



VANNINI DENTAL
Industry
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ALGINATES FOR DENTAL IMPRESSIONS

KROMALGIN PIÙ

CROMATIC

CLIPALGIN

PROTESIL CHROMATIC

PROTESIL ELASTIC RAPID

PROTESIL NORMAL RIGID

Rev. 11/2022



EN. Use protective goggles, filtering face mask suitable for powders (FFP2 or FFP3), gloves and work clothes.

Alginates

Instructions for use

INTENDED USE

Alginate for dental impression.

PRODUCT DESCRIPTION

Protesil Elastic Rapid: elastic alginate. Scent: strawberry

Protesil Normal Rigid: elastic alginate. Scent: Mint

Protesil Chromatic: chromatic alginate. The chromatic variation accompanies the different processing phases: purple during mixing, pink while working and positioning on impression tray, white during permanence time in the oral cavity until curing. Scent: tutti frutti.

Cromatic: chromatic alginate. The chromatic variation accompanies the different processing phases: purple during mixing, pink while working and positioning on impression tray, white during permanence time in the oral cavity until curing. Scent: Vanilla

Kromalgin più: chromatic alginate. The chromatic variation accompanies the different processing phases: purple during mixing, pink while working and positioning on impression tray, white during permanence time in the oral cavity until curing. Scent: Mint

CLIPalgin: elastic alginate not chromatic. Scent: Mint

PACKING

Name of the product	Cod	Pack
Protesil Elastic Rapid	005002	Box x 12 alluminium bags of 500 g.
Protesil Normal Rigid	005006	Box x 12 alluminium bags of 500 g.
Protesil Chromatic	005011	Box x 12 alluminium bags of 500 g.
Cromatic	002010	Box x 24 alluminium bags of 453 g.
	002015	Box x 300 alluminium bags of 18 g.
Kromalgin PIU	002000	Box x 24 alluminium bags of 453 g.
	002003	Box x 300 alluminium bags of 18 g.
CLIPalgin	002020	Box x 24 alluminium bags of 453 g.
	002025	Box x 300 alluminium bags of 18 g.

COMPOSITION

- **Protesil Elastic Rapid:** diatomaceous earth, sodium alginate, calcium sulphate, sodium phosphate, potassium fluorotitanate, vaseline oil, food flavour (strawberry), pigment;
- **Protesil Chromatic:** diatomaceous earth, sodium alginate, calcium sulphate, sodium phosphate, potassium fluorotitanate, zinc oxide, vaseline oil, pH indicator, food flavour (all fruits);
- **Cromatic:** diatomaceous earth, sodium alginate, calcium sulphate, sodium phosphate, potassium fluorotitanate, zinc oxide, vaseline oil, pH indicator, food flavour (vanilla and caramel);
- **Clipalgin:** diatomaceous earth, sodium alginate, calcium sulphate, sodium phosphate, potassium fluorotitanate, zinc oxide, vaseline oil, food flavour (mint), pigment;
- **Kromalgin+:** diatomaceous earth, sodium alginate, calcium sulphate, sodium phosphate, potassium fluorotitanate, zinc oxide, vaseline oil, pH indicator, food flavour (mint);

INSTRUCTIONS FOR USE

The devices are intended for use by dental sector professionals for the purpose of impression taking on dental patients.

CONTRAINDICATIONS

Do not use on patients with known hypersensitivity to any of the components. For more information on the allergens contained in scents, please contact Vannini Dental.

WARNINGS

The alginate contains respirable crystalline silica. Avoid prolonged exposure to eyes. Avoid prolonged inhalation. Do not ingest. Carefully mix water and powder, possibly away from the patient, to minimize the risk of inhalation of the powder and the quantity of volatile particles for exposed persons. The product is safe for use on intact mucous membranes.

Contact with eyes: In case of contact with eyes, rinse with plenty of water for 15 minutes. If irritation persists, consult a physician.

Inhalation: In case of inhalation, move the patient into the open air. Drink water to clear the throat and blow nose to eliminate material. If irritation or pain persists, consult a physician.

Ingestion: Do not ingest. In case of accidental ingestion, drink plenty of water.

PRECAUTIONS

Operators who use the product must wear protective goggles, filtering face mask suitable for powders (FFP2 or FFP3), gloves and suitable clothing.

In order to ensure better adhesion of the material to the impression tray, use of impression trays with retaining edges is recommended. It is advised to load the impression tray with a suitable amount of material to avoid obstructing the airway.

Avoid running multiple impressions in a single session (more than six of the same arch/area) to help prevent irritation of the oral mucous membranes. In the presence of symptoms, discontinue use immediately. If irritation persists, consult a physician.

Times for clinical use (shown in table 1) are understood to be from commencement of mixing with deionised water at 23°C/73°F. The temperature and hardness of the water may affect the times for clinical use of the material. Cold water retards curing; hot water accelerates it.

Do not contaminate the material or the teeth/surfaces with the non-polymerized acrylic resins or bis-acrylic surface layer. Residues of these materials could interfere with product jellification. If the surfaces are contaminated, it is advised to clean them with ethyl alcohol or other solvents.

Use in a well ventilated environment. Avoid inhalation of powder dispersed in the air. See Warnings.

Do not disperse the product (alginate powder, jellified alginate, impression and packaging) in the environment and dispose of in accordance with local regulations.

SIDE EFFECTS

Irritation, redness or signs of hypersensitivity may occur in case of allergy to any of the components.

CLINICAL BENEFITS

Impression material for reproducing dental arches for creating models for diagnostic and therapeutic purposes.

STEP-BY-STEP INSTRUCTIONS

Preliminary operations:

1. Read the instructions prior to use.

2. Use protective goggles, filtering face mask suitable for powders (FFP2 OR FFP3), gloves and work clothes.

3. Open the bag and put the alginate into a clean, dry and airtight container. Keep the batch number and expiry date cut from the bag. If the container has a label, remember to replace it with product name, batch and expiry date cut from the bag.

Material preparation:

4. Choose an impression tray of size appropriate to that of the oral cavity. Use the green measuring spoons.

5. Shake the container 2 or 3 times to help dispersing the powder.

6. Proceed by dosing. Using the measuring spoon, take the alginate without pressing the powder, levelling off or removing excesses of alginate using the flat part of the spatula.

7. Put the measured alginate into a rubber mixing bowl. Repeat the operation until you reach the desired amount.

8. Close the container at the end of the dosing.

9. Add water to the powder. Pour 1/3 cup of water (21 ml) for each spoonful of powder (10 g). Example: For 2 measures of powder (20 g) sufficient for an average upper impression tray, pour 2/3 cup of water (42 ml). Follow the suggested timing table for mixing

Material use:

10. Place the material on the impression tray

11. Insert the impression tray in the oral cavity by the end of working time

12. Wait for material jellification by observing the curing time from beginning of mixing and then remove the impression from the patient's mouth.

13. Ask patient to rinse mouth with water. Inspect the patient's mouth to make sure there are no alginate residues.

Disinfection of the impression:

14. After taking the impression, rinse thoroughly to remove any residues and traces of saliva. Remove the water in excess and disinfect immediately.

15. Disinfection is achieved by using a specific disinfectant for alginates. Soak the impression or spray it directly (if you use a spray disinfectant). Follow the chosen disinfectant manufacturer's instructions for contact time. Quaternary ammonium salt based disinfectants or mixtures of alcohol and surface tension reducers have been tested. Please refer to the instructions for use for each specific impression disinfectant you wish to use to check compatibility and effectiveness.

In case of mechanical or automatic mixing, follow the instructions provided by the machine manufacturer.

TIMES FOR CLINICAL USE

Times for clinical use		Protesil Chromatic	Cromatic	Clipalgin	Kromalgin più	Protesil Elastic Rapid	Protesil Normal Rigid
1	Mixing time	45"	45"	30"	45"	30"	30"
2	Working time	1'35"	1'35"	1'10"	1'35"	1'10"	1'10"
3	Time in mouth	1'00"	1'00"	1'00"	1'00"	1'00"	1'00"
4	Setting time	2'35"	2'35"	2'10"	2'35"	2'10"	2'10"

Technical data ISO 21563		Protesil Chromatic	Cromatic - Kromalgin più	Clipalgin	Protesil Elastic Rapid – Protesil Normal Rigid
1	Elastic recovery (%)	96,5	96	96	96,5
2	Tear strength (N / mm)	0,65	0,65	0,65	0,70
3	Strain in compression (%)	11,5	10,0	10,0	13,0
4	Initial setting time (23°C/73°F)	2'15"	2'25"	2'20"	2'10"

CLEANING AND DISINFECTION OF ACCESSORIES

Make sure to disinfect, and if possible sterilize, all accessories used together with the alginate before and after use. Follow warnings concerning material compatibility, maintenance and refurbishment provided by the accessory manufacturer. Follow the chosen disinfectant manufacturer's instructions for contact time. Please refer to the instructions for use for each specific disinfectant you wish to use to check compatibility and effectiveness.

STORAGE

The expiry date relates to the unopened package properly stored. It is suggested to store the product in an airtight container for up to three months. Close the container at the end of dosing and keep it at a temperature ranging between 5 and 27°C / 41-80°F.

IMPRESSION CASTING

After completing disinfection, thoroughly wash and dry the impression before casting the gypsum. It is advised to cast the impression immediately (within 15-30 minutes) using type 3 stones (e.g. Elite Model/Model Fast) or type 4 stones (e.g. Elite Rock), following the manufacturer's instructions.

CONSERVATION OF THE IMPRESSION

If gypsum cannot be cast immediately, eliminate the water in excess and store the impression at room temperature (23°C) in an airtight polyethylene bag. In these conditions gypsum casting may be postponed for up to 48 hours from impression taking

IMPORTANT REMARKS

Information provided in any way, even during demonstrations, does not invalidate the instructions for use. Users are required to check that the product is suitable for the foreseen application. The manufacturer cannot be held responsible for damage, including to third parties, deriving from failure to follow instructions or from unsuitability for an application. The manufacturer's liability is in any case limited to the value of the products supplied. Report any serious incident involving the medical device to the manufacturer and to the relevant authorities.



This symbol identifies a medical device as defined by EU Regulation 2017/745.