

WBI LightWire - Oral Myofunctional Training Device

Manufacturer: WB Integrated Health International Private Limited

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Critical Safety Warnings

- **DO NOT ALTER:** Do not bend, twist, or manipulate the wire or structure of the appliance out of its prescribed shape. Unauthorized alteration can cause improper force distribution, device failure, or injury.

- **Do not**
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1. Device Description & Principle of Operation

The WBI LightWire is a non-powered, removable oral medical device designed for physiotherapy applications. It is engineered **strictly and exclusively** for tongue posture training as part of oral myology physiotherapy. The device works by providing a physical/proprioceptive feedback to train and condition the tongue muscles into the correct anatomical resting position.

2. Intended Purpose & Indications for Use

- **Intended Purpose:** To exercise and condition the tongue muscles to promote correct tongue posture.

- **Do not**

3. Contraindications

Do not use this device if you have:

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4. Instructions for Use & Handling

4.1 Insertion

1. Thoroughly brush your teeth and rinse your mouth before inserting the appliance.

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- Wear the device only for the durations prescribed by your myofunctional therapist or healthcare provider.

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1. Using your fingers, carefully disengage the retention mechanisms from your teeth.

2. Re

5. Cleaning and Storage

5.1 Cleaning

- **Daily Clean:** After every removal, rinse the appliance with cool or lukewarm water. Brush gently using a soft-bristled toothbrush and mild, non-abrasive soap.

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- When not actively wearing the appliance, it **must** be stored inside the provided protective carry case.

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6. Emergency & Adverse Incident Protocols

6.1 Pain, Stress, or Discomfort

If you experience any level of physical stress, pain, bleeding, mucosal ulceration, or severe difficulty while wearing the appliance:

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- **If the device appears stuck, unremovable, or if you experience severe respiratory or physiological distress while the device is removed or in place:**

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If any serious incident occurs in relation to the device (e.g., death, temporary or permanent serious deterioration of health), the user must report it to WBIHI and the Competent Authority of the country in which the user is established.

7. Lifetime, Maintenance, and Disposal

- **Expected Service Life:** Five (5) Years under normal usage conditions.

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8. Administrative & Regulatory Information

- **Document Revision:** IFU-WBI-001

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9. Glossary of Symbols

Symbol · Meaning

<svg role="img" aria-label="Medical Device" width="26" height="26" viewBox="0 0 24 24"><rect x="3" y="3" width="18" height="18" rx="2" fill="none" stroke="currentColor" stroke-width="2"/><text x="12" y="16" font-size="8" text-anchor="middle" font-family="system-ui" font-weight="700" fill="currentColor">MD</text></svg> · Medical Device

<svg role="img" aria-label="Consult instructions for use" width="26" height="26" viewBox="0 0 24 24"><path d="M4 5h5.5A2.5 2.5 0 0 1 12 7.5V20a1 1 0 0 0 1 1H4z" fill="none" stroke="currentColor" stroke-width="2"/><path d="M20 5h-5.5A2.5 2.5 0 0 0 12 7.5V20a1 1 0 0 1 1 1H7z" fill="none" stroke="currentColor" stroke-width="2"/></svg> · Consult instructions for use

<svg role="img" aria-label="Medical Device Manufacturer" width="26" height="26" viewBox="0 0 24 24"><path d="M3 21V9l6 4V9l6 4V5l6 3v13z" fill="none" stroke="currentColor" stroke-width="2" stroke-linejoin="round"/></svg> · Medical Device Manufacturer

<svg role="img" aria-label="Caution" width="26" height="26" viewBox="0 0 24 24"><path d="M12 3 22 20H2z" fill="none" stroke="currentColor" stroke-width="2" stroke-linejoin="round"/><line x1="12" y1="9" x2="12" y2="14" stroke="currentColor" stroke-width="2"/><circle cx="12" cy="17.5" r="1" fill="currentColor"/></svg> · Caution: Consult accompanying documents

`REF` · Catalog Number / Model

`LOT` · Batch code / Lot number

`MFG / FAB` · Date of manufacture

Phone / Web / Email · Manufacturer Contact