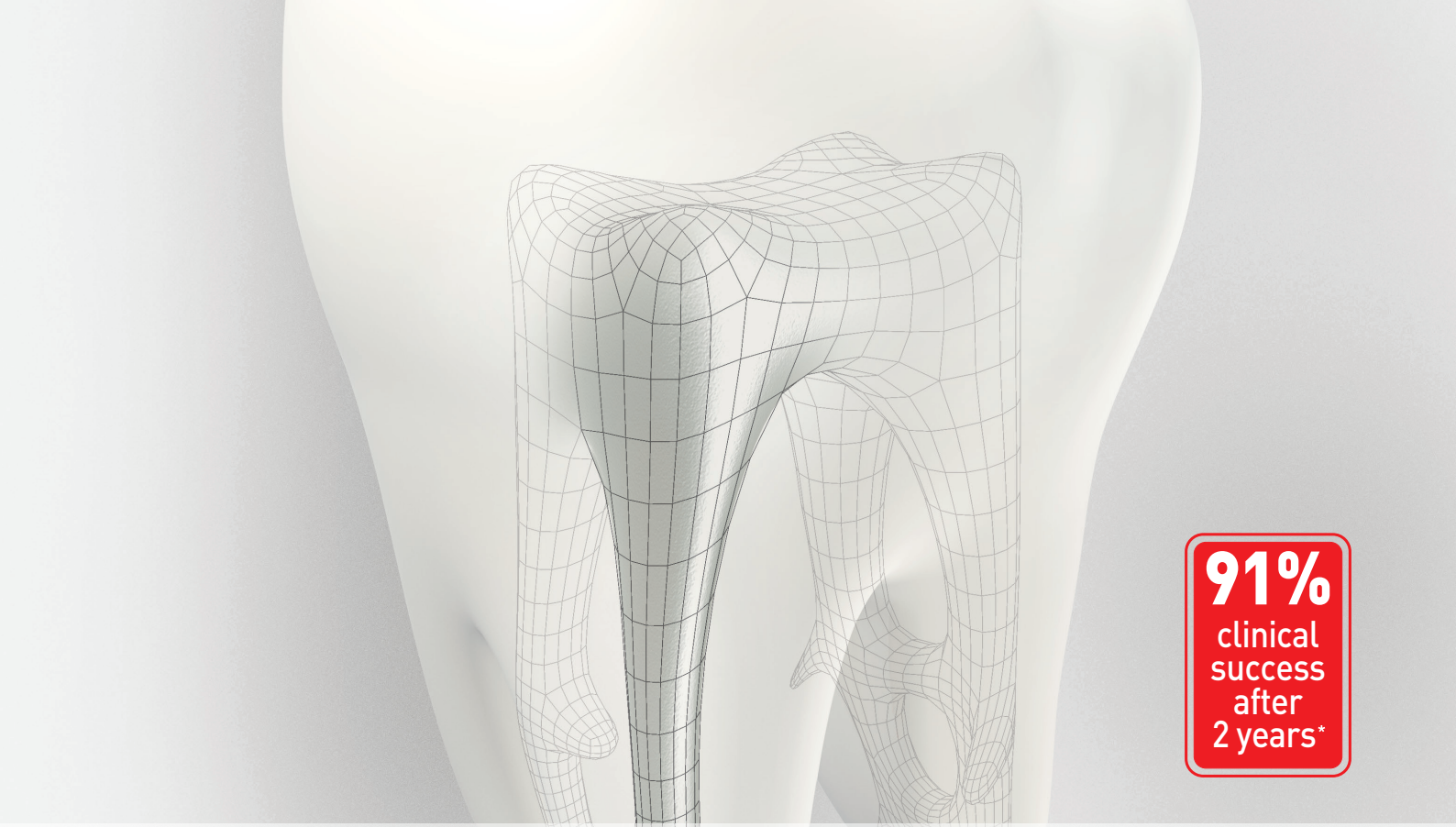

91% clinical success after 2 years*

BioRoot™ Flow

Clinical trial

Internal Clinical Data - BioRoot™ Flow
12/02/2024, page 13 NCT04757753, www.clinicaltrials.gov*

European medical device regulations require the development of clinical evidence using robust and high-quality clinical data. Consequently, Septodont has set up an open randomized single blind comparative study evaluating the efficacy of an endodontic treatment after 2 years post-obturation with BioRoot™ Flow versus BioRoot™ RCS as Root Canal Sealers. It is a prospective clinical study performed in 160 adults who required a non-surgical root canal obturation for root canal sealing.
The efficacy of BioRoot™ Flow vs BioRoot™ RCS was determined through the use of clinical and radiological criteria. Data was reviewed at six months (Q2, 2022), 12 months (Q4, 2022), and then final study outcomes at 24 months (Q4, 2023).

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BioRoot™ Flow - Clinical trial

The clinical data demonstrate that:

BioRoot™ Flow is performant when used as intended. The clinical performance of BioRoot™ Flow has been demonstrated with preclinical data and is confirmed with pivotal clinical data from a clinical investigation held and generated by Septodont. Indeed, the non-inferiority of BioRoot™ Flow compared with BioRoot™ RCS is demonstrated in this study. The clinical success rates of **91.0%** and 86.6% using respectively loose and strict criteria were reported for BioRoot™ Flow at 24 months. These results are comparable of those reported for BioRoot™ RCS (90.4% and 87.7%) and are within the range, if not higher than those found in the literature (between 68% to 82% and 82% to 90% for a primary endodontic and between 71% to 82% and 77% to 89% for a retreatment, based on strict and lenient criteria respectively).

Furthermore, the clinical performance of BioRoot™ Flow is supported by 2 surveys where 100% of the dentists are satisfied by the quality of the root canal treatment when viewing immediate post-op radiograph and 100% of the dentists are overall satisfied with the obturation results using BioRoot™ Flow. Finally, the clinical performance of BioRoot™ Flow is validated by preclinical tests where the device was demonstrated to be technically performant.

BioRoot™ Flow is safe when used as intended. There is a full consistency between the clinical study held and generated by the manufacturer, the information materials supplied by the manufacturer, the clinical risk analysis document and the current knowledge from the state of the art. Safety analysis of clinical data from investigation shows that 3 adverse events possibly or probably related to BioRoot™ Flow or to the procedure according to investigators opinion (i.e. pain during mastication, post-operative pain, headaches) were reported in 2 out of 66 patients at 24 months. No adverse events were related to root canal sealers (no causal relation). Masticatory pain appeared 5 months after the endodontic treatment and was resolved without any specific action. BioRoot™ Flow is a biocompatible component that cannot trigger reaction such as pain on the treated teeth. Additionally, on the cone beam radio, it is observed that the opposite tooth (tooth 36) has been proximally filled. Since pain occurred during chewing, this latter may be the causal tooth. On the other hand, headache can have several causes (such as dehydration, fatigue, stress, viral infections...) and time relationship between event occurrence and placement of the device is not in favour of a causal relationship. Based on the latest information from the monitoring visits, spontaneous and pressure pain is not an adverse event per se but a medical condition already present before the study device placement. Therefore, a causal relationship between the device and the event cannot be considered as possible.

One deficiency of BioRoot™ Flow and one of BioRoot™ RCS have been notified by investigators and did not lead to any adverse event. Note that the subgroup of patients treated by BioRoot™ Flow will be followed-up until 5 years.

Safety analysis of preclinical data shows that BioRoot™ Flow is biocompatible, which is confirmed by vigilance activities. **BioRoot™ Flow is safe when used as intended**.

The details of the clinical and safety design and the results can be found on clinicaltrials.gov and the future publication of this study.

*Source: Clinicaltrials.gov: Root canal obturation with a ready-to-use root canal sealer (PA1704) versus BioRoot™ RCS: a randomized controlled trial.

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