


INSTRUCTIONS FOR USE – Impressa/Sure

This IFU is applicable to all current and previous generations of this product

1. IDENTIFICATION OF THE COMPANY

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2. IDENTIFICATION OF THE PRODUCT

Product Name: Impressa/Sure

Product Description: Impression Material

3. INDICATIONS FOR USE

Impressa/Sure is to be prescribed only by licensed dental professional and/or orthodontic professionals to patients during orthodontic treatment.

American Orthodontics' products are used for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

4. CONTRAINDICATIONS & SIDE EFFECTS

American Orthodontics sells products to trained dental professionals and orthodontists. It is the primary responsibility of the dental professional and/or orthodontist to identify any possible contraindications that may preclude the use of American Orthodontics' products. It is also the responsibility of the dental professional and/or orthodontist to determine any pre-starting procedures, as well as working sequence of the medical devices.

It is the primary responsibility of the dental professional and/or orthodontist to identify any possible risk of injury and/or contraindications that may arise during treatment, relay any possible unwanted side effects to the patient and to individualize treatment accordingly. During treatment, unwanted side effects may include: tooth discolorations, decalcification, root resorption, periodontal complications, allergic reactions, difficulties in oral hygiene maintenance, discomfort and pain.

5. PRE-STARTING PROCEDURES

General Recommendations:

The mixing ratio for all kneadable silicones is 1:1. In order to avoid any failures during the hardening process of the kneadable A-silicones, it is recommended not to wear latex gloves when processing them! If the material is packed in tins, please take care that you do not mix up caps and measuring spoons. This could lead to an early hardening of the material inside to tin. (Please take note of the color coding!)

6. STEP-BY-STEP INSTRUCTIONS

Recommendations for the use of the wash technique:

Knead the required quantity of Impressa/Sure (equal quantities of A and B component) until the material develops a homogeneous color. Apply the mixture into a customized impression tray and insert it into the patient's mouth for taking a preliminary impression. After a maximum of 3 min. the impression can be removed.

Use of mixing appliances:

Before its first use, remove the lid and insert cartridge into the mixing appliance (e.g. Impressa/Sure Dispenser 50). Before attaching the dynamic mixing tip, squeeze out a small quantity of the material until some material has come out of both openings. Then put the dynamic mixing tip on the cartridge (please take note of the correct position) and turn the bayonet ring enclosed so that the cartridge is fixed. Now the tray can be filled. Only just before using the material, the dynamic mixing tip is changed; the used mixing tip always remains on the cartridge until next usage.

Recommendations for the final impression

To prepare the final impression, the critical areas of the preliminary impression must be cut off. This concerns mainly the cervical borders of the non-prepared teeth as well as the interdental spaces.

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For correction, the fine-flowing Impressa/Sure cartridges is suitable.

After that the preliminary impression is inserted into the patient’s mouth and, by applying a short vigorous pressure (approx. 10 sec.), it is placed into the correct position. After 3 minutes the impression can be removed.

Additional Information:

- When using hydrophilic silicones, an impression of especially high precision and an unsurpassed surface finish is achieved which is due to its excellent flowing properties, particularly in moist areas. However, even when using hydrophilic silicones, special attention should be paid to the fact that a “drying” of the surrounding areas should take place at any rate!
- To obtain a model of highest surface quality, you should wait about 30 minutes before pouring the model.
- Some hemostatic products may cause irritations during the polymerization of addition-curing silicones!
- **DISINFECTION:**
 - Impressa/Sure impression silicones can be treated with all disinfectants generally used in dental practice (e.g. 2% glutaraldehyde solution).

Physical / technical data	S1	S4
Consistency:	Putty	Light
Color (only component B):	Blue-grey	Violet
Linear Shrinkage (max%):	0.1	0.1
Thixotropic/ hydrophilic:	-/+	+/+
Final hardness (approx. shore-A)	67	45
Mixing time (sec. Tubes/double chamber cartridge):	30	N/A
Working time (approx. min:sec from beginning of mixing):	2:00	2:00
Setting time in the mouth (max. approx. min:sec)	>2:30	>2:30
ADA 19, type 1 ISO 4823, type:	Type 0	Type 3

7. RECOMMENDATIONS FOR STORAGE

Impressa Sure impression silicones can be stored at a maximum temperature of 25°C, larger quantities should be stored at cellar temperature (approx. 18 °C)

The addition-curing Impressa/Sure impression silicones have a shelf life of 3 years, please see the best before date on the package.











8. ENVIRONMENTAL RECOMMENDATIONS

Small quantities of cured Impressa/Sure impression silicones do not present any ecological problem when they have hardened and small quantities of this material (e.g. material for one impression) may be disposed of with household refuse. Non-cured silicones must be cured (hardened) before being disposed of!

9. SERIOUS INCIDENT REPORTING

If, during the use of this device or as a result of its use, a serious incident has occurred or a product performance issue has been observed, please report it to the manufacturer and/or its authorized representative or your local affiliate, and to your national authority.

10. REGULATORY INFORMATION

	MANUFACTURER		NOT STERILIZED
	RX ONLY		MEDICAL DEVICE
	KEEP AWAY FROM DIRECT SUNLIGHT		REF NUMBER
	SINGLE USE ONLY		LOT NUMBER
	STORE BELOW 25°C		CONSULT INSTRUCTIONS FOR USE