

NeoShine® Non-Sterile Single-Use Disc Polishers Instructions for Use (IFU)

CAUTION:

Rx Only. These instructions, in whole or in part, are not a substitute for formal training in rotary polishing. Appropriate professional education is **STRONGLY RECOMMENDED** prior to using this device clinically. NeoShine polishers are 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 mandrel. These polishers are thin flexible discs and available in two sizes. The devices are intended to remove excessive restorative material and striations. The discs are packed in a plastic tray with a mandrel.

INDICATIONS

NeoShine polishers 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, i.e. composite, precious metal, non-precious alloys and amalgam.

CONTRAINDICATIONS TO USE

Use of NeoShine polishers are contraindicated on any patient who is allergic to any of the product components. The disc polishers are identified as single-use devices and **NOT** to be re-processed and/or re-sterilized or it will adversely affect their performance. Do **NOT** re-use. 

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

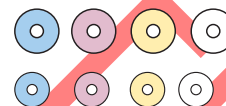
COMPONENTS:

After adjusting restorations use NeoShine polishers in a slow-speed, right-angle handpiece. All disc headpiece products are used as single-patient-use, while the metal mandrel may be re-sterilized and re-used.

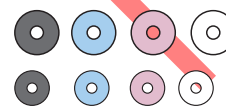
DISCS:

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

COMPOSITE/METAL DISCS
10 & 14 MM



COMPOSITE/PORCELAIN DISCS
10 & 14 MM



MANDREL RA LATCH



PROPER USE:

- Polishing paste is **NOT** required.
- Keep the disc dry and cool tooth with air at least every 10 to 15 seconds to avoid excess heat build-up.
- These polishers must only be used with dental handpieces (drive unit) that are technically and hygienically maintained.
- Protective eyewear should be worn at all times. If improperly used, materials can break away and become dangerous flying objects.
- Wearing a respiratory mask will prevent inhaling dust from polishers.
- Insert the instrument shaft into the driving unit as far as possible.
- Unmounted polishers must be centered after shaft mounting in order to avoid vibrations during use.

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- Choose *disc* for gross reduction of necessary diameter.
- Place *disc* for gross reduction by gentle pushing of the connector onto preliminary sterilized mandrel until the *disc* is securely connected (*disc* must not wobble on mandrel).
- Move the disc in one direction: from gingiva towards restoration (back and forth movement over the composite-enamel margin is not recommended).
- Use *discs* of all 4 types successively - otherwise the quality of restoration polishing may be reduced.
- Start polishing at a speed not more than 10,000 rpm. (see chart for recommended speed).
- Bring polisher to the recommended rotation speed before applying to the surface being treated
- **Improper use of these instruments may lead to poor results and increased patient risk.**

	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

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

PRECAUTIONS AND WARNINGS:

ROTATION SPEED

- Immediately discard any deformed, non-concentric rotating polishers.
- Never exceed the maximum rotation speed stated.
- Please refer to the rotation speeds indicated on the product packaging.
- Do not operate mandrel without *disc*.
- 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.
- Do not re-use polishing disc. Second use can lead to:
 - tissue infection,
 - tissue damage caused by delamination of abrasive coating,
 - tissue damage by parts of disintegrated *disc*,
 - tissue damage caused by disconnection between *disc* and mandrel.
- If package with *discs* or mandrels are broken or disrupted *discs* or mandrels prior to use must be sterilized by a standard method.
- **Failure to observe maximum rotation speeds may cause excessive heat buildup resulting in a damaged tooth pulp.**
- **Failure to observe recommended rotation speeds can cause vibration and deformation to the disc or mandrel which can increase damage and possible injury.**

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- Always keep track of lot numbers of NeoShine to ensure traceability. Lot numbers are listed in the format of PYYMMDD.

APPLICATION OF PRESSURE:

- Excessive pressure can 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. Store within a range of 10°-30°C (50°-86°F).
- The storage in direct light can cause disc color change and decreased flexibility.

PRODUCT SHELF-LIFE:

- Shelf-life of discs is 5 years since date of production. The expiration date is printed on the label.
- Shelf-life of mandrels 5 years since date of production 25 or uses.
- **Improper use of these instruments leads to bad quality results and more risks. This is why they must be used only by qualified persons.**

METHODS OF STERILIZATION

- Mandrels are sterilized after each patient using either 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.
- In case of risk of disc contamination discs can be sterilized in the following manner:
 - put discs in 2% sodium bicarbonate solution at 70°C for 15 min, mix from time to time,
 - rinse with distilled water,
 - dry at ambient temperature,
 - put in 6% solution of hydrogen peroxide at ambient temperature for 360 min or at 50°C for 180 min.
- **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.**


Cleaning Instructions

PLACE OF USE:	No special requirements
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STORAGE AND TRANSPORT:	<p>It is recommended to transport the contaminated instruments in a closed container.</p> <p>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.</p>
PREPARATION:	<p>Wear personal protective equipment (durable gloves, water-repellent coat, face protection mask or goggles and protection mask).</p>
PRE-TREATMENT:	<p>Pre-clean under running water with a brush (plastic) directly after use.</p> <p>Equipment: plastic brush (e.g. Interlock, #09084), tap water (20± 2 °C) (at least drinking water quality)</p> <ol style="list-style-type: none"> 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	<p>Note: Coarse surface contamination on the instruments must be removed before manual reprocessing (see pre-treatment)</p> <p>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)</p> <ol style="list-style-type: none"> 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 polishers in the solution. 3. Expose the products for 1 minute to the ultrasonic bath. 4. Remove the polishers 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

TRACEABILITY





















Each package includes **Lot number**  on its label.

This number must be quoted in any correspondence regarding the product.

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

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	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.
	Temperature limit	Indicates the upper and lower limits of temperature to which the medical device can be safely exposed.		Keep away from sunlight	Indicates a medical device that needs protection from light sources
	Single Patient – Multiple Use	Indicates a medical device that may be used multiple times in a single operation.		Medical Device	Indicates device is designed and intended for medical use.
	Keep Dry	Indicates a medical device that needs to be protected from moisture.		Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	CE marking	Signifies European technical conformity.		Authorized European representative	Indicates the Authorized representative in the European Community.

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REVISION HISTORY

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