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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.

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

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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 an anatomically correct motion of the jaw to patients experiencing mandibular hypomobility.

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

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Product Information

TheraBite®



Product description:

An area to record your progress is printed on the reverse side of the scale and an Exercise Log comes with your device to track your progress.

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Product Information

Document ID:	PF014-03-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 Range of Motion Scale is used to monitor the progress of the rehabilitation program.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	17802 (Jaw 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:	The Range of Motion Scales includes 150 pcs of Scales and instructions for use packed in a re-sealable plastic bag made of polyethylene.		

Product Information

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

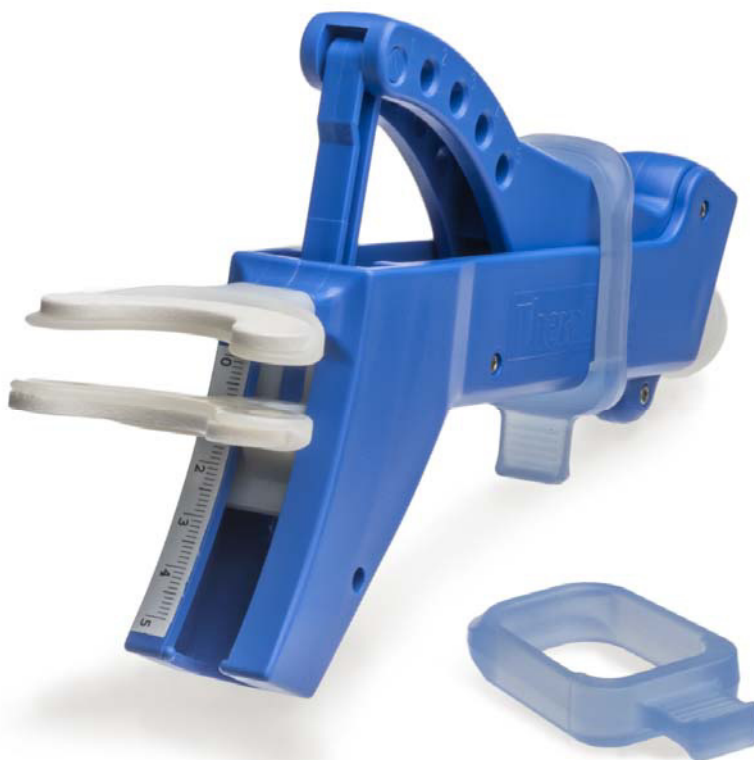
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Product Information

TheraBite®



Product description:

The TheraBite ActiveBand is an unsterile elastic silicone band for single patient use. It is looped around the Lever of the TheraBite Jaw Mobilizer. The ActiveBand's position on the Load Scale determines the level of resistance.]

Product Information

Document ID:	PF014-04-TechInfo	Edition:	06
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Classs 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.		
CE Mark:	Yes, the 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