



## Accurate Machined Fabricated Gutta-Percha Points



**IMPORTANT:**

Be sure to carefully read these directions and keep them in a safe place for future reference on this and related products.

### 1. INDICATIONS

The Genius Gutta-Percha points are indicated for filling root canals that have been shaped, cleaned, and disinfected alongside other materials.



**WARNING WARNINGS:**

- a. Read all instructions before operating this medical device. The manufacturer accepts no liability for any damage resulting from improper use of this device and/or for any purpose other than those covered by these instructions.
- b. Use only for the intended use. Failure to comply with the operating instructions may result in serious injury to the patient or operator. Therefore, verify that you have read and understood the operating instructions.
- c. U.S. Federal law restricts this device to sale by or on the order of a dentist.
- d. As per Endodontic Standards of Care, **always use a rubber dam isolation when performing endodontic treatment.**
- e. Do not use dry heat or steam sterilization.

### 2. OPERATOR POPULATION

Operation of this medical device is limited only to certified, capable, and qualified dental professionals in their regular place of business. The operator must master and comply with the rules of dental practice per science and principles of medical hygiene, such as the cleaning, disinfection, and sterilization of medical devices. This

medical device may be used regardless of the characteristics of the (adult) operator, such as weight, age, height, sex, and nationality. However, staff and the operator should wear gloves and eye protection.

### 3. PATIENT POPULATION

Genius Gutta-Percha points are intended for use with the following patient population: children, teenagers, adults, and senior citizens.

### 4. BODY PARTS AND TISSUE TYPES TREATED

Treatment should be limited only to the patient's buccal cavity.

### 5. CONTRAINDICATIONS

Patients allergic to one of the components of the product (see composition)

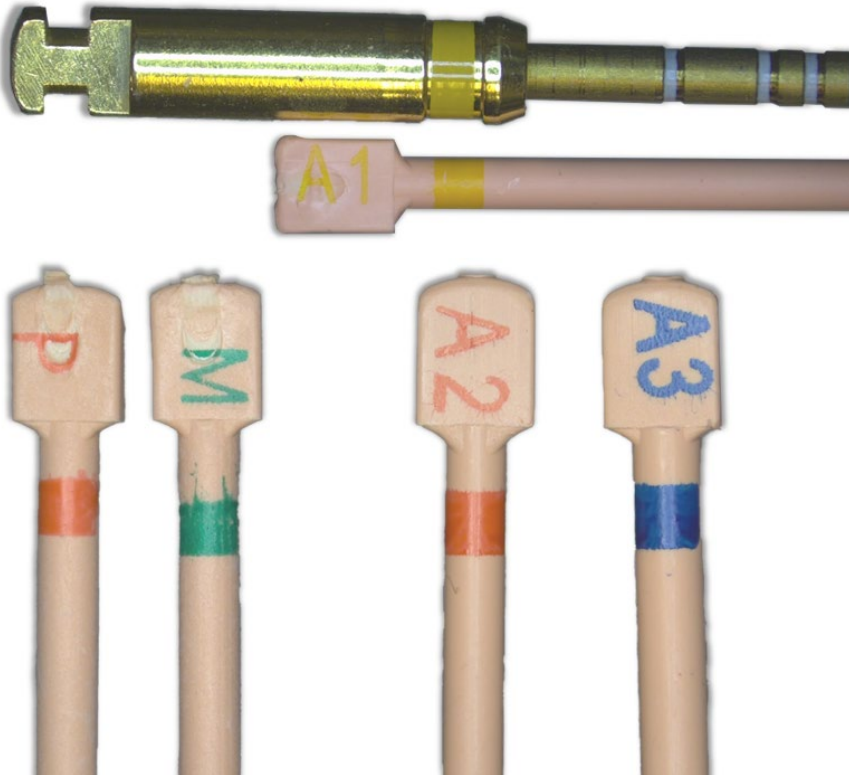
### 6. PRODUCT CONFIGURATION

SKU	Product name	Identification	Color	Packaging
<b>Genius Gutta-Percha One File G</b>				
PO-20	Genius Gutta-Percha One File G	Small 20	Yellow	Box with 60 points
PO-25	Genius Gutta-Percha One File G	Primary 25	Red	Box with 60 points
PO-35	Genius Gutta-Percha One File G	Medium 35	Green	Box with 60 points
PO-45	Genius Gutta-Percha One File G	Large 45	white	Box with 60 points
PO-AS	Genius Gutta-Percha One File G	Assorted		Box with 60 points
<b>Genius Gutta-Percha Pac-Taper</b>				
GP-A1	Genius Gutta-Percha Pac-Taper	A1	Yellow	Box with 60 points
GP-A2	Genius Gutta-Percha Pac-Taper	A2	Red	Box with 60 points
GP-A3	Genius Gutta-Percha Pac-Taper	A3	Blue	Box with 60 points
GP-A4	Genius Gutta-Percha Pac-Taper	A4	white	Box with 60 points
GP-A5	Genius Gutta-Percha Pac-Taper	A5	Yellow	Box with 60 points
GP-AS	Genius Gutta-Percha Pac-Taper	Assorted (A1, A2, A3)		Box with 60 points
<b>Genius Gutta-Percha Genius Proflex 04</b>				
GP-15-04	Genius Gutta-Percha Genius Proflex 04	15 04	white	Box with 60 points
GP-20-04	Genius Gutta-Percha Genius Proflex 04	20 04	Yellow	Box with 60 points
GP-25-04	Genius Gutta-Percha Genius Proflex 04	25 04	Red	Box with 60 points
GP-30-04	Genius Gutta-Percha Genius Proflex 04	30 04	Blue	Box with 60 points
GP-35-04	Genius Gutta-Percha Genius Proflex 04	35 04	Green	Box with 60 points
GP-40-04	Genius Gutta-Percha Genius Proflex 04	40 04	Black	Box with 60 points
GP-45-04	Genius Gutta-Percha Genius Proflex 04	45 04	white	Box with 60 points
GP-50-04	Genius Gutta-Percha Genius Proflex 04	50 04	Yellow	Box with 60 points
GP-55-04	Genius Gutta-Percha Genius Proflex 04	55 04	Red	Box with 60 points
GP-60-04	Genius Gutta-Percha Genius Proflex 04	60 04	Blue	Box with 60 points
GP-70-04	Genius Gutta-Percha Genius Proflex 04	70 04	Green	Box with 60 points
GP-80-04	Genius Gutta-Percha Genius Proflex 04	80 04	Black	Box with 60 points
GP-AS15-04	Genius Gutta-Percha Genius Proflex 04	15-40		Box with 60 points
GP-AS45-04	Genius Gutta-Percha Genius Proflex 04	45-80		Box with 60 points

<b>Genius Gutta-Percha Genius Proflex 06</b>				
GP-15-06	Genius Gutta-Percha Genius Proflex 06	15 06	white	Box with 60 points
GP-20-06	Genius Gutta-Percha Genius Proflex 06	20 06	yellow	Box with 60 points
GP-25-06	Genius Gutta-Percha Genius Proflex 06	25 06	red	Box with 60 points
GP-30-06	Genius Gutta-Percha Genius Proflex 06	30 06	blue	Box with 60 points
GP-35-04	Genius Gutta-Percha Genius Proflex 06	35 06	green	Box with 60 points
GP-40-04	Genius Gutta-Percha Genius Proflex 06	40 06	black	Box with 60 points
GP-AS15-06	Genius Gutta-Percha Genius Proflex 06	Assorted		Box with 60 points
<b>Genius Gutta-Percha Rex</b>				
RX-25	Genius Gutta-Percha Rex	RX 25	red	Box with 60 points
RX-40	Genius Gutta-Percha Rex	RX 40	black	Box with 60 points
RX-AS	Genius Gutta-Percha Rex	Assorted		Box with 60 points

### 7. IDENTIFICATION

The Genius Gutta-Percha can be identified by the corresponding letter or number of the file last used for shaping the canal.



**i** IMPORTANT:

When selecting the Genius Gutta-percha Points, opting for those that align with the color code and size of the most recently used shaping file during canal preparation is essential. These points can be identified by their number, taper, and color code.

## 8. RADIOPACITY

Equivalent to 7 mm of aluminum or more in thickness

## 9. THERMAL CONDUCTIVITY

- a. Plasticity limit <5 mm (150 to 180°C)
- b. Thermal diffusivity (m<sup>2</sup>/s) 0.28
- c. Specific heat capacity (J/Kg °C) 0.90
- d. Density (kg/m<sup>3</sup>) 1.83
- e. Thermal conductivity (W/m K) 0.42
- f. β to α phase initial phase change 41°C
- g. α to amorphous phase initial phase change 54°C

## 10. MAIN COMPOSITION

Synthetic gutta-percha, zinc oxide, inert fillers, and barium sulfate

## 11. LENGTH

28 mm



### WARNING WARNINGS:

- a. **Place rubber dam isolation before beginning endodontic treatment.** The operator must ensure the integrity of the seal and that any potential communication from the pulp chamber to the oral cavity is secure.
- b. Operators and assistants should wear personal protective equipment (gloves, glasses, mask, among others).
- c. The user is responsible for the disinfection before use.
- d. Gutta-Percha Points are designed for single use and must not be reused or subjected to further processing.
- e. Do not use heat or steam for sterilization.
- f. Inspect the packaging and product before use. Do not use if damaged.

## 12. PRE-OPERATION AND DISINFECTION

To properly prepare the Genius Gutta-Percha Points for use, it is recommended to soak them in 5.25% NaOCl at room temperature for 3 minutes. After soaking, lightly wipe the Genius Gutta-Percha Point with a sterile gauze moistened with 70% isopropyl alcohol and let it air dry. Avoid using disinfecting solutions containing Phenol.

## 13. STORAGE CONDITIONS

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

#### 14. STATEMENT

13.1. **Pac-Dent**, its representatives, and its distributors/dealers shall have no liability or responsibility to customers or any other person or entity concerning any liability, loss, or damage caused or alleged to be caused directly or indirectly by the medical device sold or furnished by us, including, but not limited to, any interruption of service, loss of business or anticipatory profits, or consequential damages resulting from the use or operation of the equipment.

13.2. **Pac-Dent** assumes no liability resulting from improper use, damage, or breakage due to misuse of these components by the purchaser. Likewise, **Pac-Dent** assumes no liability for damage to the Genius Gutta-Percha points, injuries to patients or users, or other problems resulting from improper use of accessories or other materials not supplied by **Pac-Dent**.

13.3. **Pac-Dent** reserves the right to implement changes and modifications of the product, revise this publication, and make changes in the contents without obligation to notify any person of such changes, modifications, or revisions. All rights to modify the product are reserved for **Pac-Dent** without further notice. The pictures are only for reference. Industrial design, inner structure, etc., have been claimed for several patents.

13.4. Patent pending.

**Genius**  
Gutta-Percha

**Pac-Dent**  
Passion for Excellence