IFU Size: 161 H x 104 W

NANOSEAL-S VPS ROOT CANAL SEALER



Caution: US federal law restricts this product for sale by or on order of a dentist or physician.

Product description: Nanoseal-S is a cold flow able polydimethylsiloxane based root canal sealer for permanent filling of the root canal system.

Composition:

Base: Polyvinyl siloxane, Paraffin liquid, Zirconium oxide, Microsilver powder.

Catalyst: Polyvinyl siloxane, Paraffin liquid, Zirconium dioxide, Platinum, Pigment.

Intended use: It is used as sealer for permanent filling of dental root canals.

Indications for use: Nanoseal-S is a material for permanent obturation of root canals after vital extirpation and after treatment of pulpal gangrene and temporary filling of the canal.

Instructions for use:

- 1. After standard root canal preparation, the root canal should be thoroughly irrigated with sterile water to remove traces of irrigating agents which would interfere with the curing of NanoSeal-S.
- 2. The root canal should be thoroughly dried using alcohol/paper points.
- 3. The sealer must be dispensed from the dual barrel syringe in a 1:1 ratio. The sealer must be mixed thoroughly to be make a void free homogenous mix.
- 4. The root canal can be coated with NanoSeal-S using a outta-percha point or a paste carrier.
- 5. NanoSeal-S has a working time less than 10 min and a setting time of 10-15 min.
- 6. Use of heated instruments can accelerate the setting of NanoSeal-S.
- 7. After use, the dual barrel syringe must be thoroughly cleaned using a tissue paper and properly sealed to avoid contamination.
- 8. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Removal of sealant during retreatment: NanoSeal-S can be removed by conventional methods. The sealer does not chemically adhere to dentine. Use of heat, gates glidden drills and paeso-reamers are advocated for removal of gutta-percha during post space preparation and retreatment.

Warnings: Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. Avoid prolonged inhalation. Do not take internally. Contact with the skin may cause irritation, and hypersensitivity. If contact with skin occurs immediately wipe off thoroughly with cotton alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue the use and seek medical attention. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician. It should not be used with patients who have a history of severe allergic reaction to any of the components.

Precautions: Avoid using NanoSeal-S for obturation of root canals of deciduous tooth.

Contraindications: Do not use in patients if allergic to any of its components.

Storage Conditions: Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place. Shelf life: 3 years from the date of manufacturing.

Presentation:

Ref: 40001-1

1 x 10g Cartridge, Base & Catalyst, 1 x Spatula, 1 x Mixing Pad, 1 x Instruction Manual.

Disposal Conditions: To be disposed off based on the prevailing rules of the country in which it is used.

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER" R ONLY Symbol for "PRESCRIPTION ONLY"
LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"
Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTION FOR USE" REF Symbol for "CATALOGUE NUMBER"
ECTREP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION
Symbol for "DO NOT USE IF PACKAGE IS DAMAGE" 2 Symbol for "KEEP OUT OF THE REACH OF CHILDREN" MI Symbol for "MANUFACTURER"
"" Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" MD Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.