

# Instruction For Use

## Dental Root-Canal Instruments

### Hand Files

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# Dental Root-Canal Instruments

## Instruction For Use

### Hand Files

手用根管锉使用说明书

**<Product Name 产品名称>** Dental Root-Canal Instruments 根管器械

**<Type/model 类型/型号>** K、H、Reamer

**<Specifications 规格>** 06, 08, 10, 12, 13, 15, 16, 17, 19, 20, 21, 22, 25, 27, 30, 32, 35, 37, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140;

**<Intended use 预期用途>**

The product is a dental repair instrument for the removal of dentin and root canal forming, the treatment of various pulpitis, pulp necrosis of root canal disease.

该产品是牙科修复器械，用于去除牙本质及根管成形，治疗各种牙髓炎，牙髓坏死的根管疾病。

**<Structure and composition 结构和组成>**

The hand root canal file consists of working part, handle and Stopper.

Main materials

Working part: Stainless Steel or NiTi alloy

The working part of these instruments is made of Stainless Steel or NiTi alloy

Handle: plastic PBT

Stopper: silicone rubber

手用根管锉由工作部分，手柄和硅胶垫组成。

主要材料：

工作部分：由不锈钢或镍钛合金制成。

手柄：塑料 PBT

胶垫：硅胶

**<Contraindication 禁忌症>**

The product contains Nickel and chromium should not be used for individuals with known allergic sensitivity to this metal.

该产品含有镍和铬，对这两种金属过敏的患者禁用。

#### < **Warning** 警告 >

1. This product can only be used by professional dentists;  
本产品只允许专业牙医使用；
2. Ensure that the product is disinfected every time it is used;  
确保每次使用时都要对该产品消毒；
3. Do not use this product for any purpose other than dental treatment and service.  
请勿使用本产品除牙科治疗和服务以外的用途。

#### < **Precautions for use** 使用注意事项 >

1. For your own safety, please wear personal protective equipment (gloves, glasses, mask);  
为了您自己的安全，请穿戴个人防护设备（手套，眼镜，口罩）；
2. Check whether the product is within the specified period of validity before use;  
使用前检查产品是否在规定的有效期；
3. To prevent infection, please disinfect the product with autoclave before use;  
为防止感染，请在使用前用高压灭菌器对产品进行消毒；
4. This product should be treated as medical waste.  
本产品在处置时应视为医疗垃圾；
5. This product is one-time use and is forbidden to be used twice.  
本产品为一次性使用，禁止 2 次使用。

#### < **Usage and Operation Steps** 使用方法及操作步骤 >

1. Open the pulp crown with a diamond needle.  
使用金刚砂车针开髓冠部；
2. Explore root canal with 8# or 10# file, use round-trip rotation to enter root canal, use sodium hypochlorite to flush root canal.  
使用 8#或 10# 锉探查根管，采用往返旋转方式进入根管，使用次氯酸钠冲洗根管；

3. Use a 15# file to further smooth the root canal and determine the working length.

使用 15#锉进一步通畅根管，然后确定工作长度；

4. Flush again and use a 15# file to clean the shreds to prevent debris from clogging the root canal.

再次冲洗，使用 15#锉清理碎屑，防止碎屑堵塞根管；

5. Use 20# file to pull up and down, prepare 2-3 mm, each time to clean debris gradually to the root tip.

使用 20#锉上下提拉，每次向下预备 2-3mm，清理碎屑逐步预备至根尖；

6. Use 25# file to repair the root canal with a fine file, so that the root canal smooth, in the preparation process of pre-resistance do not force down, use sodium hypochlorite to wash the root canal many times, prevent debris to the root tip, resulting in filling failure.

使用 25#锉修整根管，使根管顺滑，在预备过程中预阻不要强行向下前进，使用次氯酸钠多次冲洗根管，防止碎屑推向根尖，导致充填失败；

7. For large root canals, select the appropriate size file needle to be prepared in turn to size in turn.

对于大号根管，选择合适规格的锉针依次预备至充填的尺寸。

#### **<Cleaning, disinfection and sterilization 清洗、消毒、灭菌>**

1. After unpacking, the root canal file must be sterilized according to the requirements before use. The recommended sterilization method is high temperature and high pressure steam sterilization at 134 °C for 18min;

拆开包装后，根管锉使用前必须按照要求进行灭菌处理后才能使用，推荐灭菌方式高温高压蒸汽灭菌 134℃ ,18min;

2. After use, the root canal file was washed with running water and the residual debris on the file was cleaned with a soft brush;

使用后先将根管锉用流水冲洗同时用软毛刷清洁锉上残留的碎屑；

3. Then, the root canal file was soaked in the solution containing proteolytic enzyme for disinfection;

然后将根管锉浸泡在含蛋白水解酶清洗消毒液中进行消毒；

4. The recommended sterilization method is 134 °C and 18min;

根管锉再次使用时需重新灭菌后方可使用，推荐灭菌方式高温高压蒸汽灭菌  
134℃ ,18min;

**<Product storage conditions 产品储存条件>**

1. During transportation and storage, handle with care, do not stack, to prevent damage to packaging materials;

运输存储过程中轻拿轻放，请勿堆叠，防止损坏包装材料；

2. Avoid storage in high temperature, high humidity and direct sunlight, and store the products at room temperature;










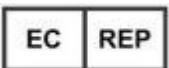
避免存放在高温、高湿和阳光直射的地方，产品要在室温下存放；

**<Validity 有效期>**

The product is valid for 5 years.

产品有效期 5 年。

**<Symbol identification 符号标识>**

				
K-file	H-file	Reamers	Non sterile	See directions for use
K 型根管锉	H 型根管锉	扩大锉	没有灭菌	见使用说明书
				
LOT number	Date of manufacture	Validity	Manufacturer	European representative
批号	生产日期	有效期	制造商	欧盟代表

**<Version or date 版本和日期>**

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