NeoShine® Non-Sterile, Single-Use (Dental Disc Polishers)

Instructions for Use

CAUTION:

Rx Only. These instructions, in whole or in part, are not a substitute for formal training in rotary polishing. Appropriate professional education is REQUIRED prior to using this device clinically. NeoShine polishers are intended to be used by qualified dental practitioners in dental clinics, hospital, lab, or schools for a dental application.

DESCRIPTION:

Microcopy discs are single-use polishers which snap onto a stainless steel re-usable contra angle mandrel. These polishers are thin flexible discs and available in two sizes, 10mm and 14mm. The discs are packed in a plastic tray with a mandrel. The mandrel is supplied non-sterile and may be reused following cleaning and sterilization instructions. NeoShine discs are available in two different material formulations, Composite/Metal and Composite/Porcelain. The Composite/Metal discs are flexible polishing discs for interproximal application with a pulling or pushing motion. The Composite/Porcelain discs are flexible polishing discs with diamond coating, optimized for porcelain polishing with a pulling or pushing motion. Each material formulation has four colors correlating to grit size from very coarse, coarse, medium, and fine. See the below graphic for an illustration of the geometries and colors.

DISCS:

- Designed to remove surface striations and anatomical defects.
- Leaves a smooth, satin shine surface.
- Discs have abrasive on one side only.

INDICATIONS

NeoShine disc polishers are indicated for any persons requiring dental polishing or adjusting. The polishing discs and mandrel fit into a slow-speed, right-angle latch dental handpiece, which provides the rotation, allowing the user to adjust or polish materials both intra-orally and extra-orally,. NeoShine disc polishers are intended for use on dental restorative materials including composite, precious metal, non-precious alloys and amalgam. NeoShine discs are intended to use the four (4) step types in succession, from the coarsest to finest.

CONTRAINDICATIONS TO USE

a) Use of NeoShine disc polishers are contraindicated on any patient who is allergic to any of the product components.

The mandrel is multi-use and may be re-sterilized. **The mandrel may be reprocessed a maximum of twenty five (25) cycles.**

CLINICAL WARNINGS

a) NeoShine disc polishers are identified as single-use devices and are **NOT** to be re-processed and/or re-sterilized or it will adversely affect their performance.

b) Do **NOT** re-use. Re-use may lead to:
   a. tissue infection,
   b. tissue damage caused by delamination of abrasive coating,
   c. tissue damage by parts of disintegrated *disc*,
   d. tissue damage caused by disconnection between *disc* and mandrel.

c) Do **NOT** use the product if the package is opened or damaged.
d) Do **NOT** use the products after their stated expiration date.
e) Do **NOT** use the product if the polisher is damaged. Immediately discard any deformed, non-concentric rotating polishers.
f) Do **NOT** exceed maximum speed as this may generate undesirable heat resulting in damaged tooth pulp. Failure to observe recommended rotation speeds may cause vibration and deformation to the polisher which may increase breakage and possible injury.
g) Do **NOT** use polishing paste.
h) Do **NOT** operate mandrel without *disc*.
i) Keep the disc dry and cool tooth with air at least every 10 to 15 seconds to avoid excessive heat build-up resulting in damaged tooth pulp.
j) Always keep track of lot numbers to ensure traceability.

Failure to follow these instructions may cause the polisher to break, crumble, or become contaminated and may result in the following: poor device performance, infection, preparation site damage, injury to the patient or user, aspiration, or swallowing of the polisher.

CLINICAL USE AND PRECAUTIONS:

- Clinicians should wear eye protection and facemak when using polishers. If improperly used, materials can break away and become dangerous flying objects.
- Surgical masks shall be work to avoid inhalation of aerosol and/or dust generated during the procedure.
- Carefully read package labels to ensure use fo the appropriate device. Failure to do so may cause procedural delays, patient injury, or user injury.
- Follow the handpiece manufacturer's instructions for use and maintenance and service all handpieces appropriately.
- A low-speed latch handpiece, air or electric, shall be utilized when operating Microcopy polishers.
- Ensure handpieces are maintained in good working order and remain correctly lubricated at all times to ensure maximum effectivess of the device. Failure to properly maintain handpieces may lead to procedural delays, injurty to patient or user, aspiration or swallowing of device, or damage to the preparation site due to vibration of a worn chuck or turbine.
- Polishers must only be used with dental handpieces (drive unit) that are technically and hygienically maintained.
- Clean and sterilize the mandrel in accordance with the directions below before first use and after each use.
- Clean and sterilize the disc before use in accordance with the directions below.
- Insert the instrument shaft into the handpiece as far as possible. Before use, run the handpiece to check for any abnormalities including overheating.
- Keep the disc dry and cool tooth with air at least every 10 to 15 seconds to avoid excess heat build-up.
- Use discs of all 4 types successively – 1. Gross Reduction 2. Contouring; 3. Finishing; 4. Polishing (Reference Table 1 Below). The quality of restoration polishing may be reduced if discs not used successively.
- Choose *disc* of desired diameter.
- Snap *disc* onto mandrel by gently pushing the connector onto sterilized mandrel until the *disc* is securely connected (*disc* must not wobble on mandrel).
- Bring polisher to the recommended rotation speed before applying to the surface being treated, reference table 2 below.
- Start polishing at a speed not more than 10,000 rpm..
- Move the disc in one direction: from gingiva towards restoration (back and forth movement over the composite-enamel margin is not recommended).

- Avoid contacting of mandrel or *disc* connector with composite - possible discoloration may require repeating polishing once more.
- Control quality of *disc* surface while operating. Rotational behavior and the appearance of the *disc* changes 10-15 seconds before separation or break. The visual appearance of the disintegrated *disc* is changed. Do not use *discs* with delaminated abrasive coating or damaged polymer part. This may cause tissue damage.
- **Improper use of these instruments may lead to poor results and increased patient risk.**

Table 1: Polisher Types

	Gross Reduction	**Contouring**	**Finishing**	**Polishing**
Standard Colors Composite Metal	Blue	Pink	Yellow	White
Standard Colors Composite Porcelain	Gray	Blue	Pink	White
Time, seconds	As needed	15 - 20	15 - 20	15 - 20

Table 2: Polisher Speeds

Polisher	**Recommended Speed**	**Maximum Speed**	**Pressure**
Discs	10,000 RPM	30,000 RPM	Light

APPLICATION OF PRESSURE:

- Excessive pressure may cause early wear of the polisher.
- **Excessive pressure during use may create excessive heat buildup resulting in damage to the tooth pulp.**

AIR COOLING:

- Cool tooth with air at least every 10 to 15 seconds to avoid excess heat build-up.
- **Insufficient air cooling can lead to irreversible damage to the tooth pulp or its surrounding tissues.**

STORAGE:

- Store discs and mandrels in a dry place away from direct sunlight.
- The storage in direct light can cause disc color change and decreased flexibility.

DISPOSAL:

- Each used disc/mandrel must be disposed in a biohazard waste container.
- Each unused disc/mandrel shall be disposed in a standard waste container.

PRODUCT SHELF-LIFE:

- Disc shelf-life is 5 years since date of production. The expiration date is printed on the label.
- Mandrel shelf-life is 5 years since date of production or 25 uses, whichever comes first.
- **Use of these instruments after product shelf-life may lead to bad product performance and increase risk harm to patient.**

METHODS OF STERILIZATION

- Mandrels are sterilized before first use and after each patient use by conventional steam autoclave or dry heat sterilizer.
- Use only sterile or high-quality water for post-rinsing.

- Dry mandrels thoroughly before sterilization.
- Do not exceed sterilization temperature of 138°C.
- Follow instructions of autoclave (sterilizer) manufacturer.
- **Do not use detergents or disinfectants containing strong alkalines (pH>9), strong acids (pH<4), phenols or iodophors, hydrogen peroxide, interhalogenic agents, halogenic hydrocarbons, strong oxidizing agents, organic solvents, aldehydes.**

Mandrel Cleaning / Sterilization Instructions

PLACE OF USE:	No special requirements
STORAGE AND TRANSPORT:	It is recommended to transport the contaminated instruments in a closed container. It is recommended that instruments be reprocessed as soon as possible, within 2 hours after use at the most. Intermediate storage of used instruments with contamination such as blood residues can lead to corrosion damage.
PREPARATION:	Wear personal protective equipment (durable gloves, water-repellent coat, face protection mask or goggles and protection mask).
PRE-TREATMENT:	Pre-clean under running water with a brush (plastic) directly after use. Equipment: plastic brush (e.g. Interlock, #09084), tap water (20± 2 °C) (at least drinking water quality) 1. Rinse the polishers under running water for 60 seconds and brush them thoroughly with a plastic brush, particularly the difficult to access areas of the head (bristles, silicone bristle tips).
CLEANING: MANUAL	Note: Coarse surface contamination on the instruments must be removed before manual reprocessing (see pre-treatment) Equipment: Multi-stage enzymatic cleaner (e.g. Dürr Dental, ID 215), tap water/flowing water (20± 2 °C) (at least drinking water quality), ultrasonic bath (e.g. Sonorex Digital 10P) 1. Prepare the cleaning solution according to the manufacturer's instructions (Dürr Dental ID 215 2% solution was validated) and fill into an ultrasonic bath. 2. Completely immerse the shanks in the solution. 3. Expose the products for 1 minute to the ultrasonic bath. 4. Remove the shanks from the cleaning solution and rinse them each thoroughly (30 seconds) under running water. 5. Check for cleanliness. If contamination is still visible, repeat the above specified steps

<table>
<tr><td>DISINFECTION: MANUAL (with subsequent sterilization)</td><td>Equipment: At least limited virucidal instrument disinfectant (VAH listed - or at least listed in the IHO with testing according to DVV) e.g. based on quaternary ammonium compound(s), alkylamine(s)/alkylamine derivative(s), guanidine(s)/guanidine derivative(s) (e.g. Dürr Dental, ID 212), preferably fully deionised water (deionised water, according to KRINKO/BfArM recommendation free of facultatively pathogenic microorganisms), ultrasonic bath (e.g. Sonorex Digital 10P), lint-free sterile cloth.

1. Prepare the disinfectant solution according to the manufacturer’s instructions (Dürr Dental ID 212, 2% solution was validated) and place into an ultrasonic bath.

2. Completely immerse the polishers in the disinfectant solution.

3. Expose the products for 2 minutes to the ultrasonic bath.

4. Further exposure time to the disinfectant solution for 5 minutes according to the desinfectant manufacturer’s instructions.

5. Remove the polishers from the disinfectant solution and allow to drip off.

6. Rinse the products with deionised water for 30 seconds.

7. Wipe with a single use sterile lint-free cloth or, if necessary, dry with medical compressed air</td></tr>
<tr><td>CLEANING AND DISINFECTION: AUTOMATIC</td><td>Equipment: Cleaning and disinfection unit according to DIN EN ISO 15883-1+2 with thermal programme (temperature 90 °C to 95 °C), detergent: mildly alkaline detergent (e.g. Dr. Weigert neodisher MediClean Dental)

1. Place the instruments in a suitable small parts tray or on the load carrier such that all surfaces of the instruments are cleaned and disinfected.

2. Close WD and start programme, see table below for programme sequence.

<table>
<tr><th>PROG. STEP</th><th>WATER</th><th>DOSAGE</th><th>TIME</th><th>TEMPERATURE</th></tr>
<tr><td>Pre-rinse</td><td>CW</td><td></td><td>5 min</td><td></td></tr>
<tr><td>Dosage of detergent</td><td></td><td>According to manufacturer's instructions</td><td></td><td>According to manufacturer's instructions</td></tr>
<tr><td>Clean</td><td>Fully deionised water</td><td></td><td>10 min</td><td>55 °C</td></tr>
<tr><td>Rinse</td><td>Fully deionised water</td><td></td><td>2 min</td><td></td></tr>
<tr><td>Disinfect</td><td>Fully deionised water</td><td></td><td>3 min</td><td>Ao-value > 3000[1]
(e.g. 90 °C, 5 min)</td></tr>
<tr><td>Drying</td><td></td><td></td><td>15 min</td><td>up to 120 °C</td></tr>
<tr><td colspan="5">[1] Authorities may issue other operational regulations (disinfection performance parameters) in their area of competence.</td></tr>
</table>

3. Remove the instruments at the end of the programme.

4. Check that the load is dry and, if necessary, dry with medical compressed air.

5. Visual inspection for cleanliness is performed after removal from the WD. If contamination is still visible, reclean medical devices again manually. Subsequently, the recleaned medical devices must again be reprocessed automatically.</td></tr>
<tr><td>STERILIZATION:</td><td>Device: Steriliser according to DIN EN 285 or small steam steriliser according to DIN EN 13060, type B process

Process: Steam sterilisation with fractionated pre-vacuum, 134 °C, holding time min. 3 min (in Germany according to KRINKO/BfArM recommendation 134 °C min. 5 min) or 132 °C min. 3 min (parameter of validation). Longer holding times are possible.

1. Place the packaged products in the sterilisation chamber

2. Start the programme.

3. Remove the products at the end of the programme and allow to cool down.

4. Then check the packaging for possible damage. Faulted packaging must be regarded as being non-sterile. The instruments must be repacked and sterilised.</td></tr>
</table>

TRACEABILITY

- Each package includes **Lot** LOT **number** on its label.
- This number must be quoted in any correspondence regarding the product.
- Always keep track of lot numbers of NeoShine to ensure traceability.

NOTICE: If a serious incident has occurred in relation to the device, the incident shall be reported to the manufacturer and if applicable, the competent authority of the Member State in which the user and/or patient is established.

To request a paper IFU free of charge, please contact Microcopy at sales@microcopydental.com or 800.235.1863, and an IFU will be delivered within seven (7) days.

APPLICABLE SYMBOLS:

	Manufacturer	Indicates the medical device manufacturer.		Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.		Non-Sterile	Indicates a medical device that has not been subject to a sterilization process
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.		Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Use By Date	Indicates the date after which the medical device is not to be used.		Do not use if package is open or damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	CE marking	Indicates European Conformity Mark.		Authorized European representative	Indicates the Authorized representative in the European Community.
	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.		Max speed	Indicates Max speed
	No polishing paste	Indicates polishing paste is not used with these instruments.		Recommended RPM	Indicates Recommended speed
	Wear eye protection	Indicates that eye protection must be used.		Wear a mask	Indicates that a face mask must be worn.

	Single Patient – Multiple Use	Indicates a medical device that may be used multiple times in a single operation.		Keep away from sunlight	Indicates a medical device that needs protection from light sources
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	MD	Medical Device	Indicates device is designed and intended for medical use.
CE	CE marking	Signifies European technical conformity.	REF	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Importer	Indicates the entity importing the medical device into the locale	EC REP	Authorized European representative	Indicates the Authorized representative in the European Community.
	Distributor	Indicates the entity distributing the medical device into the locale.			

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