REPROCESSING INSTRUCTIONS

1. All non-sterile instruments are to be cleaned, disinfected, and sterilized prior to each use, and also prior to first use.
2. 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 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.
3. Within the EU, all used and contaminated Instruments must be handled with protective gloves fulfilling the requirements of regulation (EU) 2016/425.
4. After receiving a new instrument, make sure you follow the initial cleaning, disinfection, and sterilization steps before using it for the first time. 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 must be performed in both cases.

PROCEDURE (PRE-TREATMENT):

Before processing the instruments, remove coarse impurities on the instruments immediately after application and pre-treatment within one hour 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. Use an enzymatic cleaner or a disinfectant solution during pre-soaking. The disinfectant should:

a. be free of aldehydes to prevent fixation of blood impurities,
b. possess a fundamentally approved efficiency (i.e. DGHM, RKI approval or CE marking)
c. be suitable for the disinfection of medical devices.
d. be compatible with the instruments.

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

- 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.*

REPROCESSING INSTRUCTIONS

PROCEDURE (AUTOMATIC WASHER-DISINFECTOR):

- Washer-Disinfector unit mut meet the requirements of ISO 15883 as per section 6.6.2.1
- Connect devices with lumen to flush ports in the washer-disinfector.
- Load the washer-disinfector as validated.
- Start the validated program.
- Remove the instruments after the end of program.
- Let the instruments dry.
- Conduct post-disinfection steps.

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:

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
Cleaning Solution	0.5 % cleaning solution neodisher® Mediclean Dental (Chemische Fabrik Dr. Weigert, Hamburg)
Validation 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 Julius Wirth brand instruments according to parameters which are not specified in this document lies with the customer.

PROCEDURE (MANUAL CLEANING):

- Place the devices in an ultrasonic bath containing a cleaning solution at min. 45°C for at least 15 minutes*.
- At the beginning of the soak time flush the lumens 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 shall be flushed at least 3 times with minimum.
- 50 ml cold deionized water, using a syringe or a rinsing adapter. *
- Remove the instruments from the cleaning solution.
- Rinse the instruments under running water for at least 1 minute.
- Inspect optically for proper cleaning.

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

PROCEDURE (MANUAL DISINFECTION):

- Soak the devices in the disinfectant solution for the duration intended by the disinfectant manufacturer.
- Make sure they are completely immersed.
- 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.
- Remove the instruments from the disinfectant.
- Rinse the instruments under deionized water for at least 1 minute*.
- Let the instruments dry.
- Conduct post- disinfection steps.

* 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 Julius Wirth brand instruments according to parameters which are not specified in this document lies with the customer.

5. Post-Disinfection Steps
    a. Inspection and Maintenance: If there is still contamination attached to the instruments, clean and disinfect again. Inspect all instruments after the cleaning and disinfection step for corrosion and damaged surfaces. Instruments that exhibit corrosion that cannot be removed should be removed from use. Otherwise, such corrosion could damage other instruments.
    b. Re-sharpen instruments if necessary. Afterwards, completely remove any residues, such as metal residue or sharpening oil. Assemble disassembled instruments if necessary.
    c. Hinged instruments must be lubricated with a lubricant suitable for steam sterilization.
    d. All instruments must be completely dry before packaging. Then, package immediately.
6. Sterilization: Please use only the recommended steam sterilization procedure listed below. Other sterilization procedures are the responsibility of the user.
    a. We recommend the use of a cassette system or sterilization wraps that are:
        i. In conformity with EN ISO/ANSI AAMI ISO 11607-1 and 2 and applicable parts of EN 868.
        ii. Suitable for steam sterilization
            1. Temperature resistance up to at least 141°C (286 °F)
            2. Sufficient steam permeability
            3. Sufficient protection of the instruments and the sterilization packaging against mechanical damage
    b. Steam Sterilization: For sterilizing, please remember the following:
        i. Maximum sterilization temperature of 138 °C (280 °F)
        ii. Minimum exposure time to sterilization temperature: 4 minutes at 134 °C (273 °F)
        iii. The sterilizer must be maintained per manufacturer's recommendation.
        iv. Only low contaminated and deionized water (i.e. aqua purificata) should be used.
        v. The sterilized items must be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

REPROCESSING INSTRUCTIONS

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

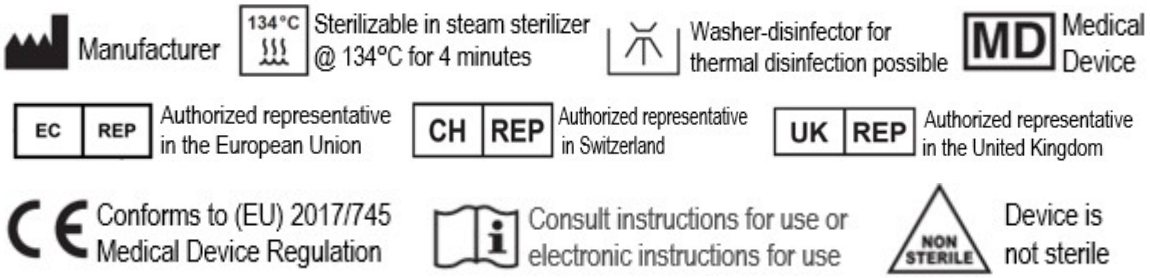
The responsibility for reprocessing Julius Wirth brand instruments according to parameters which are not specified in this document lies with the customer.

7. Storage and Transportation

   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 must be clearly indicated on the wrapped packages or the containers. In case the reprocessed instrument is transported, make sure to use air-conditioned vehicles to avoid condensate formation. For safety reasons, keep sterile and non-sterile instruments strictly apart.

8. The user is responsible for inspecting instruments prior to each use, and for the use of damaged and dirty instruments. The lifetime of instruments depends on the frequency of use, the care by the user and proper reprocessing methods.

9. Symbols Glossary:



10. **Failure to follow the above instructions may result in a risk of contamination with the potential for patient infection.**

According to the EU Medical Device Regulation, users / patients are obligated to report serious events with a Medical Device to the manufacturer and to the competent authority of the country in which they occurred.

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