INSTRUCTIONS FOR USE (IFU)
Morales® Protraction Facemask

This IFU is applicable to all current and previous generations of this product.

1. COMPANY IDENTIFICATION

	ORTOSIM SA DE CV Convento de Actopan 13A Jardines de Santa Mónica 54050 Tlalnepantla Estado de México, México MADE IN MEXICO (manufactured by Ortosim SA de CV)	**CUSTOMER SERVICE** +52 (55) 6265 7063 info@ortosim.com www.ortosim.com

2. PRODUCT IDENTIFICATION

Product Name: **Morales® Protraction Facemask**
Product Description: **Correction Device for Class III Orthodontics**

3. INDICATIONS FOR USE

The protraction facemask should only be prescribed by dental professionals and/or orthodontists to patients undergoing orthodontic treatment. Protraction facemasks are used during orthodontic treatment to correct Class III malocclusions in patients by attaching elastics intraoral from the facemask crossbar to either bracket or band hook on the upper arch.
The protraction facemask is indicated for repeated use in patients during orthodontic treatment Class III malocclusion correcting.

4. CONTRAINDICATIONS AND SIDE EFFECTS

ORTOSIM sells products to trained dental professionals and orthodontists. It is the primary responsibility of the dental professional and/or orthodontist to identify any potential contraindications that may prevent the use of the protraction facemask. It is also the responsibility of the dental professional and/or orthodontist to determine the pre-treatment procedures and the sequence of operation of the medical device.
If a patient has known allergies or hypersensitivity to any component of this product, we recommend not using it or doing so only under strict medical supervision. The professional should consider known interactions and cross-reactions of the product with other materials already in the patient's mouth before use. With proper use of this medical device, unwanted side effects are extremely rare. However, immune system reactions (allergies) and local discomfort cannot be completely ruled out.

5. WARNINGS AND PRECAUTIONS

The facemask should be used at home and during non-risk activities and should be supervised under the responsibility of the dental professional and/or orthodontist.
For individual patient use. The face mask can be reused.
This product contains elements such as nickel and chromium, chemicals known to the State of California to cause cancer.
Other residual risks include soft tissue pain, root resorption, and tooth displacement after treatment.

6. INSTRUCTIONS

1. Remove the product from the cylinder.
2. Place the facemask over the patient's face and verify that the length of the mainframe does not protrude more than 4 cm. below the chin rest. If not, mark the suggested distance with a marker and remove the facemask from the patient.
3. Cut with a carbide wheel along the marker mark to remove excess mainframe length and avoid damage to the soft tissues of the neck. The lower stop should be reattached to the lower end of the mainframe.
4. Place the facemask over the patient's face. If necessary, adjust the forehead by loosening the screw and sliding the upper rotating support along the mainframe. Once the desired position is achieved for best fit and comfort, tighten the forehead with the Allen key.
5. Adjust the crossbar by loosening the screw and sliding the bar along the mainframe. Once the desired position is achieved, tighten the crossbar with the Allen key.
6. Place the elastics on both sides of the crossbar and attached intraorally to either bracket or band hook.

7. DISPOSAL

Discard defective, incomplete, and/or faulty facemasks, for example, facemasks with burrs, rough edges or sharp edges. Handle carefully for safe use and notify the manufacturer.
Ensure proper disposal of the product to avoid adverse effects on the environment. The disposal should be in accordance with local legislation in the country of use.

8. SERIOUS INCIDENT REPORTING

If, during the use of the device or as a result of its use, a serious incident occurs or a product performance issue is observed, report it to the manufacturer or distributor, and to the competent national authority.

9. REGULATORY INFORMATION

	MANUFACTURER	NON STERILE	NOT STERILIZED
		MD	MEDICAL DEVICE
Rx only	RX ONLY	LOT	LOT NUMBER
	CONSULT INSTRUCTIONS FOR USE		
Cr Ni	Warning: Product contains chromium-nickel; keep away from patients with a nickel allergy.		