

Title:	Instructions for Use (IFU) – NeoShine® Sterile Single-Use Polishers		
Doc #:	MCD-IFU-001	Rev: 5	Effective Date: Draft
Originator:	Barb Lincoln	Owner: Quality	DCN#: DCN-20-180

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, 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.

INDICATIONS:

NeoShine 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-orally and extra-orally, i.e. composite, zirconia, lithium disilicate, porcelain, precious metal, non-precious alloys, or amalgam.

CONTRAINDICATIONS TO USE:

Use of NeoShine polishers are contraindicated on any patient who is allergic to any of the product components. In consideration of patient safety, limited extended contact to the mucosa membrane is recommended. These polishers are identified as single-use devices and NOT to be re-process and/or re-sterilize or it will adversely affect their performance. Do not reuse.  

COMPONENTS:

Neoshine polishers are available in these geometric shapes: cup and point, which are tailored to polish varying dental restorative substrates as indicated by their name. These materials are Composite, Metal, and Ceramic (Zirconia, Lithium Disilicate, and Porcelain.) Polishers are indicated to polish the material, in steps depending on the desired outcome of polishing. We recommend using the steps in order to reduce surface roughness and provide the highest amount of shine possible. The Composite and Ceramic polishers are designed with a color ID system to aid doctors in selecting the correct polisher. Each substrate has its own color with Composite being gray and Ceramic being magenta. Step 1 is a dark shade and step 2 is a light shade of that color. Metal polishers were designed as Brownies, (step 1), and Greenies, (step 2), which are industry standard. See the below graphic for an illustration of the geometries as well as an explanation of the polisher steps.

Step 1: Satin Polishers:

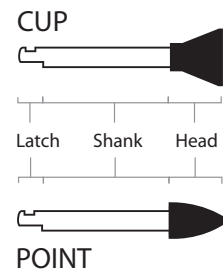
- Designed to remove surface striations and anatomical defects.
- Leaves a smooth, satin-shine surface.

Step 2: Hi-Gloss Polishers:

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

PROPER USE:

- Polishing paste is NOT required.
- Spray water 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.



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- 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.
- Prior to use, insert the polisher shaft into the driving unit per the driving unit instructions until the polisher is fully seated.
- Bring polisher to the recommended rotation speed before applying to the surface being treated (reference rotational speed chart below).
- **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

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.
- **Failure to observe maximum rotation speeds may cause excessive heat build up resulting in a damaged tooth pulp.**
- **Failure to observe recommended rotation speeds can cause vibration and deformation to the polisher which can increase breakage and possible injury.**
- Always keep track of lot numbers of NeoShine to ensure traceability. Lot numbers are listed in the format of PDDMMYY.

APPLICATION OF PRESSURE

- Do not bend the polisher or use it as a lever; doing so increases the risk of breakage.
- Excessive pressure can 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.**

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STORAGE AND SHELF LIFE

- Microcopy polishers should be stored in a dry, dark, dust-free environment at 14°F to 122°F (-10°C to 50°C).
 - The polisher box is designed to protect the polishers from sunlight.
 - The polisher pouch is designed to protect the polishers from dust and moisture.











Improper storage conditions will shorten the shelf life and may cause product to malfunction.

- Product sterility will be maintained for four (4) years if appropriate storage and handling practices are observed.
- Do **NOT** use the product if the package is opened or damaged. 
- The products are labeled with their expiry date. Do **NOT** use the products after their stated expiration date. 



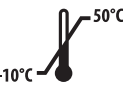







TRACEABILITY

- Each package include **Lot number** LOT 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 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
	Professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.		Recommended RPM	Indicates Recommended Speed

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	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.

CONTACT INFORMATION:



Microcopy Dental
 3120 Moon Station Rd. NW
 Kennesaw, GA 30144, USA
sales@microcopydental.com
 800.235.1863



Obelis S.A
 Bd. Général Wahis 53
 1030 Brussels, Belgiu
mail@obelis.net
 + (32) 2. 732.59.54



REVISION HISTORY:

Revision Control Log			
Rev. #	Effective Date	Change Description	DCN
5	Draft	Change Zirconia to Ceramics and the lot configuration.	DCN-20-180
4	01Jul2020	Updated to add ISO symbols, European Representative and CE Mark, and a 4 year shelf life, added lot number configuration.	DCN-20-085
3	10Mar2020	Updated to add polisher color identity	DCN-20-056