



Instructions for Use

Permatter® is a registered trademark from Permatter LLC

Permatter®

NOTICE TO USERS: Please be advised that the use of this product is subject to certain conditions and responsibilities.

DISCLAIMER: This product specifically is manufactured from Nitinol. It is crucial to note that the user must adhere strictly to the instructions and recommendations provided. Any deviation from these guidelines, including the use of third-party products in conjunction, may result in the voiding of warranties or other obligations, whether expressed or implied, by Permatter®.

USER RESPONSIBILITY: The user assumes full responsibility for determining the suitability of this product for the specific patient and circumstances. Permatter® expressly disclaims any liability for direct, indirect, punitive, or other damages that may arise from errors in professional judgment or practice in the use of products. Since the utilization of this product is entirely under the control of the user, it is the user's responsibility to ensure proper usage. Permatter® bears no liability for any damage incurred as a result.










REGULATORY COMPLIANCE: It's essential to acknowledge that certain products detailed in these instructions may not have received regulatory clearance, release, or licensure for sale in all markets. Users are advised to verify the regulatory status of each product as applicable.

PRODUCT DESCRIPTION: Permatter® is manufactured from Nitinol. This appliance is meticulously manufactured based on recent impressions of the patient's teeth. Permatter® is intended for use as a lingual retainer wire for retaining teeth positions after orthodontic treatment.

INTENDED USE: Permatter® is intended for use by orthodontists, dentists, and dental laboratories. U.S. Federal law restricts this device to sale by or on the order of a dental professional.

INDICATIONS FOR USE: Permatter® is designed to be worn by the patient as directed by the treating dental professional. The duration of wear should be determined by a dental professional.

LIMITATIONS: Permatter® should not be used in patients with active periodontal disease, active malocclusion retention (e.g., deep bite with insufficient space for bonding the retainer, less than 0.5 mm space). Additionally, it is not recommended for individuals with habits such as nail or lip biting.

-  **Wear gloves during usage**
-  **This product should not be exposed to sunlight**
-  **Don't leave under wet environment - needs to be protected from moisture**
-  **Do not use if package is damaged and consult instructions for use**
-  **Rx Only: U.S. Federal law restricts this device to sale by or on the order of a dental professional**
-  **Single Use Device: Do not Re-Use**
-  **This product is not indicated for individuals with nickel or titanium allergies.**
-  **Consult instructions for use or consult electronic instructions for use**
-  **2017/745 - Class I**

For any queries or clarifications regarding the use or application of this product, users are encouraged to contact Permatter LLC directly. Your diligence in adhering to these guidelines ensures safe and effective utilization of this custom-made medical device.

PRECAUTIONS

- This product is non-sterile.
- Rubbing of parts against tissue may cause sores.
- Hard, crunchy or sticky foods may cause damage to the appliance, additional information of wearing a fixed retainer should be explained to the patient detailly.
- Incorrect biting may lead to improper functioning of the device.
- Accidental swallowing or aspiration of parts may result in harm.

INSTRUCTION FOR USE

- **Unpacking and Cleaning:**

Remove the retainer from its packaging and clean it according to office protocols.

- **Initial Evaluation:**

Assess the fit of the retainer and the tray/jig on the model provided, whether it's the physical model sent or a 3D printed model from digital data.

- **Testing Fit:**

Remove the retainer with the transfer tray/jig from the model and rinse it under water. Dry it carefully with air flow to avoid displacement.

Insert the retainer with the transfer tray/jig into the patient's mouth to test the fitting. If satisfactory, proceed to the next step. If not, please contact the provider or Permattter® for evaluation. It's crucial to re-test the fit on the delivered model to ensure accuracy. If it fits on the model but not in the patient, refrain from bonding the retainer as the patient's situation might have changed, potentially leading to tooth movement and related consequences.

- **Pre-Bonding Preparation:**

Remove the retainer and transfer tray/jig from the patient's mouth and thoroughly clean the lingual surface and surrounding area of the teeth. It's recommended to scale and polish the anterior lingual side of the teeth to remove calculus and any obstacles for proper bonding, finally rinse and dry.


- **Etching:**


Acid etch the enamel for 30 seconds. Rinse and dry thoroughly.

- **Placement and Securing:**

Place the retainer with the transfer tray/jig back and ensure proper fit to the lingual surface of the teeth.

- **Bonding:**

 **NOTE:** According to the debonding tests results, Permattter® shows better results with the usage of "3M - Transbond™ LR Light Cure Adhesive".

 **IMPORTANT:** When seating the Permattter®, ensure the wire is held securely before removing the tray. Failure to do so may result in unsuccessful placement of the wire.

Apply prime/bonding agent only to the lingual surface of the canines. Shape the fluid material to cover ends of the retainer adequately with an instrument. Light cure the composite material on the distal ends of the lingual retainer. Wait at least 30 seconds for the next step.

- **Tray/Jig Removal:**

Carefully remove the transfer tray/jig.

- **Bonding Remaining Teeth:**


Apply a prime/bonding agent to the remaining non-bonded enamel. Shape the fluid material to cover the retainer adequately with an instrument to cover the lingual retainer.


- **Finalizing Bonding:**

Light cure the remaining enamel after bonding.

- **Post-Bonding Clean-Up:**

Thoroughly clean the patient's teeth to complete the process.

 **IMPORTANT:** Advise patients to not eat/drink anything for at least 3 hours.

 **IMPORTANT:** If Permattter® is used on the upper 1-1 or 2-2, likewise for the deep bite case, it is recommended that a clear thermoplastic retainer be incorporated with the Permattter® wire for best results.

WARRANTY: This product comes with a warranty of 36 months.

Permattter LLC recognizes its responsibility to replace the product if proven to be defective or damaged during 36 months. Permattter LLC does not accept liability for any loss or damage, direct or consequential stemming from the use of or inability to use the product as described. Before using, it is responsibility of the dental professional to determine the suitability of the product for its intended use. The dental professional assumes all risk and liability in connection therewith.

ORAL HYGIENE: Maintaining excellent oral hygiene is crucial. Patients should adhere to a diligent teeth-brushing regimen and pay close attention to their dental hygiene throughout usage. It's recommended to use waterjet for oral hygiene.

PATIENT VISIT INSTRUCTIONS: Dental professionals should provide detailed instructions for patient visits.

REPORTING SERIOUS INCIDENTS: In the event of a serious incident involving this medical device, it is imperative to report it promptly to both the manufacturer and the relevant medical authority in the user/patient's country.

DAILY CARE AND MAINTENANCE: Users should strictly follow the instructions provided by their Dental Professional for daily care and maintenance routines.