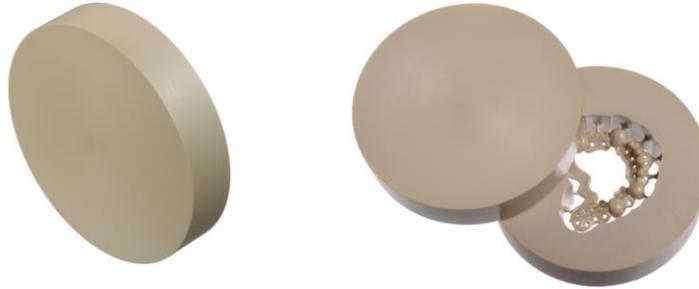


Instructions For Use

CE 0120

Device: JUVORA™ Dental Disc



Caution: US Federal Law restricts this device to sale by or on the order of a dentist

Indications

- For the manufacture of full and partial removable dentures and implant overdentures.

1. Telescope



2. Attachment



3. Overdenture



Contraindications

Not to be used in permanent (i.e., cemented or implant retained) crowns, caps, bridges or superstructures

Precautions

To be manufactured with material thickness/size in accordance with the following:

- The minimum thickness of secondary crowns and matrix housings should not be less than 0.6 mm
- The minimum thickness for “conventional” retention grids should not be less than 1.2 mm.
- Minimum size of horizontal retainer in lower jaw 5 x 2 mm
- Minimum size of horizontal band in upper jaw 2 x 8 mm

Material Information

JUVORA™ Dental Discs are manufactured from Invibio PEEK-OPTIMA® LT1 polymer, a Type 3 thermoplastic according to ISO 20795 – Denture Base Polymer.

Form:	Solid
Colour:	Grey/Brown
Odour:	Odourless
pH (Value)	Not known
Boiling Point (°C):	Not known
Melting Point (°C):	343
Flash Point (°C):	Not known

Auto Ignition Temperature (°C):	595
Oxidising Properties:	Not applicable
Vapour Pressure (Pascal):	Not known
Density (g/ml):	~1.3
Solubility (Water):	Insoluble

Processing Instructions

Detailed processing instructions are provided and must be observed by the end users (dental labs and technicians) when milling frameworks from the JUVORA™ Dental Disc. Dental labs that are supplied with the disc will be certified through JUVORA™ Ltd, a process that involves assessment of their capability to follow the processing guidance to manufacture high quality frameworks and finished dentures where applicable using their existing equipment. This assessment will be completed by JUVORA™ Ltd or their certified milling centres.

Production

JUVORA™ Dental Disc blanks can only be processed on suitable milling machines with appropriate milling programs. The milling head must be suitable for machining PEEK polymer. JUVORA™ Ltd recommends suitable adaptation of the CAM software by the software manufacturer to allow milling of the JUVORA™ Dental Disc. For an exact fit, a 5-axis milling machine is recommended. JUVORA™ Ltd also recommends cooling the milling head for more accurate milling and to prolong its useful life.*See footnote.

Prosthesis removal from the Dental Disc

Remove the prosthesis carefully from the blank using a hard metal cutter, and pay particular attention to the edges of the prosthesis.

Safety Information

While machining the JUVORA™ Dental Disc, the following safety precautions are recommended:

- Dust mask or dust extraction
- Personal protective equipment (eye protection, gloves)

Storage Information

The JUVORA™ Dental Disc should be stored in dry storage and avoid exposure to direct sunlight. The PEEK-OPTIMA® polymer from which the JUVORA™ Dental Disc is made is stable and can be stored for an extended period of time (10 year shelf life). It has a working temperature range from cryogenic up to 250°C and hence the storage temperature range for the JUVORA™ Dental Disc is any ambient temperature and humidity.

Additional Information

For additional information contact info@juvoradental.com

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*Note: Follow the instructions of your machine manufacturer regarding the processing of JUVORA Dental Discs