

SOLEBITE S Extra Hard Extra Fast

INSTRUCTION FOR USE

[Warning]

FOR DENTAL USE ONLY

Vinyl Polysiloxanes may cause irritation or other allergic reactions. Not Applicable for patients with sensitive skin and/or efflorescence.

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SOLEBITE S Extra Hard Extra Fast	
PJ8190-EX	2 x 50ml Cartridge 3 x Mixing Tips (Green)
PJ8190-1-EX	1 x 50ml Cartridge

[FORM, STRUCTURE and PRINCIPLE]

[FORM]	PASTE
[MAIN INGREDIENT]	Polydimethylsiloxane, Silicon Dioxide
[PRINCIPLE]	Cured by addition polymerization during mixing of Base and Catalyst

[INTENDED USE]

SOLEBITE S Extra Hard Extra Fast is a vinylpolysiloxane Bite Registration Material for use in the surgery and laboratory. SOLEBITE S Extra Hard Extra Fast helps to relocate the upper and lower models for production of crowns, bridges and other prosthesis.

[INSTRUCTION FOR USE]

[Caution]

- Avoid use of excessive impression materials as it may cause flow into the pharynx or accidental swallowing.
- Pay attention to the gagging/retching reflex when obtaining impressions, use the appropriate response if required.
- Working time and time in mouth change depending on the storage status of the product, room temperature, humidity, only remove the impression after confirming polymerization.
- Have the patient rinse after the use of SOLEBITE S Extra Hard Extra Fast.

[Times for Clinical Use]

SOLEBITE S Extra Hard Extra Fast	
Mixing ratio - Base:Catalyst	1:1
Working time (23°C)	20 seconds
Time in mouth (35°C)	30 seconds
Setting Time (Total time from start of mix)	50 seconds

*The operation time is shorter when temperatures are higher and longer when the temperatures are lower.

1. Taking bite registration

- Insert SOLEBITE S Extra Hard Extra Fast cartridge into a 1:1 dispenser gun.
- Remove cap of the cartridges. [Caution] Cap can be reused, keep clean to avoid cross-contamination.
- Before connecting the mixing tip, ensure that the 2 components (Base and Catalysts) are expressed evenly by applying light pressure on the dispenser.
- Connect the mixing tip and make sure that the tip is properly locked by turned clockwise 90 degrees.

[Caution] Mixing tips are single use only.

- Pull the trigger lever on the dispenser gun to apply SOLEBITE S Extra Hard Extra Fast onto the occlusal surface within 20 seconds.
- Ask the patient to bite down. We suggest applying additional material to the Buccal surface to ensure fine details.
- Leave for 30 seconds until cured and then remove from the patient's mouth.
- Take out the mixing tip from the cartridge and replace the cap.
- Trim unnecessary material.

2. Cleaning and Disinfection

Once impression has been taken, rinse well under running water, then immerse in a solution of glutaraldehyde to disinfect. Always follow the disinfectants manufacturer's instructions.

[STORAGE AND EXPIRY]

1. Storage

Product should be stored in a dry area, out of direct sunlight and in between 0-30°C (32-86°F). Made impressions should be stored at room temperature, avoiding high temperatures and humidity.

2. Expiry

- Expiry date is displayed on the packaging and/or cartridge. (i.e.: 2020-10 represents use before Oct. 2020)

[TECHNICAL DATA]

SOLEBITE S Extra Hard Extra Fast impression materials comply with the requirements of ISO 4823; Dentistry — Elastomeric impression materials.

Base/Catalyst mixing ratio	1:1
Working time (23°C)	20 sec.
Time in mouth (35°C)	30 sec.
Dimensional variation after 24hr	-0.1% or less
Hardness	95 Shore A

[PRECAUTIONS AND WARNINGS]

- Contact with latex gloves may prevent Vinyl Polysiloxanes from hardening. Avoid direct or indirect contact with latex gloves.
- Take care not to stain your clothing as Vinyl Polysiloxanes are chemically resistant.
- In sensitive subjects, Vinyl Polysiloxanes may cause irritation or other allergic reactions. If use of this product causes irritable symptoms such as rash, redness, swelling, itching, etc. stop immediately and seek medical advice.
- Do not use on patients who may have had allergic reactions with SOLEBITE S Extra Hard Extra Fast, Vinyl Polysiloxanes or any similar products. If allergic reactions occur, stop use immediately and seek medical advice.
- Avoid contact with eyes. If product enters the eye, immediately rinse with a large amount of water flow.
- Do not drink this product.

[IMPORTANT REMARKS]

Consulting services on the use of our products, provided in any form, be that verbal, written or through demonstrations, are based upon the current state of dentistry and of our know-how. They are to be considered as non-binding information, also in

whether the product is suitable for the planned use. Use and application by the user take place under no possible control by the Company and are therefore under the user's responsibility. Possible liability for damages is limited to the value of goods supplied by the Company and utilized by the user.

【MANUFACTURER INFORMATION】



Premium Plus Japan Co., Ltd.

5th Floor, 1-1-31, Nishimidorigaoka, Toyonakashi,
Osaka 560-0005, Japan
T: +81 6-6845-0066
info@premiumplus.jp
www.premiumplus.jp



Premium Plus Poland sp.z o.o.

ul. Bukowska 27
62-081 Wysogotowo, Poland
T: +48-61-880-1094
info@premiumpluspl.com



CE marked in accordance with Medical Device Directive 93/42/EEC, amended by 2007/47/EC

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