

VILLACRYL ORTHO, VILLACRYL ORTHO MIX INSTRUCTIONS FOR USE - EN

I. Product description
Villacryl Ortho: Acrylic resin for making removable orthodontic appliances.
Villacryl Ortho Mix: Acrylic resin for making removable orthodontic appliances.

ISO classification 20795-2: type 1

Processing parameters: necessary parameters for the proper processing of the materials are given in Table I.

Indications for use

Villacryl Ortho: Removable orthodontic appliances, repairs of orthodontic appliances.

Villacryl Ortho Mix: Removable orthodontic appliances, repairs of orthodontic appliances.

Clinical indications

Correcting minor changes in children, adolescents and adult's dentition.

Maintaining corrected dentition with orthodontic appliances. Preventive of returning teeth to the state before treatment.

Restoring the proper function to orthodontic appliances damaged during use.

Target group or target groups of patients and intended users of the devices

Users: Professionals in the dental technology industry - certified dental technicians producing removable orthodontic appliances.

Patients: People of different ages and sexes, with predominance of children and adolescents, with slight malocclusion, not eligible for orthodontic treatment with fixed orthodontic appliances.

People of various ages and sexes, with a predominance of children and adolescents after completed orthodontic treatment with fixed or removable orthodontic appliances.

Contraindications

Do not use the products by people diagnosed with a lack of resistance to allergenic factors, including the ingredients of the product. In such situations, use a different material suitable for the patient.

Do not use the product by pregnant women and nursing mothers in the group of dental technicians.

Product form

Separate a mixture of powder in plastic containers and liquid, color concentrates in bottles.

The product is available in the form of a set: powder + liquid + color concentrates or separately as a powder a liquid and a color concentrate.

Chemical composition

Villacryl Ortho

Powder: polymethyl methacrylate (PMMA), barbituric acid derivative.

Fluid: methyl methacrylate (MMA), cross-linking agent, N,N dimethyl-p-toluidine (DMPT), stabilizer.

Color concentrates: methyl methacrylate (MMA), oil-soluble pigments.

Villacryl Ortho Mix

Powder: polymethyl methacrylate (PMMA)/polyethyl methacrylate (PEMA), barbituric acid derivative.

Fluid: methyl methacrylate (MMA), cross-linking agent, N,N dimethyl-p-toluidine (DMPT), stabilizer.

Product compatibility

For use with standard orthodontic wires and screws.

Safety instructions

Warnings

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

The ingredients of the product and the dust generated during the fabrication of dentures may cause mechanical eye irritation.

The fluid is sensitive to temperature and UV radiation. An uncontrolled polymerization reaction may occur.

Precautions

In case of any allergic reaction, stop work immediately and consult a dermatologist.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protection clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P501 Dispose of the contents/container to an authorized consignee of the waste.

It is recommended to use gloves made of HDPE polyethylene for hand protection, a filtering fluidcompatible face mask for respiratory protection, goggles and wearocular.

It is advisable to use ventilation of rooms and workplace exhaust systems.

In the event of contact of the product ingredient or dust with the eyes, rinse them with water. Contact a doctor is recommended in case of irritation.

Do not eat or drink while working with the material. In the event of accidental ingestion of an ingredient of the product, consult a doctor immediately.

Do not pour the liquid down the sanitation system.

Before resuming the product, check if the fluid retains its properties. In the event of visible traces of density change, cloudiness or discoloration, stop using the product.

Information to be provided to patients / orthodontic appliances users

To reduce the residual monomer, it is advisable during the first three days, to soak the orthodontic appliance in water when not in use.

If any symptoms of an allergic reaction or irritation occur, discontinue using the orthodontic appliance immediately and consult a doctor.

Strong oxidizing compounds contained in cleaning agents and mouthwashes may change the color of the orthodontic appliance after polymerization. After each meal, the prosthesis should be washed with a soft brush under cool, running water. For cleaning, can be used unscented soap, various preparations for cleaning and caring for orthodontic appliance that do not contain abrasives. It is recommended to wash the orthodontic appliance from time to time in a vibration bath filled with a special cleaning liquid for dentures.

When not in use, wash the orthodontic appliance and store it in a special denture case.

Do not leave the orthodontic appliance in the sun, near sources of heat and open flames.

The orthodontic appliance may change color or lose its original physical properties when exposed to chemicals or if it is misused.

During use, the orthodontic appliance should be periodically inspected in dental office.

Report any damage of the denture to the dentist. Repairs may be only performed by a dental technician.

If a piece of damaged orthodontic appliance is swallowed, consult a doctor immediately. The material after polymerization is not visible on X-ray pictures.

Side effects

Dental technicians

Irritation, redness or symptoms of hypersensitivity, including the occurrence of anaphylactic shock, in case of allergy to any of the product ingredients.

Patients

Irritation, inflammation and allergic reactions caused by residual monomer washed out of the orthodontic appliance.

Irritation and inflammation of the oral cavity caused by fungi and bacteria adhering to the orthodontic appliance.

Storage conditions

Product and color concentrates are sensitive to temperature and UV radiation. Protect against light and UV radiation.

Store the product components in their original, tightly closed containers, in a dark and well-ventilated room, at a temperature of 5-25 °C, out of the reach of third parties.

Reporting of serious incidents: Any serious incidents related to the products must be reported to the manufacturer and the competent authority in accordance with local regulation.

Data necessary to identify the product and the contents of the package

Reference number, product name, color, package size, batch number and expiry date - imprint on the product packaging.

Cardboard packages, labels, instructions: non-hazardous segregated municipal waste - paper.

Powder; non-hazardous mixed municipal waste.

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