

AOA

**Custom-Made Device
Personalized Medical Device**

Memotain® Instructions for Use

Memotain® is a registered trademark from CA DIGITAL GmbH

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CUSTOM-MADE PERSONALIZED MEDICAL DEVICE DESCRIPTION:

Allesee Orthodontic Appliances (AOA), Memotain®* is made from Nitinol. This appliance has been specially made from recent impressions of your patient's teeth. Memotain®* is a fixed (bonded), nitinol retainer wire that is formed into the shape of a patient's final impressions after tooth realignment. This patient-specific retainer will only align with a single patient.

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INTENDED USE: Products to be used by orthodontists/dentists/dental laboratories.

INDICATIONS FOR USE: The appliance is worn by the patient on the dental arches as prescribed by the treating dentist/orthodontist. The duration of wear will range by the determination of the dentist/orthodontist. Used most commonly for post-orthodontic retention to help keep the teeth in their ideal position and minimize relapse. May also be used in restorative dentistry.

CONTRAINDICATIONS: The Memotain Retainer is contraindicated for use in patient's with active periodontal disease, active malocclusion retention (i.e. deepbite, with less than 0.7 mm space to bond the retainer), retention of teeth exceeding the tooth area of 3-3 or 4-4 with different vertical leveling or habits like nail and lip biting.



WARNINGS:

This product contains nickel and should not be used for individuals with known allergic sensitivity to these metals. After bonding the retainer, make sure not to immediately use high force on bonded teeth. Advise patient to wait at least 2 hours before using higher forces on anterior teeth.



Single Patient Use - Risk of cross-contamination.



Magnetic Resonance (MR) Safety Information: Not applicable.

PRECAUTIONS:

- Non-sterile device.
- Patient may deliberately or accidentally bite incorrectly and cause the device to function improperly.
- Sores may develop from parts rubbing on tissue.
- Parts may be accidentally swallowed or aspirated and may be harmful.
- Crunchy, hard or sticky foods could damage the appliance.
- Device not installed by a Dental Professional may cause harm to patient.

INSTRUCTIONS FOR USE:

Remove device from packaging and clean per office procedure.

1. Use a cutter to make a straight cut on the model to remove the plastic protection cover of the Memotain.
2. Evaluate the fit of the retainer and the tray/jig on the model, (either the model you sent or the 3D printed model from the Lab in case of digital data).
3. Remove the retainer with the transfer tray/jig from the model and rinse under water. Dry with air flow. Be careful not to displace the retainer with the air.
4. Insert the retainer with transfer tray/jig into the patient's mouth to test the fitting. If fitting is ok, please proceed with Step 4. If not, please contact the Lab for evaluation. Make sure to re-test the fit on the delivered model. If it fits on the model and does not fit in the patient, the actual patient situation might have changed and it is not recommended to bond the retainer in that case. Active tooth movement with related consequences can occur. Breakage of retainer and bonding material can occur with active forces. Possible consequences are described in the PRECAUTIONS section.
5. Take the retainer and transfer tray/jig out of the patient's mouth and clean the lingual surface and the surrounding area of the teeth properly. Scaling and polishing of the anterior teeth prior to bonding a retainer is recommended to remove calculus and other obstacles for proper bonding.
6. Start etching the lingual surface of the last teeth included by the retainer wire.
7. Place the retainer with transfer tray/jig on the teeth again. For addition security, you can place dental floss interdentially between the respective teeth (teeth covering the open part of the retainer that is not covered by the tray/jig) prior to placing the tray/jig with the retainer. The dental floss is placed interdentially and the tray/jig with the retainer can be placed upon the teeth and inserted dental floss. The dental floss is under the open retainer end, which is not covered by the tray/jig. Make sure the dental floss is used properly without causing damage to teeth and periodontal. The part of the dental floss that lies lingually/palatally under the open part of the retainer and can be placed around the retainer end that is not covered by the tray/jig. Secure both ends of the dental floss labially and

further secure the retainer during the bonding process. Do not remove the tray/jig after the retainer distal ends are initially bonded.

8. Use Primer on the lingual surface of the teeth. Then use a retainer bonding agent on the lingual tooth surface and shape the fluid material with an instrument to cover the retainer.
9. Light cure the composite material on the distal ends.
10. Use an instrument to carefully remove the transfer tray/jig.
11. Etch the remaining teeth(non-bonded), dry area and repeat step 7 and 8 for remaining teeth
12. Light cure remaining teeth.
13. Clean the patient's teeth.

BONDING PROTOCOL

NOTE: Before placing the Memotain retainer, thoroughly clean the lingual surfaces of the teeth. We suggest an ultrasonic cleanser.

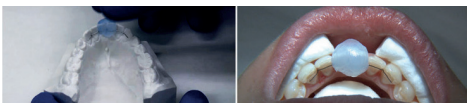
1. Isolation of the lingual surface during the bonding process is recommended. You can use a Dry-Angle and cotton rolls.



2. Start by etching only the lingual surface of the canines. This path should be recognizable. Coat with prime/bonding agent.



3. Grip Memotain retainer by the transfer tray* and place in the patient's mouth.

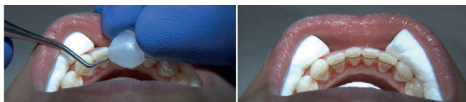


* Actual transfer tray may be made out of a different material.

4. Model and resin bonding sites on the canines and cure them.



5. Secure or hold Memotain wire in place and carefully remove the tray. (transfer tray shown here)



IMPORTANT: When seating Memotain, please make sure you hold the wire in place before removing the tray. Failure to do so may result in unsuccessful placement of the wire.

6. Etch the four remaining teeth and coat them with primer. Repeat #4.



7. Perfectly seated Memotain retainer.



Image of transfer tray

WARRANTY: 12 months

ORAL HYGIENE: It is very important for your patient to brush their teeth and pay extra attention to dental hygiene during this time.

PATIENT VISIT INSTRUCTIONS: Dental Professional to provide.

REPORTING SERIOUS INCIDENTS:

User and Patient Notice - If a serious incident occurs with this medical device, report it to the manufacturer and to the competent medical authority for the user/patient's country.

STORAGE AND HANDLING: No special storage conditions.

DISPOSAL: Follow local guidelines.

DAILY CARE AND MAINTENANCE: Follow instructions provided by your Dental Professional.

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