

1. IDE000487FICATION OF THE COMPANY

Company Name

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

24 HR EMERGENCY TELEPHONE NUMBER

(920) 457-5051

Telephone for Information

(920) 457-5051

2. IDENTIFICATION OF THE PRODUCT

Product Name: Impressa/Sure Impression

Product Description: Impression Material

Product Part Number: REF 861-136, 861-137

CAUTION: Federal law restricts this device to sale to or on the order of the dentist/orthodontist.

3. INDICATIONS FOR USE, DOMAIN OF USAGE

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

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. This will include any sterilization procedures.

5. SIDE EFFECTS

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.

6. 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!)

7. 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.

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

8. 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.


9. 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!

10. WARRANTY LIABILITY

Buyer’s remedies with respect to any claim arising out of any defect in any goods or services shall be limited exclusively to the right of repair or replacement of such goods (at the seller’s option) or to repayment of the purchase price thereof. In no event shall seller be liable for any consequential or incidental damages including lost profits incurred by buyer with respect to any goods or services furnished by seller. Claims for damage or shortage must be made within 30 days of receipt of order.

10. REGULATORY INFORMATION

 American Orthodontics • 3524 Washington Avenue • Sheboygan, WI 53081 • (920)457-5051

 SEE INSTRUCTIONS FOR USE

 NON STERILE

 SINGLE USE

 KEEP AWAY FROM DIRECT SUNLIGHT

 STORE BELOW 25°C

 Only

SEE WWW.AMERICANORTHO.COM FOR SYMBOL GLOSSARY

The information contained in the IFU is believed to be valid and accurate. American Orthodontics, however, makes no warranty, either expressed or implied, as to the completeness of information in all possible conditions. Reasonable safety precautions must always be observed.