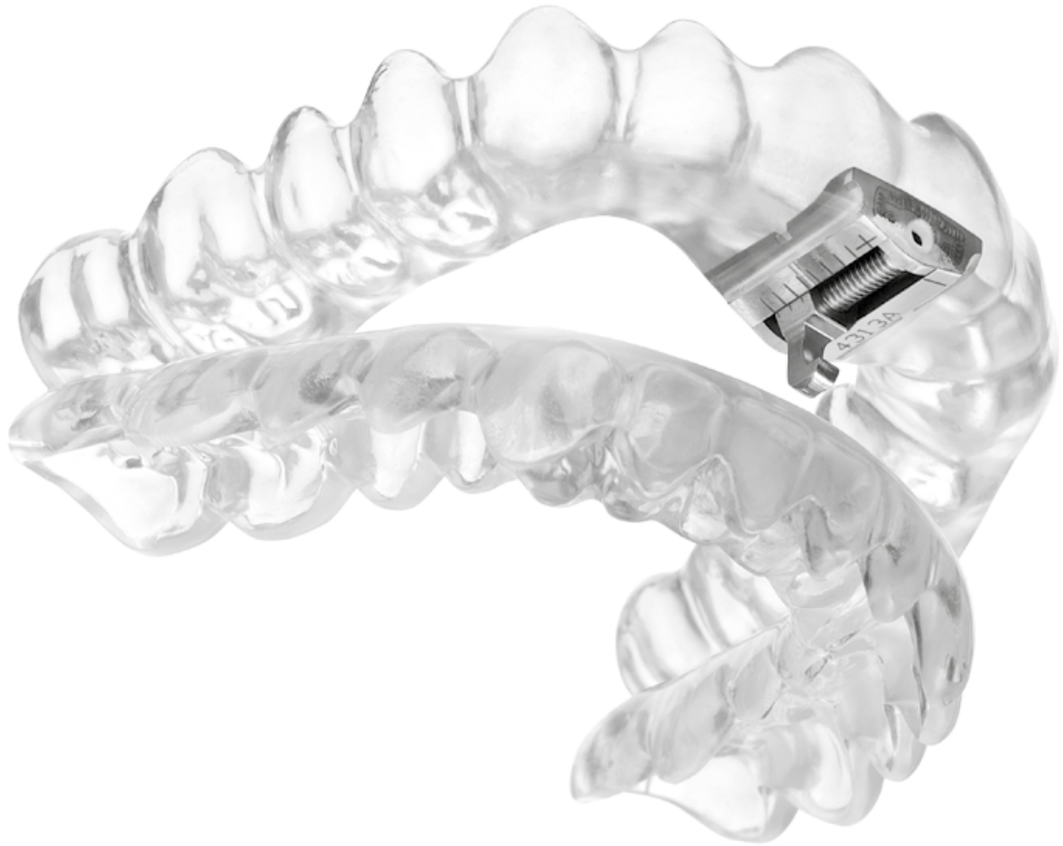
Dental Sleep Medicine

TAP®-Booklet



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SCHEU

TAP®

Thornton Adjustable Positioner

CE

DE/GB 3.000/06/26 G REF 0170.01

Content:

Introduction

Dear patient,

we are glad that you received your new TAP® device from your dentist / orthodontist. It will help to improve your problems with nighttime snoring and obstructive sleep apnea (OSA).

We understand how serious the effects of sleep disorder, caused by nighttime snoring and obstructive sleep apnea (OSA) can be. We hope that your TAP® device helps you to return to normal and recreative sleep.

For your comfort we summarized the most important steps and hints for a comfortable and effective application of the TAP® device in this brochure. For more detailed information on your TAP® device, please ask your dentist.

We would like you to sleep well.

The **T**hornton **A**djustable **P**ositioner (TAP®) devices are intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA). The appliance is for adult patients to be used when sleeping at home or in sleep laboratories and is for single patient use.

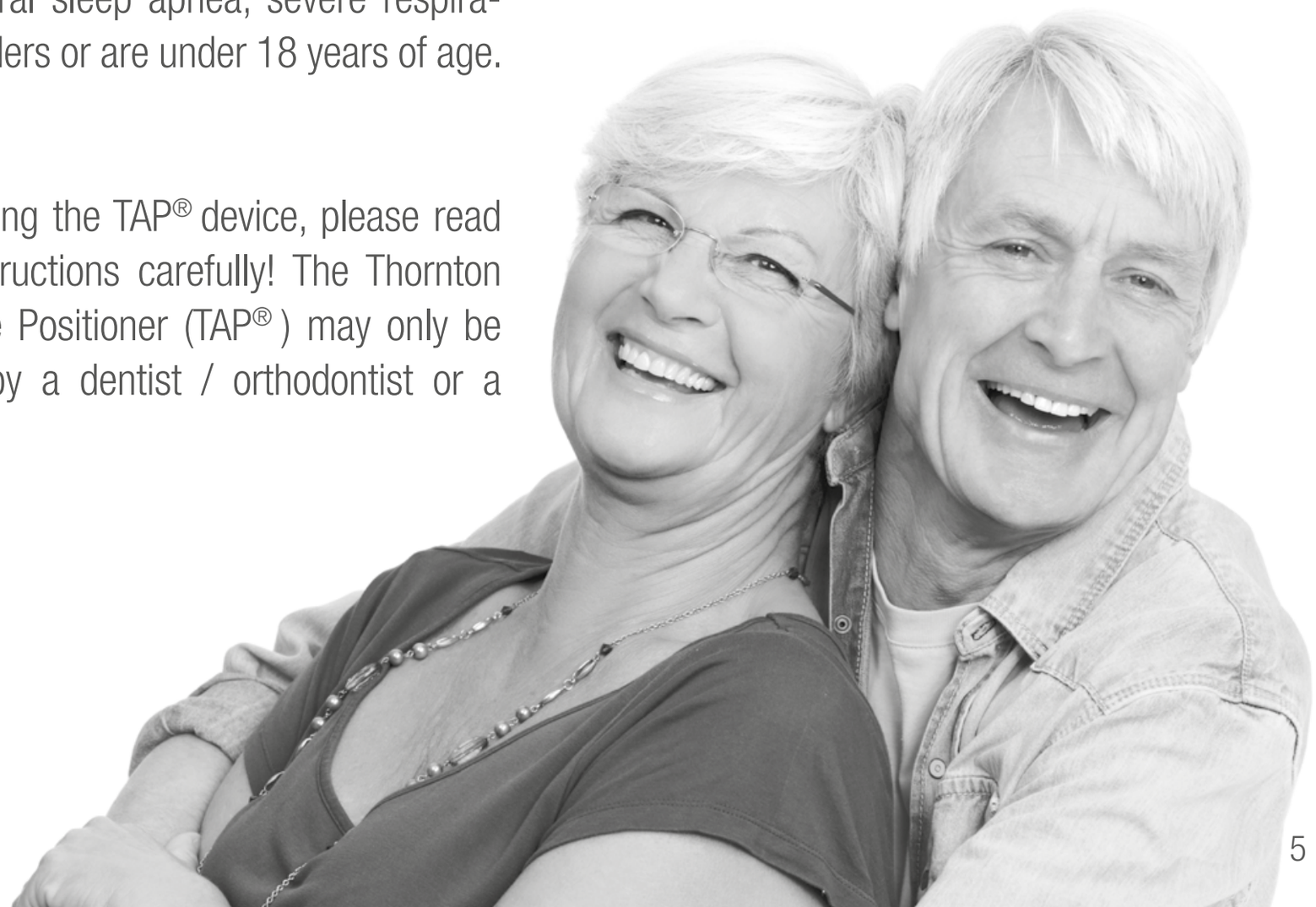
www.tap-splint.eu

CONTRAINDICATIONS

This device is contraindicated for patients with loose teeth, loose dental work, dentures or other oral conditions which would be adversely affected by wearing dental appliances. In addition, the appliance is contraindicated for patients who have central sleep apnea, severe respiratory disorders or are under 18 years of age.

ADVICE

Before using the TAP® device, please read these instructions carefully! The Thornton Adjustable Positioner (TAP®) may only be adapted by a dentist / orthodontist or a physician.



Reduction or alleviation of nighttime snoring

The Thornton Adjustable Positioner (TAP®) devices are intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA). In case you experience symptoms of breathing difficulties or other respiratory disorders - with or without TAP® - you should consult your attending physician.

There are possible side effects associated with using the TAP® appliance. You may initially experience jaw soreness, tightness or a feeling of bite change These side effects should disappear within 1 hour after application. If they continue for more than 4 hours, you should contact the prescriber. Use of occlusion trainer (see page 23) is recommended as helpful method.

Return to your prescriber at least yearly for examination and assessment to ensure the TAP® is not damaged and is still effectively treating your sleep disordered breathing.

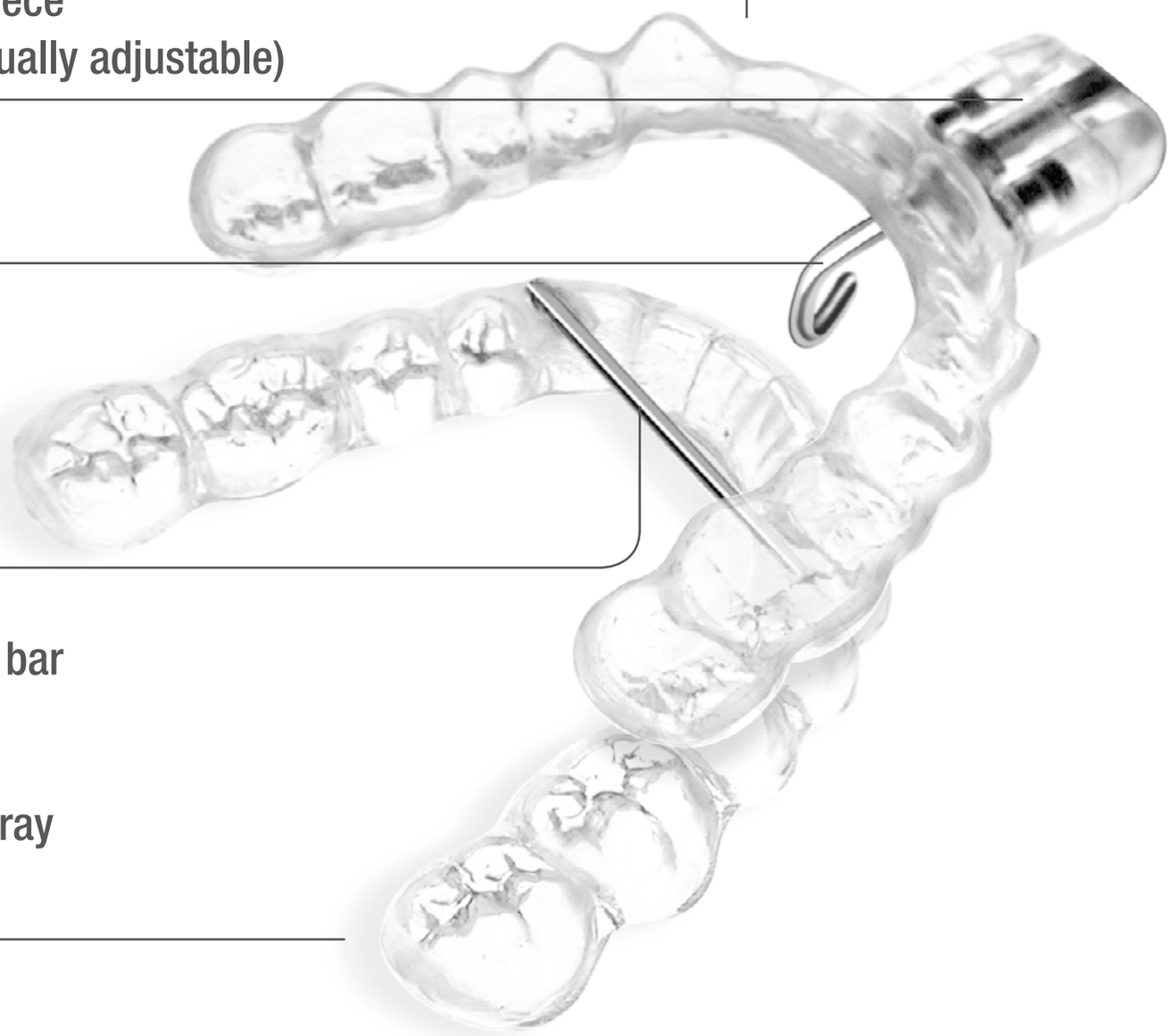
In case your TAP® device becomes loose or has been damaged, please contact your dentist immediately to have it replaced.

TAP® Device

The TAP® Device consists of two parts:
The TAP® device consists of an upper tray ❶ that fits over the upper teeth and a lower tray ❷ that fits over the lower teeth. A hook ❸ mechanism attached to the upper tray hooks around a bar ❹ attached to the lower tray and positions the lower jaw forward preventing the soft tissue of the throat from collapsing and obstructing the airway. The front piece ❺ on the TAP® permits you to adjust the protrusion of the lower jaw to the most effective and comfortable position.

1 Upper tray

5 Front piece
(individually adjustable)



3 Hook

4 Lingual bar

2 Lower tray

TAP® Device

Inspect the device prior to each use. Contact the prescriber, if you observe any material separation, material degradation or cracks.

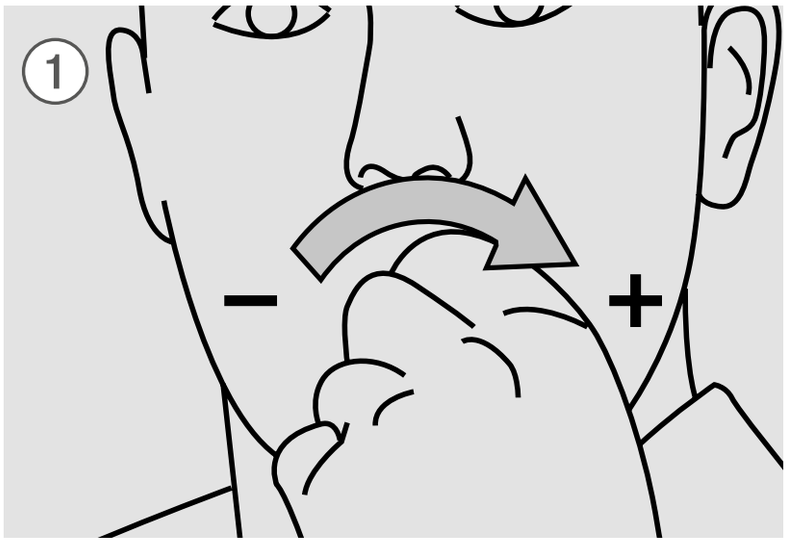
Please connect TAP® upper and lower tray prior to inserting it into the mouth. Place the hook of the upper tray behind the bar of the lower tray, letting the hook slide into the socket through a slight traction movement and a 90° rotation.

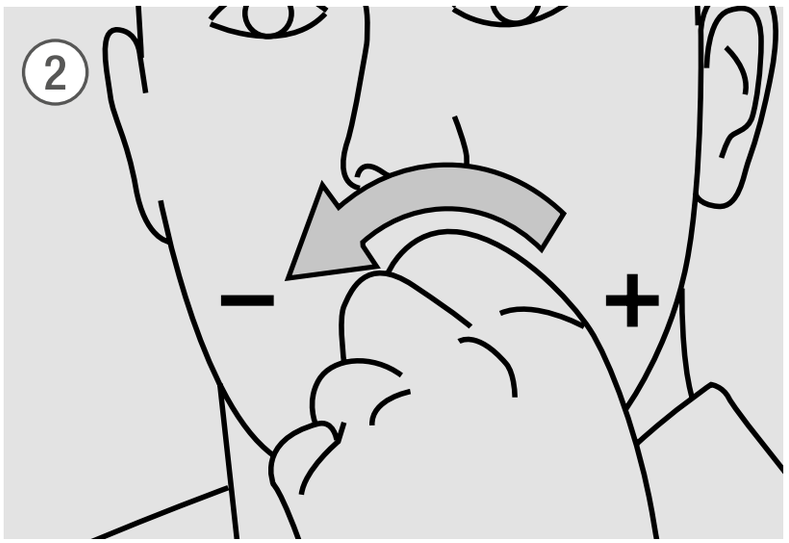
Now place the combined tray on the upper dental arch. Then move the lower jaw slightly forward, so that the lower teeth can slide into the lower tray. You can remove the TAP® device in reverse order – upper and lower tray combined.

WARNING

Do not bite down on the hook because it may bend or break. If the hook is bent, do not use the TAP® and return it to your dentist for a replacement hook.

TAP® Device





Adjustment of the TAP® should only be done with the approval of your prescriber. Note: Operating the front assembly (knob) is written from the perspective of the patient with the TAP® in his/her mouth.

① To pull your lower jaw forward with the appliance in the mouth, turn the knob counter clockwise (towards your left ear).

② To return your lower jaw to the starting position with the appliance in the mouth, turn the knob clockwise (towards your right ear).

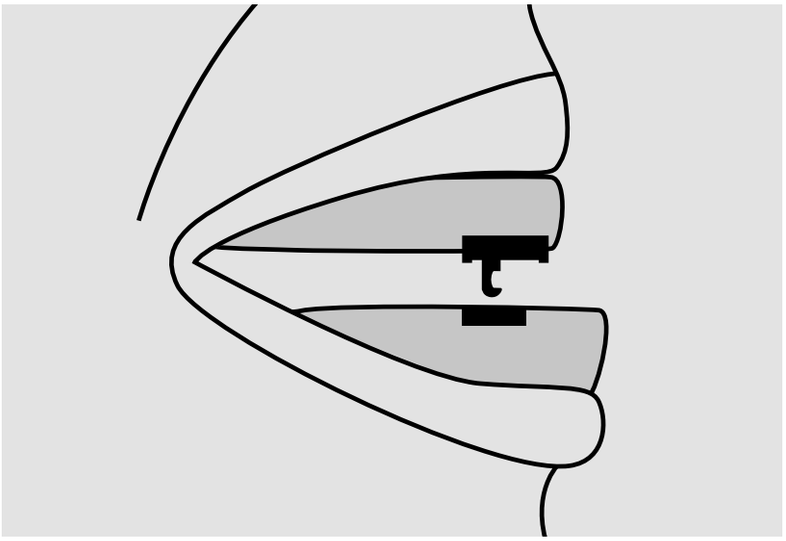
HINT

One 360° turn of the knob is 0.5 mm.

Description

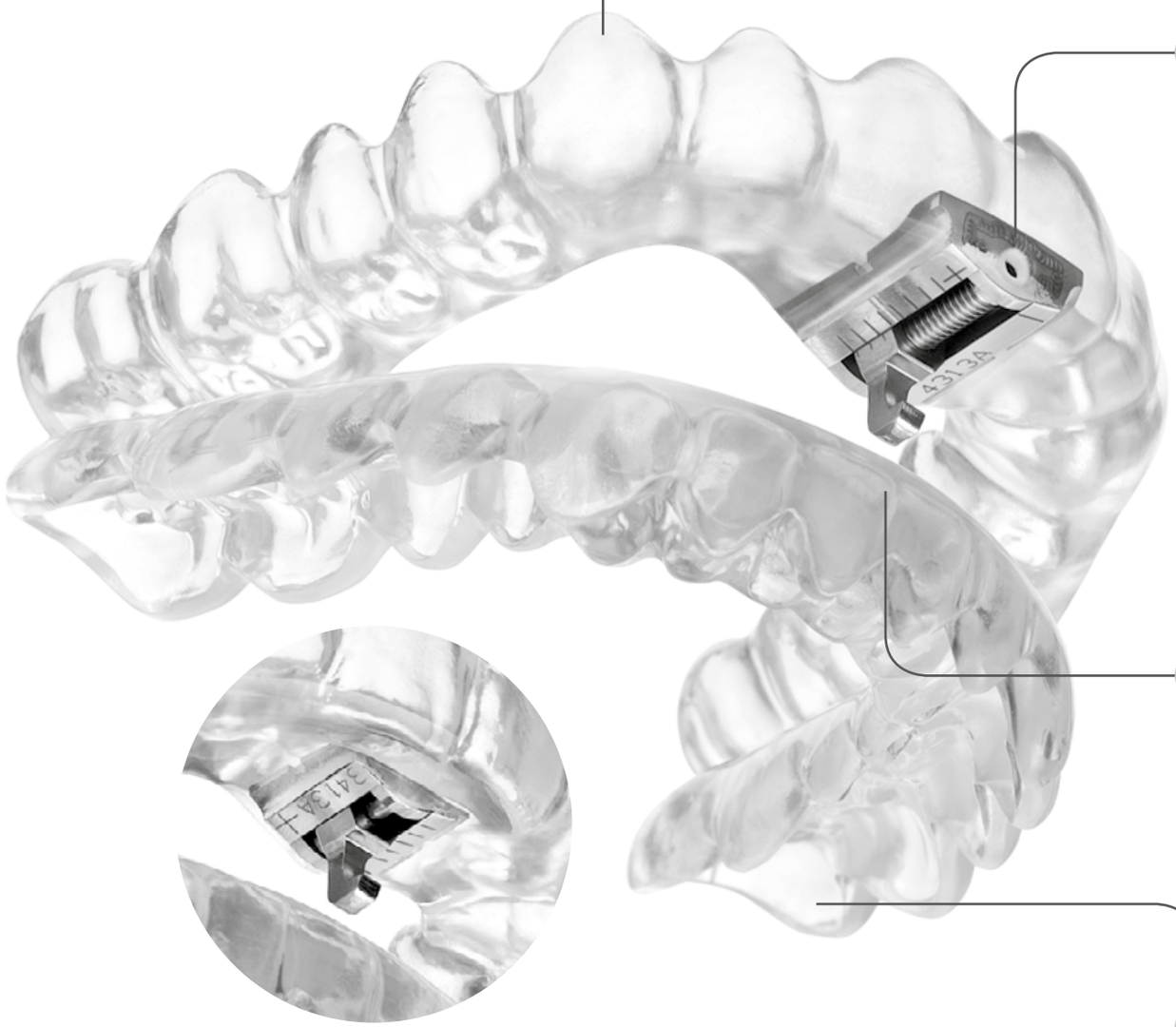
TAP®-T / TAP®-T Reverse

The TAP®-T device consists of an upper tray that fits over the upper teeth and a lower tray that fits over the lower teeth. A hook mechanism attached to the upper tray hooks around a guiding device attached to the lower tray and positions the lower jaw forward preventing the soft tissue of the throat from collapsing and obstructing the airway.



The front piece on the TAP®-T permits you to adjust the protrusion of the lower jaw to the most effective and comfortable position by use an activation key, either inside or outside your mouth (see instruction on page 14).

TAP®-T / TAP®-T Reverse



Upper tray

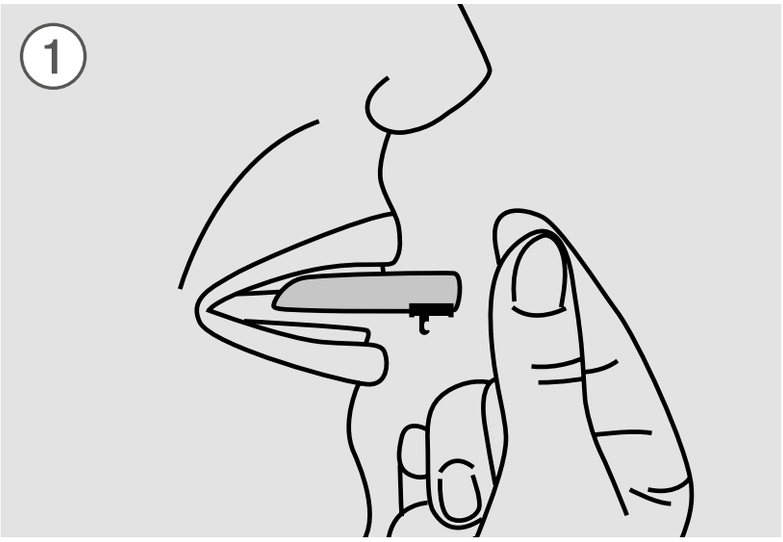
Upper protrusion adjustment device (titanium alloy)

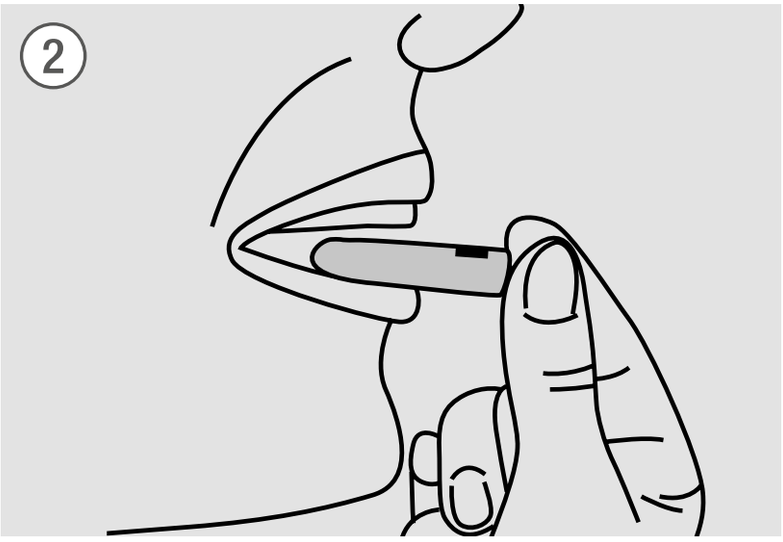
Lower guiding device (nickle free CoCr alloy)

Lower tray

TAP®-T Reverse with reduced upper protrusion adjustment device

TAP®-T / TAP®-T Reverse





Inspect the device prior to each use. Contact the prescriber if you observe any material separation, material degradation or cracks.

① Place the upper tray on your upper jaw first.

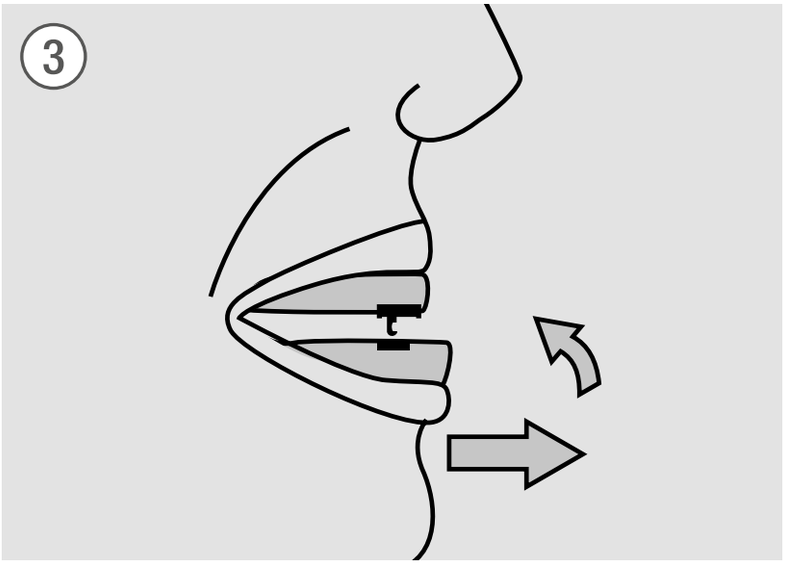
② Then place the lower tray on your lower jaw.

③ Now move your lower jaw carefully and gently forward until the hook slides into the socket and both trays are engaged.

④ In the same manner you can disengage both trays. First move the lower tray a bit forward, until the hook slides out of the lower socket.

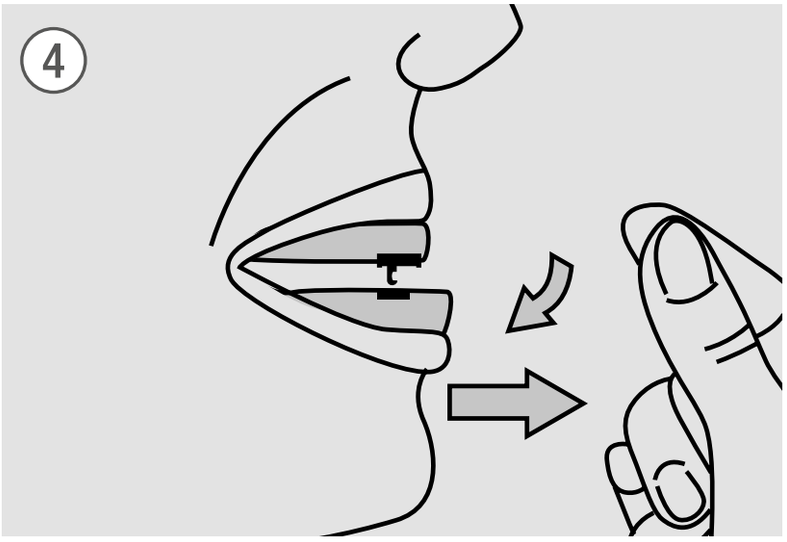
Disengage both trays like mentioned above to remove the upper and the lower tray seperately at night or in the morning.

Check the lateral movement by gentle moving your lower jaw to the left and the right.



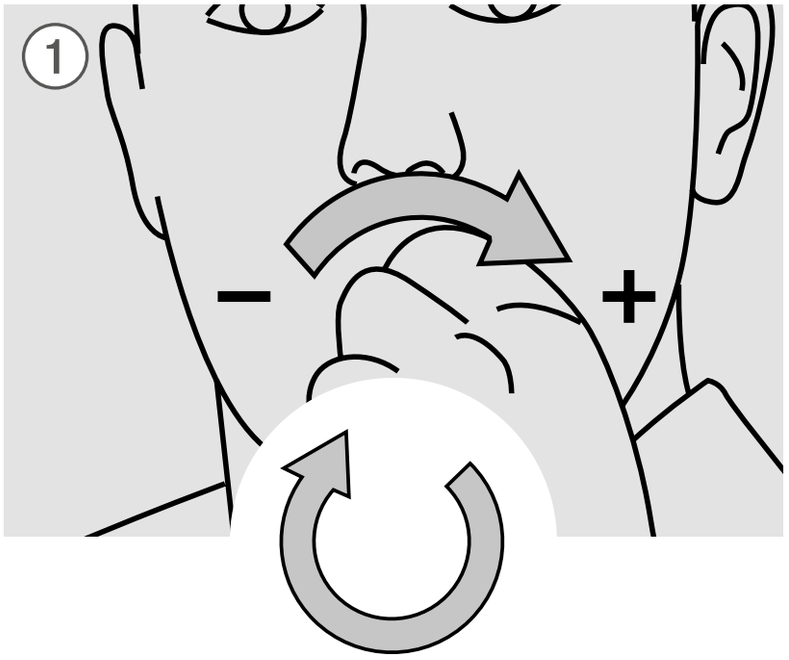
HINT

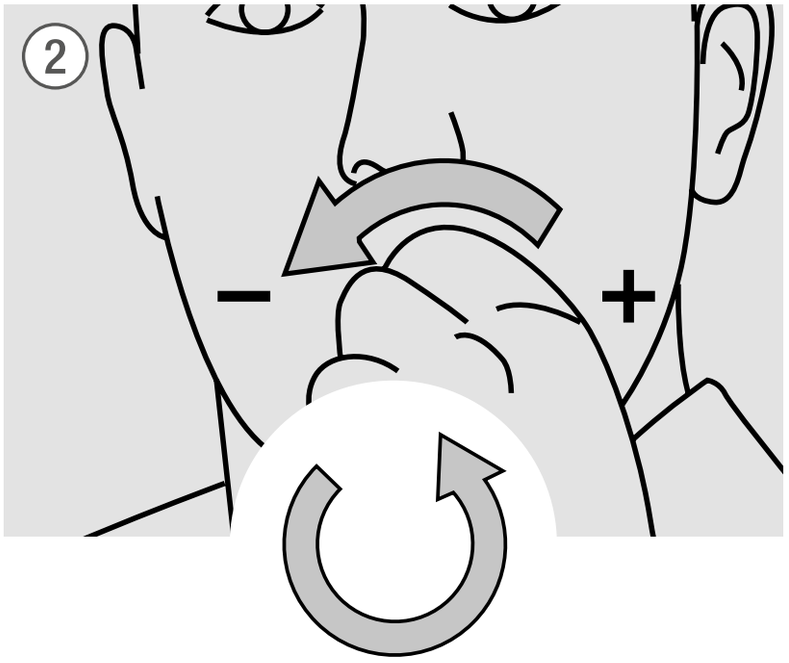
You may also engage the hook of the upper tray with the socket of the lower tray before placing the trays in your mouth. To remove the appliance at night or in the morning, it´s also possible to take out both trays at once without disengaging.



Protrusion Adjustment

TAP®-T / dreamTAP™





Adjustment of the device should only be done with the approval of your prescriber.
Note: Operating the activation key is written from the perspective of the patient with the TAP® in his/her mouth.

① To pull your lower jaw forward, insert the activation key into the opening on the front of the upper protrusion adjustment device. Turn it in the direction of the „+“ sign according to the laser marking and verify the movement with help of the scale.

② To return your lower jaw to the starting position, turn the activation key in the direction of the „-“ sign. Again you can verify the movement with help of the scale.

HINT:
One 360° turn with the activation key is 0.5 mm.

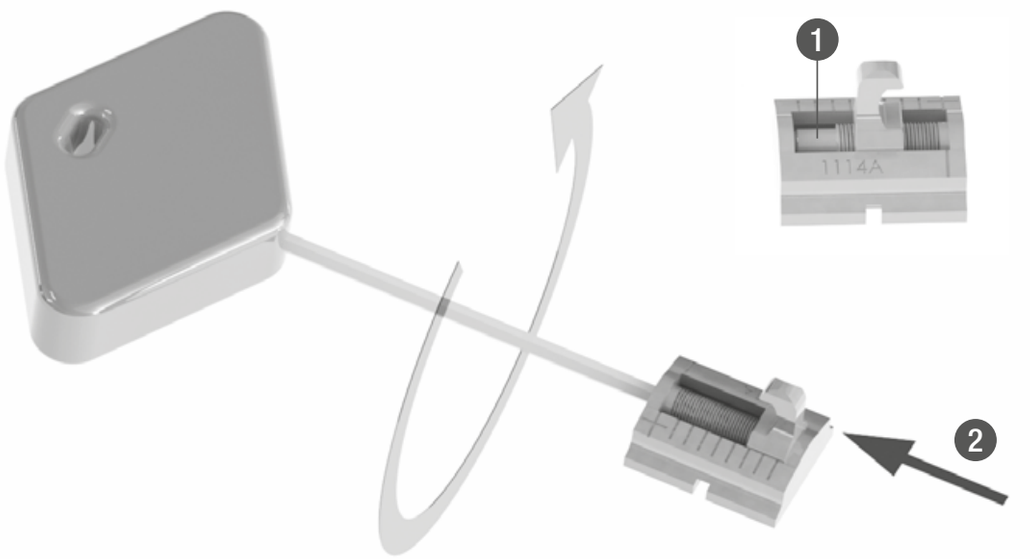
TAP®-T Reverse

With the TAP®-T Reverse device, activation directly in the mouth is not possible.

In contrast to the TAP®-T device, the activation bore for the hexagon socket wrench is located in the palatal area of the upper protrusion adjustment device, opposite the hook.
Activation (+/-) can be verified with help of the laser marked scale.

TAP®-T / TAP®-T Reverse

IMPORTANT
If the hook reaches into the “freerun” area ❶ during adjustment, it can be removed from the thread by turn the activation key in the opposite direction, applying only slight pressure ❷ to have the hook inserted again in the thread.

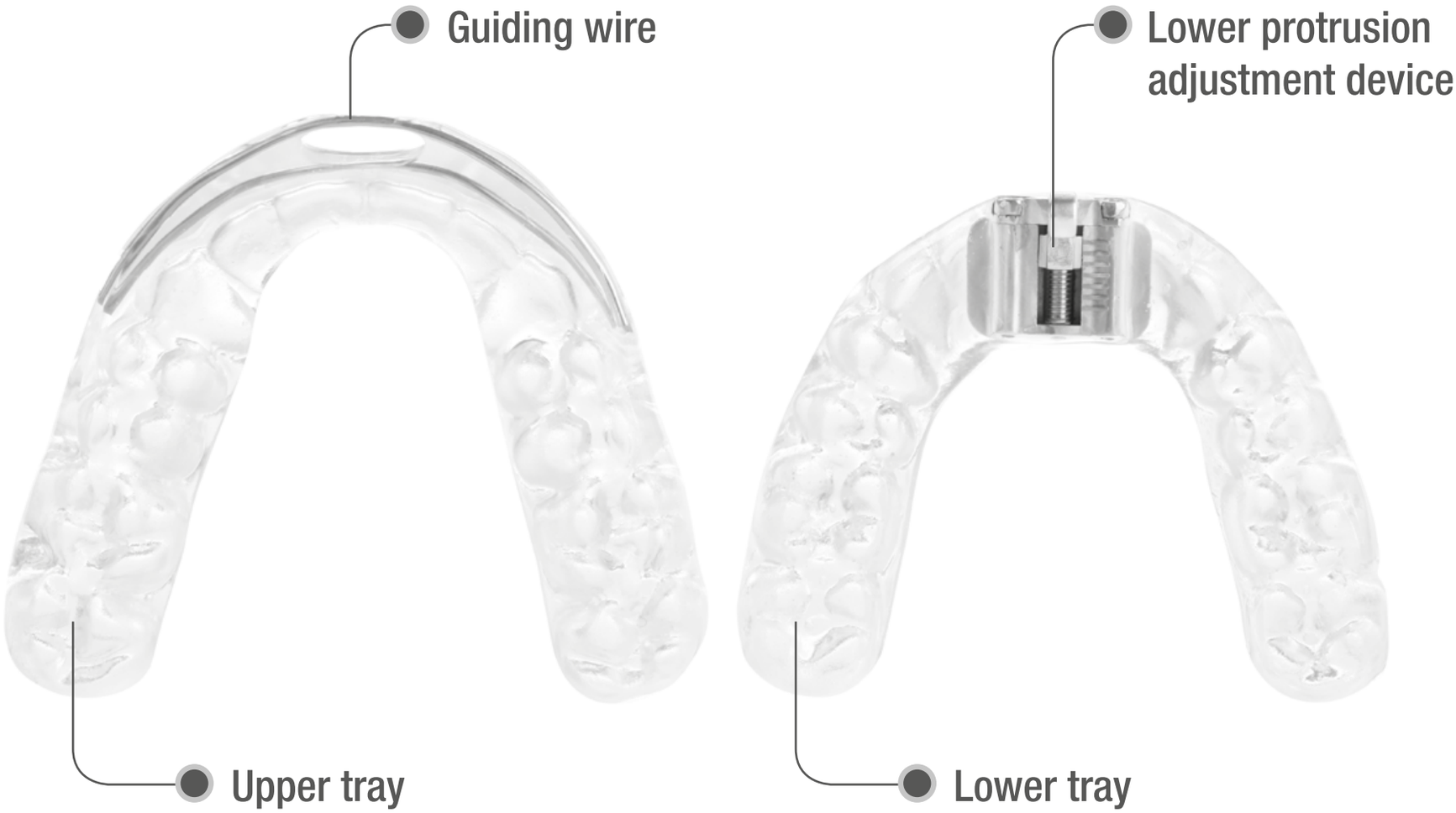


Description

dreamTAP™

The dreamTAP™ consists of two parts:
an upper tray with integrated reinforcement and guiding wires and a lower tray with a protrusion adjustment device.
Both trays engage via the hook of the protrusion adjustment device and the guiding wire in the upper jaw, thus positioning the lower jaw forward to prevent the soft tissue of the throat from collapsing and obstructing the airway.
You may engage upper and lower tray either outside or inside your mouth.

dreamTAP™


Guiding wire
Lower protrusion adjustment device
Upper tray
Lower tray

dreamTAP™

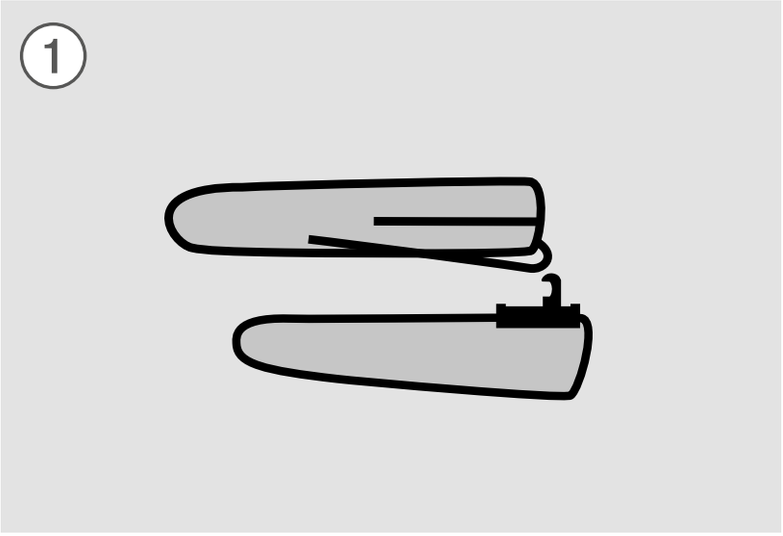
Inspect the device prior to each use. Contact the prescriber, if you observe any material separation, material degradation or cracks.

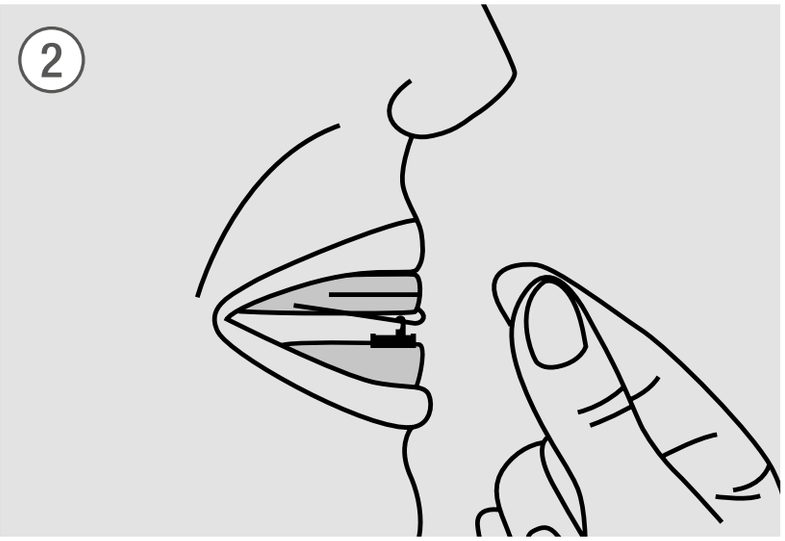
(1) Please connect upper and lower tray of your dreamTAP™ prior to inserting it into the mouth. Place the hook of the lower tray onto the guiding wire of the upper tray. The hook will only fit on the guiding wire at a designated point.

(2) Now place the combined device on the upper dental arch. Then move the lower jaw slightly forward, so that the lower teeth can slide into the lower tray. You can remove the dream TAP™ in reverse order – upper and lower tray combined.

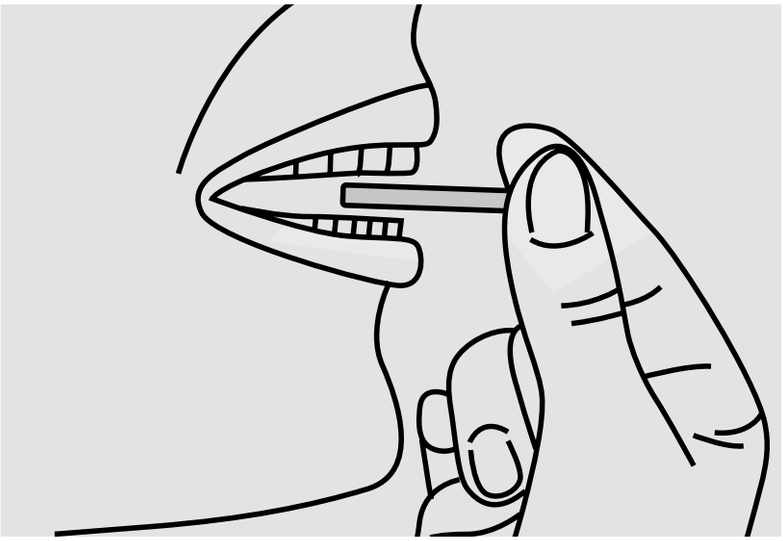
Adjusting the protrusion of dreamTAP™ is similar to adjusting TAP®-T, but with the adjustment device being located in the lower jaw.

dreamTAP™





Exercise with occlusion trainer



When the lower jaw is pulled forward during the night, it may make the jaw muscles sore and temporarily change the bite. The occlusion trainer (Exercise Bite Tabs) are intended to be used as an exercise tool to put your jaw back into a normal bite position.

WARNING

It is imperative to use the occlusion trainer each morning to reduce the risk of permanent bite change.

Occlusion trainer

① Place the occlusion trainer between the anterior teeth. Take care that the posterior teeth are not in contact.

② Now pull your lower jaw gently forward and then backward.

③ Once your lower jaw is in the back position, squeeze as if to put your back teeth together.

④ Remove the occlusion trainer to see if your teeth come together.

⑤ Repeat the process until the jaw is back in normal bite position.

AM Aligner™

The AM Aligner™ being included in the delivery of the dream TAP™ has to be adapted to your jaw by your dentist or orthodontist.

Care Instructions

Careful care and treatment guarantees durable and pleasant wearing characteristics of your TAP® device.

We recommend to clean your TAP® device daily with CETRON® care products. Alternatively, clean your TAP® device using a regular soft toothbrush, tooth paste and cool water each morning after use. Rinse thoroughly to remove saliva and other sediments. Always brush your teeth and floss well before inserting the TAP® device in your mouth.

Do not use denture cleaning agents!

Dry your appliance completely before storing in the container. It may help to leave the container open to ensure that your TAP® dries thoroughly.

Your TAP® appliance consists of a high grade thermoplastic material. This material is not resistant against hot steam, hot water and ultrasonic cleaning system.

Please avoid to expose your TAP® appliance to temperatures above 70°C as this may lead to deterioration of the material causing a loss of fitting accuracy

The following side effects have been described by patients in some cases:

- Slight tooth or gingival discomfort due to pressure of the appliance.
- Exess salivation initially. This will improve as you become accustomed to wearing the TAP®.
- Slight jaw soreness or tightness, initially and with adjustments.
- Temporary bite change. This will subside approximately 1 hour after the TAP® is taken out of the mouth in the morning and the occlusion trainer (Exercise Bite Tabs) are used.
- Unconsciously taking the TAP® out of your mouth at night. In this case please contact your dentist as the fit of your TAP® needs to be adjusted.
- It´s rarely possible that misalignment of teeth or changes in occlusion appear after long term use of the TAP® appliance.

HINT

Please contact your prescriber if side effects do not disappear and remain.

Contraindication

This device is contraindicated for patients with loose teeth, loose dental work, dentures or any other oral conditions which would be adversely affected by wearing dental appliances. Please contact your dentist in case of any modifications of your teeth/oral conditions, e.g. after loss of teeth or extractions as well as in case of any perceptible deterioration of the splint's fitting or breakage of resin and/or metal parts.

Strong aromatic food and beverages such as nicotine, coffee, tea and coke may lead to apparent discolorations of the soft splint material. Therefore it is recommended to drink only clear water while wearing the splint. Moreover, make sure not to use organic solvents, such as aliphatic alcohol, toluene, ethanol, acetone etc. for cleansing the appliance. Discolorations may also occur due to interactions of metallic dental fillings/ inlays and metallic denture parts (amalgam, chromium cobalt molybdenum or any alloys with reduced precious metal components). Please make sure to contact your dentist immediately in case of any modification of your appliance.