Vacuum Forming Machine

Sheets

Instruction manual



bio·art

CE

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▶ 1 - INTRODUCTION

Bio-Art Vacuum Forming Sheets have been specially developed for use by dental professionals with the objective of enabling the production of trays for all kinds of applications (fluoridation, bracket fixation, plate for bruxism, surgical guide, matrix for temporary prosthetic teeth, etc.).

The sheets are produced with polymer of different compositions, shapes, colors and thicknesses, according to each model and as shown in the table of item 2.

During the process of plasticizing (vacuum forming), the sheets are heated in an equipment called vacuum forming machine to achieve the ideal point of plasticizing (see item 4). Then they are formed on the plaster models of the dental arches through vacuum generated by the device, thus producing the tray(s).

In the event of any serious incident occurring in relation to the device, the user and/or patient must notify Bio-Art Dental Equipment and the competent authority in their country.



Caution! Read all the information contained in this Instruction Manual carefully before start using the product.

▶ 2 - TECHNICAL SPECIFICATIONS

Bio-Art Sheets are suitable for production of dental trays that according to their characteristics, compositions and thicknesses are indicated for different applications as described in the following table:

● *Round Sheet* / ■ *Square Sheet*

MODEL	APPEARANCE	COMPOSITION	DIMENSIONS (MM)	THICKNESS (MM)	APPLICATION
PVC Crystal Sheet	Rigid and transparent	Polyvinyl Chloride	● - Ø120 ● - Ø125 ● - Ø134 ■ - 125x125	0,30	- Tray for homemade whitening; - Tray for fluoridation; - Plate for fixing brackets; - Packaging of study models (file)
Double Sided PET-G/ TPU Sheet	One face Rigid and the other soft, with a Translucent appearance	PET-G/ TPU	● - Ø120 ● - Ø125 ● - Ø134 ■ - 125x125	2,0 (1+1) 2,5 (1,5+1) 3,0 (2+1) 3,5 (2,5+1)	- Plate for bruxism; - Space maintainer; - Orthodontic device; - Containment - Post treatment protection
PET-G Crystal Sheet	Rigid and Transparent	Polyethylene terephthalate	● - Ø120 ● - Ø125 ● - Ø134 ■ - 125x125	0,60 0,75 1,00 1,50 2,00 3,00	- Plate for bruxism; - Space maintainer; - Orthodontic device; - Individual tray; - Base plate for bite plane (wax roller); - Surgical guide;
Aligner Sheet BioAlign	Rigid and Transparent	Copolyester with LDPE low-density polyethylene adhesive protective film	● - Ø120 ● - Ø125 ● - Ø134 ■ - 125x125	0,40 0,50 0,60 0,75 1,00 1,20 1,25 1,50	- Plate for orthodontic aligners; - Plate for bruxism; - Space maintainer; - Orthodontic device;
Milky Sheet PP	Rigid and Translucent	Polypropylene	● - Ø120 ● - Ø125 ● - Ø134 ■ - 125x125	0,60	- Matrix for provisional; - Tray for homemade whitening; - Tray for fluoridation;
Soft EVA Sheet	Malleable.Some translucent and others Opaque in different colors	Ethylene Vinyl Acetate	● - Ø120 ● - Ø125 ● - Ø134 ■ - 130x130	1,00 1,50 2,00 3,00 4,00	- Tray for homemade whitening; - Tray for fluoridation; - Myo-relaxing plate; - Mouthguard (sports)
Soft EVA Sheet with antimicrobial additive (silver nano particles)	Malleable. Some translucent and others Opaque in different colors	Ethylene Vinyl Acetate with 5% Nanox®	● - Ø120 ● - Ø125 ● - Ø134 ■ - 130x130	1,00 1,50 2,00 3,00 4,00	- Tray for homemade whitening; - Tray for fluoridation; - Myo-relaxing plate; - Mouthguard (sports)

Important! There are no restrictions in terms of use indications of Bio-Art Plasticizing Plates in mouth protection and teeth whitening applications for athletes, as long as such indications are obligatorily observed by a dental professional or practitioner.

▶ 3 - PRESENTATION FORMS ◀

The Sheets are supplied in metalized packages with vacuum and the amount may vary according to the model, material and thickness. They are supplied in round shapes (Ø120 and Ø134mm) or square shapes (126 x 126mm), and the thicknesses vary from 0.3 to 4mm in different colors, depending on the model.

▶ 4 - USE INSTRUCTIONS ◀

For production of dental trays using Bio-Art Sheets, it is necessary to execute a specific plasticizing process on the device exclusively developed for this purpose.



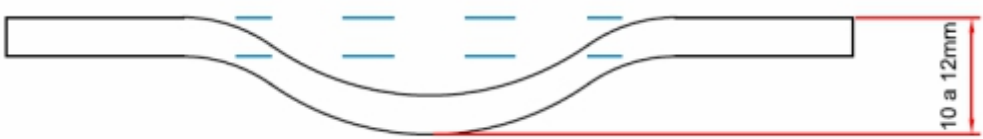
To obtain a satisfactory result in the production of trays, preferably use equipment manufactured by Bio-Art. The Bio-Art Plastvac P7 is a device exclusively designed for thermoforming processes (plasticizing) and is indicated for different applications, turning the production of trays simple, accurate and efficient.

The image illustrates the Bio-Art Plastvac P7 model.

Ideal Plasticizing Point

Due to the existence of various types of sheets with different materials and thicknesses, the ideal plasticizing point is identified by alterations in the sheet, thus occurring different heating times.

In general, the ideal point is observed by changes in the surface texture and color (brightness) for sheets more opaque, i.e., the sheet will remain bright and transparent (milky sheets) or by sheet runoff by 10 to 12 mm, as indicated in the drawing below (crystal and soft sheets).



▶ 5 - CARE DURING USE

Bio-Art sheets have their use restricted to qualified dental professionals. All sheets models are supplied in "Not Sterile", can be used for antiseptic alcohol to disinfect them.

For construction of the model to be molded (dental arch), use good quality and porous plaster, because the vacuum also acts through the model for the conformation of trays.

Set the model as lowest as possible and with smallest volume possible to avoid large deformations on the sheet.

When working with the model on a flat base, the bottom of the model should have a good finish and a good flatness to prevent the sheet from molding the gaps between the plaster model and the base of the device, thereby forming holds that impede the withdrawal of the tray. In case of model with irregular base, use the template rack provided along with your forming machine and following the instructions for use supplied by the manufacturer.

For the sheet to have a better surface finish (brightness) moisten the plaster model before the thermoforming process, thus avoiding adherence of powdered plaster on the board.

▶ 6 - SAFETY PRECAUTIONS



During the plasticizing process, do not neglect the equipment. The material of the sheets heats and softens quickly, and it may become unusable and even cause damage to the equipment if the same too soften.

When working with any type of sheet, during the construction and finishing of the tray, always use gas masks and goggles for your safety.

People unfamiliar with the procedures of vacuum forming must read the instructions for use supplied by the manufacturer before using the equipment

The responsibility of clinical treatment, technique for tray construction, side effects and the action expected of the use of trays generated by Bio-Art sheets are the sole responsibility of the dentist and/or professional responsible for the use of them.

▶ 7 - SPECIAL STORAGE CONDITIONS

Bio-Art Sheets are supplied in metalized package and vacuum closed to ensure product integrity during storage and transport.

The vacuum packaging protects the sheets from moisture and contaminants. Once opened, the sheets should be stored according to the following instructions:

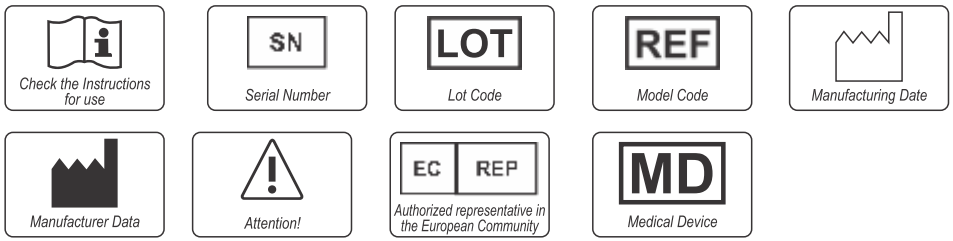
The sheets consist of PVC, PP and EVA that, if not used immediately after opening the vacuum packaging, must be kept in original package, stored in a dry place away from sources of excessive light and heat.

The sheets consisting of PET-G are highly hygroscopic (high capacity to absorb moisture). After opening the vacuum package, the sheets that are not used immediately must remain stored in desiccator and should be used within 30 days.

Before the opening of vacuum package, the same should be stored in a dry environment, away from sources of excessive heat and light (e.g., sunlight), at room temperature and strictly observing the expiration dates printed on their packaging.

The expiration date on the packages runs until the moment of opening them, because after opening the vacuum closure system loses its functionality.

▶ 8 - SIMBOLOGY



▶ 9 - WARRANTY AND TECHNICAL ASSISTANCE TERM

BIO-ART Equipamentos Odontológicos Ltda., provides warranty to the sheets according to material characteristics of each model that are printed on their packaging, according to criteria of batch and manufacturing date.

This warranty covers any manufacturing defect and shall be furnished by the replacement of the product and subject to the following requirements:

a) That the product has been transported, stored and used correctly in accordance with the instructions provided in this manual and the vacuum forming manufacturer's manual used in the thermoforming process;

b) That the complaint is accompanied by an invoice of purchase and registered within the warranty period, followed by a report describing the defect and manufacturing batch number;

Limitations of warranty:
• Normal sheet wear;
• Defects resulting from improper storage or use of the product;
• Inappropriate transportation;
• Use inconsistent with the purposes and characteristics of the product;
• Damage by exposure to adverse conditions (humidity, intense heat, chemical interaction, etc.);
• Cleaning and/or disinfection with inadequate products.

To take advantage of this warranty in the domestic market (Brazil), consumers should return the product, paying the costs, for the following address or to the nearest Bio-Art Service Center. See about the authorized service centers on our website: www.bioart.com.br.

BIO-ART EQUIPAMENTOS ODONTOLÓGICOS LTDA.
Rua Teotônio Vilela, 120 - Jardim Tangará - CEP (ZIP CODE) 13568-000 - São Carlos SP - Brasil - Tel. +55 (16) 3371-6502 - Fax +55 (16) 3372-5953 - www.bioart.com.br
CNPJ 58.538.372/0001-56 - Insc. Estadual 637.034.447.113

For other countries, the warranty is provided solely by the authorized distributor (legal importer).

▶ *10 - AUTHORIZED REPRESENTATIVE IN EUROPE*

EC REP

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The information contained herein is subject to changes that may be made without notice.

▶ APPENDIX I - VOLTAGES AND APPROXIMATE HEATING TIMES (P7 / P7 PLUS)

	VOLTAGES AND APPROXIMATE HEATING TIMES (SECONDS)				
SHEETS SPECIFICATIONS	**110V**	**127V**	**220V**	**230V**	**240V**
CRYSTAL PLATE 0,3 MM	125	139	101	90	101
CRYSTAL PLATE 0,75 MM	59	68	67	59	67
CRYSTAL PLATE 1,0 MM	66	76	75	67	73
CRYSTAL PLATE 1,5 MM	77	86	86	76	84
CRYSTAL PLATE 2,0 MM	98	109	108	94	108
CRYSTAL PLATE 3,0 MM	124	138	133	119	136
SOFT PLATE 1,0 MM	64	74	71	63	75
SOFT PLATE 1,5 MM	81	90	81	80	99
SOFT PLATE 2,0 MM	83	92	88	84	86
SOFT PLATE 3,0 MM	106	108	113	102	111
SOFT PLATE 4,0 MM	126	136	138	119	142
MILKY PLATE PP 0,6MM	92	103	94	92	85
BIOALIGN PLATE 0,6 MM	74	77	92	76	79
BIOALIGN PLATE 0,75 MM	66	76	72	63	75
BIOALIGN PLATE 1,0 MM	72	84	83	72	80
SOFT CARE PLATE 1,0 MM	65	74	73	66	74
SOFT CARE PLATE 1,5 MM	69	79	81	72	85
SOFT CARE PLATE 2,0 MM	76	88	85	75	82
SOFT CARE PLATE 3,0 MM	124	133	135	123	139
SOFT CARE PLATE 4,0 MM	151	152	166	153	151
CRYSTAL S PLATE 1,0 MM	79	85	88	74	85
CRYSTAL S PLATE 1,5 MM	84	101	100	82	96
CRYSTAL S PLATE 2,0 MM	106	103	118	103	108

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