

DD medical polymers (PMMA)



US Instructions for Use

DD Bio Splint P HI / DD base P HI

1. Indications

DD Bio Splint P HI are transparent dental milling blanks out of PMMA for the manufacture of splints, therapeutic splints and bite regulators for long-term application in the oral cavity up to 12 months.

DD base P HI are pre-colored dental milling blanks made of impact-resistant PMMA for the manufacture of denture bases for removable dentures. DD base P HI is suitable for long-term use in the oral cavity for up to 10 years.

2. Contraindications

DD Bio Splint P HI / DD base P HI

- Intolerance to the contained components
- Crowns, bridges, model casting with clasps, bars, narrow sublingual bars and transversal connectors

3. Safety information

Avoid inhalation of milling dust during processing. In case of Inhalation: Move subject to fresh air. Give oxygen or artificial respiration as required.

Avoid all contact with fluids. Wear gloves, protective goggles and a face mask to avoid skin irritation. In case of eye contact: Flush eyes promptly with copious amounts of water for 15 minutes and consult a physician. Wash skin with soap and water.

In case of ingestion: Contact your regional Poison Control Center immediately.

4. Handling and storage

Carefully read the separate instructions for use before starting work with the polymer. The medical device may only be processed by trained personnel. Only use clean, defect-free material from undamaged packaging and ensure that the blanks are stored at room temperature, in their original cartons, in a dry location and protected from light.

5. Construction

DD base P HI denture bases should be positioned in the center of the milling blank and minimum wall thickness should not fall below 1 mm.

6. Milling and further processing

Milling must be performed using a milling strategy that is aligned with the material.

Only use a single-edge cutter for the milling process, or cooled wet milling process!

Carbide cutters with FSQ toothing and black ring cutters are well-suited to the rough cutting for titanium. The fine post-processing can be performed using simple, cross-toothed HM cutters. It is possible to polish the material; however, the contact pressure should be kept as low as possible since the resulting heat could otherwise result in smearing or melting.

DD base P HI - Detailed information regarding the preparation of the gluing areas, extension, relining and repair, can be found in the current version of the instructions for use in the Download Center at: www.dentaldirekt.de/en/downloads.

7. Cleaning

- Ultrasonic bath (max. 40°C) with a gentle cleaning agent

The following should not be used for cleaning:

- Steam jets
- Autoclaves, e.g. for sterilization and disinfection (DD Bio Splint P HI / DD base P HI)
- Organic solutions and acids (e.g. acetone, hydrochloric acid)
- Highly concentrated rubbing alcohols
- Chemical denture cleaners
- Abrasive cleaning agents

For more detailed cleaning information, please refer to the latest version of the instructions for use in the Download Center at:

www.dentaldirekt.de/en/downloads.

8. Disposal

The rest of the blank material can be placed in the recycling bin.

9. Warranty

Our devices are subject to strict quality controls and reflect the current state of technology.

Note: Any serious incident that has occurred in relation to the devices should be reported to the manufacturer and the competent authority to the Member State in which the user and/or patient is established. We are continuously enhancing our devices and therefore reserve the right to make changes.

The latest version of the instructions for use can be found on our website at: www.dentaldirekt.de/en/ifu.

This version replaces all previous versions.

Explanation of symbols:

Manufacturer



Date of manufacture

Consult electronic instructions for use
www.dentaldirekt.de/IFU

Use before



Batch code



Catalog number



Keep away from sunlight



Keep dry



Medical Device



Content (Quantity)

Caution: U.S. Federal law restricts this device to sale
by or on the order of a dentist