H&H COMPANY
FINEST QUALITY INSTRUMENTS

STERILIZATION OF HAND-HELD INSTRUMENTS AND THEIR ACCESSORIES

GENERAL REMARKS
New instruments always must pass through the complete cycle of instrument reprocessing at least once prior to first use, as described in the section "**Steps in Instrument Reprocessing**". All instruments must be cleaned, disinfected and sterilized before each use. Following removal from the protective packaging, all non-sterile instruments must also be cleaned, disinfected and sterilized before first use. Effective cleaning and disinfection constitute an absolute precondition for proper sterilization of the instruments. The user is responsible for the sterility of the instruments. Therefore, make sure only validated methods are used for cleaning, disinfection and sterilization. Sterilization equipment must also be serviced and checked at regular intervals. The validated parameters for the cleaning and sterilization cycles must also be checked regularly. Comply with the exceptions applying to reprocessing of certain instruments in the section "**Special Methods".** Also comply with the legal requirements valid in your country and the hygiene regulations of the medical practice or hospital. Improper handling and care or use for purposes for which they are not intended may result in premature wearing out of surgical / dental instruments. Persons using these instruments should be familiar with use and handling of surgical/dental instruments, accessories and related devices.

INSPECTION AND FUNCTIONAL CHECK
It is very important to inspect each surgical/dental instrument for ruptures, cracks or malfunction prior to each use. Above all, areas such as the cutting edges, tips, closures, locks and catches, as well as all moving parts, must be carefully checked. Never use damaged instruments. Do not carry out repairs yourself. Service and repairs must be done by properly trained personnel only. If you have any questions in this regard, please call H & H Company.

PROTECTION OF PERSONNEL AND THIRD PARTIES
Protective gloves that comply with the specifications from OSHA must be worn when handling all used and contaminated instruments to maximize the safety of personnel handling contaminated instruments. In the stage of reprocessing, contaminated instruments must be cleaned and disinfected promptly, but not later than within 6 hours. After the treatment of a patient being infected with the Creutzfeldt-Jakob Disease, the instruments must neither be reused nor reprocessed. These instruments must be disposed of.

STEPS IN INSTRUMENT REPROCESSING
RKI CLASSIFICATION
Semi-critical: Instruments that come into contact with mucosa or pathologically changed skin.
Detail classification semi-critical "A": This group includes e.g. orthodontic forceps and other orthodontic instructions and / or instruments intended solely for this application.
Detail classification semi-critical "B": Rotating instruments not intended for invasive surgical applications. This group includes, e.g.: Instruments for general preventive, restorative or orthodontic treatment.
Critical medical devices: Invasive surgical devices. Medical devices for use of blood, blood products and other sterile medicinal products and medical devices that penetrate skin or mucosa and thereby come into contact with blood, internal tissues or organs, including wounds.
Detail classification critical "A": No special reprocessing specifications. This group includes e.g. universal procedures, probes, PA probes, tweezers, PA curettes, chisels, hoes, PA scalpels, endo instruments, forceps, clamps and needle holders, filling and modelling instruments, excavators, matrix retainers, Benex extractors, root extractors, periotomes, spacers and retractors, scissors, raspatories, scrapers, osteotomes, bone mills, sinus lift elevators and raspatories, measuring instruments.
Detail classification critical "B": With more stringent reprocessing specifications since cleaning effectiveness cannot be directly assessed by inspection. This group includes e.g. medical suction devices, water syringes, hollow cylinder osteotomes, trephines and membrane punches.

PRE-TREATMENT
Remove coarse soiling from instruments immediately after use (within max. 2 hours) before further processing in a tray/cassette system. Contaminated instruments must undergo pre-treatment within a maximum of 2 hours after use.
 Do not place in NaCI solutions (otherwise risk of pitting or stress corrosion cracking).
 Use only a released solution combing cleaning and disinfectant agents, (i.e. with DGHM or RKI approval or CE label) with no protein-fixing effect (be sure to following manufacturer recommendations for mixing).
 Avoid overfilling instrument sieves and wash trays.
 Always clean and disinfect jointed instruments in open position. Use only a soft brush, with long handle as needed, for manual removal of coarse soiling. Never use metal brushes or steel wool.
As applicable: Manual precleaning of hollow spaces shall be performed. The protection of personnel must be observed. Personal protective equipment (PPE) must be used. Manual precleaning must be performed under the water level (splash guard). Remember that the disinfectants used in pre-treatment are for personal safety only and cannot replace the subsequent disinfection step.

AUTOMATIC CLEANING
Equipment: Cleaning / disinfection device, cleaning agent
1. Place jointed instruments in the device with opened joints so that water can drain out of cannulas and blind holes.
2. Set cycle, wash for at least X minutes* and rinse for at least X minutes* (*see manufacturer's instructions).
3. When removing the instruments check cannulas, blind holes, etc. for visible soiling. Repeat cycle or clean manually if necessary.

MANUAL CLEANING
Equipment: Cleaning agent, brush, running water
1. Rinse surface soiling off the instrument thoroughly.
2. Use a brush to apply cleaning solution to all surfaces. Be sure to clean jointed instruments in both the opened and closed positions.
3. Hold instrument under running water. The running water must flow through the cannulas and blind holes must be filled and emptied repeatedly.

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Comment: Use a brush suitable for reaching the entire surface when cleaning cannulas and blind holes.

DISINFECTION
Both neutral pH and alkaline cleaning agents can be used. Disinfectant solutions can be used according to the instructions on the label (see manufacturer information). The automatic cleaning can be followed by cleaning and disinfection at 93° C / 200° F for 10 minutes (see manufacturer information for cleaning and disinfection unit). Use deionized water for the final rinse if possible. This will avoid spots, deposits and corrosion on the rinsed items.

DRYING
For a drying phase performed as part of a cleaning / disinfection cycle the temperature should not exceed 93° C / 200° F.

MAINTENANCE
Apply a very small amount of high-quality silicone spray or medical white mineral oil to the joints and movable parts. Sort out dull or damaged instruments. Check for cracks and damage. Check for proper functionality.

CONTROL AND FUNCTIONAL TEST
Check jointed instruments for ease of movement (avoid excessive play). Check locking mechanisms (locking wheel) for functionality.
All instruments: Carry out visual inspection for damage and wear. Cutting edges should be free of notching and uniform. Check long, narrow instruments (in particular jointed instruments) for damage. Instruments that are part of a larger assembly must be checked together with the respective parts.

PACKAGING
Individual: Standardized packaging material can be used. The bag must be large enough for the instrument, so the closure is not strained.
Sets: Sort instruments into appropriated trays or place on relevant sterilization trays. Cutting edges must be protected. Package trays using a suitable method.

STERILIZATION
The sterilizer and sterilization method must comply with the valid and applicable standards and directives. EN 13060 Small Steam Sterilizers distinguishes 3 classes of autoclave:
Type B for packaged, massive, hollow and porous devices
Type N for unpackaged, massive instruments
Type S for devices as listed by small sterilizer manufacturers
 Gravitational method (with sufficient device drying)
 Steam sterilizer acc. to DIN EN 13060 / DIN EN 285
 Validated acc. to DIN EN ISO/ANSI AAMI ISO 17665-2 (valid commissioning and device-specific performance assessment)
 Maximum sterilization temperature 134° C / 273° F; plus, tolerance as per DIN EN ISO/ANSI AAMI ISO 17665-2
 Sterilization time (exposure time at sterilization temperature) at least 20 min. at 121° C / 250° F or 4 min. at 132° C / 270° F

IMPORTANT: Rapid sterilization leads to high instrument wear levels.
Additional information: When sterilizing several instruments in a sterilization cycle, the maximum sterilizer charge must not be exceeded (see manufacturer information).

STORAGE
Store instruments in dry rooms, protected from dust, to avoid formation of condensation.

EXCEPTIONS!
See the reprocessing specifications for the items in the following list: The instruments listed below are made in part from chrome-plated parts for technical reasons and must not be placed in the thermal disinfector or ultrasound bath.
 Cylinder ampoule syringe thumb ring
 Replaceable ampoule holder
 Ointment cannulas
 Napkin chain
 Mouth mirror
 Resection mirror
 Chrome-plated instruments

CUSTOM-MADE INSTRUMENTS
H & H Company develops and manufactures instruments according to customer specifications to produce custom-made products that satisfy individual customer needs. If not, specific information is provided, maintenance and care of these products must also follow these instructions.

GUARANTEE
H & H Company supplies only tested and defect-free products to its customers. All our products are designed and manufactured to comply with the most stringent quality requirements. We assume no liability for products that have been altered compared to the original, used for purposes for which they were not intended or used improperly. Products that are repaired or altered at any company other than H & H Company will have the warranty voided.

The above instructions have been validated as SUITABLE for preparation of a medical device for its reuse by the medical device manufacturer. The preprocessor bears responsibility for achieving the desired results of the actual reprocessing with the equipment, materials and personnel used in the reprocessing facility for that purpose. This normally requires validation and routine monitoring of the process. Also, any deviation from the instructions provided on the part of the reprocessing should be carefully assessed for effectiveness and possible negative effects.