ImpressPLUS Bite Registration

Instructions for Use

ImpressPLUS Bite Registration is a standard bite registration material based on vinylpolysiloxanes suitable for all types of bite registrations

Product Name	ImpressPlus Bite Registration Material
Company Name	Perfection Plus Ltd
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PRODUCT CODE - REF

PP010/1350 – ImpressPlus Bite Reg Regular set
PP010/1352 – ImpressPlus Bite Reg Fast Set
PP010/1354 – ImpressPlus Bite Reg Super-Fast Set

Indications	• Accurate occlusal registrations • Key material for needle point registration • Production of small model segments		
	Super-Fast Set	Fast Set	Regular Set
Total working time*	0:30	0:40	1:30
Time in mouth	0:45	1:00	3:00
Total setting time*	1:15	1:40	4:30
Dimensional change (%)	<0.1		
Shore A hardness	85		

* **Attention!** Application is at 23ºC ± 2 / 73ºF ± 4, 50 ± 5% relative humidity. Higher temperature reduces working and setting times and lower temperature prolongs them.

Intended Use: Dental Impression material
Use environment: Dental practice
Patient target group: People treated in the course of a dental procedure with no limitations in age or gender.

MOUNTING THE CARTRIDGE

Insert cartridge onto dispensing gun following the manufacturer's instructions and remove cap. Extrude impression material until it exits both chambers at the same rate and then mount the appropriate mixing tip. An intra-oral tip may be placed on the mixing tip.

APPLICATION

Apply bite registration material according to the desired technique (occlusal or buccal). Extrude material first onto areas where teeth have been prepared keeping the end of the mixing tip immersed in the material to avoid the formation of air bubbles and ask the patient to bite. Carefully remove the set bite registration after the recommended time. Remove all residues of the material from the mouth. Trim bite registration to ensure correct seating on model. After use keep mixing tip on cartridge as it serves as a cap. Intraoral tips and mixing tips are for single use only.

DISINFECTING

Once impression is removed from mouth, rinse under lukewarm water. The impression can then be disinfected with appropriate disinfecting solutions or sprays such as 2% glutaraldehyde. Take care to follow the manufacturer's instructions for use. For further information regarding disinfecting impressions: JADA 1991; vol. 122; IS(8); p110. If disinfecting with hydrogen peroxide, thoroughly rinse with lukewarm water to avoid the formation of bubbles.

PRECAUTIONS

- Contact with latex gloves may impair the setting reaction. Vinyl gloves are recommended.
- Eugenol or certain haemostatic materials may impair the setting reaction
- Do not combine with condensation curing silicones, polyether or polysulfide.
- Avoid spillage of material on clothing as it cannot be removed chemically.
- Avoid contact of material with eyes. In case of contact rinse eyes with plenty of water and consult a physician immediately.
- Seek immediate medical attention in case of ingestion
- Do not use after the use-by date

STORAGE

Store material between 10 - 25°C (50 - 77°F).
Store impression at room temperature (max. 25°C/77°F).

LOT NUMBER AND EXPIRY DATE

The above are printed on each package and should be quoted in all correspondence which requires identification of the product.

CONTAINDICATIONS

Application of the above material is contraindicated:

- If a patient is known to be hypersensitive or allergic to any of the ingredients
- If a patient has loose teeth, since they can be further loosened or extracted by taking an impression

DISPOSAL

Dispose of the product according to local regulations as applicable

USERS / FOR PROFESSIONAL USE ONLY

These materials have been developed for use exclusively by dental professionals and must be handled according to the instructions of use. The recommendations included in the instructions correspond to the actual state of knowledge regarding dental techniques. This does not relieve the user from determining the suitability of the product for its intended purpose. The manufacturer cannot be held responsible for damages caused by other uses or incorrect handling.

REPORTING OBLIGATIONS

Should a serious incident in relation to this product occur, it should be reported to the manufacturer and the competent authority.

SYMBOLS GLOSSARY

MD	Medical device	REF	Catalogue number
	Consult instructions for use	LOT	Batch code
	Caution		Use-by date
	Keep away from direct sunlight	UDI	Unique device identifier
	Temperature limit		Manufacturer
	Importer	CE	EU conformity mark
EC REP	Authorized representative in the European Community		

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