

NeoShine® Sterile, Single-Use (Dental Polishers) Instructions for Use


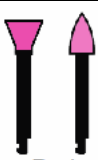
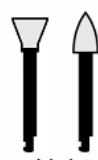

CAUTION:

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, hospitals, labs, or schools for dental applications.

DESCRIPTION:

Neoshine polishers are single-use abrasive rotary cups and points affixed to a plastic shank. The polishers are individually packaged in a plastic pouch in a dedicated cleanroom facility and terminally sterilized using gamma irradiation. STERILE R
 Neoshine polishers are available in two shapes: cup and point, and in several material formulations which are tailored to polish varying dental restorative substrates as indicated by their name. These materials are Composite and Ceramic (Zirconia, Lithium Disilicate, and Porcelain). Polishers are indicated to polish the material in steps, depending on the desired outcome of polishing. The steps are intended to be used in order to reduce surface roughness and provide the highest amount of shine possible. The NeoShine polishers are designed with a color ID system to aid doctors in selecting the correct polisher.

NeoShine Color ID

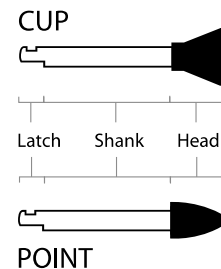
| | Composite | Ceramic |
|---------------|--|---|
| Step 1 |  Dark |  Dark |
| Step 2 |  Light |  Light |

Step 1: Satin Polishers:

- Designed to remove surface striations and anatomical defects.
- Leaves a smooth, satin-shine surface.

Step 2: Hi-Gloss Polishers:

- Designed to establish a high-gloss surface following the satin polisher.
- Ideal for anterior and esthetic restorations.



INDICATIONS:

NeoShine polishers are indicated for any persons requiring dental polishing or adjusting. The polishers fit into a slow-speed, contra-angle latch dental handpiece, which provides the rotation, allowing the user to adjust or polish materials both intra-



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orally and extra-orally. NeoShine polishers are intended for use on dental restorative materials including composite, zirconia, lithium disilicate, porcelain, precious metal, non-precious alloys, and amalgam.

CONTRAINDICATIONS TO USE:

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

CLINICAL WARNINGS

- a) Limited contact to the mucosa membrane is recommended.
- b) NeoShine polishers are identified as single-use devices and are NOT to be re-processed and/or re-sterilized. Attempting to re-process or re-sterilize will adversely affect the device's performance.
- c) Do **NOT** reuse.  
- d) Do **NOT** use the product if the package is opened or damaged.
- e) Do **NOT** use the products after their stated expiration date.
- f) Do **NOT** use the product if the polisher is damaged.
- g) Do **NOT** exceed maximum speed as this may generate undesirable heat resulting in damaged tooth pulp. Failure to observe recommended rotation speed may cause vibration and deformation to the polisher which may increase breakage and possible injury.
- h) Do **NOT** use polishing paste.
- i) Failure to spray water at a minimum of every 10 to 15 seconds may cause 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 of the polisher requiring medical intervention.

CLINICAL USE AND PRECAUTIONS:

- Clinicians should wear eye protection and facemask when using polisher. If in properly used, materials can break away and become dangerous flying objects.
- Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause procedural delays, patient injury, or user injury.
- Follow the handpiece manufacturer's instructions for use, 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 effectiveness of the device. Failure to properly maintain handpieces may lead to procedural delays, injury 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.
- Before use, run the handpiece to check for any abnormalities including overheating.
- Handle packaging and product with care to ensure sterile barrier is maintained.
- If the package is damaged or unintentionally open prior to use, the polisher must **NOT** be used and be immediately discarded.

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- For aseptic preparation open pouch immediately before use to prevent contamination.
- To open, hold the polisher in the pouch by the operative end, push the shank end through the clear plastic to insert into handpiece collet and tighten before releasing the grip on the operative end and discard the pouch.
- Insert the polisher shaft into the driving unit per the driving unit instructions until the polisher is fully seated. Failure to do so may cause the device to “walk out” of the handpiece and may lead to injury to the patient or user or aspiration or swallowing of the device.
- Never force a polisher into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- Prior to use, inspect the polisher for any deformity or non-concentric rotation. Discard damaged or potentially defective polishers immediately.
- Bring polisher to the recommended rotation speed before applying to the surface being treated (reference rotational speed chart below).
- Do **NOT** use polishing paste.
- Spray water at least every 10 to 15 seconds at the application site to avoid excess heat build-up.
- **Improper use of these instruments may lead to poor results and increased patient risk.**

| All Polishers Recommended Speed | Maximum Speed | Pressure |
|---------------------------------|---------------|--|
| 7,000 RPM | 20,000 RPM | Step 1: Light Step 2: Feather Light |

APPLICATION OF PRESSURE

- Do not bend the polisher or use it as a lever; doing so increases the risk of breakage.
- Excessive pressure may cause accelerated deterioration of the polisher.
- Excessive pressure on the polisher may cause the polisher to break resulting in possible injury.
- Excessive pressure during use may create excessive heat build up resulting in damage to the tooth pulp.

WATER COOLING

- In order to avoid the overheating of a tooth, sufficient water cooling must be used (50 ml/min). Spray water every 10 to 15 seconds to avoid heat build-up.
- Insufficient water cooling can lead to irreversible damage to the tooth pulp or its surrounding tissues.

STORAGE AND SHELF LIFE

- Improper storage conditions will shorten the shelf life and may cause product to malfunction.
- Microcopy polishers should be stored in a dry, dark, dust-free environment.
 - The polisher box is designed to protect the polishers from sunlight.
 - The polisher pouch is designed to protect the polishers from dust and moisture.
- Product sterility will be maintained for four (4) years if appropriate storage and handling practices are observed.

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- The products are labeled with their expiry date.

DISPOSAL

- Each used polisher must be disposed in a biohazard waste container.
- Each unused polisher must be defaced and disposed in a waste container.









TRACEABILITY

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














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 Resterilize | Indicates a medical device that is not to be resterilized. | STERILE R | Sterilized using irradiation | Indicates a medical device that has been sterilized using irradiation. |
| LOT | 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. |
|  | No polishing paste | Indicates polishing paste is not used with these instruments. |  | Max speed | Indicates Max speed |

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|---|-------------------------------|---|---|------------------------------------|---|
|  | Professional use only | (ref US FDA CDRH) Indicates device shall only be used by a trained professional. |  | 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. |  | Medical Device | Indicates device is designed and intended for medical use. |
|  | CE Marking | Signifies European technical conformity |  | 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. |  | Authorized European Representative | Indicates the Authorized representative in the European Community. |
|  | Distributor | Indicates the entity distributing the medical device into the locale. | | | |

CONTACT INFORMATION:



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