

▷ Set the pressure to < 5 psi.

▶ Check if the flexible endoscope is dry and dry it by hand if necessary, *see chapter Visual inspection* [p. 21]

11 Visual inspection

1. Inspect the product with regard to the following:
   – Visible soiling
   – Damage and corrosion
   – Completeness
   – Dryness
2. Subject any products displaying visible soiling to another complete cleaning and disinfection process.
3. Discard damaged and corroded products.
4. Discard incomplete products or replace missing parts.
5. Dry the product by hand if necessary.

12 Service life

The end of the product's service life is largely determined by wear, reprocessing procedures, the chemicals used, and any damage resulting from use.

12.1 Functional check

If the product does not fulfill one of the points listed below or if damage can be identified, see chapter "Maintenance, repair, servicing, and disposal" in the instructions for use.

The following checks must be carried out to detect functional limitations:

1. Check the surface of the product for mechanical integrity and changes.
2. Check the labeling for legibility.
3. Check the product for mechanical integrity.
4. Check the mobility of all moving components, if necessary once the components have been assembled in the case of products that can be dismantled.
5. Check whether the end positions of the application part are reached.
6. Check if the image is transmitted.
7. Check whether light is transmitted and whether the surface of the light input and light output is dirty or damaged.
8. Check the product for mechanical integrity by means of a leakage test.
9. Checking the suction
   - Check the suction when the suction valve and pump are connected.
10. Checking the irrigation
    - The irrigation tube is connected to the working channel.
    - The irrigation fluid can flow freely.
11. Checking the surface
    - Check the surface of the flexible sheath visually and inspect carefully by touch.
    - Inspect the flexible sheath visually and by touch to check for damage (breaks, cracks, cuts, etc.).
    - Check the surface for mechanical integrity, changes, sharp edges, and loose or missing parts.
12. Checking the flexible tip
    - Check the surface visually and inspect carefully by touch.
13. Checking the deflection
    - During actuation of the deflection lever, the distal tip must be able to move in all directions.
14. Checking the biopsy channel
    - Check for patency.
15. Checking the moving components
    - All components can be moved.
16. Videoendoscopes: Checking the control buttons
    - All buttons activate the desired function.

13 Sterilization

The effectiveness of the sterilization procedures described below has been validated and approved for this product by KARL STORZ.

- Select the appropriate procedure, taking into consideration the country-specific regulations and in consultation with the equipment manufacturer.

The packaging material must always be matched to the sterilization process being used.

Required materials:

– Standardized packaging materials and packaging systems that have been approved for the product (EN 868 Parts 2–10, EN ISO 11607 Parts 1 + 2, DIN 58953)

13.1 Hydrogen peroxide (H2O2) – ASP STERRAD

⚠ WARNING

Risk of infection due to inadequate sterilization!

Oiled products can only be adequately sterilized by means of steam sterilization with fractionated vacuum.

▷ Only oil products if they are sterilized by means of steam sterilization with fractionated vacuum.

NOTICE

Excess pressure! Risk of damage!

Excess pressure may damage the product.

▷ Place the pressure compensation cap on the vent port for sterilization and transport to ensure pressure compensation.

The following STERRAD procedures and materials have been validated and approved by KARL STORZ for the product:

STERRAD 100S Long Cycle with 2 activated Boosters	
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2, 11272VH, 11272VHU, 11910D, 11910T	APTIMAX Tray/Container HALYARD H400 Sterilization Wrap
STERRAD NX Advanced Cycle	
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2	APTIMAX Tray/Container HALYARD H400 Sterilization Wrap
11272VH, 11272VHU	39406AS Tray/Container HALYARD H400 Sterilization Wrap
11910D, 11910T	39403AS Tray/Container HALYARD H400 Sterilization Wrap
STERRAD 100NX FLEX Cycle	
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2	APTIMAX Tray/Container HALYARD H400 Sterilization Wrap
11272VH, 11272VHU	39406AS Tray/Container HALYARD H400 Sterilization Wrap
11910D, 11910T	39403AS Tray/Container HALYARD H400 Sterilization Wrap
STERRAD 100NX DUO Cycle	
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2, 11272VH, 11272VHU, 11910D, 11910T	APTIMAX Tray/Container HALYARD H400 Sterilization Wrap

13.2 Hydrogen peroxide (H2O2) – STERIS V-PRO

⚠ WARNING

Risk of infection due to inadequate sterilization!

Oiled products can only be adequately sterilized by means of steam sterilization with fractionated vacuum.

▷ Only oil products if they are sterilized by means of steam sterilization with fractionated vacuum.

NOTICE

Excess pressure! Risk of damage!

Excess pressure may damage the product.

▷ Place the pressure compensation cap on the vent port for sterilization and transport to ensure pressure compensation.

The following STERIS V-PRO procedures and materials have been validated and approved by KARL STORZ for the product:

STERIS V-PRO maX Flexible Cycle	
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2	39402AS Tray/Container HALYARD H400 Sterilization Wrap
11272VH, 11272VHU	39406AS Tray/Container HALYARD H400 Sterilization Wrap
11910D, 11910T	39403AS Tray/Container HALYARD H400 Sterilization Wrap
STERIS V-PRO maX 2 Flexible Cycle	
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2	39402AS Tray/Container HALYARD H400 Sterilization Wrap
11272VH, 11272VHU	39406AS Tray/Container HALYARD H400 Sterilization Wrap
11910D, 11910T	39403AS Tray/Container HALYARD H400 Sterilization Wrap
STERIS V-PRO 60 Flexible Cycle	
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2	39402AS Tray/Container HALYARD H400 Sterilization Wrap
11272VH, 11272VHU	39406AS Tray/Container HALYARD H400 Sterilization Wrap
11910D, 11910T	39403AS Tray/Container HALYARD H400 Sterilization Wrap
STERIS V-PRO s2 Flexible Cycle	
11001BN1, 11002BD1, 11003BC3, 11004BC1, 11009BC1, 11301AA1, 11301BN1, 11302BD2	39402AS Tray/Container HALYARD H400 Sterilization Wrap
11272VH, 11272VHU	39406AS Tray/Container HALYARD H400 Sterilization Wrap
11910D, 11910T	39403AS Tray/Container HALYARD H400 Sterilization Wrap

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