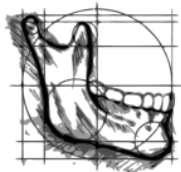


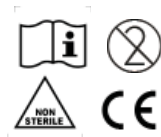
# INSTRUCTION MANUAL AND TRACKING LOG

## ORASTRETCH<sup>®</sup> PRESS JAW MOTION REHAB SYSTEM



CranioRehab.com

**READ INSTRUCTIONS BEFORE USE FOR  
SAFETY, USAGE, AND TO AVOID INJURY.**



# GENERAL INFORMATION

## Overview

The ORASTRETCH® Press Jaw Rehab System is a medical device to prevent and treat a restricted mouth and for therapy of jaw and mouth dysfunction. Users and healthcare providers should read this instruction manual for information on safety, usage, maintenance, and care of the ORASTRETCH® Press device. Users with further questions should contact their doctor.

## Function

The ORASTRETCH® Press Jaw Rehab System works by squeezing the handles to move the mouthpieces apart along the anatomical curved motion of the jaw up to 50mm wide. A user's hand provides the force to push apart the jaw for stretching of tissues and mobilizing the joint. The unit can also offer resistance for muscle strengthening. The ORASTRETCH® Press device can be used to treat the jaw joints, muscles and hypomobility (trismus), for post-operative rehabilitation, and prophylactically to prevent trismus.

**DISCLAIMER:** No promise or guarantee of results is being made or implied. Patient outcomes will vary. The device scale is approximate and should be used to track progress only.

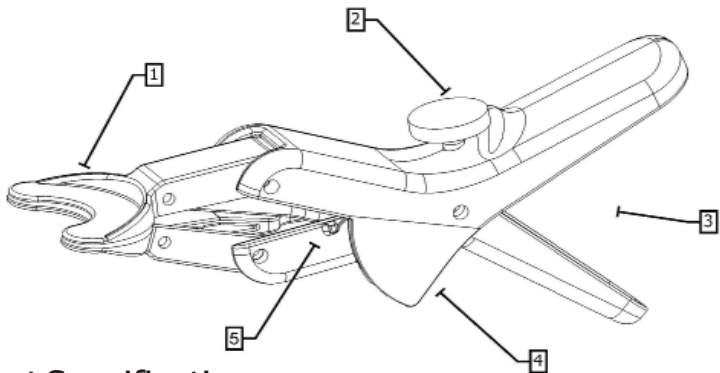
## Safety

The ORASTRETCH® Press Jaw Rehab System is user controlled allowing users to avoid hyper-extension and excessive force over the small distance of jaw motion. A limit screw is included for the provider or user to set a maximum opening and prevent over-stretching.

As a medical device, the ORASTRETCH® Press device is available by recommendation of a licensed health care professional who understands the usage and purpose of the ORASTRETCH® Press device. A prescription may be required for this device, and varies by country. This instruction manual is subject to review and periodic updates. Please review this manual carefully before prescribing and/or use of the ORASTRETCH® Press device.

**DISCLAIMER:** The ORASTRETCH® Press device is a manually controlled medical device, and should not be used without the consultation and direction of a health care professional. As a manually controlled device, the user must take care to proceed slowly with therapy and to avoid any sharp or prolonged pain.

# FEATURES



## Product Specifications

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- |                   |                    |
|-------------------|--------------------|
| 1.....Mouthpieces | 4.....Scale        |
| 2.....Limit Screw | 5.....Scale Marker |
| 3.....Handles     |                    |

## Accessories

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### Mouthpiece Bitepads



### Carrying Bag



### MIO Patient Scale



### Manual and Tracking Log



## Contents

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| 2.....General Information | 7.....Warning and Cautions |
| 3.....Features            | 8-9.....Tracking Logs      |
| 4.....Indication & Usage  | 10.....Notes               |
| 5.....Rehabilitation      | 11.....Warranty            |
| 6.....Maintenance         | 12.....Order Form          |

# INDICATIONS

## Indications

The ORASTRETCH® Press device is indicated for orofacial post-surgical rehab; limited range-of-motion of the jaw and mouth, trismus or jaw hypomobility; for facial or muscle pain; and for temporomandibular joint dysfunction. Patients should consult with a health care professional to determine if the ORASTRETCH® Press device is an appropriate treatment for their medical conditions.

## Contraindications

The ORASTRETCH® Press device is contraindicated for patients with weak, weakened, fractured, or infected bones of the upper and lower jaw (maxilla and mandible); or patients suffering from ankylosis, osteomyelitis, or osteoradionecrosis of the jaw.

# USAGE INSTRUCTIONS

The ORASTRETCH® Press device was designed to assist patients to stretch, mobilize and train their jaw and mouth:

Bitepad Application	<ul style="list-style-type: none"><li>• Peel off the backing from the foam pads.</li><li>• Apply a pad to the upper and lower biteplate.</li><li>• Raise the ORASTRETCH® Press device and insert the biteplates into the mouth. Align teeth and bite down on the pads to strengthen bitepads' adhesion.</li></ul>
Adjustable Safety Screw	<ul style="list-style-type: none"><li>• Thread limit screw into hole on upper handle.</li><li>• Squeeze the handles to move the biteplates apart.</li><li>• Rotate the limit screw to force the device closed to maximum opening desired. Use the scale as an approximate guide.</li></ul>
Basic Use	<ul style="list-style-type: none"><li>• Raise the ORASTRETCH® Press device and insert the biteplates between the upper and lower teeth.</li><li>• Squeeze the handles to move the biteplates apart.</li></ul>
Measuring	<ul style="list-style-type: none"><li>• Squeeze device open to a light stretch and note scale marker's position in relation to the scale.</li><li>• Record opening at start and end of each session.</li></ul>

The ORASTRETCH® Press device was designed to be small and light for portability. Use it at home, at work, or on vacation, and do not skip or discontinue usage without instructions from your health care provider. If you are experiencing sharp or prolonged pain, contact your doctor.

# REHABILITATION

## Suggested Treatments\*

<b>7-7-7 Stretch</b>	<ul style="list-style-type: none"><li>• Insert the device, and squeeze the biteplates apart.</li><li>• Hold the device open for 7 seconds. Release.</li><li>• Repeat 7-second hold for 7 repetitions.</li><li>• Perform 7 times a day.</li></ul>
<b>5-5-30 Stretch</b>	<ul style="list-style-type: none"><li>• Insert the device, and squeeze the biteplates apart.</li><li>• Hold open for 30 seconds. Release.</li><li>• Repeat 30-second hold for 5 repetitions.</li><li>• Perform 5 times a day.</li></ul>
<b>Passive Motion</b>	<ul style="list-style-type: none"><li>• Insert the device. Slowly squeeze the device open.</li><li>• Slowly release the squeeze to close the device.</li><li>• Repeat opening and closing for 5 minutes.</li><li>• Perform 3 times a day.</li></ul>
<b>Strength Training</b>	<ul style="list-style-type: none"><li>• Insert the device. Slowly squeeze the device open.</li><li>• Bite down against the open device and hold for 5 seconds. Release. Repeat 10 times.</li><li>• Perform 3 times a day.</li></ul>
<b>Muscle Training</b>	<ul style="list-style-type: none"><li>• Insert the device. Slowly open and close the device.</li><li>• Try to keep your teeth lightly in contact with the pads as they move.</li><li>• Repeat opening and closing for 5 minutes. Perform 3 times a day.</li></ul>

\*These are suggested protocols and should only be followed as specified by a health care provider. Only use the device as instructed by provider.

## Tracking

Measure your opening at the beginning and end of each therapy session. This manual contains a log for the user to record their opening. Keep track of the user's opening and changes over time. Share this information with the healthcare provider, so they may evaluate your progress and make therapy changes as needed. Measurements by the device or paper scale are approximations for use with progress tracking.

## Therapy Compliance

Stretching, passive motion and muscle training therapies only work with repeated daily therapy. Success in recovering and increasing range-of-motion requires commitment and dedication to your rehabilitation. Progress is often slow with improvements noticeable after weeks of rehab.

# MAINTENANCE

## Care

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Replace or cover the bite pads with a new pad as desired. Apply bite pads only when the device is dry. If bitepads do not stick adequately, lightly rough the mouthpiece with nail file or heat with a hair dryer to improve adhesion.

Store the ORASTRETCH® Press device in its convenient carrying bag when not in use to help keep it clean. Discoloration of the device may occur. It may be caused by direct sunlight, minerals in the water, extreme temperatures, and prolonged moisture exposure. Keep dry and out of direct sunlight.

## Cleaning

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Clean only the mouthpieces of the device. For basic cleaning rinse the mouthpieces and pads with water or antiseptic mouthwash. For more extensive cleaning, use a toothbrush and toothpaste to brush the mouthpieces and pads clean. Wipe and allow to fully dry.

Do NOT fully submerge or allow the device to get completely wet. Do NOT put the OraStretch press in the dishwasher. If the device is wet, wipe, shake dry, and allow to fully dry out.

You may also use soap and warm water to clean the ORASTRETCH® Press device. Thoroughly rinse the mouthpieces, shake out any remaining liquid and allow to completely dry on clean paper or cloth towel. If the device needs to be cleaned beyond the mouthpieces, spot clean that area only and make sure to fully dry the unit.

Do not use alcohol to clean the mouthpieces, as it may interfere with the adhesion of the pads. Do not use chemical agents or autoclave systems to clean or sterilize the ORASTRETCH® Press device, as they may weaken the device.

## Additional Information

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CranioMandibular Rehab, Inc. focuses on the therapeutic needs of head, neck, face, and jaw patients.

For customer service, more information or to order additional ORASTRETCH® Press devices, accessories, or other products, please contact CranioMandibular Rehab, Inc at 1-800-206-8381 or visit us on our web site at [www.cranio rehab.com](http://www.cranio rehab.com).

# WARNINGS AND CAUTIONS

**⚠️ WARNING:** The ORASTRETCH® Press device is capable of significant force on the user's jaw, mouth and teeth, which may cause injury or damage to tissues, dentition, and/or dental/orthodontic appliances. Patients with weak or damaged dentition, bones, joints obturators, and gap-bridging spans should inform their doctor of such conditions and use extra caution with the ORASTRETCH® Press device. Stop use of the ORASTRETCH® Press device if the user feels sharp, extended, or unexpected pain, and contact the prescribing health care provider. Continued use with pain may cause injury.

**⚠️ WARNING:** Do not use the ORASTRETCH® Press device for excessive periods of time, with excessive force, or in a manner that does not follow your health care provider's instructions. Before using the ORASTRETCH® Press device, all users should be evaluated, diagnosed, and instructed by a health care professional on the need for and use of the device. All treatment programs and protocols should be regularly monitored and reviewed by the health care provider. Deviating from protocols and health care provider instructions may cause short- or long-term damage.

**⚠️ WARNING:** Do not sterilize the ORASTRETCH® Press device. The ORASTRETCH® Press device is intended for single-patient use and is non-sterile. Care should be taken with patients susceptible to infection in applicable areas. Sterilization may weaken the device to cause injury, and sharing devices could spread infection.

**⚠️ WARNING:** Users should inspect the device carefully before each use. The device and its accessories should be free from damage and cracking. Use of a damaged or cracked device may cause failure of the device or injury.

## **⚠️ CAUTIONS:**

- Only use the ORASTRETCH® Press Jaw Rehab System under the guidance and instruction from your doctor or therapist.
- Do not expose the ORASTRETCH® Press device to excessive heat, cold, sunlight, or moisture, as it may weaken or discolor the device.
- Do not wash the ORASTRETCH® Press device in the dishwasher as it may weaken or discolor the device.
- Do not disassemble or modify the device, except as instructed by a healthcare professional as it may weaken the device.
- All scales, paper or on the device, use an approximate gradient for individual progress tracking. Scales are not intended as a measuring function for prognosis or specific treatment.

# TRACKING LOG

Maximum Interincisal Opening (MIO)  
mm)

60	
55	
50	
45	
40	
<b>35mm</b>	
30	
25	
20	
15	
10	
5	

**Functional Range**

**Average MIOs**  
Men: 50-60mm  
Women: 45-55mm

Prevent trismus with an OrasStretch press jaw motion rehab system.

**Mild:** 25-35mm  
Functional Loss.  
**Rehab:** Use with Pads.

**Mod:** 15-25mm  
Major Functional Loss.  
**Rehab:** Use with Pads.

**Severe:** 0-15mm  
Extreme Functional Loss  
**Rehab:** No Pads.  
<9mm: Use mouthpiece side.  
<6mm: No system fit.

**Trismus**

Start: \_\_\_\_\_  
Date: \_\_\_\_\_

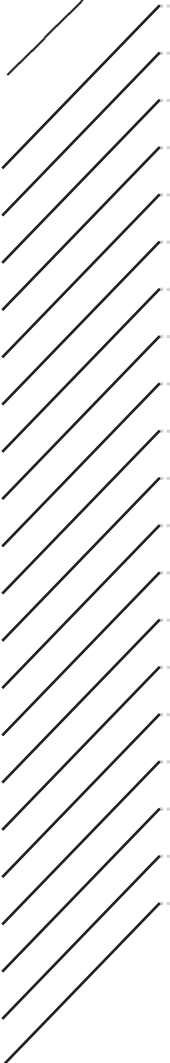


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Extreme Functional Loss  
Rehab: No Pads.  
<9mm: Use mouthpiece side.  
<6mm: No system fit.



# LIMITED WARRANTY:

The manufacturer warrants to the initial domestic consumer user that the ORASTRETCH® Press device meets the Manufacturer's specifications and is free from defects for one-year from purchase of the product by the original registered user.

This warranty is contingent upon proper usage of the ORASTRETCH® Press device in the application for which it was intended and shall not extend or apply to any damage or defect resulting from product misuse, abuse, neglect, modification, alteration, unusual stress, improper storage or handling, or disregard for product warnings and cautions.

Except for the express limited warranty set forth above, the manufacturer grants no warranties with respect to the ORASTRETCH® Press device, expressed or implied, either in fact or by operation of law, by statute or otherwise, and the manufacturer specifically and expressly disclaims any implied warranty of quality, warrant of merchantability, warranty of non-infringement of third-party rights.

The manufacturer's liability under the above warranty shall be limited to a replacement with a comparable product when the device is returned to the manufacturer's address. In no event shall the manufacturer be liable for any special consequential, or incidental damage for breach of warranty.

State limitations may preempt above provisions. This warranty gives you specific legal rights and you may have others granted by your state.

The ORASTRETCH® Press device has been manufactured for:



**CranioMandibular Rehab, Inc.**

2600 W 29th Ave, #102G, Denver, CO 80211

Tel: 303-433-8770 Fax: 303-480-9115 [www.CranioRehab.com](http://www.CranioRehab.com)



**Medical Technology Promedt Consulting GmbH**



Altenhofstrasse 80, 66386 St. Ingbert Germany

+49 6894 581020 [www.mt-procons.com](http://www.mt-procons.com)





## Patents and Trademarks

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ORASTRETCH® is a trademark of CranioMandibular Rehab, Inc. The ORASTRETCH® Press Jaw Rehab System is covered by patent US8307745 and protected by United States and international law.

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# ACCESSORIES

	Item Description
<b>JAW REHAB SYSTEM MOUTHPIECE BITEPADS</b>	
	Bitepad Pack - 1/8" (3mm) thick 4 pads, 2 sets.
	Edentulous Bitepad Pack - 3/8" (9.5mm) thick 4 pads, 2 sets.
<b>ORASTRETCH DYNAMIC BANDS</b> - For Dynamic Stretching.	
	OraStretch Dynamic Bands Pack of 4 - Alternative for progressive stretching.
<b>RANGE-OF-MOTION SCALES</b> - Improved for small ROMs and simple usage.	
	OraStretch ROM or MIO Scales Packs of 50.
<b>THERMAL THERAPY KIT</b>	
	JawBra and Gel Packs (4) - Soft compressive head wrap and hot-cold gel packs to reduce swelling and pain of the face and joint.

**TO ORDER:** Visit [www.cranio rehab.com](http://www.cranio rehab.com) or call us at 1-800-206-8381.  
\*Prices subject to change, S/H, and other charges.

## ORASTRETCH® MIO Scale Usage

Vertical Range



**Severe:** 3-12mm



**Rotational:** 6-35mm



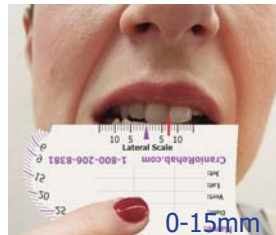
**Alt Scale:** 35-50mm

Protrusion Scale




0-15mm

Lateral Scale



0-15mm

 See scale instructions for complete information.