Instructions of use innoBlanc ® medical PEEK Juvora –
High performance polymer for the CAD/CAM technology

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1. General product specification
innoBlanc ® medical PEEK Juvora discs are industrially highly-meshed, homogeneous milling discs made of highly biocompatible, pure PEEK Optima ® LT1 polymer of the company Invibio for the CAD/CAM technology for the production of metal-free, removable restorations for all indications I the combination technique, clasp-fixed structures (“model casting”), conditional removable constructions on implants and glued / cemented frameworks. PEEK Optima ® LT1 polymer has been used with great success since many years in orthopedy, vascular surgery and anaplasty.

- innoBlanc ® medical PEEK Juvora is configured for the permanent stay in the oral cavity.
- In case of appropriate dimensioning and construction, innoBlanc ® medical PEEK Juvora is suited as replacement for various structures which were up to now made with either alloys or zirconium dioxide.
- The material can be combined with itself or with other non-metallic and metallic materials by gluing or veneering.
- Due to its high breaking strength and stiffness and at the same time elasticity and ductility, it ideally suits the anatomical and mechanical circumstances of the stomatognathic system.
- Due to its bone-similar behaviour and the bone-similar density, innoBlanc ® medical PEEK Juvora is allowed to be classified as body-similar (bionic). Structures made of innoBlanc ® medical PEEK Juvora are light, comfortable to wear, free of hot-cold feelings, chemically inert and show no electro-chemical, galvanic reciprocal effects with other, dissimilar materials in the oral cavity.
- Due to its low coefficient of friction and the excellent abrasion resistance, the material fulfills the ideal, constant tri-biological characteristics (e.g. at telescopes) and shows a physiological abrasion behaviour in case of antagonistic contacts.
- Due to the damping effect and the very good resistance against erosion, it is excellently indicated for chronic bruxism in terms of bars or unveneered masticating areas.

Available measures
Strength of the disc 16mm / 20mm / 25mm
Blocks are under preparation

Available colours
Grey-brown

2 Material composition
Polyether ether ketone – pure, without additional additives (such as e.g. colour pigments, zirconium dioxide, nano-glasses or glass fibres)

3 Notes for indications and application duration
Removable and under certain conditions removable
- Clasp-retentive restorations (“model casting”), telescopic structures
- Intermediate friction caps
- Thin prosthetic bases (e.g. total prosthesis)
- Internal one-piece bases on primary parts of zirconium dioxide in case of cover denture restorations
- Attachment structures
- Screwed, implant-carried supra constructions in posterior and anterior region
- Fully anatomical masticating areas (ideally suited at bruxism)

The material can also inserted not veneered from basal

Revision 03 / 3.2014
Fixed / cemented
Fixed crowns and bridges are possible, however, you absolutely have to take the material-specific characteristics under consideration (see point 4 – design of prosthetic constructions)

4 Design of the prosthetic constructions

In general
PEEK is a partial crystalline high performance polymer. At a sufficient dimensioning, these materials have a very high stiffness at a low remaining elasticity. At appropriate construction, PEEK has a high impact resistance. The listed characteristics must be taken into consideration for all constructions.

Too thin constructions that would promote a too high remaining elasticity, bear the risk of cracks at the transition between veneering material and finishing resins to the base material.

Sharp edges, e.g. of end margins or the scratches and engravings of the cutting wheel, e.g. at interdental connections, have to be avoided.

Construct all geometries and edges round with soft transitions.

Take as rule of thumbs: Dimensioning of the non-precious metal constructions plus 20-30% = dimensioning of the PEEK construction

Design of crowns and bridges

- Dimension the connectors in a way that no appreciable, elastic deformation of the bridge occurs.
- Round all transitions, edges and cavities (e.g. of interdental connectors) so that no notch effects occur.
- Observe the cementing rules to avoid loosening (see: surface conditioning and cementing).
- Observe the connection techniques (see: surface conditioning and veneering).
- If possible, design garlands in the oral area (180°) or ¼ backrest plates.

Design of primary parts – crowns

Important note to primary parts of alloys

PEEK is an exceedingly abrasion-resistant material. At the connection with primary parts made of metal and secondary parts of PEEK, it may come to an abrasion of the alloy at the PEEK material.

Therefore, we recommend to produce the primary telescopes and bars of zirconium dioxide or PEEK.

Primary telescopes

- Design primary telescopes parallel, with 0° wall.
- Minimum height of the friction area – 3mm.
- If possible prepare a step with slight chamfer (as in case of galvano).
- Mill / polish primary parts to high glaze.
- Ring telescopes are possible (take care of the wall thickness of the secondary part).

Design of primary parts – bars

- Design the primary bar with 0° wall. Conical diminution in the occlusal area as insertion assistance.
- Height of the bar: min. 4mm
- Width of the bar: min. 3mm
- Distance between 2 implants at these measurements: max. 20mm

Bars and Locators or friction aid

Ideal completion at the bar technique is the prophylactic construction of additional, frictive, metal-free elements as they are provided in the common CAD programs (e.g. Preci Vertix or Preci Horix).
They realize an even further friction and own a certain damping effect.

Secondary constructions with transversal ribbons and sublingual bows - single piece or several parts in gluing technique

If your CAD and CAM software is suited for such constructions, it is possible to produce single piece, secondary and tertiary constructions. The material also allow the separate construction of secondary parts with gluing adaptors and “model casting” parts with corresponding cavity shares.
These can be permanently fixed with glues, such as e.g. Panavia (Kuraray), Multilink Implant (Ivoclar) or Vario Link (Ivoclar) or similar products. (Please essentially take the conditioning of the PEEK base material into consideration).

Advantages of separate constructions

Separate constructions have their advantages. So, in case of need, all frictive elements can be after-milled separately. This can be necessary due to a
collective impression, differences of fit or in case one frictive part has a different friction than the other elements caused by the cumulated abrasion of the millers.

A combination of existing non-precious metal model casts with frictive elements made of innoBlanc® medical PEEK Juvora is also possible.

Clasp-impacted structures ("Model casting")

In general, all clasp model castings known from the casting technique can be designed with innoBlanc® medical PEEK Juvora.

Design the non-precious metal castings according to the rule:
Dimensioning of the non-precious metal constructions plus 20-30% = dimensioning of the PEEK construction

- Minimum strength of conventional hole retentions  1,2mm
- Minimum size of the transversal bow in the lower jaw  5x2mm
- Minimum size of the transversal bow in the upper jaw  2x8mm

Note for transversal connectors and upper dentures: In case of total upper jaw plates the strength of the plate can be reduced to max. 1,0mm.

Please consider the following specifications which are different to spring hardened non-precious metal alloys:

- Classical n ey-rules can vary or can be avoided, as innoBlanc® medical PEEK Juvora has a considerably different behaviour with regard to elasticity, restoring- and abrasion behaviour of spring hardened alloys for clasp model casting.
- If possible, exploit completely the undercuts below the equator.
- Clasps can be designed clearly expanded in order to reduce their thickness.
- If possible, design oral clasp parts like back protector plates of ribbons.
- If possible, design the clasps closed.
- Design all margins and retentive areas (e.g. margin borders, garlands, interdental spaces) rounded, with chamfer and with soft transitions.

innoBlanc® medical PEEK Juvora as replacement for galvano gold

The material is ideally suited as a replacement for all frictive elements produced with galvano technology.
Due to the small density (factor 14,5 lower than galvano gold) and the low material price a considerably saving of material is caused (see chart)

<table>
<thead>
<tr>
<th>Material</th>
<th>Density g/cm³</th>
<th>Weight Example: 5 identical frictive caps in 0,3 mm</th>
<th>Price of the Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>innoBlanc® medical PEEK Juvora</td>
<td>1.32</td>
<td>0.3 Gramm</td>
<td>ca. 8 €</td>
</tr>
<tr>
<td>Galvanogold</td>
<td>19.3</td>
<td>4 Gramm</td>
<td>ca. 300 €</td>
</tr>
</tbody>
</table>

Design for the Veneering

Secondary parts, that are not framed in a tertiary construction, as well as crowns and bridges should not undergo a wall thickness of 0,6mm. Ideally suited is the construction of garlands and fine margins in the neck area of the tooth (labial or circular), if possible.
Clear veneerings from vestibular are possible at a sufficient strength of the framework. In this case, apply a watch glass frame with a smooth chamfer.

- Design a watch-glass frame.
- If possible, mill retention pearls or a scratch structure during the CAD/CAM process ("rice terrace design").
- Do not design notches, sharp retentions (notch effect.)
- If possible, design a thin, labial or circular shoulder (1mm).
- A complete "veneering" according to the multilayer design (split file technology – gluing of the frame and crowns – e.g. PEEK frame and composite.
- Crowns of innoBlanc® occlusal is ideally suited.
- No antagonist contacts in the transition area frame/veneer.

(see also individualization / veneering)

Recommended geometries for the frame construction

Note: extend the connectors to the most possible measurements!
As benchmark for the dimensioning of the frame the measurements for the theoretically identical non-precious metal frame + 20-30% are valid.
- Minimum thickness of secondary crowns and cavity box 0,6mm
- Intermediary telescopic caps as galvano replacement 0,2-0,4mm
- Minimum thickness of “conventional” hole retentions 1,2mm
- Minimum size of transversal bows in the lower jaw 5x2mm
- Minimum size of transversal bows in the upper jaw 2x8mm

Note for transversal connectors and upper dentures: In case of total upper jaw plates the strength of the plate can be reduced to max. 1,0mm.

5 Manual processing and polishing

<table>
<thead>
<tr>
<th>In general, this is valid:</th>
<th>Use sharp milling instruments. A material friendly removal of PEEK with blunt or used milling instruments is aggravated or not possible.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Work with low pressure and average rotation speed (10-20.000 turns per minute)</td>
</tr>
<tr>
<td></td>
<td>You absolutely have to avoid a notching of the material with sharp instruments or cut-off wheels (e.g. finishing margins at “model casts”, interdental connections, etc.)</td>
</tr>
</tbody>
</table>

For rough treatments with the technique hand piece we recommend special milling instruments like you use them for the treatment of non-hardening materials such as e.g. Acetal (e.g. FSQ milling instruments). Black ring milling instruments for titanium are also ideally suited. At an adequate use, also sharp twist drills which are also used for the RSS technique, can be used in certain areas.

For the fine preparation use your common cross-linked hard metal millers (black, green, yellow or red ring).

For the preparation of the high gloss polish use your classical abrasive cloth up to 1000µm grain and fine or medium-fine pumice flour. Gummy rubbers entail the risk of a smearing of the surface.

High glaze can be obtained e.g. with Sidol, Viss or suited polishing pasts.

CAD/CAM Treatment

innoBlanc ® medical PEEK Juvora can either be milled with all popular milling strategies used for thermoplasts and the appropriate milling instruments.

It is important to work with sharp milling tools especially at the precise fitting parts of a construction.

Note: In comparison with other thermoplasts, innoBlanc medical PEEK Juvora has a very high softening temperature of 343°C. But nevertheless you have to take care that there is no high entry of warmth into the material during the milling Process, e.g. because of a too high rotation speed or due to a too high feed.

Punctual, strong overheatings can discolour the material or can cause local damages of the structure.

Especially in case of parts with thin walls (e.g. frictive caps with 0,2-0,3mm) and owing to the circumstances it can cause small changes of the shape.

In case of fitting parts as e.g. bar rides or secondary telescopes, it is important to apply the last layer with a small lining (e.g. 0,05mm) to get a preferably smooth, plane surface.

At thin parts which can avoid the pressure of the milling instrument it is recommended to treat at first the fitting side where an after-treatment should not be mate, is treated completely to the end finish (e.g. inner side of a clasp, inner side of friction caps), and then the outer side is treated.

6 Surface conditioning before coating / veneering / gluing / finishing / cementing

Preparations of the surfaces

Note: innoBlanc ® medical PEEK Juvora is highly resistant against chemical factors. The surface is very dense and plain, the structure is compact and there are no free chemical connections on the surface. This aggravates the chemical connection with other polymers such as cold polymerisates. An optimum conditioning of the surfaces before the veneering or gluing is therefore absolutely necessary and essential.

Conditioning

The surface must be free of grease. The incorporation of roughnesses, e.g. by leaving the last fine feed of frames is of advantage.

You have to work with a bonding system. An ordinary blasting is not sufficient for an optimum adhesion and/or the avoiding of cracks.

Ideally suited is the conditioning of all functional surfaces with the Rocatec System (3M Espe) or alternatively with Visio Link (Bredent). You will find all further tested combinations in the chart.
As ideally proved we found the use of so-called base-or foundation opaquer, as they grant an optimum moistening of the surface due to their viscosity.

<table>
<thead>
<tr>
<th>System</th>
<th>Surface treatment</th>
<th>Bonder</th>
<th>Opaquer</th>
<th>Veneering</th>
</tr>
</thead>
<tbody>
<tr>
<td>JUVORA certification System I</td>
<td>ESPE Rocatec plus</td>
<td>ESPE (ESPE Sill)</td>
<td>GC</td>
<td>Gradia GC oder</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bredent Visiolink</td>
<td></td>
<td>anaxdent flow</td>
</tr>
<tr>
<td>JUVORA certification system II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clearfill/ESPE</td>
<td>Aluminiumoxid 2bar/50µm</td>
<td>Clearfill Alloyprimer</td>
<td>Clearfill Opaker</td>
<td>3M Espe Sinfony</td>
</tr>
<tr>
<td>Shofu</td>
<td></td>
<td>Shofu Photo Primer</td>
<td>Shofu Flow Opaker</td>
<td>Shofu Solidex</td>
</tr>
<tr>
<td>Shofu Ceramage</td>
<td></td>
<td>ML Primer</td>
<td>Pre/Opaker</td>
<td>Ceramage</td>
</tr>
<tr>
<td>Heraeus Signum</td>
<td></td>
<td>Heraeus Signum</td>
<td>Heraeus Signum Opaker</td>
<td>Heraeus Signum</td>
</tr>
<tr>
<td>Heraeus Signum</td>
<td></td>
<td>Metaillbond I und II</td>
<td>Opaker F</td>
<td></td>
</tr>
<tr>
<td>3M ESPE Sinfony</td>
<td>Rocatec Plus</td>
<td>Espe Sill</td>
<td>Sinfony</td>
<td>Sinfony</td>
</tr>
<tr>
<td>IVOCLAR Adoro</td>
<td>Aluminiumoxid 2bar/50µm</td>
<td>SR Link</td>
<td>SR</td>
<td>SR Adoro</td>
</tr>
<tr>
<td>GC Gradia</td>
<td></td>
<td>GC Metallprimer II</td>
<td>GC</td>
<td>GC Gradia</td>
</tr>
<tr>
<td>Schütz Ar+B Komposit</td>
<td></td>
<td>Bonding fluid</td>
<td>Opake Paste</td>
<td>A+B Komposit</td>
</tr>
<tr>
<td>Bredent VisioLine</td>
<td></td>
<td>Visiolink</td>
<td>Combo lien</td>
<td>Crea lien</td>
</tr>
</tbody>
</table>

Please ask the manufacturer of your bonding system, if an intra-oral application is also possible (e.g. CRB Bonder, Shofu and Visio Link of Bredent)

7 Veneering

innoBlanc® medical PEEK Juvora can be individualized with the common veneering and composite materials, gingiva parts of partial or complete prostheses can be finished with cold- and warm polymerisates.

The use of a veneering resin with identical or similar modulus of elasticity like the frame material is ideal. In case of removable dentures this is necessary to avoid cracks or a separation of very brittle resins (e.g. highly filled composite) due to the intrinsic mobility of the construction.

For removable constructions, we therefore recommend a complete or ¾ veneering (garland 180°) of crowns or frames and the application of a circular shoulder (1mm).

Also gluing of e.g. milled composite over-crowns in multilayer technology which are designed in split file technique e.g. in the 3shape DentalDesigner is possible.

8 Individualization and plaque vulnerability

Although innoBlanc® medical PEEK Juvora is a highly biocompatible, surgically used bio material, the plaque adsorption is minor. Adsorbed plaque can be removed very easily with cleaning tabs.

For patients with bruxism a fully anatomic, monolithic construction of masticating areas can absolutely be indicated. This achieves advantages for the function and also a certain damping effect.

Note:
Light hardening colours for the individualization or light hardening varnishes increase under certain circumstances the risk of a plaque settlement.

The best protection against plaque vulnerability and superficial discolourations of innoBlanc® medical PEEK Juvora is a homogeneous, by polishing compressed surface of the pure basic material.

9 Extra oral agglutination (e.g. post & core, components in the multilayers' technology)

Preparation of innoBlanc® medical PEEK Juvora

See item 6 preparation of the surfaces

Preparation of zirconium dioxide frames
- Blast the surface carefully with aluminium oxide, 50 µm at 1-1.5 bar pressure
- Degrease with acetone or ethyl acetate (one-time brush, q-tip). Ventilate well.
- Silanization/application of primer (e.g. Monobond plus (Ivoclar), Alloy Primer (Panavia/Kuraray), Metal Primer (GC) or similar products.

Preparation of adhesive build-ups made of titanium
- Blast the surface careful with aluminium oxide, 50 µm at 2.5 bar pressure
**10 Chemical Duration / Cleaning and Sterilization**

PEEK is resistant against almost all organic and inorganic chemicals. Up to approx. 280 °C it is also resistant against hydrolysis. It is inconstant against durable UV-radiance (discolouration), concentrated nitric acid, generally against acid oxidizing conditions and against some halogenated hydrocarbons, and also against aliphatic carbon hydride at higher temperatures. In concentrated acid sulphur, it already dissolves at room temperature.

**Steam Cleaning**
Due to its very high softening temperature of 343°C, **innoBlanc® medical PEEK Juvora** is thermically very resilient.

**Sterilization and Disinfection**
Parts made of **innoBlanc® medical PEEK Juvora** can be sterilized in the autoclave with all common systems and techniques.

**Cleaning**

**Fixed Denture**
Use medium-hard toothbrushes / tooth cleaning brushes and non-abrasive tooth paste.

**Removable Denture**
The use of medium-hard tooth brushes and a non-abrasive tooth paste or mild cleaning soaps or suited cleaning tabs are sufficient.

**11 Storage/store conditions**

**Ideal storage temperature**
No extreme temperatures, optimal are 15 - 20 °Celsius.
10 - 40 °Celsius is unproblematic.

**Environment**
Dry, no humidity, no high air dampness, storage in the inside area.

**Light**
No direct sunlight, no illuminants with high UV-percentage, dimming is optimum.

**Resistance and contamination**
Contact with other substances, as e.g. with oils, greases or solvents, has to be avoided.

**Maximum durability of the disc without loss of the material qualities at the store conditions given above:**
5 years.

**12 Disposal**
The milled-out discs can be disposed of over the domestic rubbish.

**13 Final remarks**
All details are based on the research results of the company Juvora, clinical tests, our own experiences and details out of the literature. The statements and recommendations made do not lay any claim to completeness. We reserve the right to change these instructions of use due to new findings about the material and the applied techniques.

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