

INTENDED USE:

Primary impression in edentulous patients for fabrication of complete dentures.

COMPOSITION:

Resin, Gum Damar, Fillers, additives, Pigment and Excipients

PRODUCT DESCRIPTION & PROPERTIES:

Impression compound is a type-1 low fusing thermoplastic material supplied in the form of cake or disc (type-1 low fusing impression compound). Attains high viscosity at comfortable temperatures 60-65°C makes it ideal for recording primary impression during preparation of removable complete denture prosthesis. It adapts well to the oral tissues recording the details clearly to give a sharp impression on cooling. Rapidly cools down on contact with saliva or water and develops resiliency that minimises the risk of distortion during removing the impression from the patient's mouth.

PROCEDURE:

1. Immerse the required quantity of Impression compound in warm water (60 °C) and allow the material to attain a softer consistency.
2. When softened knead thoroughly with fingers and adapt it to the dry edentulous impression tray.
3. Before inserting the impression tray-with compound into the patient's mouth allow it temper down by placing it in lukewarm water enough to keep the impression compound at softer consistency.
4. Apply a thin film of lubricant gel on the surface to facilitate the release of Impression from the mouth
5. Insert the impression tray-with compound into the patient's mouth and record the details by application of mild pressure in load bearing areas over the tray, the borders can be recorded by asking the patient to make the muscular movements of cheek, lip and tongue.
6. Remove the impression tray from the patient's mouth once the impression compound attains the plasticity as it cools down.
7. After removal, put the tray with recorded impression into bowl of cold water to stabilize the impression and prevention from distortion.

CAUTION / WARNING:

1. Softened / Molten Impression compound may cause burns to skin if it comes in contact with skin, it may also cause burn injury to oral mucosa if it is overheated.
2. If impression compound is heated above 100°C while heat source remains active, it may ignite and burn on its own.
3. Ensure device to be used only by a qualified dentist or dental technician.
4. Inhalation of hot vapours for impression compound should be avoided.
5. Impression compound should be inserted into a patient's mouth for a short time and not continuously.

6. When a direct flame is used to soften the impression compound, the compound should not be allowed to boil or ignite. Prolonged immersion or overheating in the water bath is also not indicated; as the material may become brittle and grainy.
7. The excess Impression compound can be cut using a warm wax knife or any sharp instrument when it is hardened. While soft, one should not try to cut it as it can dislodge the entire mass of the compound from the place and leave traces on tray surfaces.
8. The recommended disinfectant solution for the compound is 2% chlorhexidine solution.

PRECAUTIONS

- 1) Avoid prolonged or repeated contact of soft impression compound with skin (allergic contact dermatitis). Avoid contact with eyes. Avoid inhalation of the fumes. Do not take internally.
- 2) Skin Contact: If hot material comes in contact with Skin, it may cause skin burn / sensitization, if contact with skin occurs immediately remove excess material and pour water on contacted part. If skin rash and sensitization or other allergic reaction occurs seek medical attention.

CONTRAINDICATION:

It should not be used with patients who have a history of severe allergic reaction to any of the components.

INTERACTIONS WITH OTHER DENTAL MATERIALS :

No such Reactions Noted . Kindly communicate and inform manufacturer in details of any instance.

ADVERSE REACTIONS :

No such Reactions Noted . Kindly communicate and inform manufacturer in details of any instance.

STORAGE CONDITIONS:

- 1) Keep Away from Direct Sunlight
- 2) Keep locked up and out of the reach of children.
- 3) Store at Temp. between 10°C to 40°C
- 4) Shelf life not affected after opening if stored in a cool dry place.

DISPOSAL CONDITIONS:

Dispose in accordance with local, state and federal environmental regulations.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel.

Manufactured by: Shiva Products

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





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Revision	05
Date	02-01-2021

These instructions for use should be kept for the duration of product use.

-  Symbol for "BATCH CODE"
  Symbol for "USE BY"
  Symbol for "NON STERILE"
  Symbol for "KEEP DRY"
-  Symbol for "CONSULT INSTRUCTION FOR USE"
  Symbol for "CATALOGUE NUMBER"
  Symbol for "HANDLE WITH CARE"
-  Symbol for "EUROPEAN COMMUNITY AUTHORIZED REPRESENTATIVE"
  Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"
-  Symbol for "KEEP OUT OF THE REACH OF CHILDREN"
  Symbol for "MANUFACTURER NAME & ADDRESS"
-  Symbol for "TEMPERATURE LIMITATION"
  Symbol for "KEEP AWAY FROM SUNLIGHT"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding.