

Instruction for Use

Gutta Percha Points

(English Version) 

Hand-Rolled Endodontic Points

Used to fill a prepared root canal prior to tooth restoration.

Composition

Gutta Percha, Zinc Oxide, Barium Sulfate, Coloring Agent

Application

1. Check the product if it is damaged, presence of impurities, and shape is suitable for use.
2. Check if the product is within the expiration date.
3. After treating the root canal of the damaged tooth, use the proper size gutta percha to fill.
4. This product is disposable and discarded after use.

Intended Purpose

1. Intended Use: Used to fill a prepared root canal prior to tooth restoration.
2. Indication: Fill the root canal to prevent infection and instability of the root canal.
3. Contraindication: Do not use for patient who is allergic to this product.
4. Patient Population: All age group
5. Intended user: Dentist
6. Side Effects/Adverse Effects: There are no side effects or adverse effects reported.
7. Potential risk if re-used: Re-use of used Gutta percha point may cause inflammation.
8. Can be used with sealer or cement and it shall be used under the control of the dentist according to the clinical indication.
9. Single Use Device

Precaution

1. Do not use other than dental specialist.
2. Do not use if the product is expired.
3. Before use, check for infection inside the root canal.
4. Do not use for patient who is allergic to this product.

Storage

Store at room temperature away from direct sunlight

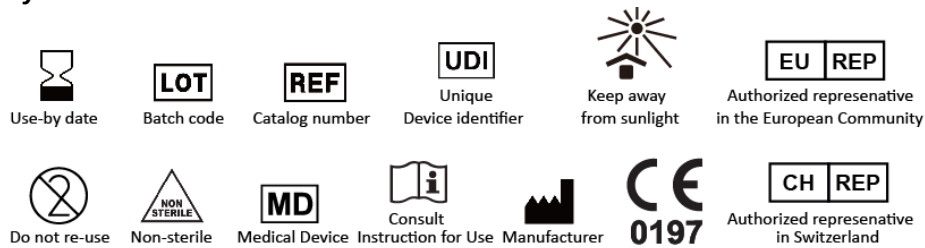
Disposal : Dispose of contents/container according to the related regulations of the country.

Shelf Life : 4 years from the date of manufacture

Radiopaque : Equivalent to 6mm aluminum stepwedge

Nominal Length : 28 mm

Symbols



SURE DENT CORPORATION (Manufacturer)

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- In case that any serious incident that has occurred in relation to the device, please report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Size Designation and Length: Please contact the manufacturer for size designation and length
- The SSCP (Summary of Safety and Clinical Performance) can be downloaded at EUDAMED database (<https://ec.europa.eu/tools/eudamed>). In case the module is not available, the SSCP will be provided upon request.
- A free printed copy of the IFU in the appropriate language is available upon request, within 7 days in the EU. Please contact us at suredent@suredent.com. An electronic version of IFU is available at <https://www.suredent.com/media/instructionOfProducts>.