



Title:	Instructions for Use (IFU) – Dental Polishers (Gazelle®, Minnow®)		
Doc #:	MDC-IFU-001	Rev: 1	Effective Date: 13Nov2018
Originator:	Emily Brayman	Owner: Quality	DCN#: DCN-18-038

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.

DESCRIPTION:

Microcopy polishers are abrasive rotary devices affixed to a plastic shank. The devices are indented to remove excessive restorative materials, such as composite. The polisher head is pre-mounted to a shank that is held by a low speed, contra-angle latch dental handpiece. There are various shapes including point, cup, disk, mini-point, and mini-cup. The devices can be used both intra-orally and extra-orally. The polishers are packed in a plastic pouch in a dedicated cleanroom facility and terminally sterilized using Gamma Irradiation  by a contract sterilizer. These burs are identified as single-use devices and NOT be re-processed and/or re-used. 

INDICATIONS

Microcopy devices fit into a low 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 restorations

CONTRAINDICATIONS TO USE

Use of Microcopy Polishers is contraindicated on any patient who is allergic to any of the components of the product. Do not reuse. Microcopy polisher components are single use. Attempts to sterilize these products will adversely affect their performance.

CLINICAL PRECAUTIONS AND WARNINGS:

- a) Discard any damaged Polishers immediately.
- b) Microcopy Polishers are for SINGLE-PATIENT-USE ONLY, in a dental setting on teeth or dental restorations.
- c) Do not use chemical or dry heat to sterilize devices, as these processes have not been validated for use
- d) Do not use worn-out or dull devices
- e) Always refer to the product packaging for the Maximum RPM
 - Excessive rotational speed can generate high heat, which may damage the tooth, the surrounding soft tissues, or the restoration. Avoid long periods of applied pressure to avoid heat build up. Apply water spray to cool if needed.
 - Operating a polisher or abrasive with too high of an RPM may cause the polisher to fail
- f) Use with slow-speed, rotary contra-angle handpiece only.
- g) Ensure that the Polisher is securely in the chuck of the handpiece, and perform a test run outside of the patient’s mouth before intra-oral use.
- h) Excessive lateral or vertical pressure can damage the Polisher.
- i) Protect patient’s eyes and vulnerable tissues when using these Polishers.
- j) Clinicians should wear eye protection and facemask when using Polishers.
- k) Always keep track of Lot Numbers of Polishers to ensure traceability.
- l) For dentistry use only

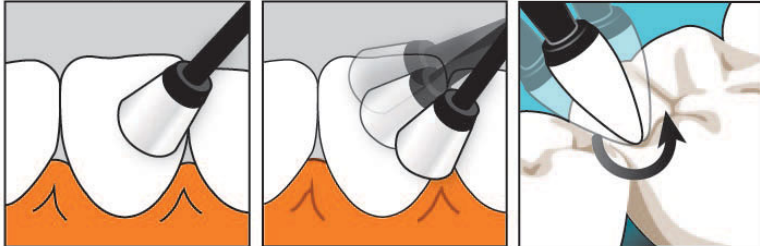
CLINICAL USE:

Place a composite restoration as you normally would. Shape the occlusal anatomy, fissure pattern and initial contours with a finishing carbide or diamond bur.

Use Microcopy Polishers in a slow-speed, rotary contra-angle handpiece at a maximum speed of 5,000 RPM. Products are designed to be used dry with intermediate use. To avoid heat build-up, apply water to cool.

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Satin Composite Polishers



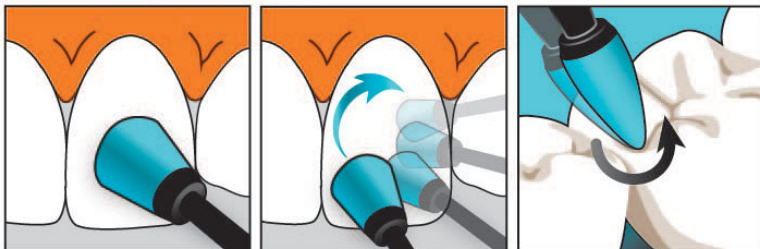
Gazelle

Minnow

Step #1 Satin Polisher

- Removes surface striations and anatomical defects.
- Leaves a smooth, satin gloss surface.
- Apply light pressure.

Hi-Gloss Composite Polishers



Gazelle

Minnow

Step #2 Hi-Gloss Polisher









- Creates an aesthetically smooth surface with a smooth, lustrous, high gloss.
- Use feather light pressure to create high gloss shine.

STORAGE

Microcopy Polishers should be stored in a dry, dark, dust-free environment at 2 - 28°C (36 - 82°F). Improper storage conditions will shorten the shelf life and may cause malfunction of the product. The expiration date is printed on the label.

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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.		Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	Lot 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	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.

CONTACT INFORMATION:



Microcopy Dental
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REVISION HISTORY:

Revision Control Log			
Rev. #	Effective Date	Change Description	DCN
1	13Nov2018	New	DCN-18-038