



TheraBite[®]

JAW MOTION REHABILITATION SYSTEM[™]

*Let's
talk about
life[®]*

ATOS
MEDICAL



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Limited Jaw Mobility

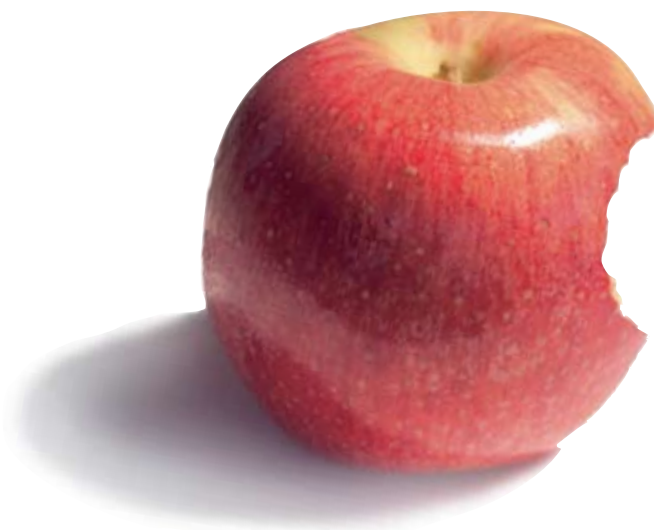
Difficulty or pain when opening the mouth may be a sign of limited jaw mobility or trismus. Patients suffering from this condition can be found within many clinical disciplines, including speech & language pathology, radiation oncology, maxillofacial surgery and prosthodontics, otolaryngology, physical therapy, and dental surgery.

Trismus is a serious yet frequently overlooked condition. In many cases, it can not only cause pain, but can also significantly impair important day-to-day functions, such as chewing and swallowing, maintaining adequate oral hygiene, and communicating effectively with others.

Who is affected?

Trismus can affect people of all ages. The condition is attributed to muscle fibrosis; joint damage and/or scarring, which in turn may be caused by the following:

- **Head and neck radiation therapy**
- **Temperomandibular joint (TMJ) dysfunction**
- **Surgery**
- **Systemic diseases such as rheumatoid arthritis or scleroderma**
- **Direct trauma**
- **Indirect trauma such as whiplash**
- **Clenching and grinding of the teeth**
- **Stress-induced disorders**
- **Burns**
- **Stroke**
- **Aging**



Life with Trismus

What are the complications?

Trismus can cause difficulty in:

- **Biting**
- **Chewing**
- **Swallowing**
- **Speech**
- **Maintaining oral hygiene**
- **Intubation**

In turn, these difficulties can result in costly medical complications and can increase the risk of:

- **Malnutrition**
- **Inflammation and pain**
- **Disuse atrophy**
- **Changes in the joints**
- **Poor wound healing**
- **Inadequate oral assessment**
- **Aspiration**
- **Compromised airway**
- **Osteoradionecrosis**





Quality of life!

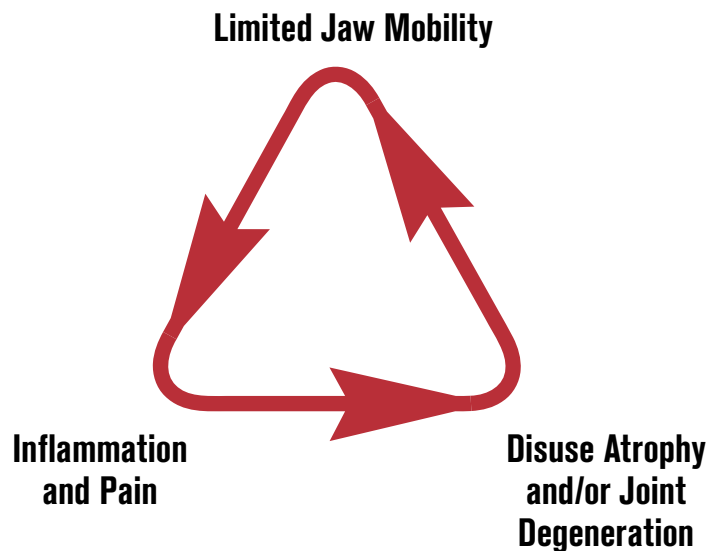
Trismus may not only affect an individual's physical health, but also his/her psychosocial well-being:

- Social interactions are often affected due to reduced ability to communicate and to eat in public.
- Exhaustion is common because more effort is required to execute simple tasks.
- Appetite for life diminishes and can result in social withdrawal, feelings of helplessness and resignation.
- Depression can arise leading to decreased ability to cope with the condition.

Early detection and intervention can help patients counter this debilitating condition and prevent costly complications which may compromise a patient's quality of life and health.

The vicious cycle of trismus

Patients at risk of developing trismus should be evaluated and treated by a qualified clinician to prevent further restrictions to jaw opening or associated chronic pain. The diagram below best illustrates the vicious cycle of limited jaw mobility.



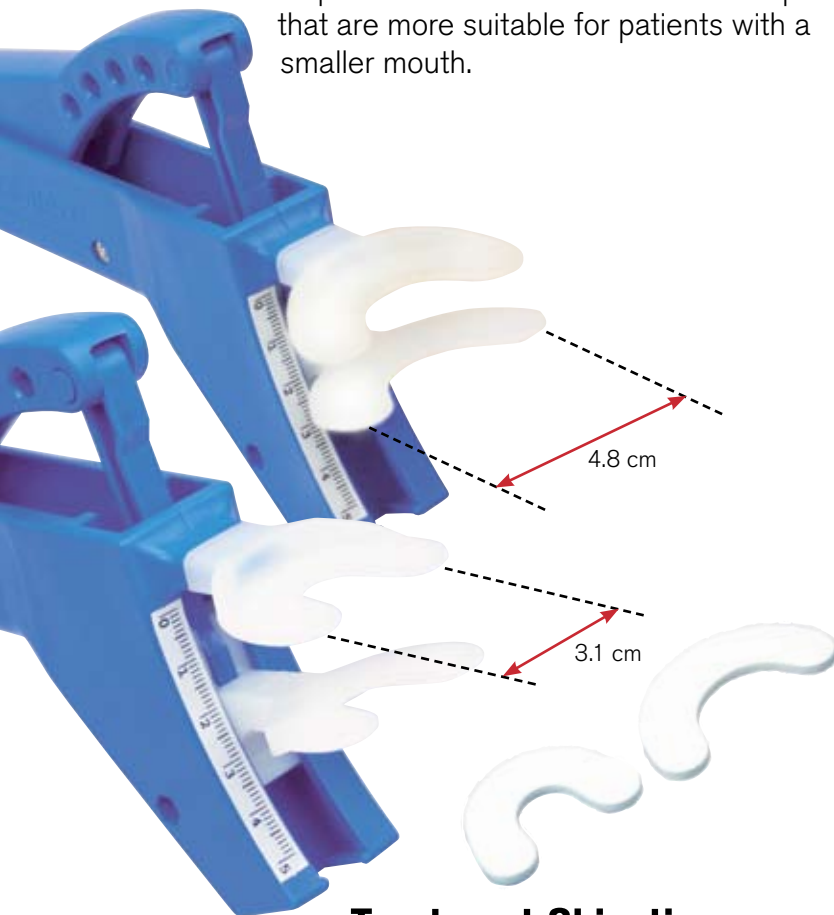
The TheraBite®

Jaw Motion Rehabilitation System™

The TheraBite® Jaw Motion Rehabilitation System™ is a portable system which utilizes repetitive passive motion and stretching to restore mobility and flexibility of the jaw musculature, associated joints and connective tissues.

The TheraBite Jaw Motion Rehabilitation System is available in an adult and a pediatric version.

The pediatric version has smaller mouthpieces that are more suitable for patients with a smaller mouth.



Treatment Objectives

Numerous clinical studies have demonstrated the efficacy of the TheraBite system ^{ref: 1-5}. The TheraBite system is designed to accomplish two treatment objectives:

1. Increases Range of Motion of the Jaw:

- Stretches connective tissue

Fibrous scar tissue causes tightening of muscle and joints and requires stretching to re-align the collagen fibers within. The TheraBite system provides passive repetitive stretching to lengthen and reform these fibers and does so in an anatomically correct fashion.





- **Strengthens weakened muscles**

Muscles that have suffered from disuse atrophy require strengthening across the full range of motion.

Using passive range of motion exercises, the TheraBite system helps to increase muscle mass and endurance.

- **Mobilizes joints**

Joints that have been immobilized can undergo degenerative changes in a matter of days.

The TheraBite system can safely mobilize the temporomandibular joint across its full range of motion via passive motion.

2. Pain Reduction

- **Reduces joint inflammation**

Immobilized joints lead to thickening of the synovial fluid and thinning of cartilage. This stiffening of the joints ultimately leads to inflammation and pain.

Exercising with the TheraBite system activates anti-inflammatory agents that promote joint lubrication and reduce inflammation and pain.

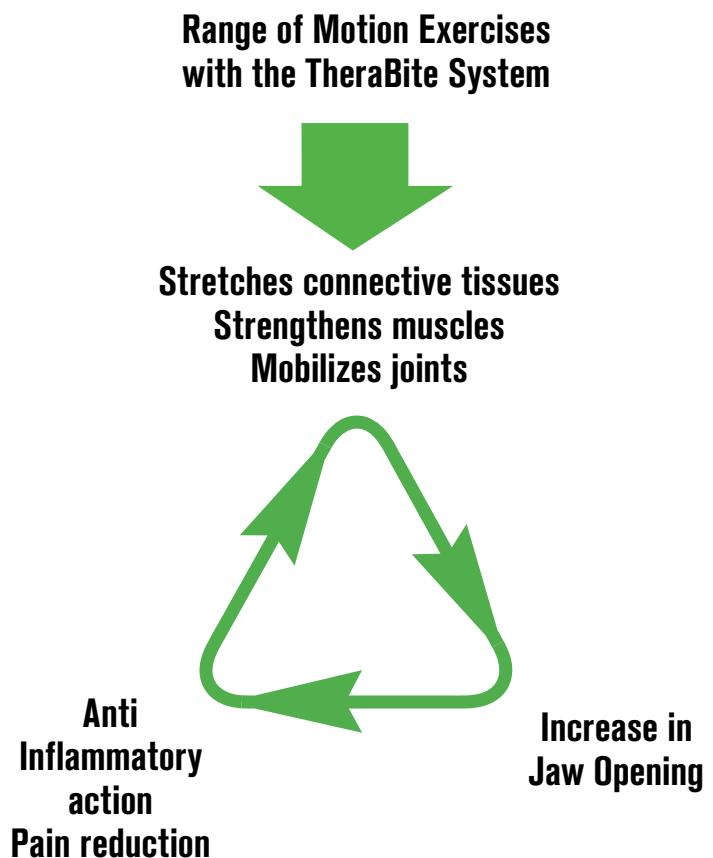
- **Reduces muscle pain**

Muscle pain (myofascial pain) is usually caused by inflammation which creates abnormal pressure on nerves, muscles, and bones. This inflammation process can be corrected through passive motion exercises.

Rehabilitation with the TheraBite system has been proven to reduce joint and/or muscle pain in as little as two weeks of therapy ^{ref.4}.

The TheraBite cycle

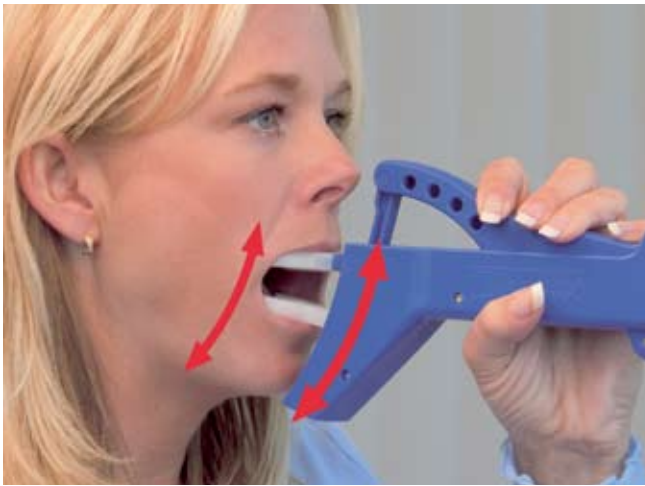
The diagram below illustrates how passive movement and stretching with the TheraBite system can help to transform a vicious cycle into a positive one.



Features

Anatomically correct

A unique feature of TheraBite system is its ability to follow natural curved motion of the jaw. The patented curved track of the TheraBite Jaw Mobilizer guides the mandible along an anatomically correct pathway.



The opening motion of the Jaw Mobilizer follows the natural pathway of the mandible.

Patient controlled

When using the TheraBite system, the patient is in control. Speed and opening range can be adjusted directly by the patient, using manual force, or the Fine Adjustment Knob. This feature helps to reduce anxiety levels and improve compliance.



The hand-operated Jaw Mobilizer is easy to use and gives the patient control over the rehabilitation program.

Lee Laino

"One problem I faced after radiation for my base-of-tongue cancer was that I couldn't open my mouth wide enough to chew properly. This also affected my speaking ability and oral hygiene, which are essential in my business practice and for my overall quality of life. My speech-language therapist told me that I should try to improve my jaw mobility as quickly as possible when I finished my treatment. Initially, I pursued the traditional manual exercises and stacking tongue depressors to force open the mouth. The results were disappointing. Then a progressive-thinking therapist recommended the TheraBite system, which I began using immediately. I am happy to say that within weeks my range of motion was restored to pre-treatment levels and my oral health and lifestyle are uncompromised."

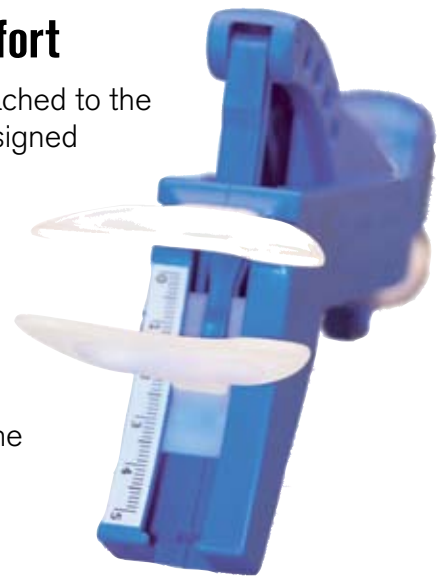


Portable

The TheraBite system is durable and lightweight. It can be conveniently stored in the Carrying Bag provided for patients to continue their rehabilitation program wherever they go.

Load-bearing comfort

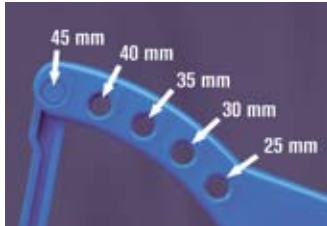
The mouthpieces are attached to the Jaw Mobilizer and are designed in such a way that the load-bearing forces of stretching spread across the teeth. This, together with the Bite Pads, promotes a comfortable and even stretch while protecting the patient's teeth.



Effective

Passive motion and stretching exercises with the TheraBite system are clinically proven to be an effective form of jaw therapy. It has been used with success by thousands of patients suffering from more than 30 different conditions, ranging from post-radiation trismus to orofacial pain.

The TheraBite system consists of...



Range Setting Arm

The position of the Range Setting Arm can be adjusted between 25-45 mm and is used to determine maximum opening appropriate to each stage of rehabilitation.

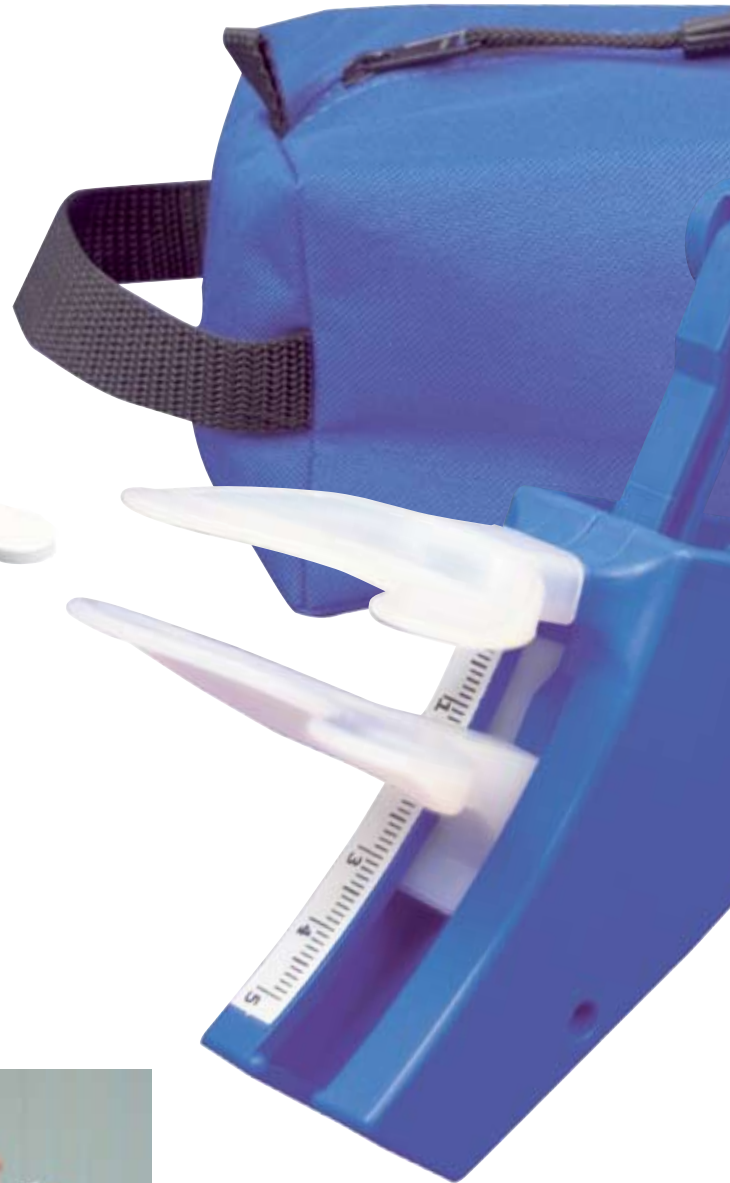
Bite Pads

The self-adhesive Bite Pads spread the force across the teeth and can be trimmed or stacked for customized protection. The Bite Pads come in adult, pediatric and edentulous versions.



Range of Motion Scales

The disposable Range of Motion Scales allow the patient and his/her clinician to make jaw opening measurements and to monitor progress.





Carrying Bag

The durable nylon Carrying Bag keeps the TheraBite system and accessories together.



Patient Progress Log

The daily and monthly Patient Progress Log enables the user and his/her treating clinician to monitor progress.



Fine Adjustment Knob

The Fine Adjustment Knob can be used to regulate opening speed and distance if needed.



Hand-Aid

The Hand-Aid assists the patient in maintaining constant opening during stretching or strengthening programs.



Treatment Program

Treatment

Prior to using the Therabite system, each patient should consult his/her clinician, who will prescribe an individualized program of exercise tailored to the patient's unique needs and abilities.

A commonly used treatment program is 7-7-7: 7 stretches performed 7 times per day, each stretch held for 7 seconds. In total, this is an investment of less than ten minutes a day.

Individuals who suffer from muscle and/or joint pain may benefit from longer stretch exercises. An example of a treatment program with longer stretches is 5-5-30: 5 stretches performed 5 times per day or more, each stretch held for 30 seconds.

Regular monitoring, review, and evaluation by a properly trained clinician is essential for all treatment programs. Depending on a patient's condition and the judgment of his/her clinician, the type of program required may be modified over time.

Expected Treatment outcomes: 1 – 1.5 mm per week

A typical patient will gain from 1-4 mm of jaw opening ability in the first session; however, this gain is likely to be lost within the next few hours. Only by continuing to stretch and mobilize the jaw for several sessions per day can any lasting benefit be achieved.

Increased pain during the exercises should be avoided, as it can result in muscle guarding that may impair the effectiveness of the therapy and reduce compliance.

The average sustainable gain is around 1 – 1.5 mm per week. Thus, to achieve 10 mm of sustainable gain, a patient may need to exercise from six to ten weeks.

The number of daily exercise sessions with the TheraBite system typically decreases over time. Ultimately, many patients are usually able to maintain the gain they have achieved by using the device just once or twice a day.



7-7-7 Protocol



1
Peel off tape from Bite Pad to apply the Bite Pads to the mouthpieces.



2
The longer the Bite Pads sit on the mouthpieces, the stronger they adhere.



3
Place mouthpieces comfortably between teeth



4
Squeeze the Lever gently to the point of resistance. Hold for 7 seconds.



5
Slowly close the mouth and pause for 7 seconds.



6
Squeeze the Lever again to the point of resistance and hold for 7 seconds.

7 seconds followed by a 7 second pause

7 stretches

7 times per day

Testimonials



Prof. D. Buchbinder

Division of Maxillofacial Surgery, Department of Otolaryngology,
Continuum Cancer Centers, New York, NY, USA

"I have been prescribing the TheraBite system for more than ten years for my patients who have limited range of motion of the jaw. Many of my patients have had surgery or radiation treatment to the head and jaw area, and many of them have difficulty in opening their mouth.

For many years, we used tongue depressors to help patients with limited range of motion of the jaw, but have determined that the TheraBite system provides a much better and faster result."

Prof W. Mendenhall

Department of Radiation Oncology, University of Florida Health Science Center, Gainesville, FL, USA

"While treating patients with radiation for head and neck cancer, we have noted a meaningful number of cases of trismus. We have tried many different approaches to the treatment of this condition, but are most impressed with the results of the TheraBite system. It is easy for patients to use, and offers consistently positive results."



Lynn Acton

MS, CCC/SLP, Speech Language Pathologist, New Haven, CT, USA

"Head and neck cancer patients who undergo surgical resection, external beam radiation therapy or a combination of both treatments often suffer from trismus. Trismus effects ability to masticate, speech intelligibility and oral care. I have found the Therabite jaw motion system to be effective in the remediation of trismus in this population. The Therabite not only stretches the muscles but passively moves the mandibular joint"

Prof R. Reich

Department of Oral and Maxillofacial Surgery,
University of Bonn, Germany

"Over the past 13 years, I have used the TheraBite system in a wide variety of cases of limited jaw function, including persons with trismus, persons recovering from TMD surgery, and persons who have experienced facial trauma.

I have found the device to be well-tolerated by the patient, and have seen quite consistently good results across this wide range of etiologies. As with many therapeutic treatments, we see that early intervention provides the best result for the patient."

Dr. B. Stack

Department of Otolaryngology, Head and Neck Surgery,
University of Arkansas Center for Medical Sciences, Little
Rock, AR, USA

"I have used the TheraBite device in a variety of patients, including patients suffering from post-surgical and post-radiation trismus, as well as on TMJ patients. The typical patient responds well to the device, showing significant improvement in function. While rehabilitation does take some time and effort, it is encouraging to many patients, who find that they can resume eating and speaking properly."

Insurance and Reimbursement (USA only)



Atos Medical Inc. handles all aspects of the insurance process. We also accept assignments for Medicare patients.

The TheraBite system is eligible for Medicare reimbursement, however, reimbursement amounts may differ from state to state. Many private insurance companies will also cover the TheraBite system. Please note that each insurance plan is individualized, and reimbursement may vary.

How can I order?

You can call, e-mail, or fax your order to:

Atos Medical Inc.

11390 West Theodore Trecker Way
West Allis, WI 53214-1135

Tel: 1 800 217 0025

Fax: 1 414 227 9033

E-mail: info.us@atosmedical.com

www.atosmedical.com






It is also possible to order the TheraBite system from the Atos Medical Inc. webshop – www.atosdirect.com




Should you require further information about the TheraBite system, please contact our customer service representatives at the above-mentioned address.

Patient information forms, prescription forms, and certificates of medical necessity can be sent to you upon request or you can download them from the www.atosmedical.com webpage.

For Canadian insurance issues please contact Atos Medical Inc.

Ordering Information

	Quantity	REF
TheraBite® Jaw Motion Rehabilitation System™, Adult	1 pc	TH001
TheraBite® Jaw Motion Rehabilitation System™, Pediatric	1 pc	TH002
 <p>Set contents:</p> <ul style="list-style-type: none"> ▪ The Jaw Mobilizer ▪ Bite Pad ▪ Hand-Aid ▪ Range of Motion Scale ▪ Carrying Bag ▪ Instructions for Use ▪ Patient Progress Log 	1 pc 4 pcs 1 pc 30 pcs 1 pc 1 pc 1 pc	
TheraBite® Range of Motion Scale 	150 pcs	SC001
TheraBite® Bite Pad, Regular 	4 pcs	PA001
TheraBite® Bite Pad, Edentulous 	4 pcs	PA002
TheraBite® Bite Pad, Pediatric 	4 pcs	PA003

	Quantity	REF
TheraBite Instructional DVD  <p>This 14-minute film provides useful information on trismus and demonstrates the functions and benefits of the TheraBite system. This DVD is divided into several chapters and features testimonials from a former patient and two clinicians. Available in English and Spanish.</p>	1 pc	7840 (PAL) 7840-N (NTSC)
TheraBite Picture CD-ROM  <p>The Picture CD presents a comprehensive collection of digital JPEG pictures and may be used for scientific presentations.</p>	1 pc	7846
TheraBite Display Stand  <p>This display stand is made of frosted plexiglass for the demonstration of the TheraBite system (adult version only). It comes with an extra panel to display accessories. Note: No accessories come with the display stand.</p>	1 pc	7845

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About Atos Medical

Atos Medical was founded in 1986 with a vision to improve the lives of people suffering from ear, nose, and throat (ENT) problems. Today, we develop and manufacture a wide range of reliable, safe and cost-effective ENT products. We are a global leader in voice and pulmonary rehabilitation products and are expanding steadily in the areas of dysphagia, orofacial, otology and rhinology.

Atos Medical acts and excels in every step of the product cycle - development, quality control, production, marketing, and sales to ensure that we are at the pinnacle of innovation and quality. We believe in building a close working relationship with clinicians and patients. Some of our most innovative products have been developed in close collaboration with our customers.

Atos Medical is an expansive and dynamic worldwide corporation based in the renowned Öresund cluster for medical device and pharmaceutical companies in the south of Sweden. Our headquarter houses state-of-the-art production and R & D facilities which meet the rigorous requirements for manufacturing medical devices. We have subsidiaries in the US, UK, Germany, the Netherlands, Spain, Belgium and Switzerland as well as exclusive distributors in over 50 countries.

Through an intimate and extensive network of interconnected companies, scientists, clinicians and patients, we are able to integrate the benefits of research and development as well as foster continual innovation. Our success is also reflected by our net turnover which has risen by an average of 20% to 40% annually for the past 10 years.

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User manual and prescriber information

This catalog does not replace nor does it set forth the complete contents of the User Manual for the TheraBite® Jaw Motion Rehabilitation System™, and is not a substitute for reviewing and understanding that important information. Therefore, before using the TheraBite® Jaw Motion Rehabilitation System™, please review the entire contents of the User Manual.

The User Manual and Prescriber Information for the TheraBite® Jaw Motion Rehabilitation System™ are available online at www.atosmedical.com. You may obtain a copy of the User Manual by calling 1-800-217-0025 (in the USA), sending an e-mail to info@atosmedical.com, or writing to Atos Medical AB (PO Box 183, SE 242 22, Hörby, Sweden). In addition, copies of the User Manual can be obtained from your TheraBite® Jaw Motion Rehabilitation System™ supplier.

Intended use / Indications

The TheraBite® system is intended for use in individuals who are restricted in their ability to open their jaws (trismus or jaw hypomobility). The TheraBite® system is intended for use in individuals who experience pain in the joints and/or muscles of the jaw. The TheraBite® system may also be used as a rehabilitation tool for postoperative physical therapy of the jaw. Patients at risk of developing limited jaw motion may consider the TheraBite® system for prophylactic use on the advice and under the supervision of a trained clinician. Prospective users should consult their clinician to determine whether the TheraBite® system is appropriate for their individual conditions.

Contraindications

The TheraBite® system should not be used by individuals who have or may have a fracture in the maxilla or mandible (upper or lower jaw) or other weaknesses of the bones of the jaw. Patients with infections of the jaw, osteomyelitis, or osteoradionecrosis of the jaw should not use the TheraBite® system.

Warnings

If the user feels unexpected pain at any time while using the TheraBite® system, the user should immediately stop using the product and should immediately contact his or her clinician.

Injury may occur if excessive force is applied while using the TheraBite® system, especially in users with weakened dentition, periodontal disease, weakened bones or joints, or gap-bridging plates. Users should disclose any such condition to their clinician before using the TheraBite® system and should exercise extreme caution while using the product.

Before commencing any rehabilitation regimen involving the TheraBite® system, all users should receive a thorough, professional evaluation by a clinician who is properly trained in the diagnosis of mandibular dysfunction. All therapeutic programs and rehabilitation regimens involving the TheraBite® system should include regular monitoring, review, and evaluation by a clinician.

Cautions

The TheraBite® system is intended for single-patient use only. Do not expose the TheraBite® system to direct sunlight and excessive moisture. Do not expose the TheraBite® system to extreme temperatures. Do not sterilize the TheraBite® system. Sterilization processes may weaken the materials out of which the device is manufactured, as well as the bonding of the mouthpieces, and cause failure under load. Always handle the TheraBite® system with care.

Limited Warranty

Atos Medical makes no warranty, either expressed or implied, as to the lifetime of the product delivered to the purchaser hereunder, which may vary with individual use and biological conditions. Further, Atos Medical makes no warranty of merchantability or fitness of the product for any particular purpose.

Please note:

Information in French is available online at www.atosmedical.com.

Patents and Trademarks

The TheraBite® Jaw Motion Rehabilitation System™ is protected by patents (US 4.909.502, US 5.035.420, US 5.361.506 and JP 3.007.372), as well as by other patents and patents pending worldwide.

TheraBite® is a registered trademark owned by Atos Medical AB, Sweden.



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MEDICAL

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