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**ELECTRONIC INSTRUCTIONS FOR USE - Elastic Attachers D-00960 REV-0****• Creatures of the Sea® Elastic Directors****Manufacturer Information**

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

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

**PRODUCT INFORMATION**

Name: Creatures of the Sea® Elastic Directors

Description: The elastic attachers make placing and removing elastics easier for patients. The elastic attachers are small, handheld, plastic devices that come in assorted colors.

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

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**INSTRUCTIONS FOR USE**

1. Remove product from packaging.
2. Hook elastic to elastic attacher.
3. Attach elastic to or remove elastic from orthodontic appliances per orthodontist's recommended instructions.

**GENERAL INFORMATION FOR THE DENTIST/ORTHODONTIST**

- As part of developing a treatment plan, and before elastic use, assess the need for interdisciplinary coordination with other professionals, such as speech pathologists, otolaryngologists, physicians, dentists and/or orthodontists.
- Orthodontic training in standard procedures will determine appropriate instruments for use during elastic placement and removal.
- Follow the manufacturer's instructions for instruments in the orthodontic treatment.
- 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:**

Polypropylene and Homopolymer

**INTENDED USERS**

Elastic attachers are offered by licensed dental professionals and/or orthodontic professionals to patients undergoing orthodontic treatment.

**INTENDED PATIENT POPULATION**

Elastic attachers are applicable to any patient demographic undergoing orthodontic treatment using elastics.

**INTENDED USE**

The elastic attachers are used to assist the patient with attaching and removing intraoral elastics to and from orthodontic appliances as instructed by the orthodontic/dental professional.

**INDICATIONS FOR USE**

The elastic attachers are intended to be used by the patient to attach and/or remove intraoral elastics to/from orthodontic appliances.

**LIMITATIONS**

If hook section is damaged, elastic attacher may not hold elastic.

**CONTRAINDICATIONS**

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

**WARNINGS**

- Take special care during placement as elastic or elastic attacher could break
- Poking of soft tissue
- Choking hazard

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**ELECTRONIC INSTRUCTIONS FOR USE - Elastic Attachers D-00960 REV-0****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.

**CAUTIONS**

- For use by prescription only.
- Monitor patient's inability or unwillingness to cooperate/follow the treatment plan.
- Continuously monitor patient's oral hygiene during treatment.
- The product is shelf life sensitive and must be used by the date on label/packaging.
- Before use, counsel patients on the materials contained in this device. Also, counsel the patient of the potential for allergy/hypersensitivity to these materials.

**SIDE EFFECTS**

Although uncommon, possible side effects from elastic attachers may include:

- Soft tissue damage or irritation due to slippage or breakage of the elastic attacher or elastic during attachment or removal

**CLINICAL BENEFITS**

Aid orthodontic treatment and correction of malocclusions.

**PERFORMANCE CHARACTERISTICS**

The elastic attacher is used to assist the patient in placement and removal of Intraoral or Extraoral Latex and Non-Latex Elastics.

**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 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.

**PACKAGING FOR STERILIZATION**

Elastic Attachers are not provided sterile.

**ELECTRONIC INSTRUCTIONS FOR USE - Elastic Attachers D-00960 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](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 without any additional cost within 7 calendar days.

**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, without any additional cost, within 7 calendar days.

**Symbol glossary visit:** [ifu.orthotechnology.com](http://ifu.orthotechnology.com)



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














**EC|REP**  
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.

## Elastic Directors - Reference Numbers

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Last Updated 2021-12-23

Product Name	REF	Product Description
Elastic Directors	500-307	Elastic Directors Multicolored 100 per pack