

# roeko

## GuttaFlow bioseal

### Instructions for Use

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Please read the Instructions for Use carefully before using the product. Keep for later reference.

#### 1. PRODUCT DESCRIPTION

**SEALER:** GuttaFlow bioseal is a cold flowable filling system for root canals, combining sealer and Guttapercha in one product. It consists of a polydimethylsiloxane matrix highly filled with very finely ground Guttapercha as well as a bioceramic material.

**MIXING TIPS:** The mixing tip ensures that all components are mixed in the correct proportions. The mixer is a static mixer, which means that there are no rotating or moving parts.

#### 2. INTENDED USE / CLINICAL BENEFIT

**INTENDED USE SEALER:** GuttaFlow bioseal is a cold flowable filling system for root canals, combining sealer and Guttapercha in one product. It is used during a root canal treatment for filling the root canal of a prepared tooth, in strict accordance with internationally recognized standards.

**CLINICAL BENEFIT SEALER:** To prevent reinfection after treating the original inflammation.

**INTENDED USE MIXING TIPS:** The mixing tips are intended for single use and must be discarded after use. They are used to determine the correct mixing ratio. They ensure that all components are mixed properly and in the right proportions, so that the GuttaFlow works according to its intended use.

**CLINICAL BENEFIT MIXING TIPS:** N.A.

#### 3. COMPOSITION

**SEALER:** Guttapercha powder, polydimethylsiloxane, platinum catalyst, zirconium dioxide, pigments, bioglass.

**MIXING TIPS:** N.A.

#### 4. INDICATION / CLINICAL BENEFIT

**SEALER:** For permanent filling of root canals after vital extirpation of the pulp or after treatment of gangrenous pulp and temporary fillings.

**MIXING TIPS:** Ensure the right mixing ratio for obturation within a root canal treatment.

#### 5. CONTRAINDICATION

**SEALER:** GuttaFlow bioseal must not be used with deciduous teeth.

**MIXING TIPS:** N.A.

#### 6. SAFETY INSTRUCTIONS

**⚠ DANGER**

N.A.

**⚠ WARNING**

**SEALER:**

- This medical device must be kept out of the reach of children.
- The safety and efficacy of use have not been established for children, pregnant or breastfeeding women.
- Do not use this medical device after the expiry date.
- Do not apply GuttaFlow bioseal directly into the root canal to avoid overfilling.

**MIXING TIPS:**

- This medical device must be kept out of the reach of children.

**NOTICE**

**SEALER:**

- Heat instruments may instantly cure GuttaFlow bioseal placed in the canal. Therefore, care must be taken not to pull cured GuttaFlow bioseal from canal walls during warm condensation.
- We do not recommend the use of further sealers in addition to GuttaFlow bioseal due to possible incompatibility.
- We do recommend a master Guttapercha Point during obturation of the root canal.

**MIXING TIPS:** N.A.

#### 7. SIDE EFFECTS / INTERACTIONS

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

#### 8. USER / PATIENT GROUP

**SEALER AND MIXING TIPS:** The intended users are dental practitioners (dentist) and dental assistants (dental nurse). The product is suitable for all patient groups with permanent teeth requiring an endodontic treatment. The safety and efficacy of use have not been established for children, pregnant or breastfeeding women.

#### 9. PREPARATION

**SEALER AND MIXING TIPS:**

**CAUTION:** We recommend to thoroughly rinse the root canal with sterile water or highly concentrated alcohol and dry with paper points to completely remove any residue of rinsing solutions (NaOCl, EDTA and CHX 2%) and temporary filling materials from the canal. Any remaining residue may prevent the GuttaFlow bioseal from curing.

GuttaFlow bioseal consists of two components, which are separated in a two-chamber system in the cartridge. Remove the brown cap of the applicator before using it and attach a mixing tip. Place the mixing tip on the cartridge opening and fix it by turning it ¼ (90°). Make sure the product is levelled before the mixing tip is placed on the syringe. By applying slight pressure on the end of the cartridge both components are mixed bubble-free at a ratio of 1:1. The appropriate amount of mixture is applied to a mixing block for further process steps.

**RECOMMENDATION:** Rubber dam should be used during the whole root canal treatment.

#### 10. PROPER USE

**SEALER:** Spread GuttaFlow bioseal on a mixing block and insert into the root canal with the Guttapercha Point or the last used apical file. The GuttaFlow bioseal material expands slightly during condensation process and fills small dentinal tubules.

**MIXING TIPS:** After removing the mixing tip and before placing the brown cap the openings of the applicator should be wiped clean carefully with a tissue to avoid contamination of the two components. It is most important that the two components do not come into contact. The applicator must always be resealed after use with the brown cap. Use GuttaFlow bioseal only with the associated mixing tips (REF 60019562).

For further application of GuttaFlow bioseal, a new mixing tip needs to be attached to the cartridge.

Working time: 5 minutes (heat reduces working time)

Setting time: 12 - 16 minutes

#### 11. TEST METHOD FOR CORRECT APPLICATION

**SEALER AND MIXING TIPS:** The product must be levelled before attaching the mixing tip to the syringe. Then add GuttaFlow bioseal onto the mixing block by applying pressure on the end of the cartridge. If the product does not mix properly (ratio of 1:1), the product cures too quickly, too slowly or not at all.

See step by step card.

#### 12. REPROCESSING, CLEANING, DISINFECTION, MAINTENANCE

N. A.

#### 13. SHELF LIFE / STORAGE

**SEALER:**

- Expiry date: see primary packaging.
- Do not use after expiry date.
- Avoid temperature fluctuations.
- Use the material no later than three months after opening.
- After opening, place it back into the aluminium bag to keep it protected from moisture.

**MIXING TIPS:**

- The mixing tip is intended for single use and should be discarded after use.

#### 14. DISPOSAL

Dispose of waste according to applicable legislation. Special country-specific regulations may apply.

#### 15. TECHNICAL DATA

Technical data according to ISO 6876.

#### 16. 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.

#### 17. SAFETY DATA SHEET

See: <http://www.coltene.com/> -> SDS Portal -> GuttaFlow bioseal

#### 18. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The summary of safety and clinical performance is publicly available on Eudamed (<https://ec.europa.eu/tools/eudamed>) it is linked to the Basic UDI-DI (+E165ENDO1GFBX0017T, ++E165ENDO1GFBX001A6) and/or can be provided upon request.

Glossary	
	Consult instructions for use
	Keep away from sun light
	Single use only
	Keep dry
	Temperature limitation
	Marking of Conformity Europe with Notified Body Registration Number
	Conformity mark Ukraine
	Legal Manufacturer
	Expiry Date
	Batch Code
	RX only: restricted device for professional use only
	Medical Device
	Manufacturing Date
	Unique Device Identifier
	Authorized representative in Switzerland
	Low-density polyethylene
	Reference Number

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