



Carefully read the operating instructions and processing instructions prior to clinical application and keep them safe and at hand. The instructions and notes contained therein must be followed.

Contents

- 1 Safety and responsibility
- 2 Scope
- 3 Scope of supply
- 4 Product description
- 5 Technical data
- 6 Putting the Instrument into operation
- 7 Reprocessing
- 8 Storage
- 9 Accessories
- 10 Liability
- 11 Repair
- 12 Disposal
- 13 Description of symbols and icon

1 Safety and responsibility

1.1 Proper use

Intended purpose

Surgically invasive disposable product for temporary use. The instrument is used only in combination with an original working element and an original resectoscopy sheath.

Indication

This instrument is designed for use in minimally invasive surgery and, in particular, urology. It serves to dissect, coagulate and cut tissue using HF current.

Contraindication

This instrument is not designed for use on the central nervous and circulatory system. The application of HF current can damage pacemakers and in vivo cardiac defibrillators. The instrument should not be used in the immediate vicinity of bone, tooth root and metal.

Risks as a result of improper use

- Material fatigue and loss of function through multiple use.
- Risk of infection through multiple use.
- Risk of electric shock due to damage to the insulation which can result from reuse and exceeding the operating conditions.
- Risk of injury from using the instrument without HF current.

1.2 Safety instructions

Before Using the Instrument

- ▶ Read and follow the Instructions for Use. Keep these Instructions for Use in a place where they can be easily seen for reference at a later date.

The basic risks identified for the reprocessing process are summarised below based on the nature of the hazard. Warnings which relate to specific actions can be found directly next to the relevant action together with a classification of the risk... → see section „Description of symbols and icon“.

Risk of electric shock

- ▶ Only use compatible HF generators.
- See section „Accessories“.

Risk of infection

- ▶ Reprocess the instrument before initial use.
- ▶ Do not reuse.
- ▶ Discard after use.

Risk of injury

- ▶ The instrument may only be used by qualified medical and technical specialist personnel. For surgical use by doctors only.
- ▶ In the case of patients with pacemakers, ensure compatibility of the latter with HF radiation.
- ▶ Do not use the instrument in the vicinity of conducting implants.
- ▶ Do not use explosive substances during the intervention.
- ▶ Prevent carbonation of tissue!
- ▶ Use the instrument only with a recovery peak voltage of 3000 Vp max. in combination with original working elements.
- ▶ Do not place the instrument on the patient.

- ▶ Only coagulate if the contact surfaces of the instrument are visible.
- ▶ Do not touch any other metallic objects during coagulation.
- ▶ Use suitable HF generators.
- ▶ Only use original accessories.
- ▶ Do not use damaged instruments and do not repair.
- ▶ Do not reuse the instrument
- ▶ Remove from the packaging with care.
- ▶ Do not touch the sharp edges and tips.

2 Scope

These Instructions for Use apply for product group monopolar electrode:

article-no.
51.07.10; 51.07.11; 51.07.12; 51.07.14; 51.07.15; 51.07.16; 51.07.18; 51.07.19; 51.07.22; 51.08.10; 51.08.12

3 Scope of supply

The scope of supply comprises only the instrument ordered. This is not an article in a set.

- ▶ After unpacking, check all parts for any damage caused during transit.
- ▶ In the event of complaints, contact the manufacturer.

4 Product description



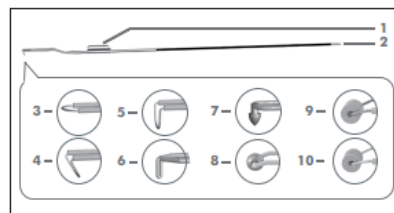
WARNING

- ▲ Risk of injury due to incorrect handling and worn instruments.
- ▲ Do not use the instrument for spray coagulation
- ▲ Do not reuse.

The electrode is pushed onto a working element via a guide and clamped into place using the locking pin. The working element supplies the electrode with power via a contact socket.

→ See operating instructions working element G510701

The following figure shows various types of electrodes for resectoscopy.



- 1 Guide
- 2 Locking pin
- 3 Loop electrode, straight
- 4 Loop electrode for 30° telescope, curved
- 5 Loop electrode for 0° telescope, curved
- 6 Knife electrode
- 7 Cone electrode
- 8 Ball electrode
- 9 Roller electrode
- 10 Vaporisation electrode

Note:

The instrument cannot be disassembled.

Areas of application

The following overview shows the areas of application for the various electrodes.

Ball electrode

51.07.15; 51.07.16

Application	+ compatible / - incompatible
Coagulation	-
Cutting	+
Vaporisation	+

Knife electrode

51.07.10,

Application	+ compatible / - incompatible
Coagulation	-
Cutting	+
Vaporisation	-

Loop electrode

51.07.11, 51.07.12; 51.07.22

Application	+ compatible / - incompatible
Coagulation	-
Cutting	+
Vaporisation	-

Roller electrode

51.07.18; 51.07.19

Application	+ compatible / - incompatible
Coagulation	+
Cutting	-
Vaporisation	-

Vaporisation electrode

51.07.14

Application	+ compatible / - incompatible
Coagulation	-
Cutting	-
Vaporisation	+

5 Technical data

Designation	Value
Peak voltage	3000Vp
Ambient temperature	≤137 °C
Duty cycle	≤30 s; not suitable for continuous operation

6 Putting the Instrument into operation



Product lifetime: Disposable product. Do not reuse!

Risk of electric shock from HF current.

- ▲ Wear 2 pairs of gloves on top of each other when putting the instrument into operation and during use.

Risk of burns from HF current.

- ▲ Use a suitable neutral electrode.
- ▲ Position the neutral electrode so that its entire surface is touching the patient.
- ▲ Only use the instrument if the insulation is **not** damaged.
- ▲ Do not activate the HF current until the instrument is within your field of vision.
- ▲ Only touch the insulated areas of the HF cables with your fingers and **not** the contact pin.
- ▲ Do **not** use explosive substances during the intervention.
- ▲ Use original working element

Risk of bladder perforation due to intravesical oxyhydrogen gas explosion.

- ▲ Completely vent the feeding irrigation system.
- ▲ Keep the accumulation of gas on the anterior wall of the bladder as low as possible.

▲ Prevent direct contact between the gas bladder and the resection loop.

Risk of infection from non-sterile instruments.

- ▲ Reprocess the instrument before initial use.

Risk of injury from the sharp edges and tips.

- ▲ Do **not** touch the distal end.
- ▲ Do **not** bend the distal end.

Note:

Adjust the voltage of the HF generator to the cutting speed to support primary haemostasis.

Prerequisite: The HF generator is switched off.

- ▶ Attach the neutral electrode to the patient and connect with the HF generator.
- ▶ Put on two pairs of gloves.
- ▶ Insert the electrode into an original working element.
- ▶ Connect the HF cable with the contact socket of the working element.
- ▶ Connect the other end of the HF cable to the monopolar output of the HF generator.
- ▶ Insert the working element with attached electrode into the resectoscopy sheath and lock in place.
- ▶ Switch on the HF generator.
- ▶ Perform the intervention.

- ▶ Dispose of the electrode.

7 Reprocessing

Risk of infection from non-sterile instruments

- ▲ Reprocess the instrument before initial use.
 - ▲ Avoid damaging product through residues from disinfectants and detergents on the contact connections.
 - ▲ Instrument must not be disinfected in solution.
- The instrument is assigned to „Reprocessing group 1“

The manufacturer does not assume any liability for damage as a result of incorrect reprocessing and care. The methods described for manual and mechanical reprocessing have been validated by the manufacturer. These are recommendations from the manufacturer. If using different and/ or modified reprocessing methods, the user must provide proof of the effectiveness of the method.

The basic risks identified for the reprocessing process are summarised below based on the nature of the hazard. Warnings which relate to specific actions can be found directly next to the relevant action together with a classification of the risk.

Risk of infection

- ▶ Reprocess the instrument before initial use.
- ▶ Reprocess the instrument before each use.
- ▶ Reprocess the instrument before returning it to the manufacturer.
- ▶ Follow the instructions for use of the cleaning agents and disinfectants used as well as of the cleaning and sterilisation devices used.
- ▶ Wear personal protective equipment during reprocessing.
- ▶ Discard disposable components after initial use.
- ▶ Note the special reprocessing requirements if there is a suspicion of prions and Creutzfeldt-Jakob disease.

Risk of injury

- ▶ Do **not** use damaged instruments and do **not** repair.
- ▶ Only use original accessories.

Validated reprocessing methods

In the following synoptic table, the validated reprocessing methods are shown itemised according to the instrument groups. The individual instruments are assigned to the different reprocessing groups in the respective Instructions for Use. This synoptic table is not a substitute for the following sections of these Guidelines for Care, Maintenance and Cleaning.

Note:

Reprocessing step	Reprocessing methods	Reprocessing group 1	Reprocessing group 2	
Pre-cleaning ¹	Enzymatic	++	++	
Cleaning	Manual cleaning ²	++	++	
	Mechanical cleaning ³	Alkaline	++	++
		55°C 5 min.	++	++
Ultrasound ⁴	Ultrasound bath	++	++	
Drying	Temperature	40-45°C 10-15 min.	40-45°C 10-15 min.	
		90-110 °C 15-25 min.	90-110 °C 15-25 min.	
Disinfecting	Manual disinfecting ²	Chemical	++	
	Mechanical disinfecting ³	Thermal 90+3 °C	++	
Sterilising ⁵	Moist heat autoclave pre-vacuum	++	++	
		134-137 °C 4 min.	134-137 °C 4 min.	

¹ For detailed information see the section „Pre-cleaning“
² For detailed information see the section „Manual cleaning (enzymatic) and chemical disinfection“
³ For detailed information see the section „Mechanical cleaning (alkaline) and thermal disinfection“
⁴ For detailed information see the section „Manual cleaning (enzymatic) and chemical disinfection“
⁵ or „Mechanical cleaning (alkaline) and thermal disinfection“
⁶ For detailed information see the section „Sterilising“

More detailed information on reprocessing is available from the Robert Koch Institute (RKI) and the Instrument Reprocessing Working Group (AKI): RKI: Hygiene Requirements for Reprocessing Medical Devices (www.rki.de, as last amended) AKI: Proper Maintenance of Instruments (www.a-k-i.org, as last amended)



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Material compatibility

The following synoptic table shows for which instrument groups and which reprocessing methods materials are compatible. The user must validate these

Reprocessing step	Reprocessing methods	Reprocessing group 1	Reprocessing group 2
Pre-cleaning directly after use	Cleaning	+	+
	Immersing	+	+
Cleaning	Mechanical cleaning	Wipe with a damp cloth (water)	+
		Alkaline *	55-85°C 3-20 min.
	Enzymatic †	+	+
		45-50°C 5-20 min.	45-50°C 5-20 min.
Ultrasound	Ultrasound bath	40-50°C 5-20 min.	40-50°C 5-20 min.
		Demineralised water	+
Disinfecting	Manual disinfecting Mechanical disinfecting	Chemically up to max. 60°C	+
		Thermally up to max. 93°C	+
Drying	Temperature	+	+
		50-110 °C 15-25 min.	50-110 °C 15-25 min.
Sterilising	Moist heat autoclave pre-vacuum	+	+
		134-137 °C 4-30 min.	134-137 °C 4-30 min.
	Low temperature (steam formaldehyde)	+	+
		60 °C 60 min. 2% formaldehyde 200 ml/air abs.	60 °C 60 min. 2% Formaldehyd 200 ml/air abs.
	Ethylene oxide	40-50 °C 5 h 644-707 mg/l ETO 595-625 ml/air abs.	40-50 °C 5 h 644-707 mg/l ETO 595-625 ml/air abs.
		Hot air Gas plasma (Sterrad)	-

* For detailed information see the section „Mechanical cleaning (alkaline) and thermal disinfection“

† For detailed information see the section „Mechanical cleaning (enzymatic) and chemical disinfection“

methods! The individual instruments are assigned to the different reprocessing groups in the respective Instructions for Use. This synoptic table is not a substitute for the following sections of these Guidelines for Care, Maintenance and Cleaning.

Note:

More detailed information on reprocessing is available from the Robert Koch Institute (RKI) and the Instrument Reprocessing Working Group (AKI): RKI: Hygiene Requirements for Reprocessing Medical Devices (www.rki.de, as last amended) AKI: Proper Maintenance of Instruments (www.a-k-i.org, as last amended)

Preparing decontamination

To prevent surgical residue from drying on, the following steps must be performed directly after surgery.

- ▶ Rinse the instrument with cold water.
- ▶ Remove coarse dirt with cold water.
- ▶ Rinse out cavities with cold water.

Note:

If it is not possible to rinse with cold water, the instrument must be wrapped in a moist cloth to prevent any residues from drying on.
▶ Always transport the instrument to the reprocessing site in a closed container to prevent product damage and contamination of the environment.

Pre-cleaning

Pre-cleaning prevents surgical residue from drying on. It must therefore be carried out directly after surgery.

Pre-cleaning was validated with the cleaning agent Cidezyme from Johnson & Johnson:

Cleaning	Dosage	pH value
Enzymatic	0,8%	7,8-8,8 (diluted)

WARNING

- Risk of infection and pyrogenicity from residues if unsuitable cleaning agents are used.
- ▲ Do not use fixing agents.
 - ▲ Do not rinse with hot water.
- IMPORTANT!** Avoid damaging product.
- ▲ Do not use abrasive brushes or scourers.
 - ▲ Only use the cleaning agents which are listed in this section.
 - ▲ Use disinfectant with corrosion protection.

TIP: Remove caked-on tissue residues with a plastic brush.

- ▶ Immerse the instrument in a cold water bath with 0.8% cleaning solution: >5 min.
- ▶ Brush the instrument under cold water until all visible signs of soiling have been removed.
- ▶ Dismantle the instrument (if possible).
- ▶ Open stop cocks (if relevant).

Note: Rinse the instrument under the surface of the water. This prevents contamination of the surrounding area.

- ▶ Brush the outside and inside under cold water with a round brush until no more residue is visible.
- ▶ Rinse out cavities, drill holes and threads (if relevant) with a cleaning gun: >10 s at 3-5 bar.
- ▶ Remove from the water bath and rinse off with cold water..
- ▶ Immerse in combined cleaning and disinfectant solution until subsequent cleaning to prevent any residue from drying on.

Cleaning and disinfection

Unless specified otherwise in the description of the reprocessing method, use water of the following quality:

- Pre-rinsing: Tap water
- Cleaning and rinsing: Demineralised water
- Final rinsing: Demineralised water

WARNING

Risk of infection due to insufficient reprocessing.
▲ Remove protective caps (if relevant).

IMPORTANT! Avoid damaging product.

- ▲ Do not use abrasive brushes or scourers.
- ▲ Only use the cleaning agents which are listed in the individual sections.
- ▲ With plastic instruments avoid contact with hydrogen peroxide (H2O2).
- ▶ Choose between manual and mechanical cleaning.

WARNING

Risk of infection due to insufficient reprocessing.
▲ Special reprocessing requirements must be observed if there is a suspicion of prions and Creutzfeldt-Jakob disease.
Observe the recommendation "Hygiene requirements for Processing of medical devices" by RKI and BfArM.

Manual cleaning (enzymatic) and chemical disinfection

Manual cleaning was validated with the cleaning agents Cidezyme/Enzol from Johnson & Johnson and Mucadont Zymaktiv from Merz Hygiene GmbH:

Cleaning agent	Cleaning	Dosage
Cidezyme/ Enzol	Enzymatic	0,8 %
Mucadont Zymaktiv	Enzymatic	0,8 %

Note:

Rinse the instrument under the surface of the water. This prevents contamination of the surrounding area.

Preparation

- ▶ Dismantle the instrument (if possible).
- ▶ Open stop cocks (if relevant).

Cleaning

- ▶ Place the instrument in cold water: >10 min.
- ▶ Brush the instrument under cold water until all visible signs of soiling have been removed.
- ▶ Rinse out cavities, drill holes and threads with a cleaning gun with cold water: >20 s at 3-5 bar.

- ▶ Unless specified otherwise in the instrument's Instructions for Use, clean the components in the ultrasonic bath with 0.8% cleaning agent with the following settings:

Temperature	Frequency	Duration
40-45°C	35kHz	10-15 min.

- ▶ Turn and move the components several times during cleaning in the ultrasonic bath.
- ▶ Rinse out cavities, drill holes and threads with a cleaning gun with cold water: >20 s at 3-5 bar.
- ▶ Immerse the instrument in deionised water and rinse through the cavities several times with deionised water.

Note:

Also clean the inner chambers of the instrument below water using a cleaning brush.

Drying

- ▶ Dry on the inside and outside: >10 min. at 50-100° C and/or blow through with sterile compressed air.

Disinfecting

Disinfection was validated with the disinfectant Mucocit-T from Merz Hygiene GmbH:

- ▶ Disinfect with disinfectant: >10 min

See manufacturer's Instructions for Use.

Disinfectant	Dosage	pH value
Mucocit-T	4%	10,5 (diluted)

Mechanical cleaning (alkaline) and thermal disinfection

Mechanical cleaning was validated with the cleaning device G 7735 CD from Miele.

Mechanical alkaline cleaning was validated with the cleaning agent Neodisher FA from Dr. Weigert:

Cleaning	Dosage	pH value
Alkaline	0,5%	12,2-14 (diluted)

Preparation

- ▶ Dismantle the instrument (if possible).
- ▶ Open stop cocks (if relevant).
- ▶ Place instruments in a sieve tray on the cleaning device MIS mobile unit so that the cleaning agent can reach all inner and outer surfaces.
- ▶ Connect flush opening (if any) to MIS mobile unit.

Cleaning

▶ Unless specified otherwise in the instrument's Instructions for Use, additionally clean the components prior to or in combination with mechanical cleaning in an ultrasonic bath with the following settings:

Temperature	Frequency	Duration
40-45°C	35-45 kHz	10-15 min.

- ▶ Turn and move the components several times during cleaning in the ultrasonic bath.

Proper cleaning depends on the right cleaning program. Compare the cleaning program with that of your cleaning system and save where necessary:

- ▶ Start the cleaning program.
- 1. Pre-rinsing with cold water: 1 min.
- 2. Emptying
- 3. Repeated pre-rinsing with cold water: 3 min.
- 4. Emptying
- 5. Cleaning with 0.5% enzymatic cleaning agent: at 45° C for 5 min
- 6. Emptying
- 7. Rinsing with deionised water: 3 min.
- 8. Emptying
- 9. Rinsing with deionised water: 2 min.
- 10. Emptying

Drying

- ▶ Dry inside and outside in the cleaning and disinfection device: 15-25 min. at

- 90-110° C. The cleaning and disinfection device cycle must include a drying phase.
- ▶ Remove the product from the cleaning and disinfection device immediately at the end of the cycle.
- ▶ If necessary, also blow through the product with sterile compressed air until it is completely dry.

Disinfecting

Disinfection was validated with the device Getinge 88 series:

Disinfectant	Temperature	Dwell time
Demineralised water	90+3°C	≥ 5 min.

→ Observe the national requirements as regards the A0 value (see ISO 15883)

Checking and care

Checking

The right care of instruments will lengthen their service life and should therefore be carried out after every cleaning process.

WARNING

Risk of injury from faulty or damaged components
▲ Do not use damaged instruments and do not repair.

- ▶ Check to ensure they are clean and, if necessary, repeat cleaning.
- ▶ Check for damage (e.g., sharp edges, rough surfaces).
- ▶ Replace brittle and cracked seals (if relevant).
- ▶ Lubricate moving parts (e.g., joints, rotating stop cocks) with medical oil.
- ▶ Remove any excess oil.
- ▶ Assemble instruments (if possible) and check to ensure they are in perfect working order.

Packaging

The instrument must be packed appropriately prior to sterilisation to ensure that the sterile barrier remains intact after removal from the steriliser.
▶ Package the instrument to comply with ISO 11607 and EN 868.

Sterilising

Unless stated otherwise in the instrument's Instructions for Use, sterilisation is performed with the instrument assemble.
Sterilisation was validated with the sterilisation device Selectomat S 3000 from MMM Group and Varioclav 400 E from Fisher Scientific.

IMPORTANT! Avoid damaging product.

▲ Observe the device's maximum load.

→ See manufacturer's Instructions for Use.

WARNING

Risk of infection due to insufficient reprocessing.
▲ Special reprocessing requirements must be observed if there is a suspicion of prions and Creutzfeldt-Jakob disease.
/ Please note the recommendation "Hygiene requirements for the reprocessing of medical devices" by RKI and BfArM.

Sterilisation was validated at 134° C and 4 minutes. The sterilisation time must therefore be at least 4 minutes.

The following countries make different stipulations which must be observed:

Country	Sterilisation time
Germany	≥ 4 - 30 min.
France	≥ 18 - 30 min.
Switzerland	≥ 18 - 30 min.

Note:

- Dwell times of 4-30 min. do not have a negative influence on the instrument/ material.
- ▶ Open stop cocks (if relevant).
- ▶ Place in the sterilisation device so that the components are not touching each other and the steam can circulate freely.

▶ Set the sterilisation parameters (3-fold fractionated pre-vacuum):

Temperature	Pressure	Duration
134 -137 ° C	3 bar/ 44 psi	See details in this section.

IFU ID: G510700

Gebrauchsanweisung
 Operating Instructions
 操作说明书
 Manual de instrucciones
 사용 설명서
 Instructies voor gebruik

Rev.: 10-07-2020 REV 01**Rx only**

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EN**MONOPOLAR ELECTRODE**

- ▶ Start the sterilisation process

Information on validation

The following materials and machines were used for validation:

Cleaning agent:

- Cidezyme/Enzol from ASP
- Mucadont Zymaktiv from Merz Hygiene GmbH
- Neodisher FA from Dr. Weigert
- deconex 23 Neutrazym from Borer

Disinfectant:

- Mucocit-T from Merz Hygiene GmbH

Cleaning and disinfection devices:

- G 7735 CD from Miele

Sterilisation devices:

- Selectomat S 3000 from MMM Group
- Varioclav 400 E from Fisher Scientific

Sterilising agent:

- Moist heat

8 Storage

- ▶ Only transport and store the instrument with appropriate protection.

To avoid reducing durability and forfeiting any resistance to bacteria the following storage conditions must be observed:

- ▶ Store the sterile device sealed in a clean, dust-free and dry sterile container.
- ▶ Protect from direct light.
- ▶ Store the sterile container in a clean and dry environment with controlled humidity at room temperature.
- ▶ Do **not** store the sterile container in the vicinity of aggressive substances (e.g., alcohols, acids, bases, solvents and disinfectants).

Note:

Also observe your internal storage standards for sterile devices.

9 Accessories

Risk of injury from the use of incompatible instruments

- ▲ Only use original accessories.

Working elements for use with electrodes 24 Ch.

Passive cutting working element, electrode in resting position inside the sheath, aluminium handle, with the article number51.07.06

High-frequency cable

Use only medical HF cables that are approved in accordance with the directive 93/42/EEC..

Select the cable connection suitable for the working element used and on the generator side suitable for the generator used.

→ See HF cable 's Instructions for Use.

HF generators

Use HF generators that comply with the technical requirements in chapter „ Technical Data “.

→ See the HF generator 's Instructions for Use.

The electrodes were tested with the HF generator W.O.M. Electrosurgical Unit Model HF400..

10 Liability

CAUTION: According to US federal law, in the USA this product may be bought only by a physician or hospital or upon prescription!

In the event of any discrepancies between the non-German and the German version of these operating instructions, only the German version shall be authoritative. Only the latest revision of the operating instructions applies.

Due to constant technical development, the content of these MEDICON operating instructions is updated regularly. Please use the IFU-Website ifu.medicon.de to ensure that you are using the current version. The version date of the respective edition of the operating instructions is included in the printout. MEDICON eG assumes no liability for damage caused by improper use, incorrect postoperative conduct, care or maintenance, or non-compliance with the restrictions on use and other guidelines in the operating instructions. MEDICON eG will not accept liability either for changes or repairs made to the product without the prior written

authorisation of MEDICON eG, nor for repairs that were not carried out by workshops authorised by MEDICON eG or the MEDICON Repair Service (MRS).

11 Repair

Risk of injury from improper repairs.

- ▲ Only allow repairs to be performed by the manufacturer or by persons authorised by the manufacturer.
- ▶ Send the instrument back to the manufacturer in a reprocessed state and in its original packaging.

12 Disposal

Disposal of damaged instruments or of instruments that are not functionally reliable: To avoid a risk of infection to third parties, the instruments must be cleaned and sterilised before disposal.

In addition, the instruments must be disposed of in specific and appropriately labelled containers, in order to protect third parties from cutting injury. Observe the applicable national laws when disposing of reusable surgical instruments! The product, the packaging material and the accessories must be disposed of in accordance with the regulations and laws specific to the country in which they are used.

13 Description of symbols and icons

Icon	Description
	Manufacturer
	Production lot number, batch
	Item number
	Non-sterile
	Caution
	Observe the operating instructions
	CE label acc. to Directive 93/42/EEC
	Medical device
	Do not reuse