

# Product Information

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This document has been electronically signed by the persons above.



### 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

# Product Information

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

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

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

**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.

## Product Information

<b>CE Mark:</b>	Yes. Devices are CE-marked.
<b>GMDN code:</b>	17802 (Jaw exerciser)
<b>Sterilization:</b>	Non-sterile
<b>Raw material:</b>	ActiveBand: Silicone Scale: Polypropylene (PP)
<b>Latex information:</b>	Not manufactured with natural rubber latex
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
<b>Waste handling and disposal:</b>	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.
<b>Hazardous components:</b>	None
<b>Expiration date:</b>	5 years after manufacturing.
<b>Packaging:</b>	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

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