



IMPORTANT INFORMATION / PLEASE READ CAREFUL BEFORE USE

DIN EN ISO 9001 / EN 46001 / DIN EN ISO 13485 / MDD 93/42/EWG

CAUTION

Please read all information contained in this insert. Incorrect handling and care as well as misuse can lead to premature wear of surgical/dental instruments. All persons using this device should have knowledge in the use and handling of surgical instruments, accessories and related equipment.

INITIAL USE OF NEW INSTRUMENTS

Every instrument must be cleaned and sterilised before it is used for the first time.

All instruments, especially the bipolar forceps, were developed for sterilisation by autoclave and have shown good results using this method.

INSPECTION AND FUNCTIONAL CHECK

It is very important to carefully examine each surgical/dental instrument for breaks, cracks or malfunctions before use. It is especially essential to check areas such as blades, points, ends, stops and snaps as well as all movable parts.

Do not use damaged instruments. Never attempt to make repairs yourself. Service and repairs should be referred to trained qualified persons only. Refer questions about repair to the manufacturer or your biomedical engineering department.

CLEANING AND MAINTENANCE

Every surgical/dental instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Sterilise all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument.

Special attention should be paid to slots, stops, ends hollow tubes and other highly inaccessible areas. Do not use damaged instruments. If an instrument can be disassembled, it should be cleaned in the disassembled state. (Note: Keep all parts together and protected from being misplaced, do not intermix with other or similar devices of other manufacture.)

Cleaning and rinsing must take place immediately after each use for best effect. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilisation.

Instruments must be completely cleaned and rinsed of all foreign matter. Use warm water and a commercially available instrument presoak or cleaning agent. Enzymatic cleaners should be used to remove protein deposits.

- Do not use corrosive cleaning agents (i.e. bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best.
- Do not use abrasive cleaners.
- Only a soft bristle brush should be used.
- Rinse and maintain all parts and inaccessible areas like inside channels etc.
- Ultrasonic cleaners can be used. Check and retighten any fittings that may have vibrated loose.
- Can be disinfected in the washing machine up to 203°F (95°)
- Rinse thoroughly with distilled water.
- Prepare for storage and / or sterilisation.

After cleaning and rinsing, dry instruments completely and carefully with compressed air (Highly inaccessible areas like inside channels etc. have to be blown out).

NOTE: after cleaning and before sterilisation, treat all instruments with an oil which is considered as being physiologically safe (paraffin oil according to DAB 8 of Ph. Eur. USP XX.) especially their blades, ends, stops, snaps and all movable parts.

STORAGE AND STERILISATION

Instruments should be stored in a clean, dry moisture free area. The instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect tips with cloth, gauze or tubing if stored in drawers.

Steam autoclave sterilisation is recommended. Thoroughly clean instruments of all debris, tissue and foreign matter prior to sterilisation. Follow the sterilizer manufacturer's instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the instruments being sterilised including the internal surface and tubes channels. Allow instrument to air cool to room temperature before use.

STANDARD STERILISATION METHODS

Steam autoclave sterilisation is recommended. Do not sterilise in hot air. Standard autoclave cycle: Steam sterilise at 270°F (132°C) for 15 minutes. Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. (Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilisation times.) Autoclave temperatures should not exceed 280°F (137°C); handle or other non-metallic parts may be damaged.

STERILISATION OF OPTICS:SEE SEPARATE LEAFLET.

HANDLING

All surgical/dental instruments should be handled with the greatest care when being transported, cleaned, treated, sterilised and stored. This is especially true for blades, fine points and other sensitive areas. Surgical/dental instruments corrode and their functions are impaired if they come into contact with aggressive materials. The instruments should not be exposed to acids or other aggressive cleaning agents.

CUSTOM DEVICES

HELMUT ZEPF can develop and manufacture medical devices and accessories to better serve an individual physician's or patient's need. We have the expertise to handcraft devices to meet your particular specifications. Our staff will work with you to customise the products you require. Contact HELMUT ZEPF for more details. Should no special instructions be made, those products have to be maintained and cleaned according to this instruction sheet, too.

WARRANTY

All HELMUT ZEPF products are guaranteed to be free from defects in material and workmanship at the time of shipping. All of our products are designed and manufactured to meet the highest quality standards. We cannot accept any liability for failure of products which have been modified in any way from their originals, for any failure due to misuse or application which is not in accordance with the designer's intentions. Products will lose their right to carry the CE sign in case they will be changed or repaired at another place than HELMUT ZEPF or a company authorised by HELMUT ZEPF to do the change or repair.

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Anlage 2 VA 7.3.2	0	25.04.2003	Seite 1 von 1	Important info please read b use(0)_New_0906