

ORIGINAL

**Instructions for use
Of
Dental Root Canal Instruments
GATE DRILLS**

Doc. No.: DJYL-IFU-B051W

Version: A1

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SHENZHEN DENCO MEDICAL CO., LTD

Please read the manual carefully before using the device

Revision History

Item	Rev	description	release date
1	A0	The first release	2023-6-12
2	A1	Modify European representative information	2026-5-8

1. Brief of the product

The Dental Root canal Instruments (Model: GATE DRILLS #3) is an enlarger power-operated endodontic instrument used for improving access to the root canal by enlarging its coronal opening. It is used by connecting to active device (Allowable engine speed: MAX 800min⁻¹) and rotates to enlarge root canal orifice.

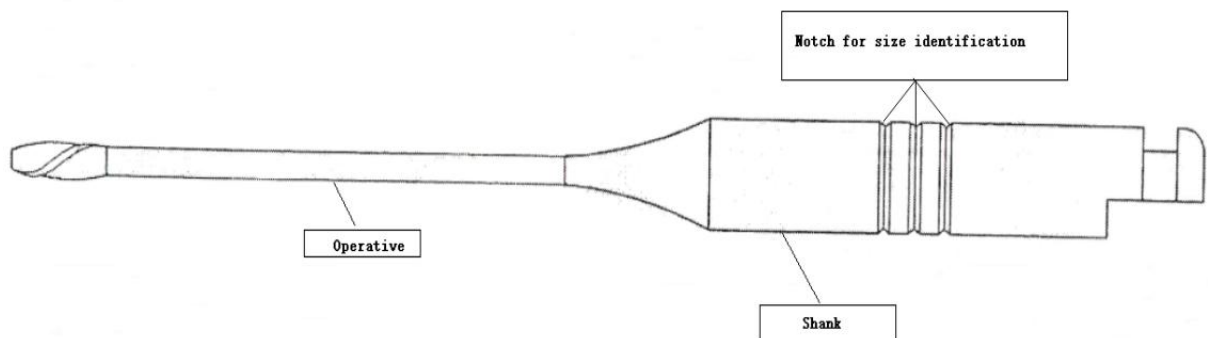
It is shape instrument, which is type 5 classification base on ISO 3630-1:2019.
It is non sterile instruments.

2. Product Structure and materials

The GATE DRILLS #3 is integrated instrument having shank and the operative part in one piece, which is no assembly required.

It is Enlarger Type G base on ISO 3630-2.

The main Materials: Stainless steel



3. Warnings

- 3.1 Only skilled dentists are allowed to use.
- 3.2 Be sure to sterilize this product for each use.
- 3.3 Do not use this product except for the dental service and treatment. Use it in accordance with the intended use.

<Contraindications and prohibitions>

Do not use this product for a patient who indicates sensitization and allergic reaction.

4. Re-Processing

The GATE DRILLS #3 are single use and not approved for re-use.

The number of sterilizations should not exceed six times.

5. Method of operation

Its pilot tip end has been removed but its football shape retained so it cuts a stagnating preparation down to the file segments following the canal path already shaped by the separated file before the fracture. The maximum diameter of this bur is 0.9 mm and the tip diameter is 0.45mm. It is used at 1000RPM in clock-wise direction.

6. Specification

6.1 The Specification of GATE DRILLS #3 as the below table:

Size	Working Length (mm)	Tip Diameter (mm)	Ring marking
#3	28mm 32mm	0.90	III

6.2 **Allowable rotation speed: MAX 800min⁻¹.**

6.3 This instrument is under the provisions of ISO 3630 performance test, products' durability for twisting and bending must exceed specified value of our standard.

6.4 Use the active device which can hold the shank precisely: Diameter of Contra Angle shank: 2.35mm and the active device which could control all allowable engine speed.

7. Precautions for use:

7.1 To prevent infection, please clean and disinfect the product (Please see item 8) and make sure sterilization is completed before using.

7.2 Before using, make sure the instruments outside of oral cavity that there are no deformations, scratches and cracks.

7.3 If the head of product is thin, long or large, there are possibilities for breaking or twisting. Because of this, be sure to avoid using unreasonable angle and excessive pressure.

7.4 Wear rubber dam etc. to avoid accidental ingestion and falling.

7.5 Do not use this instrument for any purposes except for listed applications above.

7.6 Only for use by dentists.

7.7 This product should be treated as medical waste when disposed.

7.8 Dispose the product if damaged or contaminated.

7.9 After using, wash it with medical cleaning agent and brush, then wash away foreign substances like adherent body fluids and body tissues.

7.10 Set the product to a stand when cleaned by ultrasonic cleaner to avoid deterioration of cutting part.

7.11 Use this product with great care to avoid puncturing fingers because of its possession of sharp-edged part.

7.12 This product has possibility that be corrosive if sunk into NaOC1, EDTA and etc. for a long time.

8.2.1 Disassembling: Remove the stopper from the instrument and dispose of it

8.2.2 Rinsing: Rinse extensively (at least 1 minute) under flowing deionized water (ambient temperature). While rinsing, use a soft brush (made of nylon, polypropylene, acrylic) for pre-cleaning until visible impurities are removed.

8.2.3 Cleaning and Disinfection

8.2.3.1 Manual Cleaning assisted by an ultrasonic device:

- 1) Manual cleaning with ultrasonic equipment
- 2) Place the instrument in a kit, stand or container (made of stainless steel, polypropylene or titanium).
- 3) Immerse in a detergent solution (for example, Metrex EmPowder concentration 1:128) with cleaning properties, if appropriate, soak for at least 15 minutes with the aid of ultrasonic equipment.
- 4) Flushing: Perform a large amount of flushing (at least 1 minute) under flowing deionized water temperature 20°C ~ 40°C.
- 5) Drying: Dry with a disposable non-woven fabric or hot air dryer not exceeding 110°C.

8.2.3.2 Automated Cleaning using a cleaning and disinfecting device

- 1) Place the instrument in a kit, stand or container (made of stainless steel or titanium).
- 2) Perform the defined cycle with detergent solution (for example, Metrex EmPowder concentration 1:128 ~ 1:512) for at least 5 minutes in the washer-disinfector with temperature 20°C ~ 40°C.

8.2.3.3 Disinfection using a washer-disinfector device

- 1) Place the instrument in a kit, stand or container (made of stainless steel or titanium).
- 2) Perform the defined cycle with mild neutral enzyme cleaning agent solution (for example, Metrex EmPowder concentration 1:128) for at least 5 minutes in the washer-disinfector with temperature >90°C, A0 >3000.

Note:

- > Discard any instruments with obvious defects (broken, bent, etc.).
- > When the instruments are placed in the cleaning kit, support or container, avoid any contact with each other.
- > Follow the instructions and concentration provided by the detergent solution manufacturer (see also general recommendations).
- > Follow the instructions of the washer-disinfector and verify the success criteria after each cycle is reached according to the manufacturer's instructions.
- > The final rinse step should use deionized water. For other steps, follow the water quality defined by the manufacturer. Place the devices in a kit, support, or container (made from stainless steel or titanium) to avoid any contact between devices or posts.

8.2.3.4 Rinsing: Abundant rinsing (at least 1 min) under running water (ambient temperature).

- 1) Use deionized water for rinsing.
- 2) If the previously used cleaning solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the autoclaving.

8.2.3.5 Drying: Devices should be thoroughly dried before inspection and packaging.

- 1) Dry on a single use non-woven cloth, or with a hot air drier at not more than 110°C.
- 2) Devices should be dried until visual traces of moisture are eliminated.
- 3) Particular attention has to be paid to effectively dry joints or cavities within a device.

8.2.3.6 Inspection:

8.3.6.1 Inspect the devices functionality.

8.3.6.2 Inspect devices and sort out those with defects.

- 1) Dirty devices must be cleaned again.
- 2) Do not re-use silicon stops.
- 3) Discard devices, which show any defect

8.2.3.7 Packing: Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in “Sterilization pouches”.

- 1) Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers.
- 2) For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing.
- 3) Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated.
- 4) Check the validity period of the pouch given by the pouch manufacturer to determine the shelf life.

8.2.4 Sterilization:

- 1) Steam sterilization at **134°C / 273°F during 5 min** is recommended for these devices, for the purpose of de-activating potential prions.
- 2) The instruments and posts must be sterilized according to the packaging labelling.
- 3) Place the pouches in the steam sterilizer according to the recommendation given by the sterilizer manufacturer.
- 4) Use only steam sterilizer that are matching the requirements of EN 13060 (class B, small sterilizer), EN 285 (full size sterilizer).
- 5) Use a validated sterilization procedure according to ISO 17665 with a minimum drying time of 20 min
- 6) Respect the maintenance procedure of the sterilizer given by the sterilizer manufacturer.
- 7) Control the efficiency and acceptance criteria of the sterilization procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters).
- 8) Store traceability records and define shelf-life according to packaging manufacturer guidelines.
- 9) Shorter sterilization cycles according to local regulations are possible but are not guaranteed to de-activate prions.

8.2.5 Storage

Keep devices in sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature.

- 1) Sterility cannot be guaranteed if packaging is open, damaged or wet.
- 2) Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date).

9. Transportation

9.1 To prevent damage to the medical device during transit, use a specific racks, trays or rigid containers may be recommended.

9.2 When the package was broken, then it is non-sterilize, must be cleaned, disinfected and sterilized before using.

10. Storages and duration of use

10.1 Avoid storing at high temperature, humidity and direct sunlight. Keep liquids away. Store it at room temperature.

10.2 Do not damage or make a pinhole to packaging materials.

10.3 The product is subject to be improved without previous notice. Enforce the first-in first-out method for stock management.

10.4 Do not keep under germicidal lamp to avoid deterioration.

10.5 The shelftime of root canal files are 5 years.




11. Disposal













For proper disposal, always observe national laws and recommendations of the authorities.

12. Packaging

1 pcs/package

13. Explanation of related symbols

Symbols	Explanation
	Medical device
	For Dental Use Only
	Do not reuse

	Rotary Use
	Batch code
	Non-Sterile
	NB 0197 certified
	Expired Date
	Consult instructions for use
	The operative part is Stainless Steel
	Authorized representative in the European Community
	Manufacturer
	Can be sterilized at the specified temperature
	1pcs/pack
	Unique device identifier

15. <Legal manufacturer>



Shenzhen Denco Medical Co., Ltd

Address: Room 3108, Block 6, Tian'an Cloud Park, Bantian street, Longgang District, Shenzhen, 518129 Guangdong P.R. China

Factory Address: Room 101, 201, 301B, 401&801, Block 5, Renluo 6 Road No. 6, Shuikou Street, Huicheng District, Huizhou, 516000 Guangdong, P.R. China

www.dencoendo.com

< EU representative >



Share info GmbH
Am Schulzentrum 12, 41564 Kaarst,
Germany

