INSTRUCTIONS OF USE



Flex Pack













Flex Pack

Flex Pack is a nickel titanium condenser that performs gutta-percha insertion in treatment procedures.

Available in sizes:

#.35/02 | #.40/02 | #.45/02

Lengths: 25 mm.

Available in procedure kits and individual sizes.

Contraindications and adverse reactions:

As with all mechanically driven root canal instruments, Flex Pack mechanical condensers should not be used in cases of sudden and severe apical curvatures due to the increased risk of separation.

Precautions:

Before clinical use:

- Clean and sterilize the product according to the method indicated.
- Don't use a rotation speed different from that suggested in this instruction manual.
- For best performance efficiency, a torque control as suggested in the table of this IFU (according to the identified model) is recommended.
- Never force the mechanical Flex Pack capacitor apically. Insert the mechanical Flex Pack capacitor gently and passively.
- If any distortion is observed, it should be discarded immediately.
- Gently push the gutta percha against the root canal during the casting/procedure.
- The Flex Pack mechanical condenser is designed for single patient use.
- Reuse of the Flex Pack mechanical condenser may increase the risks of: cross contamination, due to the possibility of using it on different patients, fracture of the active part or detachment of the active part from the handle rod, due to wear and tear generated by excessive use.
- Dispose of the used Flex Pack mechanical condenser in an appropriate biohazard needle container.
- Don't use the Flex Pack mechanical condenser after the expiration date. The product may perform less than specified.

Use:

The use of an endodontic motor with torque control is indicated. The Flex Pack mechanical condenser should be used with rotation between 13000RPM and 15000RPM according to the level of professional training or individual preference.

Before inserting it into the tooth, check that the direction of rotation of the contra-angle handpiece is correct.

Dispose of used Flex Pack instruments in an appropriate biohazard needle container.

Only for dental use

Composition:

The functional part (blade) of the instrument is made of a nickel-titanium alloy.

Indications for use:

Modeling of the root canal system in endodontic procedures. Every dentition patient is subject to endodontic treatment and the use of NiTi rotary files.

Warnings:

The Flex Pack mechanical condenser must be handled by qualified professionals. The instruments must be sterilized before use. This product contains nickel and should not be used by persons with known allergic sensitivity to this material.

Connection of the endodontic file to the contra-angle handpiece:

Flex Pack mechanical condenser must be connected to the contra-angle handpiece in order to use it correctly. The head of the contra-angle handpiece must be open and the latch of the Flex Pack mechanical condenser connected from the inside. The head of the contra-angle handpiece must be locked and the operator must verify that it is ready for use. After use, the contra-angle handpiece must be unlocked and discharged.

Cleaning methods for endodontic files:

Before use, all parts should be subjected to an ultrasonic bath with distilled water for 60 minutes at 80°C, according to the instructions of the ultrasonic device. After the ultrasonic bath, they should be rinsed with clean water. Once dry, the Flex Pack mechanical condenser can be placed in an appropriate autoclave package. For dental use only.

Sterilization method indicated:

Use steam sterilization at a temperature of 134° C for 7 minutes at 1.20 kgf/cm2 (1.15 ATM).

Side Effects:

No side effects have been reported with the use of NiTi endodontic files.