NeoShine® Lab Polishers
Instructions for Use

CAUTION:
The device is to be used as per the following instructions by physician or licensed practitioner Rx Only. These instructions, in whole or in part, are not a substitute for formal training. Appropriate professional education is STRONGLY RECOMMENDED prior to using this device clinically.

DESCRIPTION:
The Lab Polishers intended to be used by professional dentists and dental technician in the dental laboratory.

Microcopy's Dental Lab Polishers consist of synthetic/silicone rubber pigments and abrasive, the shanks are made of stainless steel. The Polishers are provided mechanically clean, but non-sterile 

and may be reused following cleaning and sterilization instructions as described in this IFU.

INDICATIONS
Microcopy Dentals lab polishers are intended for final polishing of acrylics, metals, and ceramics including zirconia, porcelain, and Lithium disilicate. The dentist will apply composite material for a tooth restoration and then smooth the surface.

CONTRAINDICATIONS TO USE
a) Used Dental Lab Polishers shall be considered as contaminated and as such, appropriate precautions shall be taken during re-processing and disposal. Suitable eye protection, glove and a mask should be worn when re-processing.
b) In the event of Dental Lab Polishers will be returned to Microcopy, please ensure any contaminated and/or potentially contaminated Dental Lab Polishers have been effectively cleaned and are appropriately packaged for return.

STORAGE (PRE-USE)
Store in a dry and clean environment at ambient temperature.

PRECAUTIONS:

All polishers have been designed and engineered for their specific application. Improper use can lead to tissue damage, increased wear, or destruction of the polisher, as well as cause risks to the user.

Proper Use

a) Only turbines, handpieces and contra-angle attachments that are in perfect technical and hygienical conditions should be used, meaning that they should be well maintained and correctly cleaned. Turbines and contra-angle attachments used must ensure precise and concentric rotation.
b) Instruments must be inserted as far as possible. Before applying the instruments to any surface, they must be brought to speed. check the safe connection of the polisher before using it and perform a test run.
c) If possible, polish in slightly circular movements to avoid indentations.
d) Tilting or levering is to be avoided as it leads to an increased risk of breakage.
e) Immediately discard any deformed or non-concentric rotary instruments.
f) Protective goggles should be worn at all times.
g) The Dental Lab Polishers are intended for dental applications in dental clinics and hospitals by licensed dentist. Rx only
h) Always wear Gloves when handling contaminated instruments.
i) Eye protection must be worn to protect against ejected particles.
j) Surgical mask must be worn to avoid inhalation of aerosol or dust generated.
k) Before each use, inspect the polishers for damaged blades or excessive wear. Discard worn polishers.

ROTATION SPEED INSTRUCTIONS

NeoShine® Lab Polishers
Instructions for Use

- 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 buildup.**
- **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 PYYMMDD.

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 buildup.**

WATER COOLING

- In order to avoid the overheating of a substrate, 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 overheating.**

REPROCESSING INSTRUCTIONS

Warning Notices

- Observe the manufacturer's information on material compatibilities for cleaning, disinfection, and sterilization.
- All instruments are delivered unsterile and must go through the indicated cycle before and after each use.
- Strong acids and strong bases may oxidize the stainless-steel shank.
- Avoid temperatures >150 °C.
- Ultrasonic bath must not exceed temperatures of 42 °C because of the possible coagulation of protein.
- Instruments that have not completely dried after cleaning and disinfection must be dried again (e.g. with medical compressed air) to avoid compromising the success of sterilization.
- Instructions of cleaning and/or disinfecting solutions must specifically state "suitable for rubber polishers or synthetics/silicones".
- The exposure time and concentration specified by the manufacturer must be followed.
- Used Dental Lab Polishers should be considered as being contaminated and appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn.
- Used Polishers are considered as biohazard and need to discard as biohazard waste unless reprocessing instruction has been done.

Cleaning and Preparation

- If manual cleaning is implemented, the polishers should be cleaned in a sink reserved for the purpose.
- Pre-clean under running water with a brush (plastic) directly after use.
- 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.

Manual Cleaning

NeoShine® Lab Polishers
Instructions for Use

- Coarse surface contamination on the instruments must be removed before manual reprocessing
- Clean manually - Under running water with a brush (plastic bristles)

Automated Ultrasonic Cleaning:

- Clean with a suitable cleaning agent and disinfectant using multi-stage enzymatic cleaner.
- Prepare the cleaning solution according to the manufacturer's instructions (Dürr Dental ID 215 2% solution was validated) and fill into an ultrasonic bath.
- Completely immerse the polishers in the solution.
- Expose the products for 1 minute to the ultrasonic bath.
- Remove the polishers from the cleaning solution and rinse them each thoroughly (30 seconds) under running water.
- Check for cleanliness. If contamination is still visible, repeat the above specified steps.

DISINFECTION

Manual (with Subsequent Sterilization)

- Prepare the disinfectant solution according to the manufacturer’s instructions (Dürr Dental ID 212, 2% solution was validated) and place into an ultrasonic bath.
- Completely immerse the polishers in the disinfectant solution.
- Expose the products for 2 minutes to the ultrasonic bath.
- Further exposure time to the disinfectant solution for 5 minutes according to the disinfectant manufacturer's instructions.
- Remove the polishers from the disinfectant solution and allow to drip off.
- Rinse the products with deionized water for 30 seconds.
- Wipe with a single use sterile lint-free cloth or, if necessary, dry with medical compressed air.

Maintenance

Visual check of all instruments with optical magnification (5-10 folds).

Inspection

No residues - continue to sterilization.
Visible residues - repeat cleaning. Reject and dispose of instruments in the event of discernible defects.

STERILIZATION
Steam Sterilization

- Process: Steam sterilization with fractionated pre-vacuum, 134 °C, holding time min. 3 min or 132 °C min. 3 min (parameter of validation). Longer holding times are possible. Threshold values of contents for feed-water and steam condensates
- Place the packaged products in the sterilization chamber.
- Start the program
- Remove the products at the end of the program and allow to cool down.
- Then check the packaging for possible damage and screening effects.
- Faulted packaging must be regarded as being non-sterile.
- The instruments must be repacked and sterilized.
- Loading of sterilizer according to manufacturer’s instructions follow manufacturer’s

NeoShine® Lab Polishers
Instructions for Use

operating instructions

The device should be stored in the sterilization pouch (or instrument block) until required.

***Note**: Local legislation may require that burs/discs will be wrapped in pouches for processing in either type of autoclave.*

Sterilization Process

***Note**: Local infection control practice may recommend a different combination of holding time and temperature.*

TRACEABILITY:

Each package includes **Lot number** LOT on its label.
This number must be quoted in any correspondence regarding the product.

APPLICABLE SYMBOLS:

	Manufacturer	Indicates the medical device manufacturer.		Consult instructions for use	Indicates the need for the user to consult the instructions for use.
REF	Catalog Number	Indicates the manufacturer's catalog number so that the medial device can be identified	LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
EC REP	Authorized European representative	Indicates the Authorized representative in the European Community.	CE	CE Marking	Indicates European Conformity Mark.
NON STERILE	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.	RxOnly	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.
MD	Medical Device	Indicates device is designed and intended for medical use.		Importer	Indicates the entity importing the medical device into the locale

CONTACT INFORMATION:

Microcopy
3120 Moon Station Rd. NW
Kennesaw, GA 30144, USA

CE

EC REP

Obelis S.A
Bd. Général Wahis 53
1030 Brussels, Belgium
Tel: + (32) 2. 732.59.54
Fax: +(32) 2.732.60.03
E-Mail: mail@obelis.net

REVISION HISTORY

MCD-IFU-018 Rev. 2

Date of Issue: 20May2021