

USER INSTRUCTIONS FOR THE BIO-ACTIVATOR A.M.C.O.P.

NEUROFUNCTIONAL ORTHOPEDIC ORTHODONTICS

INTENDED PURPOSE

Elastic thermoplastic bioactivator, for cranial occlusal postural multifunctional harmonizer, for a functional, systemic and personalized rehabilitation and to re-educate the disturbed neurovegetative functions such as suction-swallowing, oral breathing, chewing and phonation; it is also indicated for bruxism and nocturnal snoring. Non-toxic, hypoallergenic, non irritating.

INTENDED USER

Patient on dentist indication / prescription

POPULATION

Children (3+), adults and elderly patients for any sex and condition.

GENERALITY

Always use the appliance as described in this leaflet as your prescriber has told you to do. In case of non-compliance with the safety standard, there is the possibility to damage the user and the environment.

- Keep this leaflet because you may need to use it.
- If you want more information and advices you may need to read it again.
- If you experience side effects, contact your prescriber.



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ORTHOGNATHOPOSTUROLOGY

An innovative method for treating teeth, based on two fundamental principles:

- the global vision of the body;
 - the concept of the correct form and function.
- Treat the dental arches and in combination with the body, as they are closely related to each other.

COMPOSITION

A.M.C.O.P. Bio Activators are made from a polymer/elastomer mixture (TPE) and colour additive polymers. The material is free of latex and phthalates.

DESCRIPTION

A.M.C.O.P. Bio-Activators are functional, orthopedic skeletal, articular (TMJ), neuro-muscular-occlusal and postural appliances. The A.M.C.O.P. BIO-ACTIVATORS are the synthesis of all existing functional orthodontic appliances.

The appliances should be used for an initial period of 7/10 days in the daytime phase only, then also at night, following the exercises below.

A.M.C.O.P. Bio-Activators Thermo-activable elastic harmonizers are suitable for a functional, systemic and personalized rehabilitation of the patient in a broader and more correct approach of the treatment.

Treatment with Bio-Activators A.M.C.O.P. can be considered as an extraordinary Bio-Orthopedics Oral-Skull-Facial. The appliances work mainly by modifying the growth of the cranial-facial skeleton.

A.M.C.O.P. Bio-Activators are characterized by a complete range of appliances for all types of mouths, in relation to the skeletal class and the type of cranial conformation.

Orthognathosthodontics, with the use of A.M.C.O.P. Bio-Activators, deals with reconditioning the neuro-muscular system and placing straight teeth in a correct relationship with the bone bases and, therefore, with the skull, the temporo-mandibular joints (TMJ) and the cervical spine and more specifically, with the cranio-sacral system (posture). Orthopedic-postural therapy is therefore proposed to rebalance and harmonize occlusal-postural imbalances in relation to the different dental- cranial-mandibular-cervical disorders.

The treatment aims to re-educate the disturbed neurovegetative functions such as **suction-swallowing, oral breathing, chewing and phonation**; it is also indicated for **bruxism and nocturnal snoring**.

The appliances can be considered true arch harmonizers and, thanks to the "plastic effect", allow a true expansion, stimulation and growth of the skeletal, maxillary and mandibular bases. Contextually they orient the commute of deciduous teeth in a correct bone-tooth-alveolus ratio during the harmonic growth of the jaws towards an ideal shape. The treatment with the A.M.C.O.P. Bio-Activators allows to make the correction more complete and stable over time and therefore not susceptible to relapse. It is a method of systemic orthodontics suitable

for restoring the main causes of different types of malocclusions. This challenging and articulated therapeutic approach provides the use of removable oral A.M.C.O.P. Bio-Activators which are true regulators of function and can be used in the stage of deciduous, mixed or permanent dentition to intercept early orthodontic orthopedic functional problems.

The treatment with the A.M.C.O.P. Bio-Activator also aims to treat other imbalances and para-functions through a physiotherapeutic action procured by the plasticity of the materials used, through a specific intra-oral activity that promotes the stimulation of the nervous and muscular trunks with rehabilitation effect, anti-inflammatory, decontracting, muscle relaxant.

The appliance is therefore able to harmonize and rebalance the dental arches and also to release the sutures and the structures of the skull through the plastic effect of the appliance, through a real gymnastic procured by natural stimulation movements of the facial muscles, to restore the balance of dentition and occlusion. Therefore, it allows a type of therapy of a functional, conscious character, as the patient uses his state of consciousness, performing bucco-facial gymnastics exercises suitable for the rebalancing of the stomatognathic system.

Treatment with the A.M.C.O.P Bio-Activator is therefore surprisingly simple, atraumatic and non-invasive. The method is defined as systemic, global, as it has the capacity to involve and correct the deficiency functions of the whole stomatognathic system: the teeth, the alveoli, the chewing muscles, the TMJ, the cheeks, the lips, the soft tissues, salivary glands, mandibular and maxillary bones, innervation and vasculature and therefore the whole dental-cranium-facial and cervical-postural system.

The system is particularly valid as regards the interaction of the same in the arch.

The main objectives of the treatment are to remove interferences capable of modifying the normal growth of the jaws through a direct orthopedic action on the neuromuscular system, to restore the Sfero-Occipital system acting on the mandibular kinematics, to create a functional harmony in the stomatognathic system enough to improve masticatory efficiency, to establish a correct functioning of all the neurovegetative functions of the mouth and to obtain an optimal postural condition.

INDICATIONS OF USE

A.M.C.O.P. Bio-Activators are indicated in cases of:

- Skeletally malpositioned dental arches of cranio-mandibular character such as second classes; third classes; latero-deviated arches; twisted arches; deep bites (deep bite); open bites (open bite)
- Dental elements not aligned in arches
- Postural imbalances
- Tensional decompensation of neuromuscular character
- Articular decompensation (TMJ)
- Atypical swallowing
- Oral breathing
- Bruxism

CONTRAINDICATIONS

A.M.C.O.P. Bio-Activators are contraindicated:

- In the presence of rotated, highly inclined, mesialized and diastematized posterior dental elements;
- In case of accentuated mobility of dental elements;
- In case of severe gingivitis;
- In case of specific joint problems (TMJ) with very severe joint damage.

INSTRUCTION MANUAL

For the optimization of this appliance and to obtain the maximum benefit, it is advisable to:

- Before wearing the appliance, wash it under warm running water to loosen its fibers;
- Work in a calm and concentrated environment, in order to better perceive your movements and sensations;
- Perform the exercises slowly and without haste;
- Take breaks between exercises and resume breathing slowly without increasing the pace

EXERCISES

The therapy is based on the use of the activator during day and night.

Daytime: exercises in the active phase with functional exercises to educate correct swallowing (speech therapy) and nasal breathing, associated with biting the appliance. At night: keep the appliance positioned in the mouth in passive condition.

Functional education exercises

Find yourself in a comfortable and relaxed condition, inhale and exhale without any forcing. When breathing is calm, work can be started with the exercises.

Swallowing and breathing

Swallowing should be done in a normal way. The tongue must be positioned on the spot right behind the upper incisors and precisely in the area where there is a button, suitable for stimulation, for 10 seconds. Next, swallow the saliva and place the tongue against the palate for 10 seconds and then release it in a rest condition. Breathe regularly for a few seconds and inhale in maximum nasal ventilation, hold your breath for a few seconds and then exhale. Repeat the process for 5 times. The breathing exercise must be associated with an action coordinated with the diaphragm muscle. Repeat the exercise of swallowing and breathing 10 times, alternating between the two exercises.

Chewing (munching of the activator)

After the swallowing and breathing exercises, the active mastication phase of the appliance can be started. Exert a pressure on the occlusal plane of the activator with the teeth and let go intermittently (nibbling). The nibbling should last 20 minutes, up to about 30 minutes. The exercise consists of alternating these closing and opening movements without ever losing contact between the activator and the teeth and without any excessive force. The slightest tension should cause the exercise to stop for a few minutes, breathing and relaxing the muscles of the cheeks. The rhythm of the nibbling can be relatively slow: nibbling with an unforced rhythm of two frames every second, resting at times according to your needs. The rhythm is indicative; you should find

your own, whatever makes you feel good. These exercises must be performed 3 times a day in an interval of at least 3 hours.

Using the activator during night-time

After taking daytime therapy for 7 to 10 days, treatment can be completed during night-time. To begin with, put the activator on every night. The beginning of this phase can cause difficulty in falling asleep and / or loss of the activator from the mouth during sleep. Then keep the appliance in place for a certain time and remove it for the rest of the night. Try again every night to get more comfortable with it. The goal is to keep the activator positioned in the mouth all night. It is possible that the anterior teeth (incisors) are painful when waking up, a sensation that usually fades very quickly after about 15 to 20 minutes.

Maintenance

To ensure great hygiene of the activator, it is advisable to treat it before use with some antiseptic products, possibly natural ones. Alternatively, you could immerse the A.M.C.O.P. Bio-Activator in a glass of water with a teaspoon of baking soda.

Warnings and possible side effects

If you experience pain when using the appliance due to rubbing the A.M.C.O.P. Bio-Activator against your cheek or gums, you should consult your dentist who will have to readjust the activator at the rubbing points.

This may happen during the use the activator with inflamed gingiva (gingivitis for poor hygiene), which may be the cause of bleeding, gingivitis may be present. When this is treated, the activator will no longer cause pain and bleeding. In case of a cold, suspend the use of the A.M.C.O.P. Bio-Activator at night until the cold is resolved and in the daytime try to use it with nasal ventilation exercises to increase healing.

The A.M.C.O.P. Bio-Activator must be prescribed by a dentist. We recommend that you should strictly follow all of our instructions.

During the use of the appliance you should not feel symptoms such as: strong tension, contraction, pain in the teeth, mouth, neck, back of the neck, etc ... In case of an allergic reaction or irritation to the mucous membranes, immediately suspend the application and consult with a doctor.

Once treatment with the A.M.C.O.P. Bio-Activator has begun, it must be used according to the schedule established by your doctor and in any case no longer than 6 months. Do not speak with the A.M.C.O.P. Bio-Activator on and do not play with it. Keep it away from pets.

Dispose of the appliance in accordance with applicable waste disposal regulations.

A.M.C.O.P. DTM BIO-ACTIVATORS

The DTM appliances have the same arch shape characteristics as the standard appliances, but are more comfortable because they are less invasive thanks to smaller vestibular and lingual flanges. The colors of the appliances are the same as those of the standard appliances according to the type of arch form and skeletal class, but on the left side the abbreviation DTM (Temporo Mandibular Dysfunction) appears. The A.m.c.o.p. DTM Bio-Activators have been designed specifically for the treatment of patients with- Tensional decompensation of neuromuscular character- Articular decompensation (TMJ)- Bruxism. They can also be used for the restraint phase after the use of integral activators or other orthodontic treatments with fixed appliances or splints.

APPLIANCE FOR THE TREATMENT OF NOCTURNAL SNORING (ELASTOOSAS)

WHAT ELASTOOSAS IS AND WHAT IT IS USED FOR

ELASTOOSAS is a functional appliance designed for the treatment of night snoring, sleep apnea and it must be prescribed by the dentist doctor, competent in this area, after a careful diagnosis regarding the problems of the case to be treated. The appliance is made of medical material with thermoelastic characteristics and has the purpose of freeing the respiratory tract through a specific functional action, procured by ELASTOOSAS, and limiting snoring and episodes of sleep apnea.

WHAT YOU MUST KNOW BEFORE USING ELASTOOSAS

NIGHT SNORING is a particular acoustic phenomenon characterized by a variable intensity noise generated along the respiratory tract by mobile and vibrating structures caused by the obstruction of the airways. If the obstruction is complete, the passage of air is interrupted and apneas occur. Night snoring can be a health problem, it can cause: restless sleep, headache, poor concentration, waking up in the morning with a sense of fatigue, feeling of not getting enough sleep, easy irritability, feeling of suffocation, coughing, gasps inspiratory, tachycardia, drowsiness, obesity. Major health problems related to heart disease and stroke may also arise in the long term.

There are specific causes that can cause night snoring, these causes concern altered conditions of the correct functions of the mouth with an abnormal occlusal pictures caused by a cranio-mandibular condition out of the norm; specifically, reference is made to a reduced vertical size of the mouth, and to a rear-positioned jaw which involves the simultaneous posterior displacement of the tongue, which, in itself, is in complete opposition with the posterior wall of the pharynx. In this cranio-mandibular and lingual configuration, sleep apneas frequently occur, characterized by the drastic increase in respiratory mobility, so as to significantly affect the health and psyche of the individual.

It must be taken into account that when the tongue is tipped back in complete opposition with the posterior wall of the pharynx it is easy that both oral and nasal breathing can be conditioned, as the air is no longer able to reach the lungs. Thus we speak of sleep apnea (**OSAS - Obstructive Sleep Apnea Syndrome**) which is the alteration of normal sleep physiology, characterized by an interruption of sleep or a pause of the same, due to a blockage of the passage of air at the level of the nose and the throat which determines the vibration of the uvula, the soft palate and the tonsillar pillars.

Another important fact to consider, with reference to an altered breathing from abnormal posture of the tongue, concerns the reduced vertical size of the mouth, the tongue will in fact be flattened downwards and therefore will consequently be rear positioned. Therefore, with regard to sleep disturbances, ELASTOOSAS appliance will be indicated in consideration of specific causes that will entail a reduced vertical dimension of the mouth with a retracted jaw and to a tongue with a low posture and rear position.

Ultimately, in order to establish an ideal nasal respiratory scheme, the presence of an adequate cranio-mandibular conformation will be necessary, with the jaw positioned forward compared to the norm, associated with a correct posture of the tongue which is also positioned forward and projected towards the upper part in contact with the spot (retro incisor palatine area) able to allow the normal patency of the nasal and oral airways.

DESCRIPTION OF THE ELASTOOSAS APPLIANCE

The appliance for night snoring, ELASTOOSAS, consists of two occlusal showers joined together by a sliding and retractable occlusal guide so as to compose a monobloc appliance suitable for containing the teeth of the upper and lower dental arch. The main elements that make up the appliance so that the desired action can be carried out concern, first of all, the modelling of a reference guide to the lower arch which is more forward (protruding) than the norm, and an adequately raised occlusion plane accompanying a particular ramp-type modelling, which extends along the entire perimeter of the lower lingual flanges, having the specific function of a true lingual elevator supported by a repere (BUTTON) suitable for the stimulation (INPUT) of the tongue itself in the palatine area, incisive back area (SPOT LINGUAL). These elements are generally decisive for the recovery of correct nasal breathing, as they allow further release of the pharyngeal area. A further aid regarding better nasal breathing is constituted by an adequate shielding provided by the vestibular flanges (FRONT SHIELDS) which act as a barrier to oral breathing during sleep. Ultimately it will be possible to obtain a better air ventilation through an adequate opening of the pharyngeal area and of the whole oral area. A better air ventilation will ultimately limit the uvula to vibrate.

INDICATIONS

ELASTOOSAS appliance is also indicated in case of:

- Bruxism (Night grinding)
- Specific neuro-muscular tension problems
- Muscle-tension headaches in predisposed patients

CONTRAINDICATIONS

ELASTOOSAS appliance is contraindicated in case of:

- Articular-Temporo-Mandibular (TMJ) problems
- Accentuated periodontal mobility
- Important gingivitis

MATERIALS

The material used to make ELASTOOSAS appliance consists of a composition of elastomer polymer with thermoelastic characteristics supported by extraordinary elasticity and excellent mechanical properties; all this to ensure a comfortable adaptation to the dental arches and sufficient resistance to the chewing load. This is a certified medical material, completely non-toxic, it does not contain phthalates, it is hypoallergenic, there is no presence of latex, and finally it is not irritating to the mucous membranes. It therefore has characteristics of complete biocompatibility for greater safety in the health sector.

What distinguishes it from others, concerns the specific thermoelastic characteristics that make it adaptable to the different types of arch shape, when it is needed, by means of a suitable modelling of the flanges through heat instruments suitable for the case. The prescribing dentist will modify the appliance if it interferes with the gums, the cheek muscles, the lips and the tongue in order to make it as comfortable as possible.

USE OF THE APPLIANCE

ELASTOOSAS appliance must be used at night. Before wearing ELASTOOSAS it is necessary to wash it under running water to loosen the fibers of the same. The first nights, after placing the appliance in the oral cavity, there may be difficulties in falling asleep and keeping it all night. These difficulties may be determined the first nights by the particular invasiveness of the appliance and by the predisposition of the user subject to breathing with the mouth, where the appliance itself is predisposed for nasal breathing. The first nights the appliance must be kept for the compatible time in consideration of the subjective difficulties and, therefore, if necessary remove it, trying to increase the time later and without being discouraged. As the nights go by, the appliance will be more and more tolerated, until you can keep it all night. In some cases, always at the beginning of the treatment, the loss of the appliance during sleep may occur and also in this case try again every evening. As you get used to it, you can keep it until morning.

MAINTENANCE

To ensure a good hygiene of ELASTOOSAS appliance, it is ALWAYS recommended, after it has been removed from the mouth, to eliminate the excess salivation under running water and treat it with some antiseptic product. It's better a treatment with a teaspoon of mouthwash, possibly natural, diluted in cold water with the appliance immersed for about sixty seconds, then remove it and rinse to eliminate excess mouthwash, then keep it in cold water until the next use. If necessary, dry it with hygienic tissues and deposit it in a special pouch provided, taking care in this case to rinse the appliance before inserting it into the oral cavity the following evening. Alternatively, treatment with a teaspoon of baking soda always in cold water in a suitable container is recommended. It is also possible to brush with a toothbrush and toothpaste.

WARNINGS

ELASTOOSAS appliance must be prescribed by the dentist. It is advisable to scrupulously follow all its indications. During use of the appliance, symptoms such as: STRONG tension in the teeth, mouth, neck, neck and back should not be felt. In the event of allergenicity or irritation to the mucous membranes, discontinue the application immediately and consult the prescribing doctor. Avoid using the appliance in case of periodontal disease and highly mobilized teeth. A possible soreness of the teeth in the morning upon awakening is to be considered normal, the discomforts will disappear after twenty minutes after removing the appliance from the mouth. During the night use, there should be no pain due to the rubbing caused by the appliance itself, if this happens, the dentist will touch up the points corresponding to the painful areas. In case of a cold, it will be necessary to stop the treatment until the cold is resolved. In case of excessive breakage of the appliance, it will be replaced.

Keep it away from pets.

For disposal, comply with current regulations regarding waste disposal.