Chris O'Brien Lifehouse

# Restorabite™

ARTG ID: 407358

Integrated Prosthetics & Reconstruction

IPR-003_A

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# CAUTION

The RestorabiteTM is to be used according to the recommendations and instructions for use. Please read all information in this Product Brochure carefully and use the contact details below if you require further information.

This Product Brochure contains general safety, operating, maintenance and care instructions for RestorabiteTM. This information should be reviewed by both prescribers and patients using this device. This Product Brochure does not replace the personalised guidance from a treating clinician.

# INFORMATION

## Purpose of the device

RestorabiteTM is a device intended to improve mouth opening in patients with trismus (restricted mouth opening defined by an interincisal distance less than 35mm) (Dijkstra et al 2006), or to prevent trismus in patients who are at risk of developing trismus.

## Intended Use

RestorabiteTM is intended to assist with jaw stretching and strengthening for treatment of trismus (restriction of jaw opening)

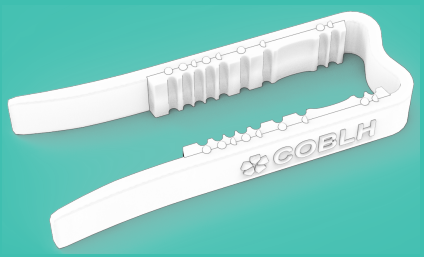


Figure 1

Figure 2

## Device Features

Its' unique multiple exercise level design allows for a varied force to be selected based on a patient's specific needs, to ensure that:

- Adequate force and effort are being used for maximal therapeutic gains.
- Excessive force is not applied to the teeth and jaw, to reduce or prevent the risk of complications and injuries relating to jaw stretching and strengthening exercises.
- The force applied to the jaw can be modified by user needs.

## Device Description

The RestorabiteTM consists of:

- Frame (Figures 1)
- Insert (Figure 2)
- Instruction For Use

The RestorabiteTM outer frame can house an insert at different locations providing varying resistance.

The RestorabiteTM is portable and hand-held device. The outer wings of the frame are squeezed together by the user and placed between the upper and lower teeth or gums. The user then gradually releases the pressure applied by their fingers to allow the wings of the frame to deploy force to the jaw, stretching it open (passive range of motion exercise). The user can then bite down to activate the jaw muscles for a strengthening exercise (active range of motion exercise).

# INDICATIONS

The RestorabiteTM is indicated for use in individuals whose mouth opening is limited. Restricted mouth opening is known as 'trismus'. Trismus can arise because of many medical conditions. Commencing rehabilitation for trismus should always be undertaken under the guidance of the user's physician and experienced clinician.

The RestorabiteTM can be used for both rehabilitation and prevention of trismus. Rehabilitation exercises are undertaken when a user has trismus to improve their condition. Prevention or prophylactic use is for those who are at risk of developing trismus.

The minimum mouth opening distance RestorabiteTM is able to accommodate for is 8.0 mm.

# POTENTIAL BENEFIT and RISK

## Potential Benefits

The purpose of the RestorabiteTM is to increase mouth opening. Reduced ability to open the mouth can lead to several health-related problems such as pain, difficulty swallowing, speaking, conducting oral/dental care and accessing the airway.

Addressing trismus using RestorabiteTM has led to improvements in mouth opening, speech and swallowing related quality of life and improved pain scores. The amount of improvement depends on the individual and their personal circumstances.

The use of RestorabiteTM for trismus therapy provides a personalised exercise program for patients. Patients who used RestorabiteTM report increased adherence to exercise program and motivation for exercise program, improved quality of life, and a decreased pain (Charters et al 2022)

The report has shown the following benefits:

- Improved mouth opening
- Increased adherence to exercise program and motivation for exercise program
- Improved quality of life

## Risks

Failure to follow the instructions for use may result in complications. Incorrect device handling (such as overstretching of the device), and device cleaning (such as using the wrong cleaning agent) will increase the risks.

The RestorabiteTM should not be used without an individualised exercise program provided by your physician and/or trained clinician. Application of excessive force to the teeth or jaw can cause complications such as fractures. A patient's physician can select the maximum force suitable for a patient based on their individual circumstances to mitigate this risk.

The following risks were associated with the RestorabiteTM:

- Tension headache
- Neck pain
- Temporomandibular joint (TMJ) pain
- Tooth loss

**If any of these complications occur, the user should contact their prescribing clinician.**

# CONTRAINDICATIONS

RestorabiteTM is not recommended for patients with any of the following conditions:

- Osteomyelitis or osteoradionecrosis of their jaw (maxilla or mandible)
- Fracture of their jaw (maxilla or mandible)
- Unstable dentition
- Have active disease (e.g. untreated cancer of the jaw)
- The Restorabite has not been trialled in patients under the age of 18 years.


# WARNINGS AND PRECAUTIONS

## Warnings

- If you feel unexpected pain at any time while exercising, DO NOT continue to exercise. You should immediately stop using the device and contact your clinician.
- If you have weakened teeth, gum disease, weakened bones or joints in jaw, dental implants or dentures, DO exercise with great caution. Injury may occur if excessive force/inappropriate force selection is used.
- DO use appropriate force level to avoid injury.
- DO NOT share the RestorabiteTM. It is intended for single patient use only.
- DO NOT use the RestorabiteTM if the package seal is broken before use. Contact your supplier.

## Precautions

- Use of RestorabiteTM must be done according to clinician led individualized exercise program to avoid injury.
- Do not sterilise the RestorabiteTM or put the RestorabiteTM in dishwasher. The sterilisation and dishwashing process may weaken the RestorabiteTM and it may break during use.
- Store the RestorabiteTM according to the Instruction for Use.

## Care regimen

For the RestorabiteTM to perform as intended, it is critical that you understand the warnings and precautions (as outlined in the section above) and follow the directions given by your prescribing clinician. It is important that you have regular follow-up appointments with your treating clinician. When using the RestorabiteTM it is important to observe good hygiene (cleanliness) to minimise the risk of infection. For additional information, please see Hygiene Recommendations on page 9 of this manual.

# OPERATING INFORMATION

## Pre-exercise

The RestorabiteTM allows a specified force to be exerted on the jaw to facilitate stretching (passive) and strengthening (active) exercises.

Your clinical team will conduct a thorough assessment to determine what level of force is best suited to your needs. This will involve selection of a frame location for the insert to commence your program and ensuring the correct position for the RestorabiteTM within your mouth.

## Exercise Program

### Prepare

- Measure the distance between your top and bottom teeth or gums before and after an exercise set.
- Warm-up by placing heat packs on the jaws and/or manual jaw stretches.
- Set up the RestorabiteTM with the insert in the position as per Figure 3.

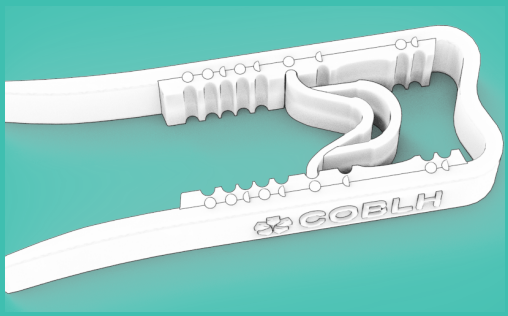


Figure 3

### Exercise

- Exercises should be incorporated into a daily routine.
- Stretch duration, number of repetitions and frequency should be tailored to the individual user.
- General exercise programs are outlined below:
  - 5-10 minutes of warm up, passive and active stretching, 5 times a day.
  - 30 minutes of stretching at a lower intensity comprised of warm up, passive and active stretching.
  - A combination of the two
- **Passive** range of motion exercises
  - Squeeze the wings of the RestorabiteTM together.
  - Insert the RestorabiteTM between upper and lower teeth or gums, keep your fingers in position as per Figure 4 .

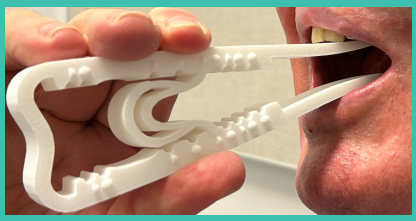

Figure 4

  - Gradually release the pressure from your fingers, allowing the RestorabiteTM to open and press against your upper and lower teeth or gums.
  - Relax and let the RestorabiteTM stretch open your mouth.
  - Hold the stretch for up to 30 seconds. Do not hold the stretch over 30 seconds.
  - Release the RestorabiteTM.
  - Rest briefly before the next repetition.
  - It is normal for the stretch to be somewhat uncomfortable, however it should not be painful. Cease the stretch if you experience pain.

- **Active** range of motion exercises
  - Squeeze the wings of the RestorabiteTM together.
  - Insert the RestorabiteTM between upper and lower teeth or gum, keeping your fingers in position.
  - Gradually release the pressure from your fingers, allowing the RestorabiteTM to open and press against your upper and lower teeth or gums.
  - Bite down on the RestorabiteTM for up to 30 seconds. Do not hold the exercise over 30 seconds.
  - Release the RestorabiteTM.
  - Rest briefly before the next repetition.
  - It is normal for the stretch to be somewhat uncomfortable, however it should not be painful. Cease the stretch if you experience pain.

# CLEANING

It is important to inspect and clean the RestorabiteTM after each use.

- The RestorabiteTM should be cleaned thoroughly following each use by rinsing in warm water, wash with a PH neutral detergent removing any soiling or debris with a soft toothbrush.
- Alternatively, the RestorabiteTM should be wiped with a clean wet cloth and PH neutral detergent.
- Let all the components of RestorabiteTM air-dry completely after each clean.

**DO NOT sterilise or use a dishwasher to clean the RestorabiteTM, this can damage the device.**

# WHEN TO CONTACT YOUR DOCTOR

For your safety, comfort and best therapeutic gain, it is important to follow these recommendations:

**YOU MUST IMMEDIATELY CONTACT YOUR TREATING DOCTOR IF:**

- You experience sudden pain.
- There is a swelling in your jaw.
- The location where your RestorabiteTM contacts your teeth or gum becomes inflamed, swollen or painful.
- There is a break in the tooth, or loss of tooth.

Contact your physician or clinician if you have any questions about your exercise program.

# HYGEINE

It is important to inspect the area where the RestorabiteTM contacts your dentition or gums prior to commencing your exercises. Good oral care involving twice daily cleaning (or as guided by your dentist) is recommended.

You should not use the RestorabiteTM on any areas of broken gum or exposed bone.

**IN CASE OF IRRITATION OR INFECTION**

- If you have sings of infection stop using the device and notify your clinician.
- If you have any signs of irritation or infection such as redness, or mild pain stop using the device and notify your clinician
- **IN CASE OF ANAPHYLAXIS, HIGH FEVER AND/OR SEVERE PAIN, YOU SHOULD IMMEDIATELY GO TO THE HOSPITAL EMERGENCY ROOM.**

# EXPECTED DEVICE LIFE SPAN

When used every day as part of a patient specific program, the RestorabiteTM is tested for life-expectancy of 10 weeks. This duration may be extended with less frequent or less intensive use. Should the user fail to comply with the recommended use, care or cleaning guidelines, or if the device withstands trauma such as a fall or compression, the RestorabiteTM may require replacement at an earlier date.

It is the responsibility of the user to ensure familiarity and compliance with the recommendations outlined in this document. It is the responsibility of the prescribing health care professional to select the appropriate insert and treatment regimen.

The Integrated Prosthetics & Reconstruction at Chris O'Brien Lifehouse is only responsible for the RestorabiteTM performance when it is used in accordance with the Product Brochure and Instructions for Use.

It is important that you understand the recommendations, warnings and precautions outlined in this document and follow the directions of your doctor and/or health care professional.

# REFERENCES

Dijkstra, P. U., Huisman, P. M., & Roodenburg, J. L. (2006). Criteria for trismus in head and neck oncology. International journal of oral and maxillofacial surgery, 35(4), 337–342. https://doi.org/10.1016/j.ijom.2005.08.001

Charters, E., Cheng, K., Dunn, M., Wu, R., Palme, C., Howes, D., Low, T. H., Heng, C., Ricketts, V., Kneebone, K., Loy, J., & Clark, J. R. (2022). A pilot study of intensive intervention using a novel trismus device. International journal of speech-language pathology, 1–8. Advance online publication. https://doi.org/10.1080/17549507.2022.2130429

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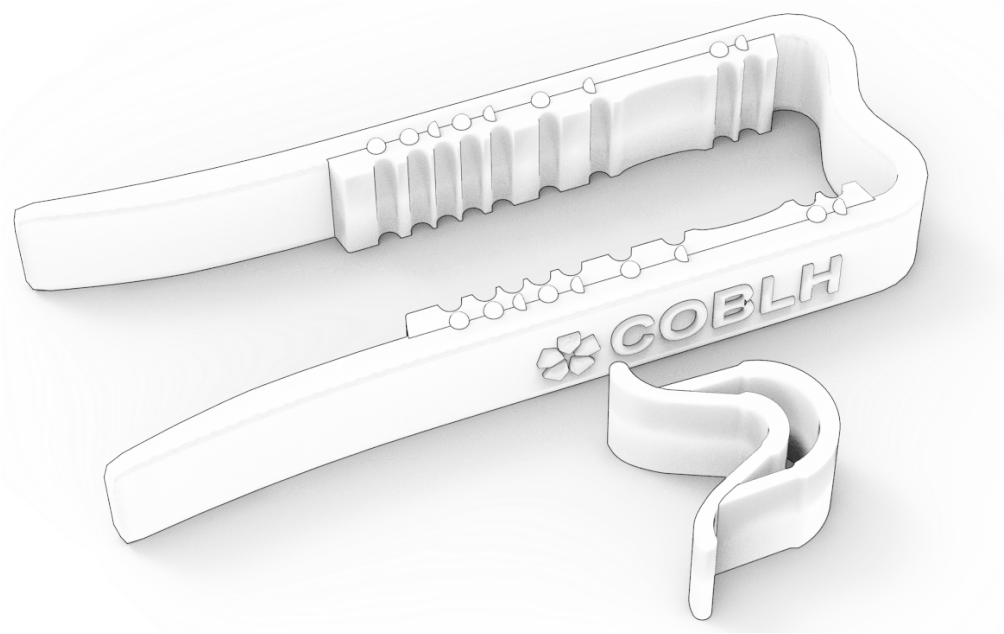


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