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This document has been electronically signed by the persons above.

## 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.

# Product Information

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

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

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

**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.

## Product Information

<b>Contraindications:</b>	The TheraBite is not intended to be used by: <ul style="list-style-type: none"> <li>• 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.</li> <li>• Individuals with infections of the jaw, osteomyelitis (inflammation of bone and bone marrow), or osteoradionecrosis (necrosis of bone due to radiation) of the jaw.</li> </ul>
<b>CE Mark:</b>	Yes. Devices are CE-marked.
<b>GMDN code:</b>	17802 (Mastication muscle exerciser)
<b>Sterilization:</b>	Non-sterile
<b>Raw material:</b>	Coated paper
<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>	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