These instructions are recommended for the care, cleaning, disinfection, maintenance and sterilisation of NICHROMINOX devices. This document has been created to assist healthcare personnel in the safe handling, maintenance and effective reprocessing of NICHROMINOX medical device instruments and accessories to ensure the safety of the patient and healthcare personnel.

1. DEVICE IDENTIFICATION

All instruments and accessories of medical devices in Silicone, Teflon and Stainless Steel from NICHROMINOX (Class I medical device references listed in the appendix).

2. INDICATIONS

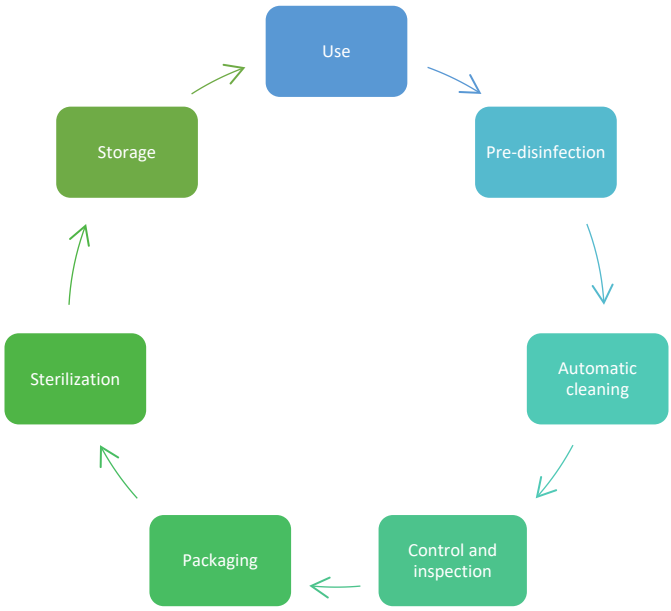
Medical devices and accessories for medical devices in Silicone, Teflon and Stainless Steel from NICHROMINOX are intended for use by qualified dental and medical professionals in a healthcare environment such as dental practices, hospitals, clinics and university laboratories in a dedicated reprocessing area.
These devices can be used with ultrasound, thermo-disinfectors and chemiclaves (only the thermo-disinfector process has been validated by NICHROMINOX).

All new and used non-sterile instruments must be carefully treated, i.e. cleaned, disinfected and sterilised according to these instructions before each use and before the first use.

The health care staff (i.e., those responsible for reprocessing) are responsible for the proper reprocessing of instruments using on-site equipment and validated safety procedures for cleaning, disinfection and sterilization. It is also essential that sterilization equipment is also maintained and controlled in accordance with the manufacturer's recommendations and validated parameters applied to each cleaning and sterilization cycle.

In addition, account must be taken of the legal provisions in force in the country in question as well as the hygiene instructions of the practitioner's practice or the care establishment.

3. REPROCESSING STEPS



Steps to follow:

Step 1: Pre-cleaning with tap water, wipe the instruments before replacing them in the NICHROMINOX holders.

Step 2: Ultrasonic cleaning with detergent at 55°C for 5 minutes with demineralised water

Step 3: Rinsing with demineralised water for 1 minute

Step 4: Washer/disinfector with demineralised water at 93°C for 5 minutes

Step 5: Control and visual inspection, making sure that all dirt has been removed during cleaning and that the devices are perfectly dry.

Step 6: Wrapping and packaging

Step 7: Sterilisation and storage

- **AUTOMATIC CLEANING AND DISINFECTION**

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

Washer-disinfector	Type Miele PG8581 Serial No.: 00/018417797 The washer/disinfector used is a standard device used for reprocessing purposes for dental medical device instruments and accessories.
Detergent used for cleaning	0.5% neodisher® Mediclean Forte (Dr. Weigert, Lot: 663303/0720)
Elution for cleaning	1% SDS (sodiumdodecylsulphate) - 5mL
Elution for disinfection	TSB (trypticase soya broth) - 10mL
Validation report	Laboratory test identification: SN 30900 Test no.: 2020-3078

- **PACKAGING**

All instruments must be completely dry before packing. Once dry, they must be immediately packed in medical sterilization bags suitable for NICHROMINOX medical devices and complying with the packaging standards for medical devices (AAMI ST79, ISO 11607, EU Regulation 2017/745, FDA).

- **STERILISATION**

Use only the recommended sterilisation procedures described below. Other sterilization procedures are the responsibility of the user.

- It is imperative to follow the manufacturer's instructions for routine inspection and regular maintenance of the sterilizer.
- It is imperative that the sterilizer is maintained in accordance with the manufacturer's recommendations.
- Use only slightly contaminated and deionised water (i.e. purified water).

- Sterilised instruments must be perfectly dry after sterilisation and before handling. It is recommended to use sterilisers with automatic drying programmes.
  - Minimum exposure time at the sterilization temperature:
    - 3 minutes at 132 °C and 20 minutes drying time (US method)
    - 18 minutes at 134 °C and 20 minutes drying time (EU method)

The suitability of the instruments for effective sterilisation has been demonstrated by two independent accredited testing laboratories under the following conditions:

Sterilization method	**Steam sterilization**
Sterilizer	Tuttnauer ELARA 11-D (K090783) The steriliser used meets the requirements of EN 13060 and is a standard device for sterilising dental instruments and accessories.
Sterilization temperature	134°C or 132°C
Waiting (full cycle)	18 minutes or 3 minutes
Drying time	20 minutes
Validation reports	1) Study N° : 276194 Report reference: VMI-04-0-COF-RA-m8 2) Laboratory test identification: SN 30900 Test no.: 2020-3079 3) Laboratory test identification: SN 31358 Test no.: 2021-0577

The responsibility for reprocessing NICHROMINOX instruments with parameters not specified in this document lies with the customer.

- **<u>TRANSPORT AND STORAGE OF REPROCESSING DEVICES</u>**

- Place the sterilised material in the area intended for its storage, in a dry and dust-free place.
- Ensure that sterile material is kept separate from non-sterile material for safety reasons.
- Check that the conditions of humidity, temperature and cleanliness of the environment are respected.
- Ensure that the protocol for maintaining an effective sterile barrier is followed as specified in the structure.
- Check labelling, markers and packaging for tampering before reusing an instrument.

4. RESTRICTIONS

Rapid sterilisation should not be used at all.
Do not use radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or plasma gas sterilization.

Any product showing deterioration must strictly not be used. These instructions must be strictly adhered to for the safe and effective use of NICHROMINOX medical devices.

5. PRECAUTIONS

Aureoles and water stains

Brown stains on sterilized products are often mistakenly considered to be rust stains, with some residues brownish to dark brown. These residues are mainly found in the least accessible places when cleaning or rinsing, such as in joints. These traces can be avoided by rinsing thoroughly with pure water and drying carefully.

In order to avoid the production of water stains and stains on the surface of stainless steel, demineralised water should also be used as steam generating water and as rinsing water. It is important to carry out a thorough and meticulous drying process before sterilisation.

Corrosion

Sometimes disinfection or cleaning baths are used for too long and their concentration increases through evaporation. During sterilisation, these deposits burn and turn brown or brown.

Rare surface corrosion can be caused by contact with a strong acid or caustic solution.
It may be the result of rust deposits from other instruments of inferior quality.

Note: It is important to select enzyme solutions intended for the dissolution of blood and body tissues and fluids. Some enzyme solutions are specifically designed to dissolve faeces or other organic contaminants and may not be suitable for use with dental instruments or accessories.

- Repeated treatment according to the instructions in this manual has a minimal effect on NICHROMINOX instruments and medical device accessories, unless otherwise stated. The end of life of these stainless-steel medical devices is determined by wear and tear due to the intended medical use and not by reprocessing.

- Do not clean instruments, sterilization trays or sterilization containers with wire brushes or steel wool.
- Do not expose instruments, cassettes, trays or sterilization containers to temperatures above 141 °C. Effects from exposure to higher temperatures are the responsibility of the user.

- NICHROMINOX does not indicate the maximum number of reuses allowed for MD instruments and accessories in stainless steel, Teflon and silicone. The service life of the products depends on various factors, including the type of handling and treatment between uses. The best way to determine when a device should no longer be reused is to carry out a visual and functional inspection to check that there is no damage to the device. Please note that if the silicone parts are damaged (loss of elasticity, tearing or discolouration), they are available in stock and can be easily changed without the need to change the whole device.

6. SYMBOL AND LABELLING

LOT	Lot number
REF	Catalog number
MD	Medical Device
UDI	Unique Identification Number

	Consult instruction for use
	Caution
CE	Complies with EU Regulation

NON STERILE	not been subjected to a sterilization process
	Manufacturing date
	Manufacturer

7. COMPLAINTS AND REQUESTS FOR INFORMATION

NICHROMINOX makes every effort to design and supply safe and high-performance devices, in accordance with its Quality policy. However, in the event of a serious incident occurring in connection with a NICHROMINOX device or in the event of a manufacturing defect, the healthcare professional (user, prescriber, etc.) or the patient must contact NICHROMINOX immediately.
Complaints or any other reason for dissatisfaction regarding NICHROMINOX devices must be indicated, specifying the reference, batch number and a full description of the incident.
For further information, please contact customer service directly via the contact details below:

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