

Gutta-Percha Points

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*FOR DENTAL USE ONLY
FOR PROFESSIONAL USE ONLY
SINGLE-USE
NON-STERILE – TO BE DISINFECTED BEFORE USE*

INSTRUCTIONS FOR USE

PROTAPER® UNIVERSAL (REF. A022X), ISO STANDARDIZED (REF. A022C, A022E, A022G, A022M, A022N), AUXILIARY (REF. A022F, A022L), PROTAPER GOLD®, PROTAPER NEXT®, TRUNATOMY®, AND WAVEONE GOLD® CONFORM FIT® GUTTA-PERCHA POINTS (REF. B00PGG, B00PNG, B00TNG AND B00WGG)

1 INDICATIONS FOR USE

Application field:

Endodontic obturation.

Intended Purpose:

Gutta-Percha Points are intended to fill the shaped, cleaned and irrigated root canal space.

Indication for use:

Gutta-Percha Points are indicated for treatment of endodontic disease.

Patient Population:

Patients who need root canal treatment.

Intended User:

Endodontic devices are to be used only in a clinical or hospital environment, following good dental practice, by qualified dental professionals such as general practitioners as well as Endo specialists (Endodontist) and dental assistants.

2 CONTRAINDICATIONS

None.

3 DELIVERY FORMS

Not applicable

4 PHYSICAL AND CHEMICAL PROPERTIES

- Radiopacity: Equivalent to 6 mm of aluminum or more in thickness
- Melting Temperature: < 100°C

- Nominal Length: ≥ 28 mm
 - Auxiliary gutta-percha points (REF: A022F and A022L): ≥ 24 mm

5 COMPOSITION

5.1 ProTaper® Universal

The following composition is only applicable to the following: REF. A022X

Components:

- Zinc Oxide (60–75%)
- Synthetic Gutta-Percha (18–25%)
- Inert Fillers (<15%)
- Barium Sulfate (5–10%)
- Pigment (0.005–1%)

5.2 ISO Standardized and Auxiliary gutta-percha points

The following composition is only applicable to the following: REF. A022C, A022E, A022F, A022G, A022L, A022M and A022N

Components:

- Zinc Oxide (75–85%)
- Synthetic Gutta-Percha (15–25%)
- Inert Fillers (<4%)
- Pigment (0–3%)

5.3 ProTaper Gold®, ProTaper Next®, TruNatomy® and WaveOne Gold® Conform Fit® gutta-percha points

The following composition is only applicable to the following: REF. B00PGG, B00PNG, B00TNG and B00WGG

Components:

- Synthetic Gutta-Percha (20–30%)
- Zinc Oxide (45–55%)
- Barium Sulfate (15–20%)
- Inert Fillers (<10%)
- Titanium Dioxide (1–5%)
- Yellow Colorant (<2%)
- Red Colorant (<2%)

6 COMPATIBLE DEVICES

Gutta-Percha Points are used in combination with:

- Spreaders and Pluggers. These instruments are used to assure the gutta-percha point is distributed throughout the entire root canal system.

- Calamus® and Gutta-Smart™. They are heating devices that are used to extrude gutta-percha material into the root canal system.
- Gutta-Condensor. Gutta-Condensor is a thermal condenser used to soften and fuse gutta-percha points together.
- AH Plus® Bioceramic Sealer. AH Plus® Bioceramic Sealer is used to coat root canal walls and remains at the interface between the root canal and the gutta-percha material.
- Shaping files and Paper Points. They are devices used to shape and dry the root canal system.

7 WARNINGS

Gutta-Percha Points are a single-use product. Single-use products shall not be re-processed nor reused. Reusing these products increases the risk of cross-contamination and/or breakage.

Use of the devices might lead to the following residual risks:

- Dissatisfaction of the user and delay in treatment / Patient discomfort.
- Retreatment (initial infection never healed).
- Serious infection / Serious health consequences for the patient (infection, toxic or allergic reaction for the patient).
- Fracture of the tooth due to obturation instruments.

8 PRECAUTIONS

- Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children.
- Inspect the packaging and product before use: if the packaging or the product is damaged, do not use the product and discard it.
- Products shall be disposed of according to local regulations for the safe disposal of sharp and contaminated devices.
- Do not sterilize with heat.
- Do not use disinfecting solutions containing Phenol or any products which are not compatible with gutta-percha.
- Use a rubber dam system during the endodontic procedure.

9 ADVERSE REACTIONS

In the present technical state, no adverse reaction has been reported so far.

10 STORAGE CONDITIONS

- Keep away from sunlight and heat.
- Maintain under room temperature (< 30°C (86°F)).
- Store in a dry area.

11 STEP BY STEP INSTRUCTIONS

The gutta-percha points shall only be used in a clinical or hospital environment, by qualified dental professionals. After shaping and cleaning the root canal, the obturation technique must be set by the professional. This procedure includes the use of gutta-percha points and sealer. Gutta-percha points selected shall correspond to color code and shaping file size of the last instrument used during canal preparation. The points are to be disinfected prior to use. A heated instrument can be used to soften the material and ensure perfect sealing and dimensional adaptation of the root canal (excluding ISO standardized and auxiliary gutta-percha points which are intended for lateral/cold compaction). In the use of a heated instrument, follow the IFU of said instrument. Use an appropriate tool to cut the gutta-percha points, including color coding ring, if present, after the insertion of the gutta-percha point in the root canal. The colored ring shall not remain in the root canal after insertion.

11.1 Branded gutta-percha points

ProTaper® Universal (REF. A022X), ProTaper Gold®, ProTaper Next®, TruNatomy®, and WaveOne Gold® Conform Fit® gutta-percha points (REF. B00PGG, B00PNG, B00TNG and B00WGG)

The described gutta-percha points are part of a complete system and should only be used in combination with the corresponding shaping files and paper points. They are identifiable with their system brand, size name and color code.

12 DISINFECTION

- Immerse the obturation devices in 5.25% NaOCl for 1 to 5 minutes at ambient temperature. Remove all the bubbles from the surface of the obturation device.
- Gently wipe the gutta-percha with sterile gauze moistened with 70% isopropyl alcohol.
- Let the obturation devices air dry.
- Do not use disinfecting solutions containing Phenol or any products which are not compatible with the treated filling material.
- Please follow the General Processing Instructions For Endodontic Products (<https://www.dentsplysirona.com/en/service-contact/ifu.html>) for the disinfection, cleaning and sterilization steps.

13 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Information is available at both the European database on medical devices (EUDAMED) and the IFU website, where it is linked to the Basic UDI-DI.

EUDAMED

<https://ec.europa.eu/tools/eudamed>

IFU

www.dentsplysirona.com/ifu

13.1 ProTaper® Universal gutta-percha points

The Basic UDI-DI number is: ++J00310041DT

13.2 ISO Standardized and Auxiliary gutta-percha points

The Basic UDI-DI number is: ++J00310042DV

13.3 ProTaper® Gold, ProTaper® Next, TruNatomy®, and WaveOne Gold® Conform Fit® gutta-percha points

The Basic UDI-DI number is: ++J00310043DX

14 ADDITIONAL INFORMATION

- To get a free printed copy of IFU please see section “Get a print copy of IFU” on website <https://www.dentsplysirona.com/en/service-contact/ifu.html>.
- Explanation of non-harmonized symbols for IFUs and labels, see IFU Symbols (<https://www.dentsplysirona.com/en/service-contact/ifu/ifu-symbols.html>).

15 LOT NUMBER AND EXPIRATION DATE

Do not use after expiration date.

16 SERIOUS INCIDENT REPORTING

- Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.
- Products shall be disposed of according to local regulations for the safe disposal of sharp and contaminated devices.

DISCLAIMER

Users are solely responsible for any deviation from these instructions, and/or the use of alternative methods for processing. Dentsply Sirona accepts no liability for damage, injury, or any legal responsibility incurred directly or indirectly by the user due to a deviation from the instructions for use set forth below. The user shall observe safe and lawful practices including, but not limited to, those set forth in this document.

Manufacturer



Maillefer Instruments Holding Sàrl
Chemin du Verger 3
CH-1338 Ballaigues
Switzerland



Authorised Representative

DENTSPLY DeTrey GmbH
De-Trey-Straße 1
D-78467 Konstanz
Germany



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