

REPROCESSING OF HU-FRIEDY DENTAL HAND INSTRUMENTS AND ACCESSORIES

1.0 Fundamental Points

All non-sterile instruments are to be cleaned, disinfected, and sterilized prior to each use, and also prior to first use.

The person responsible for reprocessing (i.e. the operator) is responsible for proper instrument reprocessing using onsite equipment and safe procedures that are validated for cleaning, disinfection, and sterilization. The sterilization equipment must also be maintained and checked per the manufacturer's recommendation as well as the validated parameters applied to each cleaning and sterilization cycle.

Additionally, consider the legal provisions valid for your country as well as to the hygienic instructions of the doctor's practice or hospital. Use only freshly prepared detergent solutions, as well as only low contaminated and deionized water (maximum 10 cfu/ml) as well as low endotoxin contaminated water (maximum 0.25 endotoxin units/ml), i.e. aqua purificata (highly purified water acc. Pharmacopeia), and HEPA-filtered air for drying, respectively.

Water quality may influence the result of the cleaning and disinfection of the instruments. Corrosion could be caused by high contents of chloride or other minerals in the tap water. If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in your area. With the use of completely deionized or distilled water most water quality problems can be avoided beforehand.

Within the EU, all used and contaminated Instruments must be handled with protective gloves fulfilling the requirements of regulation (EU) 2016/425. Hu-Friedy provides such protective gloves (Partcodes: Size 7 = 40-060; Size 8 = 40-062; Size 9 = 40-064; Size 10 = 40-066). Contaminated Instruments must be disinfected as early as possible in the reprocessing process, in order to maximize safety for staff members when handling contaminated instruments.

Using an instrument management system like the Hu-Friedy IMS system gives you considerable benefits. It is the ideal solution for arranging your instruments in an organized manner, cleaning, disinfecting, sterilizing and storing in an efficient way, providing maximum security.

In case of a serious incident that has occurred in relation to our devices within the European Union, please report by either calling Hu-Friedy for assistance Tel 00800 4837 4339 or send an e-mail to info@hu-friedy.eu. In addition, please inform your national competent authority.

2.0 Receiving a new Instrument

After receiving a new instrument, make sure you follow the initial cleaning, disinfection and sterilization steps before using it for the first time. This step is essential for the patient's health.

3.0 Instrument Reprocessing Steps

If possible, an automatic procedure in a Washer / Disinfector unit should be used for cleaning and disinfection of the instruments. A manual procedure - even in case of application of an ultrasonic bath - should only be used if an automatic procedure is not available or if such a method is not compatible with specific materials; in this case, the significantly lower efficiency of a manual procedure must be considered. The pre-treatment has to be performed in both cases.

All assembled instruments must be <u>disassembled before reprocessing</u> (for further details, please see 9.0 Special Procedures section). Effective cleaning and disinfection are an indispensable requirement for proper instrument sterilization.

3.1 Pre-Treatment

Before processing the instruments, <u>remove coarse impurities</u> on the instruments immediately after application <u>and pre-treatment within</u> <u>one hour</u> from the application. In case the instruments are transported to an external service provider, ensure the instruments remain soaked to avoid fixation of proteins e.g. by using a pre-cleaning product such as Enzymax Spray Gel (IMS-1229).

Use an <u>enzymatic cleaner</u>, e.g. Hu-Friedy Enzymax (Partcodes: Enzymax Liquid: IMS-1222, IMS-1224, IMS-1226, or Enzymax Powder: IMS-1230, IMS-1232) <u>or a disinfectant solution during pre-soaking</u>.

The disinfectant should...

- be free of aldehydes to prevent fixation of blood impurities,
- possess a fundamentally approved efficiency (i.e. DGHM, RKI approval or CE marking),
- be suitable for the disinfection of medical devices and
- be compatible with the instruments (see 7.0 Material resistance section and 9.0 Special Procedures section).

Consider, that the disinfectant used in the pre-treatment step serves only for personal safety and cannot replace the disinfection step, which should be performed later.

Only use soft brushes such as Art. No. 1003414000 (Schellenberger), Art. No. MED100.33, MED100.43, MED100.18, or MED100.17 (Insitumed).





PROCEDURE:

Completely disassemble the instruments, if applicable.

Pre-soak the devices for at least 5 minutes* and make sure that all surfaces are wetted and lumens are filled with water. Brush the instruments to remove residues from the surface, paying special attention to lumens and dead ends. Also make sure that movable parts are brushed in open and closed position.

Difficult to reach positions such as hinges, mating surfaces, lumens or dead ends shall be flushed at least 3 times with minimum 50 ml cold deionized water, using a syringe or a rinsing adapter.*

* These parameters are validated for Enzymax Liquid. For other cleaning agents and disinfectants, the instructions of the manufacturer must be observed.

3.2 Cleaning and Disinfection

3.2.1 Automatic Cleaning and Disinfection in a Washer-Disinfector Unit

When using a Washer-Disinfector unit, make sure that...

- the efficiency is fundamentally approved (e.g. EN ISO 15883, DGHM approval, CE marking),
- your process is validated, including equipment, detergents, temperatures, durations and loading, and
- regular maintenance and inspection/calibration is done.

For the selection of detergents to be used with the Washer-Disinfector unit, consider the following items:

- Fundamental suitability for cleaning of medical devices
- Compatibility with the instrument materials (see 7.0 Material resistance section and 9.0 Special Procedures section)
- Detergent manufacturer instructions regarding concentration and soaking time

PROCEDURE:

<u>Connect</u> devices with <u>lumen</u> to flush ports in the washer-disinfector. Load the washer-disinfector as validated. Start the validated program.

Remove the instruments after end of program. Let the instruments dry.

Conduct <u>post-disinfection steps</u> (see section 4.0)

The fundamental suitability of the instruments for an effective automatic cleaning and disinfection was demonstrated by an independent accredited test

Washer-Disinfector	Miele Professional G 7836 CD	
Racks	Mobile injector unit (Miele) E429, Four-level rack (Miele) E 493	
Cleaning Cycle	 2 minute pre-cleaning with cold tap water Draining 5 minute cleaning with 55 °C cleaning solution Draining 3 minute rinsing with cold deionized water Draining 2 minute rinsing with cold deionized water Draining 2 minute rinsing with cold deionized water Draining 	
Cleaning Solution	0.5 % cleaning solution neodisher® Mediclean Dental (Chemische Fabrik Dr. Weigert, Hamburg)	
Validation Report	tion Report Project Number: 00418-1 Examination of an Automated Cleaning Process using quantitative Detection of Protein and Hemoglobin and the Radionuclide Method	

The responsibility for reprocessing of Hu-Friedy instruments according to parameters which are not specified in this document lies with the customer.

3.2.2 Manual and Ultrasonic Cleaning and Disinfection

For the selection of detergents to be used for manual cleaning and disinfection, consider the following items:

- Fundamental suitability for cleaning of medical devices.
- Approved efficiency (e.g. VAH/DGHM, RKI approval or CE marking).
- Compatibility with the instrument materials (see 7.0 Material resistance section and 9.0 Special Procedures section).
- Detergent manufacturer instructions regarding concentration, temperature and soaking time

Combined cleaning/disinfection solutions should be used only in the case of extremely low contamination (no visible impurities), unless indicated explicitly otherwise by the manufacturer of the combined detergent/disinfectant.





CLEANING PROCEDURE:

<u>Place</u> the devices in an <u>ultrasonic bath</u> containing a cleaning solution at min. 45°C for at least 15 minutes*. At the beginning of the soak time <u>flush the lumens</u> with 5 ml of the cleaning solution using a syringe.

Non-rigid components shall be operated during the immersion.

Difficult to reach positions such as hinges, mating surfaces, lumens or dead ends <u>shall be flushed</u> at least 3 times with minimum 50 ml cold deionized water, using a syringe or a rinsing adapter.*

<u>Remove</u> the instruments from the cleaning solution.

<u>Rinse</u> the instruments under running water for at least 1 minute.

Inspect optically for proper cleaning.

^b These parameters are validated for Enzymax Liquid. For other cleaning agents and disinfectants, the instructions of the manufacturer must be observed.

DISINFECTION PROCEDURE:

<u>Soak</u> the devices in the <u>disinfectant solution</u> for the duration intended by the disinfectant manufacturer.

Make sure they are <u>completely immersed</u>.

Difficult to reach positions such as hinges, mating surfaces, lumens or dead ends shall be flushed with the disinfectant, using a syringe or a rinsing adapter.

Non-rigid components shall be operated during the immersion

<u>Remove</u> the instruments from the disinfectant.

<u>Rinse</u> the instruments under deionized water for at least 1 minute*.

Let the instruments <u>dry.</u>

Conduct <u>post- disinfection steps</u> (see sections 4.0)

* These parameters are validated (Validation Report: 10918-1)

The fundamental suitability of the instruments for an effective automatic cleaning and disinfection was demonstrated by an independent accredited test laboratory under the following conditions:

Cleaning Solution	0.8 % Enzymax Liquid (Hu-Friedy Mfg. Co., LLC, USA)
Validation Report	Project Number: 00418-2 Examination of a Manual Cleaning Process using quantitative Detection of Protein and Hemoglobin and the Radionuclide Method

The responsibility for reprocessing of Hu-Friedy instruments according to parameters which are not specified in this document lies with the customer.

4.0 Post- Disinfection Steps

4.1 Inspection and Maintenance

If there are still <u>contamination</u> attached to the instruments, clean and disinfect again.

Inspect all instruments after the cleaning and disinfection step for <u>corrosion and damaged surfaces</u>, Light corrosion on the surface can be removed with Hu-Friedy Penetrating Oil (IPS). After treating an instrument with IPS, the instrument must be cleaned and sterilized once more. **If the corrosion cannot be eliminated or other surfaces are identified**, **do not further use those instruments**. Keep in mind that instruments shall no longer be reused in case the <u>labelling</u> is fading.

<u>Re-sharpen</u> instruments if necessary. Afterwards, completely remove any residues, such as metal residue or sharpening oil. <u>Assemble</u> disassembled instruments if necessary (see 9.0 Special Procedures section).

Hinged instruments have to be lubricated with a lubricant suitable for steam sterilization, like Hu-Friedy Instrument Lubricant Spray (ILS).

4.2 Packaging

All instruments must be completely dry before packaging. Then, package immediately.

We recommend the use of a cassette system, like the Hu-Friedy IMS System and Hu-Friedy Bagettes (pouches) or Hu-Friedy Sterilization wrap (Hu-Friedy IMS-1210M, IMS-1211M, IMS-1212M or suitable sterilization containers, if the following requirements are fulfilled:

- Conformity with EN ISO/ANSI AAMI ISO 11607-1 and 2 and applicable parts of EN 868
- suitable for steam sterilization (temperature resistance up to at least 141 °C (286 °F), sufficient steam permeability)
- sufficient protection of the instruments and the sterilization packaging against mechanical damage
- regular maintenance according to the manufacturer's instructions (Sterilization Containers: limitations also see 9.0 Special Procedures section)

5.0 Sterilization

Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user.





Restrictions:

The flash sterilization procedure must not be used!

Do not use radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization, or plasma sterilization!

The application of dry heat sterilization is the responsibility of the user. For some products the dry heat sterilization procedure has been explicitly excluded (Please see 9.0 Special Procedures section).

5.1 Steam Sterilization

For sterilizing, please remember the following:

- maximum sterilization temperature of 138 °C (280 °F)
- Minimum exposure time to sterilization temperature:
 - 20 minutes at 121 °C (250 °F) or
 - 5 minutes at 132 °C (270 °F)/
 - 4 minutes at 134 °C (273 °F)
- The manufacturer's instructions with respect to routine inspection and the regular maintenance of the Sterilizer must be observed.
- The sterilizer must be maintained per manufacturer's recommendation.
- Only low contaminated and deionized water (i.e. aqua purificata) should be used.
- The sterilized items have to be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

STERILIZATION PROCEDURE:

Use properly installed and validated sterilizers, following instructions of the manufacturer. Load sterilizer as recommended by the manufacturer. Run validated program.

The fundamental suitability of the instruments for an effective sterilization was demonstrated by an independent accredited test laboratory under the following conditions:

Sterilization Method	Pre-vacuum Mode
Sterilizer	W & H Lisa MB 17 Steam Sterilizer
Sterilization Temperature	134 °C (273°F)
Pre-Vacuum Phases	3
Holding (full cycle)	4 minutes
Drying Time	30 minutes*
Validation Report	Project Numbers: 25517-1; 25517-2 Validation of a Sterilization Process using Steam Sterilization in Pre-vacuum Mode Method MD 4.0: Sterilization validation of medical products with moist heat Project Numbers: 10918-1; 10918-2 Determination of Residual Moisture after Sterilization using Steam Sterilization in Pre-vacuum Mode

The responsibility for reprocessing of Hu-Friedy instruments according to parameters which are not specified in this document lies with the customer.

6.0 Transport and Storage of Reprocessed Instruments

Please store the instruments after sterilization in a dry and dust free place.

Sterilization can only be maintained, if the instruments remain packaged or wrapped - impermeable to micro-organisms - following validated standards. The status of the sterilization has to be clearly indicated on the wrapped packages or the containers. In case the reprocessed instrument is transported, make sure to use air-conditioned vehicles in order to avoid condensate formation. For safety reasons, keep sterile and non-sterile instruments strictly apart.

7.0 Material resistance

We <u>recommend</u> not to use <u>detergents</u> such as strong alkalines (> pH 9), strong acids (< pH 4) phenols or iodophors, interhalogenic agents/ halogenic hydrocarbons/iodophors, strong oxidizing agents/peroxides and organic solvents.

Do not clean any instruments, sterilization trays or sterilization containers using metal brushes or steel wool!

<u>Do not expose</u> any instruments, cassettes, trays or sterilization containers to <u>temperatures higher than 141 °C (286 °F)!</u> Exposure to higher temperatures is the responsibility of the user.

Please also consider the information under the 9.0 Special Procedures section.



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8.0 Reusability and Single Use

8.1 Reusability

<u>The user is responsible for inspecting instruments prior to each use, and for the use of damaged and dirty instruments.</u> The instruments can be reused, unless indicated otherwise (see 9.0 Special Procedures section). The lifetime of instruments depends on the frequency of use, the care by the user and proper reprocessing methods. Please contact your local Hu-Friedy agent with questions about the expected life of any Hu-Friedy product.

8.2 Single Use

Single use instruments are intended and manufactured for one use only.

9.0 Special Procedures for Specific Hu-Friedy Instruments

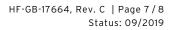
Aluminium Instruments	Cleaning / Disinfection:
	- Use neutral cleaning agents and disinfectants suitable for Aluminium.
	- Check cleaning agent label for precautions for use with Aluminium.
	- Do not clean in an ultrasonic cleaner.
	- Clean by hand or in a Washer-Disinfector unit.
	Processing:
	Note: Anodized aluminium instruments, when processed with Stainless Steel instru-
	ments may cause an adverse chemical reaction.
Carbon Steel	Processing:
	- Clean, disinfect and sterilize separately.
Instruments	 Do not clean, disinfect or sterilize with other stainless-steel instruments.
	- Do not clean / disinfect in a Washer-Disinfector unit.
Hinged Instruments	Processing:
ningeu instruments	 Process in an open state and lubricate using Instrument Lubricant Spray (ILS) prior
	to sterilization.
Oversized Instruments	Note: If instruments do not fit in cassettes, other systems should be considered for re-
	processing. Please call Hu-Friedy for assistance Tel 00800 4837 4339 or send an e-mail
	to info@hu-friedy.eu.
Aspirators and	Processing:
Aspirator Tips	- Clean, disinfect and sterilize only in a completely disassembled state.
	Cleaning / Disinfection:
	- For automated cleaning and disinfection in a Washer-Disinfector unit connect-
	ing rinsing adapters must be used, if the inserts are processed inside a cassette
	system. Otherwise open tray systems for automated cleaning and disinfection or
	manual cleaning and disinfection is recommended (no Ultrasonic cleaning and
	disinfection!).
Chu's Aesthetic Tool Kit	Note: The tip will last for approximately 5 reprocessing cycles.
Tips	
i ips	Processing:
	- Clean, disinfect and sterilize with tip and handle disassembled.
	- Tips with fading markings should be replaced.
	- Do not disinfect with phenols or iodophors.
	- Do not use dry heat.
Colorvue-Tips	Note: The tip shall be disposed after a maximum of 30 reprocessing cycles.
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	Processing:
	- Clean, disinfect and sterilize with tip and handle disassembled.
	- Tips with a fading black marking should be replaced.
	- Do not disinfect with phenols or iodophors.
Comments Dr. (11)	- Do not use dry heat or rapid heat sterilization.
Composite Brush Handle	Processing:
	- Clean, disinfect and sterilize in a completely disassembled state.





Container for Sterilization	Processing:
and Accessories	- For reprocessing, the lid of the Container and the filter holding devices in the base and the lid must be removed.
	- If single use paper filters have been used, they must be removed before repro- cessing. Indicators must be removed from the label holding device.
	 Cleaning / Disinfection: For the cleaning and disinfection of anodized Aluminium Sterilization Containers only detergents and disinfectants can be used which are approved for this material.
	- For the reprocessing in a Washer-Disinfector unit the components of the Contain- er have to be placed securely in the washing baskets. Spraying nozzles and arms should not be blocked. Do not use acid neutralizers for the reprocessing of Alu- minium Containers.
	- Container made of Aluminium cannot be cleaned or disinfected in an Ultrasonic Cleaner Unit.
	- Container-Cassettes may be cleaned and disinfected with all procedures recom- mended for IMS-cassettes.
	- Permanent Filters of Teflon may be cleaned and disinfected in a Washer-Disinfec- tor unit.
	 Wrapping Drapes for aseptic removal must be cleaned with the standard proce- dures for clinical or dental office textiles, before reuse. Do not starch wrapping drapes
	 Sterilization: Sterilization Containers made of anodized Aluminium have been developed especially for sterilization in Steam Sterilizers with pre-vacuum, fractioned vacuum or fractioned flow processes. Hu-Friedy Sterilization Containers cannot be used for other sterilization methods.
	 Maintenance: The surface of Aluminium Containers is very sensitive in respect to mechanical impact. For this reason, do not use metal brushes or scouring agents.
	 For the removal of stains, residues of inscriptions or adhesive tapes only a commercial cleaner for anodized Aluminium may be used (no benzine or acetone!) After such treatment the Containers must be cleaned once more.
Crown Remover (CRL, CRU)	Processing: - Clean, disinfect and sterilize in a completely disassembled state.
	Cleaning / Disinfection: - Do not disinfect with phenols or iodophors.
	Sterilization: - Do not sterilize with dry heat.
IMPLACARE	Sterilization: - IMPLACARE disposable resin tips can be steam sterilized prior to use. - They are intended for one use only! - Clean, disinfect and sterilize in a completely disassembled state.
Mallet	Processing: - Clean, disinfect and sterilize in a completely disassembled state.
Mouth Gags (MGA, MGC, MGI)	 Processing: When using a cassette system for cleaning/sterilization, the opening where the nylon tubing slips over the instrument tip must not be covered so as to allow the tips to properly drain. Clean, disinfect and sterilize in a completely disassembled state.







Mouth Mirrors	Processing:
	 To avoid scratches on the mirror surface from other pointed instruments, reprocess
	in an instrument cassette with instrument rails.
	- Clean, disinfect and sterilize in a completely disassembled state.
	Cleaning / Disinfection:
	Note: All types of Rhodium coated Mouth Mirrors should not be cleaned and disinfected
	in an ultrasonic cleaner.
O-Rings	Sterilization:
	- O-Rings cannot be dry heat sterilized
Osteotomes and	Processing:
Osteotome Handles	Clean, disinfect and sterilize in a completely disassembled state if applicable.
Plastic Filling Instruments	Processing:
	 Process in cassettes or trays with instrument rails to avoid scratches on the sur- face from other pointed instruments.
	Maintenance:
	- Residues of Filling Materials and etching products must be removed immediately.
	 Plastic Filling Instruments are designed with an extra smooth surface, in order to provide a batter bandling with composite materials. Scratches that are not visible
	provide a better handling with composite materials. Scratches that are not visible might cause composite materials to stick to the rougher surface.
Resin Instruments, Resin	Cleaning / Disinfection:
Components or Resin Cas- settes	 For resin or silicone products do not use detergents or disinfectants containing phenols or iodophors.
	Sterilization:
	- Dry Heat is explicitly not compatible with Instruments with resin handles (handle
	#8), with resin or Silicone components, inserts on any instruments, or with resin cassettes.
Retractors, Metal	Processing:
	 Removable retractor tips must be disassembled from the handle before cleaning/ disinfection and sterilization.
Retractors, Plastic	Cleaning / Disinfection:
(CRPC, CRPA)	 Can only be disinfected by chemical disinfection. Do not clean / disinfect in a Washer-Disinfector unit.
	Sterilization:
	- Do not sterilize (steam, dry heat etc.)!
Root Canal Instruments	Processing:
	- Reprocess in suitable endodontic stands (i.e. Hu-Friedy IMS-1275).
	Cleaning / Disinfection:
	- Pre-treatment should be conducted outside the Endodontic stand.
	- Automated cleaning and disinfection in a Washer-Disinfector unit is recommend-
	ed. - Ultrasonic cleaning in the Endodontic stand is not recommended.
	on a some eleaning in the Endodonne stand is not recommended.
Scalpel Handles	 Processing: Clean, disinfect and sterilize in a completely disassembled state.







Scaler marked with Color	Processing:
	 For reprocessing, attached Color Coding Rings do not have to be removed
Coding Rings (IMS-1280L, IMS-1286L, IMS-1281,	· · · · · · · · · · · · · · · · · · ·
	Validation reports:
IMS-1287, IMS-12810, IMS-1287L,	- Project Number:00418-1
IMS-12810L, IMS-1288, IMS-12811,	Examination of an Automated Cleaning Process using quantitative Detection of
IMS-1288L, IMS-12811L, IMS-1289,	Protein and Hemoglobin and the Radionuclide Method
IMS-1281L, IMS-1289L, IMS-1282,	07-Jun-2018
IMS-1282L, IMS-1283, IMS-1283L,	- Project Number: 00418-2
IMS-1284, IMSö1284L, IMS-1234,	Examination of a Manual Cleaning Process using quantitative Detection of Protein
IMS-1285, IMS-1285L, IMS-1280,	and Hemoglobin and the Radionuclide Method
IMS-1286)	07-Jun-2018
	- Project Number: 25517-1
	Validation of a Sterilization Process using Steam Sterilization in Pre-vacuum Mode
	Method MD 4.0: Sterilization validation of medical products with moist heat
	12-Dec-2018
	- Project Number: 25517-2
	Validation of a Sterilization Process using Steam Sterilization in Pre-vacuum Mode
	Method MD 4.0: Sterilization validation of medical products with moist heat
Syringes	12-Dec-2018 Processing:
Synnges	- Completely disassemble including unscrewing of the cylinder.
Ultrasonic Inserts,	Processing:
Magnetostrictive	- Ultrasonic cleaning and disinfection as well as steam sterilization can be affected
	in suitable Hu-Friedy IMS-Cassettes.
	Cleaning / Disinfection:
	- For automated cleaning and disinfection in a Washer-Disinfector unit connecting
	rinsing adapters must be used, if the inserts are processed inside a cassette sys-
	tem. Otherwise open tray systems for the automated cleaning and disinfection or
	alternatively the manual cleaning and disinfection procedure are recommended.
	Sterilization:
	- For sterilization use steam sterilization only. Do not expose to phenols or iodo-
	phors.
	- Do not use dry heat sterilization, or heat above 135 °C (275 F).
Illeracania Incarta	Processing:
Ultrasonic Inserts,	 Piezo Ultrasonic Inserts remain in the Guardian during the complete reprocessing
Piezo with Guardian	cycle, also if reprocessed in cassettes.
	- Ultrasonic cleaning and disinfection as well as steam sterilization can be affected
	in suitable Hu-Friedy IMS-Cassettes.
	III Suitable Hu Theuy IMS Cassettes.
	Sterilization:
	- For sterilization use steam sterilization only.
	- Do not expose to phenols or iodophors.
	 Do not use dry heat sterilization, or heat above 135 °C (275 F).
Ultrasonic Piezo Handpiece	Sterilization:
	- The Piezo handpiece can be steam sterilized with all types of Steam Sterilizers at
	134°C/15minutes. Other sterilization parameters are not permitted.
360 Knife	Processing:
(K360)	- Clean, disinfect and sterilize with fixation screw unscrewed.