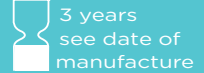
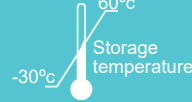


Instructions for Use



ProDesign Logic

Controlled Memory Rotary Nickel Titanium Files Glide Path Files: .01/25, .01/30, .01/35, .01/40, .01/45, .01/50

Shaping Files:

Serie 05 = .05/25, .05/30, .05/35, .05/40

Serie 03 = .03/15, .03/25, .03/30, .03/35, .03 /40

Additional sizes: .04/25, .05/15, .06/25

Lengths: 21mm & 25mm.

Available in procedure kits and individual sizes.

Contraindication & Adverse Reactions:

As with all mechanically driven root canal instruments, ProDesign Logic files should not be used in cases of severe and sudden apical curvatures due to heightened risk of separation.

Precautions

1. Before clinical use

- Cleaning and sterilize the product according to the indicated method.
- Do not use rotational speed other than that suggested in this IFU.
- For better performance efficiency, a torque control is recommended as suggested in the table of this IFU (according to the identified model).
- Do not carry out treatment on patients without teething.
- Never force ProDesign Logic apically. Insert the ProDesign Logic file gently and passively.
- Irrigate the root canal copiously and frequently during the shaping procedure.
- Sodium Hypochlorite solution should not be used as a disinfectant.
- Prodesign Logic files should be single patient use only be.
- The reuse of endodontic files can increase the risk of: cross contamination, due to the possibility of use in different patients, fracture of the active part or detachment of the active part of the handle shank, due to the wear and tear generated by excessive use.
- Dispose of used Prodesign Logic instruments in an appropriate Biohazard Sharps container.
- Do not use the endodontic file after the expiration date. The product may have a lower working performance than specified.

2. Utilize

A torque controlled endodontic motor is indicated.

3. Dispose of used ProDesign Logic instruments in an appropriate Biohazard Sharps container.

For Dental Use Only

Composition

The functional portion (blade) of the instrument is composed of nickel titanium alloy.

Indications for use

Shaping of the root canal system in endodontic procedures.

Every patient who presents a tooth in the dental arch is liable to undergo endodontic treatment and use NiTi rotary files.

Warnings

Files should be handled by qualified professionals. Instruments must be sterilized before use.

In order to obtain an efficient and safe process, the rotating equipment must comply with IEC 60601-1.

This product contains nickel and should not be used for individuals with known allergic sensitivity to this material.

Connection of the endo file to the contra angle

The endo file must be connected to the contra angle in order to use it correctly. The contra angle head must be opened and the latch of the endo file must be connected inside. The contra angle head must be locked and the operator must check if it is read to use. After the use, the contra angle must unlocked and unload.

Cleaning methods for endo files:

Before the use, all endo files must go ultrasonic bath with distilled water during 60 minutes, 80°C, according to ultrasonic device instructions. After ultrasonic bath, the files must rinse in clean water. Once the files are dry, it can be put inside autoclave paper bags and sealed.

Sterilization method indicated:

Use steam sterilization at temperature of 121°C, for 20 minutes and 1,20 Kg/cm² (1,16 atm).

Side effects:

No side effect has been reported using NiTi files.

Suggested rotation speed and torque

Size	NCM	RPM	Size	NCM	RPM	Size	NCM	RPM
#.01/25	1	350	#.03/15	2	350 to 950	#.05/15	2	950
#.01/30	1	350	#.03/25	2	600 to 950	#.05/25	4	950
#.01/35	1	350	#.03/30	2	600 to 950	#.05/30	4	950
#.01/40	1	350	#.03/35	2	600 to 950	#.05/35	4	950
#.01/45	1	350	#.03/40	2	600 to 950	#.05/40	4	950
#.01/50	1	350	#.04/25	2	950	#.06/25	4	950



Manufactured by Easy Equipamentos Odontológicos
Address: Barão de Paraopeba,230 - Jardinópolis,
Belo Horizonte-MG | Brasil CEP: 30532-150
Phone: +5531 3328-5550 Ext 5571



Name: Soprasorrisos Unipessoal LDA
Address: Street Largo de São Pedro, 15A
Sabugal – Portugal