

ELECTRONIC INSTRUCTIONS FOR USE**DuraLock® PLUS Impression Trays - D-00957 REV-0****MANUFACTURER INFORMATION:**

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

Phone: 1-813-501-1650
Website: www.orthotechnology.com

PRODUCT INFORMATION

Name: DuraLock® PLUS Impression Trays

Description: DuraLock® PLUS Impression Trays are arch-shaped receptacles used to hold the substance utilized in dental and orthodontic care to create a mold for the teeth.

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

MATERIAL COMPOSITION:

CAS	Name	Content
9003-56-9	Acrylonitrile-Butadiene-Styrene copolymer	>98 %
	Additives	≤2 %

INSTRUCTIONS FOR USE

1. Remove product from packaging.
2. Select the size of tray for the patient.
3. Insert the tray in patient's mouth on upper and lower teeth to confirm correct size.
4. Follow the manufacturer's instructions for the alginate material.
5. Properly dispose of the impression trays after the procedure as per section DISPOSAL.

GENERAL INFORMATION FOR THE DENTIST/ORTHODONTIST

Follow the manufacturer's instructions for the alginate material. It is suggested for the dental/orthodontic professional to wear gloves during the procedure to avoid contamination. Recommended for use with Ortho Technology's products.

INTENDED USERS

DuraLock® PLUS Impression Trays are to be used only by licensed dental professionals and/or orthodontic professionals during orthodontic treatment.

INTENDED PATIENT POPULATION

DuraLock® PLUS Impression Trays are applicable to any patient demographic under consideration for dental and/or orthodontic treatment.

INDICATIONS FOR USE

DuraLock® PLUS Impression Trays are indicated to be used by dental/orthodontic professionals and are applicable to any patient demographic under consideration for dental and/or orthodontic treatment to create impressions.

INTENDED USE

DuraLock® PLUS Impression Trays are arch-shaped receptacles used to hold the substance utilized in dental and orthodontic care to create a mold for the teeth.

CONTRAINDICATIONS

Contraindicated in patients with an allergic sensitivity to styrene.

WARNINGS

This product contains styrene, a chemical known to the State of California to cause cancer. Not recommended for use for patients with a high gag reflex.

RESIDUAL RISKS

Impression taking could cause patient discomfort during and after the process.

CAUTIONS

- The device is for professional dental and/or orthodontic application only.

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- The device can be used only one time. Using the product more than once can cause infection & contamination from the biological material transmitted from patient to patient.
- The device should be used as soon as possible after opening the package and destroyed afterwards.
- The device cannot be used if the package is damaged.
- After being used, the device must be thrown into a suitable waste container in compliance with local law regulations.
- The device is latex free and non-toxic.
- The valid period of the product is 3 years after manufacturing date.
- Improper sizing may result in pinching of soft tissue.
- Improper sizing may result in inaccurate impressions.

PRECAUTIONS

- Excess impression material could cause gag reflex.

SIDE EFFECTS

Although uncommon, possible side effects from use of this product may include:

- Soft tissue irritation
- Gagging

CLINICAL BENEFITS

The safe and effective holding of impression material, such as alginate, without adhesive to make an impression of patient's teeth or alveolar process (bony tooth sockets) to reproduce the structure of a patient's teeth and gums.

PERFORMANCE CHARACTERISTICS

Impression trays are used to create impressions to assist the clinician in planning for dental and/or orthodontic treatment.

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 SECTION

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

DuraLock® PLUS Impression Trays 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
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



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



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.

DuraLock Plus Impression Trays - Reference Numbers

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

Last Updated 2022-03-15

Product Name	REF	Product Description
DuraLock Plus Impression Trays	501-000	DuraLock Plus Impression Trays Trays Assortment
DuraLock Plus Impression Trays	501-001L	DuraLock Plus Impression Trays Pedo Lower-Red
DuraLock Plus Impression Trays	501-001U	DuraLock Plus Impression Trays Pedo Upper-Red
DuraLock Plus Impression Trays	501-002L	DuraLock Plus Impression Trays Extra Small Lower-Orange
DuraLock Plus Impression Trays	501-002U	DuraLock Plus Impression Trays Extra Small Upper-Orange
DuraLock Plus Impression Trays	501-003L	DuraLock Plus Impression Trays Small Lower-Blue
DuraLock Plus Impression Trays	501-003U	DuraLock Plus Impression Trays Small Upper-Blue
DuraLock Plus Impression Trays	501-004L	DuraLock Plus Impression Trays Medium Lower-Green
DuraLock Plus Impression Trays	501-004U	DuraLock Plus Impression Trays Medium Upper-Green
DuraLock Plus Impression Trays	501-005L	DuraLock Plus Impression Trays Large Lower-Yellow
DuraLock Plus Impression Trays	501-005U	DuraLock Plus Impression Trays Large Upper-Yellow
DuraLock Plus Impression Trays	501-006L	DuraLock Plus Impression Trays Extra-Large Lower-Purple
DuraLock Plus Impression Trays	501-006U	DuraLock Plus Impression Trays Extra-Large Upper-Purple