

Description

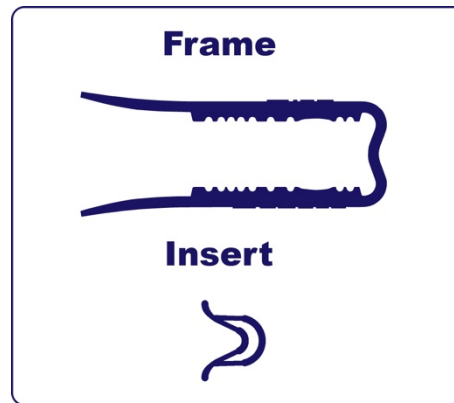
Restorabite™ is a device intended to improve mouth opening in patients with trismus (restricted mouth opening), or to prevent trismus in patients who are at risk of developing trismus.

Operation Instruction

1. Place the insert in the position recommended by your treating clinician inside the frame.
2. Press tips/ends of the frame together with your finger while supporting the body of the frame with your other hand.
3. With the frame pressed together, insert the tip of the frame between your teeth/gum or the location recommended by your treating clinician. Continue to hold the frame with your hand. Let the frame open gradually inside of your mouth. You should feel a stretch, but not pain. If it is painful, you can lower the force by moving or removing the insert. If pain continues, stop the exercise and consult your clinician for advice.
4. (Optional) Bite down on the tip of frame, aiming to press wings of the frame together. This should feel challenging, but not painful.

Content

1 Frame and 1 Insert



Consult Instruction For Use

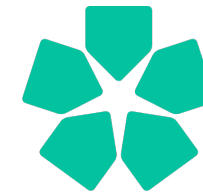


Contact Information

For any questions or concerns, please contact the Integrated Prosthetics & Reconstruction representative at:

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Chris O'Brien Lifehouse

Restorabite™

ARTG ID 407358

Instruction For Use

This document contains general instructions for use for the Integrated Prosthetics & Reconstruction, Chris O'Brien Lifehouse Restorabite™

For instructional video, please scan the QR code below.



Integrated Prosthetics & Reconstruction

Intended Use

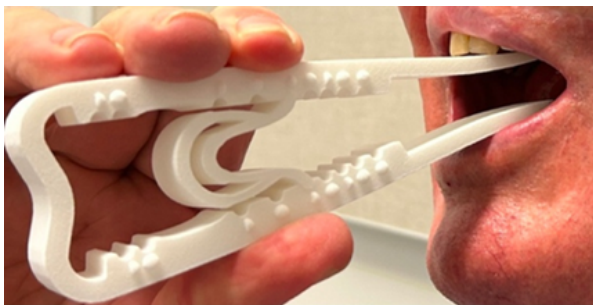
Restorabite™ is intended to assist with jaw stretching and strengthening.

It is advisable to consult a treating clinician prior to use.

Contraindications

Restorabite™ is not recommended for patients with/suspected of any of the following conditions:

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



Warning

- ◆ If you feel unexpected pain at any time while exercising, **STOP** the exercise. You should immediately stop using the device and contact your treating clinician.
- ◆ If you have weakened teeth, gum disease, weakened bones or joints in jaw, dental implants, dental plates, crown, bridge or dentures, you **MUST** consult clinicians before use. Injury may occur if excessive force/inappropriate force selection is used.
- ◆ **DO NOT** share the Restorabite. It is intended for single patient use only.
- ◆ **DO NOT** use the Restorabite if the package seal is broken before use. Contact your supplier.

When to contact your treating clinician

For your safety, it is important to follow these recommendations:

YOU MUST IMMEDIATELY CONTACT YOUR TREATING CLINICIAN IF:

- ◆ You hear a crack or experience sudden pain or swelling in your mouth or jaw.
- ◆ The location where your Restorabite™ contacts your teeth or gum becomes inflamed, swollen or painful.
- ◆ There is a break in the tooth, loss of a tooth, or the teeth feel out of alignment.

Storage and Handling

Wash your hands with soap and water or use alcohol hand sanitiser before each use.

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

- ◆ Restorabite™ should be cleaned thoroughly following each use by rinsing in warm water, and wash with a PH neutral detergent removing any soiling or debris with a soft toothbrush.
- ◆ Alternatively, Restorabite™ frame and used insert should be wiped with a clean wet cloth and PH neutral detergent.
- ◆ Let all the components of Restorabite™ air-dry completely after each clean.
- ◆ Store in a sealed container such as a Tupperware

Precautions

- ◆ Use of the Restorabite™ must be done using an exercise program from your treating clinician to avoid injury.
- ◆ Do not put the Restorabite™ in dishwasher. The dishwashing process may weaken the Restorabite™ and it may break during use.