

roeko

Surgitip-endo

Instructions for use

EN

Carefully read the instructions prior to use.

1. PRODUCT DESCRIPTION

Surgitip-endo is an aspirating tip specially designed to dry root canals. Due to the outer diameter of the Canal Tip Surgitip-endo allows access to root canals prepared acc. to ISO 60. It is a handheld device, which is connected directly to a suction system or with an adapter as an intermediate piece. The suction system is used for the removal of dental fluid and debris from the mouth. The innovative design of the suction tip allows for a multidirectional flexibility, so it can easily be introduced into hard-to-reach root canals without having to bend the Canal Tip. Aspiration is highly effective at all angles and visibility is not constricted.

2. INTENDED USE

Surgitip-endo are intended for aspiration during endodontic treatments and in specific for drying of the root canal.

3. COMPOSITION

Surgitip-endo consists of a PVC tube and a tip consisting of a connecting piece, three ball elements and a Canal Tip. The tip components are made of polypropylene.

4. INDICATIONS/CLINICAL BENEFIT

Liquid control during endodontic treatment. Drying of the root canal before filling. The root canal is dried effectively. Thoroughly dried canals ensure increased adhesion of the filling material to the root canal walls.

5. CONTRAINDICATIONS

N/A

6. SAFETY INSTRUCTIONS

N/A

7. SIDE EFFECTS/INTERACTIONS

No reciprocal or side effects for this device.

8. USER/PATIENT GROUP

The user group are dentists and dental assistants. Surgitip-endo is suitable for all patient groups.

9. PREPARATION

Surgitip-endo is a sterile device and should be unpacked only shortly before its use in the operation room. The sterility of undamaged, unopened packs is guaranteed. If packages are damaged prior to use they have to be discarded.

The black arrow on the sterile bag facilitates easy opening of the peel pack. An adapter can be used as a connecting device between aspirator tip and the suction machine in the dental unit. See the respective reprocessing instructions of the adapter.

10. PROPER USE

- Arrange the flexible green tip so that it can be introduced into the canal vertically. Due to its multidirectional flexibility this can be done without having to bend the tip.
- Avoid over straining the joints, they should not be bent more than 90°.
- Use slight tapping movements during aspiration.
- To prevent clogging the aspirator tip can be rinsed with water.
- The extremely fine aspiration opening of the

Canal Tip is not suitable for aspiration of tissue and/or larger particles. These can be removed as usual by irrigation and aspiration with the aid of Surgitip-micro or Surgitip.

11. TEST METHOD FOR CORRECT APPLICATION

N/A

12. REPROCESSING, CLEANING, DISINFECTION, MAINTENANCE

N/A

13. SINGLE USE DEVICE

Surgitip-endo is a single use device. The device is not intended to be reprocessed. After reprocessing the safety, effectiveness and performance of the product cannot be guaranteed any more.

14. SHELF LIFE AND STORAGE

See expiration date and storage symbols on the packaging.

15. DISPOSAL

Surgitip-endo can be disposed with the practice waste unless local requirements define otherwise.

16. TECHNICAL DATA

N/A

17. REPORTING OBLIGATION

All serious incidents occurring in conjunction with the product must be reported to the manufacturer and to the competent authority of the member state where the user and/or patient is registered.



Glossary



Consult instructions for use



Keep away from sun light



Do not re-use



Keep dry



Limits of temperature



Conformity mark Ukraine



Manufacturer



Use-by date



Single sterile barrier system



Do not resterilize



Batch Code



Sterilized using irradiation



Restricted device for professional use only



Medical Device



Date of manufacture



Do not use if package is damaged and consult instructions for use



Catalogue number

Coltene/Whaledent GmbH + Co. KG

Raiffeisenstr. 30
89129 Langenau/Germany
Tel.: +49-7345-805-0
info.de@coltene.com
www.coltene.com

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