Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Peter Sundsten - X-PETSUN	2020-04-21 - 08:25
Reviewed:	DD	Jon Berg - JONBER	2020-04-21 - 08:58
Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 16:06
Released:	QA	Peter Sundsten - X-PETSUN	2020-06-23 - 07:52

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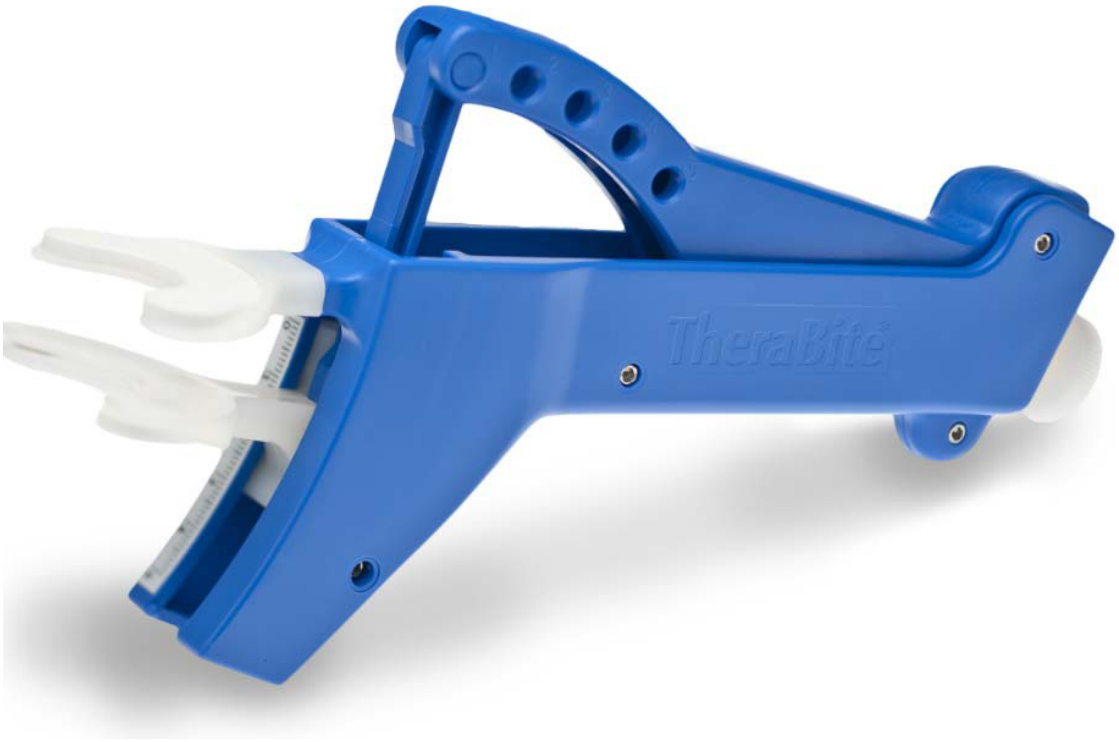
Product Information

TheraBite®



Product description:

The Therabite Jaw Motion Rehabilitation System provides anatomically correct motion of the jaw to patients experiencing mandibular hypomobility. It includes Bite Pads which protects the teeth and Range of Motion Scale which is used to monitor the progress of the rehabilitation program.

Document No: 10000038309 Edition: 10 Release date: 2020-06-23

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Product Information

Document ID:	PF014-01-TechInfo	**Edition:**	07

Manufacturer: Atos Medical AB
Kraftgatan 8, P.O. Box 183,
SE-242 22 Hörby, Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: The TheraBite Jaw Motion Rehabilitation System is indicated for individuals who have, or are at risk of developing trismus (restrictions in their ability to open their jaw), and/or experience pain in the joints and/or muscles of the jaw. The device can also be used as a rehabilitation tool for postoperative physical therapy of the jaw, or to maintain the mouth open in a stable position, for example while performing dysphagia exercises.
The TheraBite system is intended for single-patient use only

CE Mark: Yes, the devices are CE marked.

GMDN code: 17802 (Jaw exerciser)

Sterilization: Non-sterile

Raw material: Device: Polyoxymethylene (POM), Polyamide (PA), Stainless Steel (SS)
Bite Pads: Foam: Polyethylene
Adhesive: Polyester film, Rubber base adhesive
Range of Motion Scale: Coated paper

Latex information: Not manufactured with natural rubber latex

Biological origin: The device is not manufactured with materials derived from human or animal source.

Handling and storage: Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.

Waste handling and disposal: Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

Hazardous components: None

Expiration date: ≤5 years after manufacturing (depending of the expiry date of the included parts).

Packaging: The TheraBite System is separately packed in a plastic bag made of polyethylene and then in a Blue 600, Denier bag , together with two Instructions for use and one exercise log. The bag is packed in a box.

Product Information

Devices under Basic UDI-DI: 7331791-JAW-0-000-0000-98

REF	Name	UDI-DI
TH001	TheraBite Jaw Motion Reh. System Adult	07331791004872
TH002	TheraBite Jaw Motion Reh. System Pediat.	07331791004889

Atos Medical AB compatible products:

Range	BASIC UDI-DI
TheraBite Bite Pad	7331791-JAW-A-000-0001-QT
TheraBite Range of Motion Scale	7331791-JAW-A-000-0002-QW
TheraBite ActiveBand Kit	7331791-JAW-A-000-0000-QQ

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Peter Sundsten - X-PETSUN	2020-04-21 - 08:31
Reviewed:	DD	Jon Berg - JONBER	2020-04-21 - 08:57
Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 14:57
Released:	QA	Peter Sundsten - X-PETSUN	2020-06-23 - 07:52

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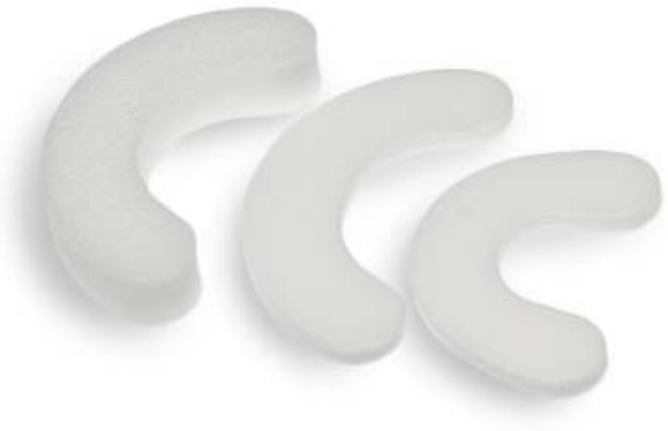
Product Information

TheraBite®



Product description:

The Bite Pads are intended to protect the teeth when used with the TheraBite Jaw Motion Rehabilitation System. The TheraBite provides training of a anatomically correct motion of the jaw to patients experiencing mandibular hypomobility.

Document No: 10000038305 Edition: 08 Release date: 2020-06-23

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Product Information

Document ID:	PF014-02-TechInfo	**Edition:**	08
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	The TheraBite Bite Pads are self-adhesive pads intended to protect the user's teeth.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	17802 (Jaw exerciser)		
Sterilization:	Non-sterile		
Raw material:	Foam: Polyethylene Adhesive: Polyester film, Rubber base adhesive		
Latex information:	Not manufactured with natural rubber latex		
Biological origin:	The device is not manufactured with materials derived from human or animal source.		
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.		
Hazardous components:	None		
Expiration date:	5 years after manufacturing.		
Packaging:	The TheraBite Bite Pads includes 4 pieces of Bite Pads packed in a plastic bag made of polyethylene.		

Product Information

Devices under Basic UDI-DI: 7331791-JAW-A-000-0001-QT

REF	Name	UDI-DI
PA001	TheraBite Bite Pad, Regular (4 pcs)	07331791004834
PA002	TheraBite Bite Pad, Edentulous (4pcs)	07331791004841
PA003	TheraBite Bite Pad, Pediatric (4 pcs)	07331791004858

Atos Medical AB compatible products:

Range	BASIC UDI-DI
TheraBite Range of Motion Scale	7331791-JAW-A-000-0002-QW
TheraBite ActiveBand Kit	7331791-JAW-A-000-0000-QQ
TheraBite Jaw Motion Reh. System	7331791-JAW-0-000-0000-98

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2022-08-19 - 11:26
Reviewed:	QA	Elin Algotson - ELIALG	2022-08-19 - 11:46
Approved:	DD	Diana Tieger - DIATIE	2022-08-19 - 12:03
Released:	QA	Carolina Johansson - SEHRBJNC	2022-08-24 - 09:55

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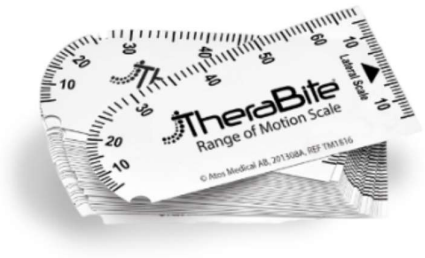
Product Information

TheraBite® Range of Motion Scale



Product description:

The Range of Motion Scale is a part of the TheraBite Jaw Motion Rehabilitation System.
The Range of Motion Scale is used to monitor the progress of the rehabilitation program.
An area to record the progress is printed on the reverse side of the scale and an Exercise Log comes with the device to track the progress.

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Product Information

Document ID: PF014-03-TechInfo **Edition:** 08

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 5

Intended Use: The Range of Motion Scale is used to monitor the progress of the jaw motion rehabilitation program.

The TheraBite Jaw Motion Rehabilitation System is indicated for individuals who have, or are at risk of developing trismus, (restrictions in their ability to open their jaw), and/or experience pain in the joints and/or muscles of the jaw. The device can also be used as a rehabilitation tool for postoperative physical therapy of the jaw, or to maintain the mouth open in a stable position, for example while performing dysphagia exercises.

Use specifications:

Intended medical indication

- trismus, and individuals who are at risk of developing trismus, (restrictions in their ability to open their jaw).
- pain in the joints and/or muscles of the jaw.
- may be used as rehabilitation tool for conditions requiring postoperative physical therapy of the jaw.
- may be used as rehabilitation tool for conditions where therapy benefit maintaining the mouth in open and stable position, for example during dysphagia exercises.

Intended patient population
The TheraBite Jaw Motion Rehabilitation System is intended for both pediatric and adult patients.

Intended usage
The TheraBite Jaw Motion Rehabilitation System is intended for single patient use only.

Intended part of the body/type of tissue applied to or interacted with
Teeth, jaw and joints of the jaw respectively.

Intended user profile
Patients and clinicians

Intended conditions of use
The TheraBite Jaw Motion Rehabilitation System is not a sterile product and shall not be sterilized. The TheraBite Jaw Motion Rehabilitation System shall be cleaned using soap/detergent with exception of REF SC001 (Range of Motion Scale) which is a disposable product. The TheraBite Jaw Motion Rehabilitation System shall be used according to a training program determined by a physician.
Primarily home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Secondarily outpatient clinic use.
The TheraBite Jaw Motion Rehabilitation System is designed and packed with respect to high mobility.

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Product Information

Contraindications: The TheraBite is not intended to 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.
• Individuals with infections of the jaw, osteomyelitis (inflammation of bone and bone marrow), or osteoradionecrosis (necrosis of bone due to radiation) of the jaw.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 17802 (Mastication muscle exerciser)

Sterilization: Non-sterile

Raw material: Coated paper

Latex information: Not manufactured with natural rubber latex

Biological origin: The device is not manufactured with materials derived from human or animal source.

Handling and storage: Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.

Waste handling and disposal: Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

Hazardous components: None

Expiration date: 5 years after manufacturing.

Packaging: 150pcs Range of Motion Scales (30pcs/bag) are packed in a re-sealable plastic bag made of polyethylene. The products and instructions for use are packed in a cardboard box.

Devices under Basic UDI-DI: 7331791-JAW-A-000-0002-QW

REF	Name	UDI-DI
SC001	TheraBite Range of Motion Scale (150pcs)	07331791004865

Atos Medical AB compatible products:

Range	BASIC UDI-DI
TheraBite Bite Pad	7331791-JAW-A-000-0001-QT
TheraBite ActiveBand Kit	7331791-JAW-A-000-0000-QQ
TheraBite Jaw Motion Reh. System	7331791-JAW-0-000-0000-98

Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Niki Svensson - NIKSVE	2023-01-26 - 07:54
Reviewed:	QA	Abdallah Almashharawi - ABDALM	2023-01-26 - 08:28
Approved:	QA	Elin Andersson - ELIAND	2023-01-27 - 09:00
Released:	QA	Niki Svensson - NIKSVE	2023-03-16 - 13:23

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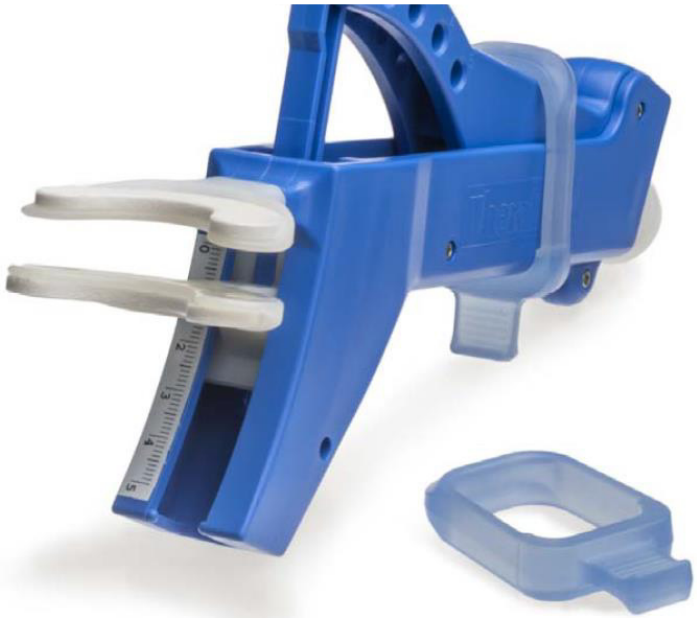

Product description:

TheraBite ActiveBand is an unsterile elastic silicone band for single patient use. It is looped around the Lever of the TheraBite Jaw Mobilizer (included in the product TheraBite Jaw Motion Rehabilitation System). The ActiveBand's position on the Load Scale determines the level of resistance

Document No: 10000038304 Edition: 07 Release date: 2023-03-16

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Product Information

Document ID: PF014-04-TechInfo **Edition:** 07

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: The TheraBite ActiveBand™ is an elastic silicone band used together with the TheraBite Jaw Mobilizer to increase and/ or maintain muscle strength and endurance of the muscles of mastication (chewing muscles). The TheraBite ActiveBand is intended for single-patient use only.

Use specifications:

Intended medical condition
For use with the Therabite, in individuals who have or are at risk of developing weak jaw musculature. Examples of patients are:
- Patients that need to strengthen their jaw musculature.
- Patients that need to maintain the strength of their jaw musculature during radiation or chemoradiation.
- Patients that need to use a jaw strengthening regimen in addition to using the TheraBite

Intended patient population
Patients of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.

Intended usage
Single patient multiple use, Over-the-counter

Intended part of the body/type of tissue applied to or interacted with
The device will have contact with intact skin.

Intended user profile
The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use
Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max usage for 6 months. Replacement is performed by the patient, clinician or caregiver.

Contraindications: Contraindications as described in the instructions for use for TheraBite Jaw Motion Rehabilitation System apply, which are;
The TheraBite is not intended to 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.
- Individuals with infections of the jaw, osteomyelitis (inflammation of bone and bone marrow), or osteoradionecrosis (necrosis of bone due to radiation) of the jaw.

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Product Information

CE Mark:	Yes. Devices are CE-marked.
GMDN code:	17802 (Jaw exerciser)
Sterilization:	Non-sterile
Raw material:	ActiveBand: Silicone Scale: Polypropylene (PP)
Latex information:	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None
Expiration date:	5 years after manufacturing.
Packaging:	TheraBite ActiveBand Kit is packed separately in a plastic bag made of polyethylene. The bag is then packed together with one instructions for use and one exercise log in a box.

Product Information

Devices under Basic UDI-DI: 7331791-JAW-A-000-0000-QQ

REF	Name	UDI-DI
8260	TheraBite ActiveBand Kit	07331791004827

Atos Medical AB compatible products:

Range	BASIC UDI-DI
TheraBite Range of Motion Scale	7331791-JAW-A-000-0002-QW
TheraBite Jaw Motion Reh. System	7331791-JAW-0-000-0000-98
TheraBite Bite Pad	7331791-JAW-A-000-0001-QT

Document No: 10000038304 Edition: 07 Release date: 2023-03-16