

ELECTRONIC INSTRUCTIONS FOR USE**Multi-Adjustable Facemask® Electronic Doctor IFU - D-00947 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: The Multi-Adjustable Facemask® is used to correct orthodontic class III malocclusions. Designed for patient comfort, with free-flow air vents, full range of motion option, fully adjustable and lightweight.

PART NUMBER CHART: [See appendix link here.](#)

STEP-BY-STEP INSTRUCTIONS**Fitting the Facemask to the Patient**

1. Remove product from packaging.
2. Position the forehead rest near the center of the patient's forehead and tighten the hexagon screw. The metallic support will oscillate for better adaptation and comfort.
3. Place the chin cup on the patient's chin and tighten the hexagon screw to the desired fit.
4. Adjust the crossbar by loosening the hexagon screw and sliding the bar along the vertical main frame. Once the desired position is achieved, tighten the crossbar with the provided hexagon key. The crossbar can also be reversed and placed on the outside of the metal frame for additional elastic force.
5. Attach extraoral elastics from the facemask bar to either bracket or band hooks on the upper arch. Elastics are to be used as prescribed to the patient by licensed dental professionals and/or orthodontic professional during orthodontic treatment.
6. Instruct the patient on how to change their elastics and how often per the treatment protocol.
7. Supply the patient with the provided replacement pads and instruct patient on how to replace pads using the steps in the following section.
8. Retain the hexagon key with the patient records in case future adjustments are required.

Replacing the Facemask Pads

Performed by the doctor or the patient.

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.

GENERAL INFORMATION FOR THE DENTIST/ORTHODONTIST

- As part of developing a treatment plan, and before appliance placement, assess the need for interdisciplinary coordination with other professionals, such as speech pathologists, otolaryngologists, physicians, dentists and/or orthodontists.
- Follow the manufacturer's instructions for any orthodontic extraoral elastics, instruments or other materials used in the orthodontic treatment.
- The provided hexagon key is to be used by the doctor and should not contact the patient.
- Recommended for use with Ortho Technology line of products.

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Ortho Technology Accessories:

Extraoral Latex Elastics

Force Level 16 oz (454 gm), Sizes:

1/4" (6.4 mm)	[REF] 500-506
5/16" (7.9 mm)	[REF] 500-507
3/8" (9.5 mm)	[REF] 500-508
1/2" (12.7 mm)	[REF] 500-509

Material Composition:

Facemask Components			
Forehead Rest	Styrene and Acrylonitrile (SAN) Copolymer		
Chin Cup			
Band Support			
End Caps			
Forehead Pad	Polyethylene Foam		
Chin Cup Pad			
Frame	304 Stainless Steel		
Shaft Band			
Element			
Cr (Chromium)*		18-20%	
Ni (Nickel)*		8-10.5%	
Mo (Molybdenum)		-	
Mn (Manganese)		2.00% max	
Si (Silicon)		1.00% max	
N (Nitrogen)		0.10% max	
P (Phosphorus)		0.045% max	
C (Carbon)		0.08% max	
Fe (Iron)		Balance	

Tool Components	
Hexagon Key	Chrome Vanadium Steel

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.

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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.
- Do not use when the packaging is damaged or unintentionally opened.
- Do not use any products which are damaged, or do not comply with the labeling specifications.

CAUTIONS

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

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.

ELECTRONIC INSTRUCTIONS FOR USE**Multi-Adjustable Facemask® Electronic Doctor IFU - D-00947 REV-0****HOW TO ORDER A FREE PAPER COPY OF THIS ELECTRONIC INSTRUCTIONS FOR USE (eIFU)**


By Web: To order a free paper copy, you need internet access:

1. Locate the [REF] number on the packaging
2. Visit ifu.orthotechnology.com
3. Look for the “Request a Printed Copy of the Instructions for Use”
4. Fill out the form by providing the Product Name, [REF] number and the address you would like to receive the paper copy of the Instructions for Use. The paper copy of the eIFU will be delivered to the indicated address within 7 calendar days without any additional cost.

By Phone: To order a free paper copy, you will need access to a telephone:

1. Locate the [REF] number on the packaging
2. Call **1-813-501-1650** during hours in Eastern Standard Time listed below:
Monday – Thursday 9:00 A.M. – 5:30 P.M.
Friday 9:00 A.M. – 3:00 P.M.
Saturday and Sunday Closed
3. Call the number and follow the operator instructions.
4. Provide the Product Name, [REF] number and the address you would like to receive the paper copy of your Instructions for Use. The paper copy of the eIFU will be delivered to the indicated address within 7 calendar days without any additional cost

Symbols Glossary visit: ifu.orthotechnology.com













Manufactured by:
 Ortho Technology, Inc.
1 Southern Ct.
West Columbia, SC 29169 USA
1-813-501-1650 • www.orthotechnology.com

 
Emergo Europe
Westervoortsedijk 60
6827 AT, Arnhem
The Netherlands

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.

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 European 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 requirements.
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the Magnetic Resonance environment.

Multi-Adjustable Facemask® - Reference Numbers

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Last Updated 2022-03-24

Product Name	REF	Product Description
Multi-Adjustable Facemask	550-400	Blue
Multi-Adjustable Facemask	550-401	Red
Multi-Adjustable Facemask	550-403	Clear
Multi-Adjustable Facemask	550-404	Pearl White
Multi-Adjustable Facemask	550-405	Teal
Multi-Adjustable Facemask	550-406	American Pride
Multi-Adjustable Facemask	550-407	Hawaiian Hibiscus
Multi-Adjustable Facemask	550-408	Racin' Flames
Multi-Adjustable Facemask	550-409	Wild Cat Print
Multi-Adjustable Facemask	550-410	Union Jack
Multi-Adjustable Facemask	550-411	Canadian Pride
Multi-Adjustable Facemask	550-412	Pink Camo
Multi-Adjustable Facemask	550-413	Green Camo
Multi-Adjustable Facemask® Replacement Pad	406-RK2	Facemask Replace Pad Kit Flag 2 Head/2 Chin Foam/ Hex Key
Multi-Adjustable Facemask® Replacement Pad	407-RK2	Facemask Replace Pad Kit Flower 2 Head/2 Chin Foam/ HexKey
Multi-Adjustable Facemask® Replacement Pad	408-RK2	Facemask Replace Pad Kit Flame 2 Head/2 Chin Foam/ HexKey
Multi-Adjustable Facemask® Replacement Pad	409-RK2	Facemask Replace Pad Kit Wild Cat 2 Head/ 2 Chin Foam/HexKey
Multi-Adjustable Facemask® Replacement Pad	410-RK2	Facemask Replace Pad Kit Union Jack 2 Head/2 Chin Foam/ HexKey
Multi-Adjustable Facemask® Replacement Pad	411-RK2	Facemask Replace Pad Kit Canada 2 Head/2 Chin Foam/ Hex Key
Multi-Adjustable Facemask® Replacement Pad	412-RK2	Facemask Replace Pad Kit Camo 2 Head/2 Chin Foam/Hex Key
Multi-Adjustable Facemask® Replacement Pad	413-RK2	Facemask Replace Pad Kit Reg Camo 2 Head/2 Chin Foam/ Hex Key
Multi-Adjustable Facemask® Replacement Pad	550-RK2	Facemask Replacement Pad Kit 2 Head/ 2 Chin Foam/ Hex Key