NeoBurr®
(Sterile Single-Use Dental Carbide Burs)
Instructions for Use

CAUTION:
Rx Only. These instructions, in whole or in part, are not a substitute for formal training in carbide dental burs. Appropriate professional education is REQUIRED prior to using this device clinically. NeoBurr carbides burs are intended to be used by qualified dental practitioners in dental clinics, hospitals, labs, or schools for dental applications.

DESCRIPTION:
Microcopy NeoBurr tungsten carbide burs are manufactured from either a single piece tungsten carbide or, from a tungsten carbide tip brazed to a surgical grade stainless steel stem. The carbide burs are further plated with a unique protective coating formula some of which contain gold plating. The range includes patterns designed to meet the needs of all surgery and laboratory applications. The burs are packed in a plastic pouch in a dedicated cleanroom facility and terminally sterilized using Gamma Irradiation STERILE R by a contract sterilizer. The carbide burs fit into a dental handpiece, which provides rotation, allowing the user to cut or finish dental materials.

INDICATIONS:
NeoBurr tungsten carbide burs are indicated for anyone requiring cutting or finishing of dental materials. NeoBurr burs are intended to cut or finish a wide variety of materials encountered in dentistry. These include tooth material such as enamel, dentin and bone, dental materials such as amalgam, composite, glass-ionomer cements, polymer and precious and non-precious alloys. **Siinä epätodennäköisessä tapauksessa, että poranterässä ilmenee vika, ÄLÄ palauta sitä Microcopylle. Ota siitä kuvia, sillä Microcopy ei voi vastaanottaa käytettyä tuotetta.**

CONTRAINDICATIONS TO USE:
Use of Microcopy NeoBurr is contraindicated on any patient who is allergic to any of the components of the product. NeoBurr-poranterät valmistetaan joko yhdestä volframikarbidipalasta tai volframikarbidikärjestä, joka juotetaan kiinni kirurgiaan soveltuvaan ruostumattomaan teräsvarteen. NeoBurr-poranterät sisältävät 10 % kobolttia, joka on tunnettu allergeeni ja joka voi aiheuttaa paikallisen tai systeemisen allergisen reaktion, eikä sitä siksi suositella käytettäväksi allergikoille tai yliherkille potilaille. Nikkeliä käytetään poraterän kärjen juottamiseen varteen, ja yksiosaiset NeoBurr-poranterät viimeistellään nikkelipinnoitteella ja kultapäällysteellä. Tämä aiheuttaa riskin potilaille, joiden tiedetään olevan yliherkkiä nikkelille ja joille se aiheuttaa allergisen reaktion, ja siksi nikkelipinnoitettuja poranteriä ei suositella käytettäväksi potilailla, joiden tiedetään olevan allergisia tai yliherkkiä nikkelille.

CLINICAL WARNINGS

a) Microcopy NeoBurr are single-use. Attempting to re-process or re-sterilize will adversely affect the device's performance.
b) Do **NOT** use the product if the package is opened or damaged.
c) Do **NOT** use the products after their stated expiration date.
d) Do **NOT** use the product if the carbide flutes or shanks are damaged.
e) Do **NOT** use excessive force to as this may cause the bur to break which may lead to patient injury.
f) Do **NOT** exceed maximum speed as this may generate undesirable heat.
g) Always keep track of lot numbers of NeoBurr to ensure traceability.

Failure to follow these instructions may cause the carbide bur to become dull, break, or become contaminated and result in the following: infection, preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the carbide burs.

CLINICAL USE AND PRECAUTIONS:

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a) Protect patient's eyes and vulnerable tissues when using these carbide burs.
b) Clinicians should wear eye protection and facemask when using carbide burs.
c) Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
d) Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause procedural delays or patient or user injury.
e) Follow the handpiece manufacturer's instructions for use and maintenance and service all hand pieces appropriately.
f) 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 or injury of the patient or user, aspiration or swallowing of the device, or damage to the preparation site due to vibration of a worn chuck or turbine.
g) Handle packaging and product with care to ensure sterile barrier is maintained.
h) If the package is damaged or unintentionally open prior to use, the bur must not be used and be immediately discarded.
i) For aseptic preparation open pouch immediately before use to prevent contamination.
j) To open, hold the bur 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 empty pouch.
k) Ensure the bur is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the device to "walk out" of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the device.
l) Never force a bur into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
m) Prior to use inspect the bur for broken and/or damaged flutes, discard any potentially defective burs. Do not use worn-out or dull devices. Discard any damaged carbide burs immediately.
n) Before use, run the hand piece to check for any abnormalities including overheating.
o) Do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to fail.
p) Move the bur continuously when in use to avoid localized heating and/or damage to the bur. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
q) Avoid removing the bur at too sharp an angle to avoid leverage and breakage which could cause patient or user injury.
r) Do not exceed the maximum speeds tabulated below as this may generate undesirable heat and damage the tooth pulp.

Instrument head diameter 01/10 (mm) - ISO	Maximum permissible speed (RPM)	Recommended operational speed (RPM)
007 - 010	450,000	100,000 - 220,000
011 - 014	450,000	70,000 - 220,000
015 – 018	450,000	55,000 - 160,000
019 - 023	300,000	40,000 - 120,000
024 - 027	160,000	35,000 - 110,000
028 - 031	140,000	30,000 - 95,000
032 – 040	120,000	25,000 - 75,000
041 – 054	95,000	15,000 - 60,000
055 – 070	60,000	12,000 - 40,000
080 – 100	45,000	10,000 - 20,000

STORAGE:

- In dry conditions and protected against contaminants. Protect instruments, in general, against chemicals, acids,

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heat and extreme temperature variations.

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

DISPOSAL:

- Each used carbide bur must be disposed in a biohazard sharps waste container.
- Each unused carbide bur must be disposed in a sharps waste container.

STERILE PRODUCT SHELF LIFE:

- On the provision that appropriate storage and handling practices are applied to all unopened pouches, product sterility will be maintained for five (5) years unless sterile package is opened or damaged.
- Sterile provided products are labeled with their expiry date.

TRACEABILITY:

- Each package includes **Lot number** LOT on its label.
- 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 re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.		Do not re-sterilize	Indicates a medical device that is not to be resterilized.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.		Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	Use-by date	Indicates the date after which the medical device is not to be used.		Consult instructions for use	Indicates the need for the user to consult the instructions for use.

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CE	CE marking	Indicates European Conformity Mark.	EC REP	Authorized European representative	Indicates the Authorized representative in the European Community.
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	Rx	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.	REF	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
1	Single Patient – Multiple Use	Indicates a medical device that may be used multiple times in a single operation.	max	Max speed	Indicates Max speed
	Wear eye protection	Indicates that eye protection must be used.		Wear a mask	Indicates that a face mask must be worn.
	Date of Manufacture	Symbol for date of manufacture.		Importer	Indicates the entity importing the medical device into the locale
	Distributor	Indicates the entity distributing the medical device into the locale			

CONTACT INFORMATION:

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