Operating Instructions
LEAKAGE:MASTER

Electronic leakage tester for watertight, flexible endoscopes

CE

Updated 03.03.2023 Rev.4

Read the operating instructions before using the equipment for the first time.
Store the operating instructions near the device so that all users have access to the instructions at all times.

These Operating Instructions apply to the following products:

LEAKAGE:MASTER REF: 7900-PL10

The LEAKAGE:MASTER is a Class I / Rule 13 active medical device as defined in Annex IV of Council Regulation (EU) 2017/745. A Declaration of Conformity can be provided on request.

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Standard and optional accessories
Use of the LEAKAGE:MASTER in accordance with the intended purpose requires special-purpose accessories that are listed under Point 3 and in Appendix II to these Operating Instructions.

All national laws and regulations applicable in the country of use as amended from time to time must be observed and applied.

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1 Intended purpose and patient safety

1.1 Field of application of the LEAKAGE:MASTER

The LEAKAGE:MASTER is for detecting leakages in watertight flexible endoscopes made by Olympus, Pentax and Fujinon, refer to Appendix. These endoscopes are equipped with an option for leakage testing and have corresponding adapters which are either supplied with the endoscope or can be ordered from the endoscope supplier.

The LEAKAGE:MASTER generates a pressure of approx. 240 mbar in the endoscope and then checks for leaks in the endoscope by monitoring any loss of pressure.

The LEAKAGE:MASTER has an automatic (pretest) function and a manual permanent test function.

Program 1, AUTOMATIC TEST:
The automatic test (pretest) runs a programmed leakage test before the endoscope is immersed in liquid, an automatic endoscope reprocessor (AER) or the WASH:MASTER and must always be carried out.

Program 2, PERMANENT TEST:
The manual PERMANENT TEST monitors for leaks during the subsequent reprocessing phase and prevents moisture, in particular in the case of microperforation detected during the automatic test.
The manual PERMANENT TEST is recommended in particular for manual reprocessing.

1.1.1 Contraindications

- Do not use the LEAKAGE:MASTER for leakage tests on endoscopes if no information regarding their suitability for use with LEAKAGE:MASTER is available.
- Do not use the LEAKAGE:MASTER for leakage tests on endoscopes which do not offer a leakage test option.
- Do not use the LEAKAGE:MASTER for leakage tests on endoscopes for which you do not have the appropriate adapter for such tests.
- If in doubt, please contact the manufacturer of the endoscopes or CREO MEDICAL Wolfgang Griesat GmbH or a service engineer authorised by us.
- Do not use the LEAKAGE:MASTER in potentially explosive atmospheres (e.g. where flammable gases are present).

1.2 Important notice when using this equipment

Read the operating instructions before using the LEAKAGE:MASTER for the first time and familiarise yourself with the functions and mode of operation of the device and accessories.

The LEAKAGE:MASTER must only be operated by staff that meet the requirements in terms of factual knowledge as defined in the German regulations governing the installation, operation, use and maintenance of medical devices (MPBetreibV) and have been instructed and trained in safe use of the device.

Never use any accessories other than those described in these Operating Instructions.

Failure to comply with these operating instructions may result in injury to patients, users, maintenance personnel and Third Parties, and may also result in damage to the device or endoscope, or the device and endoscope may stop working completely.

1.3 Liability & disclaimer

CREO MEDICAL Wolfgang Griesat GmbH is not liable for any damage, direct or consequential, which occurs under the following conditions:

- If the device or accessories are operated, treated or maintained inappropriately

- If the instructions and specifications set out in these Operating Instructions are not observed
- If repairs, adjustments or modifications to the device or accessories have been carried out by unauthorised persons
- If the device has been opened by unauthorised persons
- If the prescribed inspection and maintenance intervals are not observed.
- If any accessories other than those described in these Operating Instructions are used.

1.4 Safety instructions

1.4.1 Authorised service technicians

Only service technicians certified by CREO MEDICAL Wolfgang Griesat GmbH are authorised to carry out repairs, adjustments or modifications to the device and accessories. Authorised service technicians are registered and certified exclusively by CREO MEDICAL Wolfgang Griesat GmbH after appropriate instruction & training.

1.4.2 Instruction of staff

On-site training is provided by CREO MEDICAL Wolfgang Griesat GmbH or a person authorised by us.

1.4.3 Functional test

Before every use, check the LEAKAGE:MASTER to ensure all components are in place and that the device is working properly. Before using the device for the first time and after repairs have been carried out, always check that the equipment has been installed properly. Function checks are listed in Chapter 5 under "Functional test".

1.4.4 Hazards and risks of a general nature

 In the event there is serious risk of danger, disconnect the device from the power supply immediately (pull out the plug). 
Then call the service technician to remedy the fault and recommission the device.

1.4.5 Unauthorised opening of the device

Live components become exposed when the device is open and can cause electric shocks if touched. Never open the device yourself. The device may only be opened by an authorised CREO MEDICAL Wolfgang Griesat GmbH service technician.

1.4.6 Penetration of liquids

Liquid entering the device may prevent the device from working properly and/or present the risk of electric shock. Fluids should therefore never be permitted to enter the device. Always avoid placing fluids in the vicinity of the electrical components.
Do not operate if liquid has penetrated the device.

1.4.7 Operation in explosion-proof areas

The device is not explosion-proof. Operation in areas with explosive gases can lead to severe damage and cause serious injury.

1.4.8 Use of inappropriate accessories

The use of inappropriate accessories can cause the device to operate incorrectly, which may result in injury to patients, users, third parties and service technicians. Use only accessories specified for operation with the LEAKAGE:MASTER device (see Appendix).

1.4.9 Faulty fuses

When replacing a faulty fuse, please ensure the new fuse corresponds with the specifications displayed on the device or set out in these Operating Instructions.

The use of the wrong fuses can cause the device to function incorrectly and may result in injury to users and others.

1.4.10 Faulty device

It is generally dangerous to operate a faulty device. Do not operate the device if you suspect it to be faulty or if it is known to be faulty.
Make sure the device cannot be operated until checked by an authorised technician.

1.4.11 Setting up the device

The device may not be used stacked together with or beside other devices. If operation beside or stacked with other units is unavoidable, ensure it can still be used in accordance with its intended purpose in this arrangement.

1.4.12 EMC Directive

This device is subject to specific provisions as regards electromagnetic compatibility and must be installed and operated in accordance with the electromagnetic compatibility (EMC) instructions contained in the accompanying documentation. (Refer to Chapter 9)
Portable and mobile high-frequency (HF) communication equipment (e.g. mobile phones) may affect the way the device functions.

1.4.13 Instructions on operation

Before use, check the LEAKAGE:MASTER to ensure all components are in place and that the device is working properly. Before using the device for the first time and after repairs have been carried out always check that the equipment has been installed properly.

It is not permitted to pump fluids that are either explosive or contain alcohol through the LEAKAGE:MASTER.

The LEAKAGE:MASTER must never be used in explosive atmospheres.
Before connecting the LEAKAGE:MASTER to an endoscope, ensure the endoscope is sealed and free of leaks.

1.4.14 Instructions on maintenance

CREO MEDICAL Wolfgang Griesat GmbH stipulates maintenance intervals of 12 months.

2 Standard scope of delivery

Check the device and accessories immediately upon delivery to ensure all components are included and look for any visible external damage.

The following components are supplied with the device as standard (customised orders may differ somewhat):

1. LEAKAGE:MASTER
2. Adapter tube with corresponding cap seal (depending on order)
3. Data transfer cable (for connecting to a WASH:MASTER)
4. Shrouded mains cable with earthed plug
5. Operating Instructions

2.1 Components

– LEAKAGE:MASTER

– Shrouded mains cable with earthed plug
(spare part no. 5020-010)

– Data transfer cable for connecting to a
WASH:MASTER
(Spare part no. 7903-005)

– Adapter tube with corresponding cap seal
(depending on order)

– Operating Instructions

2.2 Returning the device

If you need to return the device, please use the original packaging. We will not accept responsibility for damage incurred during transport as a result of inappropriate packaging.

3 Machine overview

0 Pressure outlet: Leak test connection
1 Power push-button: ON / OFF switch (indicator lamp shows blue when switched ON)
2 Start push-button: Pressing the button runs the automatic test.
Hold the button depressed for more than 4 sec. to initiate the permanent test
3 Stop push-button: Ventilates the endoscope before the tube is removed
4 LED red (error): Results of the test: Red = leaks found
5 LED green (test): Results of the test: Green = no leaks
6 Display: Displays the program and pressure
7 Mains switch: Mains switch to Position I = ready for use
8 Mains fuse: To change a mains fuse
9 Shrouded 3-pin plug: Check voltage given on rating plate
10 Diode socket: Connecting the endoscope to the WASH:MASTER (optional)

4 Operating the LEAKAGE:MASTER

Any work involving contact with disinfection solutions as defined in the biological substances regulations (German enactment of EU Directive 2000/54/EC) must take account of all personal protection measures. Protective clothing must always be worn when performing the procedures described below. Because the air in the reprocessing room may contain a high level of disinfectant fumes, there must be adequate ventilation or air extraction.

It is also possible to use the LEAKAGE:MASTER for manual disinfection as a stand-alone device or in connection with the WASH:MASTER for device-based disinfection.

When operating the WASH:MASTER and while processing flexible endoscopes, observe the general requirements relating to handling endoscopes:

- Operating Instructions for the WASH:MASTER
- Robert Koch Institute: Hygiene requirements when processing flexible endoscopes and additional instruments used in endoscopy.
- Employees' safety organisations: Organic substances
- Regulations on the use of medical equipment

4.1 Functional test

4.1.1 PROGRAM 1: AUTOMATIC TEST

The automatic test is performed dry before the endoscope is immersed in liquid or placed in an automatic endoscope reprocessor (AER) or the WASH:MASTER. The automatic test must always be carried out.

If leaks are detected or if an error is displayed, the reprocessing phase must be aborted and the endoscope sent for repair.

If the automatic test is successfully completed without leaks being detected, we recommend leaving the leakage tester plugged in and running during the brush cleaning phase in every case and, preferably, for the entire duration of the reprocessing process.

Check that the mains electricity supply is correctly connected.

Switch the device ON using the mains switch ⑦ (switch position I).

Switch the LEAKAGE:MASTER ON by pressing the power button ①.

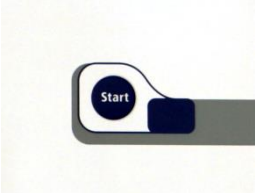
A blue indicator lamp shows that the device is switched on.

The display ⑥ shows LEAKAGE:MASTER and the program version.

Use the set of tubes to connect the endoscope to the pressure outlet ⓪. Use a corresponding leakage test cap.

(Refer to Appendices I and II).

Press the Start button ② to run the automatic test.



The automatic test (leakage test) will run.

In contrast to the instructions supplied by the manufacturers of the endoscopes, the pretest is performed with the endoscope not moving and preferably fully extended. In this way, the pretest will also detect microperforation.

During the automatic test the green LED marked "Test" will flash ⑤.

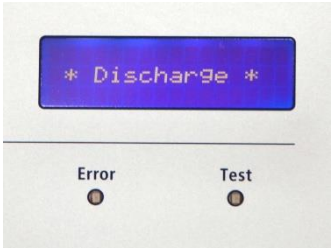
When the AUTOMATIC TEST has been completed without detecting a leak, three beeps will sound.

If the automatic test completes successfully, the display⑥ will show:

LEAKAGE:MASTER
Test passed: YES

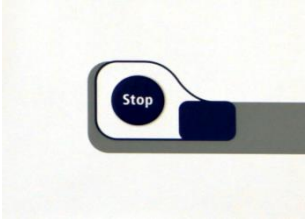
After successful completion of the automatic test, the endoscope is automatically vented.

The display shows * Discharge * (= vent).



Even if the pretest is successful, we recommend performing the permanent test as well and leaving the endoscope attached for the remainder of the processing phase.

If the automatic test does not complete without an error, vent the endoscope by pressing the Stop button ③.



The display shows * **Discharge** * (= vent).

Counterpressure remains active until the Stop button is pressed.

Now separate the endoscope from the adapter and leakage test cap.

4.1.2 PROGRAM 2: PERMANENT TEST

After the automatic test (pretest) has been successfully completed we recommend leaving the endoscope connected up and then running the Permanent Test with the endoscope immersed in water. The Permanent Test maintains constant air pressure in the endoscope and thus prevents the ingress of fluid if microperforations are later detected.

The cap seal must be connected while the endoscope is still dry!!

Do not immerse the endoscope in fluid until the pressure has been completely built up. If, during the permanent test reprocessing, air bubbles are seen, this means leaks have been detected. Abort the reprocessing and send the endoscope for repair.

There will be both visual and audible alarms.

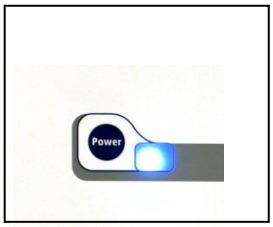
If the leakage test water used for an immersion leakage test in accordance with manufacturers' instructions is extremely cold, there may be false "leakage" detections because the air inside

the endoscope will contract, which results in a pressure drop. If there are doubts about the integrity of the test, use slightly warmer water.

Check that the mains electricity supply is correctly connected.

Switch the device ON using the mains switch ⑦ (switch position I).

Switch the LEAKAGE:MASTER ON by pressing the power button ①.
A blue indicator lamp shows that the device is switched on.



The display ⑥ shows LEAKAGE:MASTER and the program version.

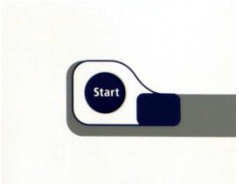
Use the set of tubes to connect the endoscope to the pressure outlet ①. Use a corresponding leakage test cap (refer to Appendices I and II).

The cap seal MUST be connected while the endoscope is still dry.

Never immerse the endoscope in fluid without running a successful automatic test (pretest) and wait while the Permanent Test generates the correct pressure.

If the automatic test (pretest) detects leakages, we recommend aborting the processing phase.

To run the Permanent Test, press the Start button ② for at least 4 seconds.



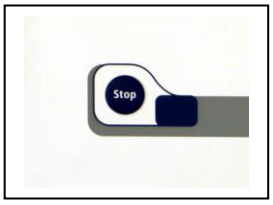
During the permanent test, the pressure level in the endoscope is maintained until either leakages are visually detected or until the Stop button ③ is pressed.

The endoscope should bend in all directions for testing

Once the location of a leak has been noted, take the endoscope out of the water.

⚠ Do not press the Stop button ③ until the endoscope has been removed from the water tank as otherwise the pressure will fall and water may find its way into the endoscope and damage it.

After taking the endoscope out of the tank, vent it by pressing the Stop button ③.



The endoscope then vents.

Now separate the endoscope from the connection tube and leakage test cap.

4.2 Error message if the automatic test is not successfully completed (pretest)

If a leak is detected, a flashing red LED will signal the error, ④, the display will show

**** Error **** ④ and a long warning note will sound, while the pressure will be maintained (until the Stop button is pressed).

Check the endoscope and the connections

and check that the adapter tube is not leaking.

If, during the automatic test, the device cannot build up pressure in the endoscope, a flashing red LED will signal the error ④, the display will show ** **Error** ** and a long warning sound will be heard (until the Stop button is pressed).

Check the endoscope and the connections and check that the adapter tube is not leaking.

If a leak is indicated, the endoscope must not under any circumstances be reprocessed (refer to manufacturer's instructions). The LEAKAGE:MASTER will continue to generate pressure to prevent the ingress of fluids into the endoscope in the event of minor leaks. However, this process does not guarantee absolute prevention against the ingress of fluids if the leaks are more major. A leaky endoscope must be repaired in line with the instructions provided by the manufacture of the endoscope before it is subjected to cleaning and disinfection.

In some individual cases, very minor leaks (microperforation) the leakage may not be indicated until later. The LEAKAGE:MASTER will maintain the pressure during the cleaning and disinfection phases to prevent the ingress of fluids into the endoscope. The endoscope should nevertheless be repaired immediately to prevent the leaks becoming more severe.

5 Maintenance and care

In order to ensure the operational safety and performance of the LEAKAGE:MASTER, annual servicing including replacement of the connection sets and a test for electrical safety according to DGUV V3 is necessary.

Repairs to faulty devices may only be carried out by individuals authorised by us and using only original CREO MEDICAL spare parts.

5.1 Responsibilities

As Manufacturer of this device, we accept responsibility for the safety, reliability and performance of the device under the following conditions only:

- Extensions, resetting, modifications and repairs may only be carried out by individuals authorised by us.
- The electrical installations in the room in which it is used must meet VDE requirements and the corresponding device must be used in accordance with the Operating Instructions.

6 Disinfecting and cleaning the device

Only validated processes may be used for the reprocessing of medical devices.

6.1 Place of use
Unplug the device from the mains and remove the accessories used (e.g. tube set, leakage tester cap)

6.2 Storage and transport
When transported outside the room in a closed container.

We recommend reprocessing medical devices as soon as possible, at the latest within 2 hours of use.

6.3 Preparation
Wear personal protective equipment (solid gloves, water-repellent protective coat, face mask or goggles and mask).

6.4 Manual cleaning and disinfection
6.4.1 Equipment required
Non-protein-fixing VAH-listed (VAH = Association for Applied Hygiene) instrument disinfectant based on quaternary compounds, acetals and aldehydes (e.g. Beta Guard RFU wipes, Dr Deppe GmbH)

6.4.2 Procedure
1) Take a disinfection wipe and wipe the surfaces of the device thoroughly.
2) Ensure that all surfaces, grooves and indentations in the device are wiped and thoroughly moistened during the cleaning process.
3) To clean the ventilation grille, wipe it thoroughly on the outside, then fold the disinfection wipe and clean all the gaps between the individual louvres.
4) Check the areas for cleanliness and, if contamination is still visible, repeat the above steps.
5) To disinfect the surfaces, take a further disinfection wipe and wipe the surfaces of the device thoroughly.
6) Ensure that all surfaces, grooves and indentations in the device are wiped and thoroughly moistened during the disinfection process.
7) To disinfect the ventilation grille, wipe it thoroughly on the outside, then fold the disinfection wipe and clean all the gaps between the individual louvres.
8) Allow the disinfectant to soak in for the time specified by the disinfectant manufacturer (e.g. Beta Guard RFU wipes require five minutes).
9) Allow the device to dry off.

6.1.5 Maintenance, inspection and testing
We recommend annual maintenance of such devices by CREO MEDICAL Wolfgang Griesat GmbH or a person authorised by us.

6.1.6 Packaging
No special requirements.

6.1.7 Storage
Store the device in a dust-protected, cool, dark and dry place, the storage time must be in accordance with the specifications of the user.

6.2 Tubing and cap seals
The inner lumen of the tube and the adapter diaphragm must never be cleaned or disinfected. Residual moisture in the tubing results in damage to the endoscope.

⚠ Notice

The tubing and leakage test adapters must never be sterilised (autoclaved).

Tubing and the cap seals can only be disinfected by wiping on the outside as described above.

Always observe the instructions issued by the manufacturer of the disinfection solution.

7 Final disposal

At the end of its useful service life, the LEAKAGE:MASTER and its detachable components have to be disposed of in accordance with applicable local regulations as medical equipment.

8 Troubleshooting

Device does not work. Check the following points:

- Mains switch ON?
- "Power" button pressed?
- Check mains cable and wall socket.
- Check fuses at rear of device.

Suspected incorrect "leak" display. Check the following points:

- Sealing of Luer lock connections to tube and device
- Sealing of tube
- Leakage test cap (O-ring OK?)
- Leakage test cap (firmly attached?)

⚠ If the water used for an immersion leakage test in accordance with manufacturers' instructions is extremely cold, there may be false "leakage" detections because the air inside the endoscope will contract, which results in a pressure drop. If there are doubts about the integrity of the test, use slightly warmer water.

If the fault cannot be remedied by simple measures, please return the device to the Manufacturer for repair.

9 Technical specifications

Mains supply, rated	230 V
Mains frequency	50 Hz
Fuses	T 250 mA, IEC 127 (2 off)
Maximum power input	54 W
Maximum current consumption	0.25 A
Protection class	I
Dimensions (height x breadth x depth)	157 x 278 x 275 mm
Weight	6.4 kg
Measuring pressure	240 mbar
Operating condition: ambient temperature	10 °C to 35 °C
Operating condition: relative air humidity: max	70%
Classification according to Council Regulation (EU) 2017-745	Risk class I, Rule 13
Electrical safety	complies with EN 61010-1:2010
Electromagnetic compatibility	complies with EN 61326-1:2013
Ingress protection	IP21
Protection category	Protection class 1, Type BF applied part
Software version	Version 2.32

This device has been constructed to meet the requirements of protection category 1 and designed for use in rooms whose electrical installations meet the requirements of VDE regulations.

CE The CE marking certifies that the product complies with EU Council Regulation 2017/745 for medical devices.

10 EMC conditions

In accordance with EN 61326-:12013

- Electromagnetic compatibility testing Group 1 Class B (section 7.2)
- Electromagnetic noise immunity: To Table 2

Testing requirements for radio-frequency interference of equipment intended for use in an industrial electromagnetic environment

Connection	Interference factor	EMC Basic standard	Test value	Evaluation criterion
Housing	Discharge of static electricity (ESD)	IEC 61000-4-2	4 kV contact discharge	B
			8 kV air discharge	B
	Electromagnetic fields	IEC 61000-4-3	10 V/m (80 MHz to 1 GHz)	A
			3 V/m (1.4 GHz to 2 GHz)	A
			1 V/m (2.0 GHz to 2.7 GHz)	A
	Mains-frequency magnetic fields	IEC 61000-4-8	30 A/m (50 Hz, 60 Hz) [e]	A
AC power supply connection (including protective earth conductor connection)	Voltage dip	IEC 61000-4-11	0% for 1 cycle	B
			40% for 10/12 cycles[g]	C
			70% for 25/30 cycles[g]	C
	Brief interruption	IEC 61000-4-11	0% for 250/300 cycles[g]	C
	Fast transients	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge voltage	IEC 61000-4-5	1 kV[a] / 2 kV[b]	B
	Conducted HF signals	IEC 61000-4-6	3 kV[f] (150 kHz to 80 MHz) N1)	A
DC supply connection [f] (including protective earth conductor connection)	Fast transients	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge voltage	IEC 61000-4-5	1 kV[a] / 2 kV[b]	B
	Conducted HF signals	IEC 61000-4-6	3 kV[f] (150 kHz to 80 MHz) N1)	A
Input/output connection (including functional earth connection)	Fast transients	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge voltage	IEC 61000-4-5	1 kV[a] / 2 kV[b]	B
	Conducted HF signals	IEC 61000-4-6	3 kV[f] (150 kHz to 80 MHz) N1)	A
Input/output connector with direct connection to the power supply network	Fast transients	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge voltage	IEC 61000-4-5	1 kV[a] / 2 kV[b]	B
	Conducted HF signals	IEC 61000-4-6	3 kV[f] (150 kHz to 80 MHz) N1)	A

[a] Symmetrical: conductor to conductor.

[b] Conductor to PE (earth).

[c] Only for long cables (see 3.10).

[d] Only for cables longer than > 3 m.

[e] Only for magnetically sensitive devices. Interference on cathode ray tube screens may occur at field strengths above 1 A/m.

[f] DC voltage connections between parts of equipment or systems not connected to a DC voltage network are treated as input/output connections.

[g] For example, "25/30 cycles" means "25 cycles for 50 Hz mains frequency tests" or "30 cycles for 60 Hz mains frequency tests".

Appendix I

Accessories for LEAKAGE:MASTER

Spare part no.	Description
7526-FU-LM	Leakage tester cap for use with Fujifilm endoscopes with a connection tube
7526-OL-LM	Leakage tester cap for use with Olympus endoscopes with a connection tube
7526-RF-PE-LM	Leakage tester cap for use with Pentax endoscopes with a connection tube
7526-ST-LM	Leakage tester cap for use with Storz endoscopes with a connection tube
7526-WO-LM	Leakage tester cap for use with Richard Wolf endoscopes with a connection tube

Appendix II

Replacement parts for LEAKAGE:MASTER

Spare part no.	Description
7526-FU	Leakage test cap for Fujifilm endoscopes
7526-OL	Leakage test cap for Olympus endoscopes
7526-RF-PE	Leakage tester cap for Pentax endoscopes
7526-ST	Leakage tester cap for Storz endoscopes
7526-WO	Leakage tester cap for Richard Wolf endoscopes
7003-910	Fuse T 250 mA, IEC 127

Reporting

Any and all incidents and near incidents occurring in connection with this product under the German Medical Devices Safety Plan Ordinance (MPSV) are to be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

For the Federal Republic of Germany, this is:

Federal Institute for Drugs and Medical Devices (BfArM)
Kurt-Georg-Kiesinger-Allee 3,
53175 Bonn, Germany
www.bfarm.de

Certificates

Certificates and Declaration of Conformity are available on request.

In the event that these documents are mislaid or if you need additional copies, please contact:

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40764 Langenfeld – Germany

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