Date Issued: March 2023

ELECTRONIC INSTRUCTIONS FOR USE

Multi-Adjustable Facemask® Electronic Patient IFU D-00980 REV-0

MANUFACTURER INFORMATION:

Ortho Technology, Inc.
1 Southern Ct.
West Columbia, SC 29169 USA

Phone: 1-813-501-1650

Website: www.orthotechnology.com

PRODUCT INFORMATION

Name: Multi-Adjustable Facemask®

Description: Orthodontic Class III Correction Device

PART NUMBER CHART: See appendix link here.

STEP-BY-STEP INSTRUCTIONS

Use of Extraoral Elastics

Follow your doctor's instructions on how to change the elastics and how often.

Replacing the Facemask Pads

1. Peel pad away from Facemask.
2. Remove excess residue from the plastic area where the pad was attached with diluted isopropyl alcohol.
3. Identify the correct replacement pad by shape for forehead rest or chin cup.
4. Peel off plastic cover from back of pad revealing the adhesive side.
5. Place pad on device in the correct orientation.
6. Repeat steps 1 through 5 for remaining pad.

INTENDED USER

Multi-Adjustable Facemask® is to be prescribed only by licensed dental professional and/or orthodontic professionals to patients during undergoing Class III orthodontic treatment.

INTENDED PATIENT POPULATION

Multi-Adjustable Facemasks are applicable to any patient demographic undergoing orthodontic treatment requiring Class III treatment.

INTENDED USE

Multi-Adjustable Facemasks are used during orthodontic treatment to correct Class III malocclusions in patients by attaching extraoral elastics from the facemask bar to either bracket or band hooks on the upper arch.

Multi-Adjustable Facemasks are single patient multiple use, provided non-sterile, and do not require processing before use.

Multi-Adjustable Facemasks are to be used only for their intended purpose.

INDICATIONS FOR USE

Multi-Adjustable Facemasks are indicated for repeated use in patients during orthodontic treatment Class III malocclusion correcting.

PRECAUTIONS

- Facemasks are recommended for single patient multiple use and replacement pads for single patient use at home during length of treatment.
- When using the hexagon key, only tighten screw until part is securely in place.
- The valid period of the product is 2 years after manufacturing date.

CAUTIONS

Extreme care should be taken to avoid hitting or pulling the appliance while being worn.

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WARNINGS

- This product contains metals that may produce heating and image artifacts at or near the device in an MR environment.
- ⚠ This product can expose you to chemicals including acrylonitrile, nickel, chromium, and styrene, which are known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov
- This product contains nickel and chromium and should not be used for individuals with known allergic sensitivity to these metals.

RESIDUAL RISKS

- Soft tissue soreness.
- Root resorption.
- Tooth shifting after treatment.

LIMITATIONS

Multi-Adjustable Facemasks are used during orthodontic treatment to correct Class III malocclusions in patients. Patients should follow the licensed dental and/or orthodontic professionals' prescribed wear time.

CONTRAINDICATIONS

Contraindicated in patients with an allergic sensitivity to nickel and/or chromium.

CLEANING

There are no specific cleaning requirements, but prior to use and between uses, you may wipe down the Multi-Adjustable Facemask with mild soap and water or diluted isopropyl alcohol.

PACKAGING FOR STERILIZATION

Multi-Adjustable Facemasks are not provided sterile.

DISPOSAL OF DISCARDED PRODUCT AND PACKAGING:

Dispose of in accordance with all local, state and federal regulations for biohazardous materials.

SERIOUS INCIDENT REPORTING

If, during the use of this device or as a result of its use, a serious incident has occurred or a product performance issue has been observed, please report it to the manufacturer and/or its authorized representative or your local affiliate, and to your national authority.

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1. Locate the [REF] number on the packaging
2. Visit **ifu.orthotechnology.com**
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Symbols Glossary visit: ifu.orthotechnology.com

Manufactured by:
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1-813-501-1650 • www.orthotechnology.com

EC REP
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CE 2460

CAUTION: Federal Law restricts this device to sale to or on the order of a dentist/orthodontist.

The information contained in the IFU is believed to be valid and accurate. Ortho Technology, Inc., however, makes no warranty, either expressed or implied, as to the completeness of information in all possible conditions. Reasonable safety precautions must always be observed.

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SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	SYMBOL DESCRIPTION
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Date of manufacture	Indicates the date when the medical device was manufactured.
	Authorized representative in the Euro-pean Community	Indicates the authorized representative in the European Community.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Single patient multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Medical device	Indicates that a given product is a medical device.
Rx Only	Prescription only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
	European conformity	CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection require-ments.
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the Magnetic Resonance environment.

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