

## **ELECTRONIC INSTRUCTIONS FOR USE**

### **Patient Relief Wax - D-00962 REV-0**

#### **MANUFACTURER INFORMATION:**

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

Phone: 1-813-501-1650  
Website: [www.orthotechnology.com](http://www.orthotechnology.com)

#### **PRODUCT INFORMATION**

Name: Patient Relief Wax

Description: For patient emergency use when appliance is irritating soft tissue. Easy to apply and provides immediate temporary relief.

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

#### **INSTRUCTIONS FOR USE**

1. Remove product from packaging.
2. Instruct patient to remove appropriate amount of wax from plastic case to cover affected area.
3. Apply wax to appliance firmly.
4. Remove wax before eating.
5. Replace wax as needed.

#### **GENERAL INFORMATION FOR THE DENTIST/ORTHODONTIST**

- As part of developing a treatment plan, assess the need for interdisciplinary coordination with other professionals, such as speech pathologists, otolaryngologists, physicians, dentists and/or orthodontists.
- Oral hygiene is of particular importance for immunocompromised patients. Closely monitor oral hygiene on immunocompromised patients.
- Assess whether further orthodontic treatment is advisable in the presence of root resorption.
- Recommended for use with Ortho Technology line of products.

#### **MATERIAL COMPOSITION**

Microcrystalline Wax

#### **INTENDED USERS**

Relief Wax is offered by licensed dental professionals and/or orthodontic professionals to patients undergoing orthodontic treatment.

#### **INTENDED PATIENT POPULATION**

Relief Wax is applicable to any patient demographic undergoing orthodontic treatment.

#### **INDICATIONS FOR USE**

Relief Wax is used by orthodontic patients as a protective barrier between the orthodontic appliance and soft tissue to help prevent or limit irritation.

#### **INTENDED USE**

Relief Wax is used as a protective barrier between the orthodontic appliance and soft tissue.

#### **LIMITATIONS**

Relief Wax is not used to heal soft tissue irritation or eliminate pain.

#### **CONTRAINDICATIONS**

Any illness and/or underlying conditions that preclude orthodontic treatment.

#### **WARNINGS**

Choking Hazard

#### **PRECAUTIONS**

- 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.
- For use by prescription only.

#### **CAUTIONS**

- Monitor patient's inability or unwillingness to cooperate/follow the treatment plan.
- Continuously monitor patient's oral hygiene during treatment.

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#### **CLINICAL BENEFITS**

Provides temporary and immediate relief of soft tissue irritation.

#### **PERFORMANCE CHARACTERISTICS**

Soft tissue irritation caused by orthodontic appliances.

#### **REUSE**

Not for reuse: designed for use for a single patient during a single procedure. Reprocessing single-use medical devices may put the user and patient at risk of illness or injury.

#### **DISPOSAL**

Dispose of in accordance with all local, state and federal biohazard regulations.

#### **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.

#### **PACKAGING FOR STERILIZATION**

Patient Relief Wax are not provided sterile.

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#### 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](http://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](http://ifu.orthotechnology.com)



Manufactured for:  
Ortho Technology, Inc.  
1 Southern Ct.  
West Columbia, SC 29169 USA  
1-813-501-1650 • [www.orthotechnology.com](http://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.
	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.
	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.

## Patient Relief Wax - Reference Numbers

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

Last Updated 2022-02-02

Product Name	REF	Product Description
Ortho Performance® Scented Patient Relief Wax	600-001	Relief Wax Grape 50/pk
Ortho Performance® Scented Patient Relief Wax	600-002	Relief Wax Orange 50/pk
Ortho Performance® Scented Patient Relief Wax	600-003	Relief Wax Cherry 50/pk
Ortho Performance® Scented Patient Relief Wax	600-004	Relief Wax Cinnamon 50/pk
Ortho Performance® Scented Patient Relief Wax	600-005	Relief Wax Mint 50/pk
Ortho Performance® Scented Patient Relief Wax	600-006	Relief Wax Glow 50/pk
Ortho Performance® Scented Patient Relief Wax	600-007	Relief Wax Bubblegum 50/pk
Ortho Performance® Scented Patient Relief Wax	600-008	Relief Wax Pineapple 50/pk
Ortho Performance® Scented Patient Relief Wax	600-009	Relief Wax Blueberry 50/pk
Ortho Performance® Scented Patient Relief Wax	600-010	Relief Wax Silver 50/pk
Ortho Performance® Scented Patient Relief Wax	600-011	Relief Wax Coconut 50/pk
Ortho Performance® Scented Patient Relief Wax	600-012	Relief Wax Chocolate 50/pk
Ortho Performance® Scented Patient Relief Wax	600-013	Relief Wax Cotton Candy 50/pk