

ROEKO Retracto / roEKO Stay-put

Instructions for use

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Please read the Instructions for Use carefully before using the product.

1. PRODUCT DESCRIPTION

Retraction cords are used to expose the sulcus before an impression of the jaw is made.

2. INTENDED USE

Roeko retraction cords are intended to open the sulcus and, due to the resulting pressure on the tissue, to avoid hemorrhage.

3. COMPOSITION

ROEKO Retracto

Non impregnated braided or twisted cotton cord.

ROEKO Stay-put

Non impregnated braided cotton cord in which a copper wire (wrapped with nylon threads) is braided.

4. INDICATIONS FOR USE / CLINICAL BENEFIT

Temporary retraction of gingival margin.

5. CONTRAINDICATIONS

No contra-indications known.

6. SAFETY INSTRUCTIONS

⚠️ WARNING

Regarding ROEKO Stay-put: Avoid touching the cord with electrotomy and laser equipment.

Medical devices should be kept out of reach of children.

7. SIDE EFFECTS / INTERACTIONS

No harmful reactions or secondary effect of the patients and/or dental personnel are known.

8. USER- / PATIENT GROUP

The intended users are dental practitioners (dentist) and dental assistants (dental nurse). The product/product family is suitable for all patient groups.

9. PREPARATION

Cut the retraction cord to the required length. Retracto and Stay-put can be soaked in common gingival retraction solutions. Please follow instructions for use of the chosen liquid.

10. PROPER USE

Place the centre of cord into the sulcus. Next work out towards the ends of the cord. Overlapping is not necessary. Leave the cord, if it's non-impregnated for at least 5 minutes in the sulcus. If using a common haemostatic liquid, follow the instructions for use of the liquid for regarding the time specification. Remove the cord directly before taking the impression.

11. TESTMETHOD FOR CORRECT APPLICATION

Visual examination, the sulcus must be visually noticeably wider.

12. SHELF LIFE / STORAGE

See expiry date and storage symbols on the packaging. The package with the cord has to be stored in a dry place.

13. DISPOSAL

The product can be disposed in household waste. Special country-specific regulations may apply.

14. REPORTING OBLIGATION

All serious incidents occurring in conjunction with this 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



Single use only



Keep dry



Marking of Conformity Europe



Legal Manufacturer



Expiry Date



Batch Code



Restricted device for professional use only



Medical Device

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COLTENE