



EndoHandle



Read instructions before use



Non Sterile

Before using the EndoHandle, please see the instruction manual as indicated below.

<Warnings>

1. Only skilled dentists are allowed to use.
2. Sterilize before each use
3. Do not use this product except for the dental service and treatments. Use it in accordance with its intended use.

<Contraindications and prohibitions>

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

<Structures and principles>

1. This is a handle with a locking chamber that fits standard endodontic files. It is used for initial canal management in root canal treatment.
2. Main materials: Anodized Aluminum.

<Purpose of use>

It is used for initial canal management in root canal treatment. This includes locating canals, filing a straight line access and Glide path for safe, unstressed rotary instrumentation, as well as cleaning and shaping the canal.

<Method of use>

The EndoHandle uses a simple and effective Circumferential Linear Filing technique. It is a straight-line/up-down filing motion done sequentially around the periphery of the canal. The file is placed in the canal and withdrawn in a directional manner against each side of the canal wall. No rotation, just safe straight-line filing to sculpt and clean the walls of the canal.

<Precautions for use>

1. Only for use by dentists.
2. Do not use the EndoHandle except for the dental service and treatment. Use it in accordance with the intended use.
3. Be sure to sterilize the product by autoclave before each use. Make sure sterilization is complete.
4. The user is responsible for inspecting instruments prior to each use. Dispose of product if damaged.
5. Straight hand files should not be used in the EndoHandle. A contra-angle bend must be placed in the shaft of the file.
6. Do not use hand files that have serrations on the shaft.
7. Make sure hand file is secure in the locking chamber before filing.
8. Do not use this product for a patient who indicates sensitization and allergic reaction.
9. This product should NOT be placed in solutions that have a PH above or below seven. Do not place in an ultrasonic cleaner.

<Storage>

Store in dry place that is protected from contamination. Avoid high temperatures and humidity. Keep liquids away.

<Packaging>

Single EndoHandle
Intro System: set of 3 EndoHandles
Standard System: set of 5 EndoHandles

<Maintenance and inspections>

1. Before sterilization remove the disposable hand file from the locking chamber of the EndoHandle.
2. Wipe instrument down with neutral solutions by hand. This product should NOT be placed in solutions that have a PH above or below seven. Do not place in an ultrasonic cleaner.
3. Sterilize this product by autoclave under established method and term for each use*

Method of sterilization:

Put product in sterilization pouch and place it on a sterilization tray for autoclave sterilization with reference to the following terms*

Terms for sterilization:

Use fractionated vacuum or gravity procedure sterilizers. Defer to the sterilizing manufacturer's instructions for the equipment used. Sufficient product drying must be ensured after sterilization and before handling; see below for recommendations.

Minimum Cycle times for wrapped instruments:

Gravity-displacement steam sterilization:

Exposure time (at 121°C / 250°F): 30 Minutes

Drying time: Minimum 30 minutes

Fractionated vacuum/dynamic-air-removal steam sterilization:

Exposure time (at 132°C/ 270°F): 4 minutes

Drying time: Minimum 30 minutes

4. The life time of the EndoHandle depends on the frequency of use, the care of the user and proper reprocessing methods. The user is responsible for inspecting instruments prior to each use.
5. Dispose of the product if damaged or decreased performance.

<Legal manufacturer>

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- ◆ Always keep this document near at hand. In case of loss, please contact dental department the manufacturer for copy
- ◆ The specifications, structures and materials are subject to be changed without previous notices for the demands of improvement.
- ◆ The contents of this instruction manual are subject to be revise without previous notices.