ENA CAD Composite Disks and Blocks Instructions

Contents

ENA CAD Composite Disks and Blocks

Specifications

- **Product Name:** ENA CAD Composite Disks & Blocks
- **Material:** Radiopaque, ultra-hard composite material with ceramic-based optimized, high-density filling technology
- **Usage:** Production of inlays, onlays, veneers, crowns, bridges (max. one pontic), and partial crowns in CAD/CAM technology

Product Usage Instructions

Indications

ENA CAD Disks & Blocks are indicated for the production of inlays, onlays, veneers, crowns, bridges (max. one pontic), and partial crowns in CAD/CAM technology.

Contraindications

The application of ENA CAD Disks & Blocks is contraindicated when:

- There is a known allergy to components of ENA CAD
- The required application technique is not possible
- The required machine template for milling could not be adhered to

Important Working Instructions
Always use the intended machine templates to prevent overheating of the material. Failure to do so can lead to damage and deterioration of physical properties.

Veneering
The surface can be veneered with light-cured K+B composite after proper activation. Refer to the manufacturer's recommendations for guidance.

Attachment Cleaning
Clean the polished restoration in an ultrasonic cleaner or with a steam cleaner. Dry gently with an air syringe.

Storage Life
The maximum storage life is printed on the label of each packaging unit and is valid for storage at the prescribed temperature.

ENA CAD COMPOSITE DISKS & BLOCKS

USA: RX only. If there is anything in this instruction for use that you do not understand, please contact our customer service department before using the product. As the manufacturer of this medical device, we inform our users and patients that all serious events occurring in connection with it must be reported to us (the manufacturers) as well as the relevant authorities in the Member State where the user and/or patient is resident.
ENA CAD is a radiopaque, ultra-hard composite material with a ceramic-based optimised, high-density filling technology.
ENA CAD is available as Disks and Blocks in different colours for use in CAD/CAM technology, and can be used for the production of inlays / onlays, veneers, partial crowns, as well as crowns and bridges (max. one pontic).

General information

The information provided in this instruction manual must be passed on to any person using the products mentioned therein.
The products must only be used by qualified personnel. The user is obliged to use the products in accordance with the present instruction manual and with appropriate hygiene measures and to verify on his / her own responsibility whether the products are suitable for the individual patient situation. The user will be held fully responsible for the appropriate and correct use of the products. The manufacturer assumes no liability for incorrect results in form of direct or indirect damages or any other damages that occur from the use and / or the processing of the products. Any claim for damages (including punitive damages), is limited to the commercial value of the products.

Independently of this, the user is obliged to report all serious incidents that occur in connection with the products to the competent authority and to the manufacturer.

Delivery size Disk

- Height: 10 mm, 15 mm, 20 mm • Diameter: 98.5 mm

Delivery size Blocks

- Height: 18 mm • Length: 14,7 mm • Width: 14,7 mm

Composition

The main component of the composite is based on highly cross-linked polymer blends (urethane dimethacrylate and bu-tanedioldi-methacrylate) with like inorganic silicate glass filling material with an average particle size of 0.80 µm and a variation range of 0.20 µm to 3.0 µm embedded to 71.56 % by weight (guideline). Stabilisers, light stabilisers and pigments are also included.

Indications
Production of inlays, onlays, veneers, crowns and bridges (max. one pontic) and partial crowns in CAD/CAM technology.

Contraindications
The application of ENA CAD Disks & Blocks is contraindicated, when:

- there is a known allergy to components of ENA CAD
- the required application technique is not possible
- the required machine template for the milling of the Disks / Blocks could not be adhered to.

Type of application

The ENA CAD Disks & Blocks is fixed in previously cleaned clamp in accordance with the instructions of the machine manu-facturer. In doing so, attention must be paid to the correct positioning. ENA CAD is compatible with imes-icore, VHF N4, S1 & S2 mills and other mills. The milling/grinding procedure and the associated machine templates can be requested at the respective machine manufacturer. Make sure during any work that the average sharpness of the cutter used is adequate for the planned milling work.

For crowns and bridges, the following values must not be undercut:

- Wall thickness cervical: at least 0,6 mm
- Wall thickness occlusal: at least 1,2 mm
- Connecting bar profiles in the anterior teeth area: 10 mm^2
- Connecting bar profiles in the posterior teeth area: 16 mm^2

To increase the stability of the construction, the height of the connector must be selected as large as clinically feasible. Observe general statics and design guides provided by the machine manufacturer. The milled / ground pieces have to be removed carefully without damaging Use a low number of revolutions and a minimum of pressure to avoid thermal damage. Ensure sufficient cooling. The surface of the milled / ground pieces must be further processed and given a high polish like conventional composites.

ENA CAD Blocks

Geometric requirements, basically:

- Please be sure to follow the implant manufacturer's instructions regarding the maximum height of the meso structure including the crown. The mesostructure should be designed comparable to a preparation of a natural tooth. In general, sharp edges and corners should be avoided. Circular step with rounded inner edges or groove. Wall thickness of the meso structure around the screw channel: at least 0.8 mm. Occlusal wall thickness: at least 1.0 mm
- Marginal step width: at least 0.4 mm For self-adhesive attachment of the crown to the meso-structure, retentive surfaces and sufficient "stump height" must be created. The manufacturer's instructions must be followed. Strongly asymmetrical superstructures with extensive extensions are contraindicated for static reasons. The crown width is therefore circularly limited to 6.0 mm in relation to the screw channel of the meso structure. The opening of the screw channel must not be in the area of contact points or on surfaces that are functional for chewing, otherwise a 2-part abutment crown with a mesostructure must be manufactured. Closure of the screw channel with cotton wool and composite (Ena Soft – Micerium). Contraindications: free-end fitting, parafunction (e.g. bruxism).

Important
Working ENA CAD Disks & Blocks should always be performed with the intended machine templates in order to prevent overheating of the material. Failing this, damage to the material can occur, which in turn can lead to deterioration of the physical properties.

Tooth preparation
Full Restorations – A minimum axial reduction of 1.0 mm with a 3-5 degree taper and an incisal/occlusal reduction of at least 1.5 mm in the centric occlusion and all excursions is required. Shoulders must be extended to 1.0 mm lingual to the proximal contact area. All line angles should be rounded with no bevel lines. Inlays/Onlays – A traditional inlay/onlay preparation design with no undercuts is recommended. Taper the cavity walls 3-5 degrees to the long axis of the preparation. All internal edges and angles should be round. A minimum occlusal reduction of 1.5 mm in the centric occlusion and all excursions is required. Laminate Veneers – A standard reduction of the labial surface with approximately 0.4 to 0.6 mm is recommended. The reduction of the incisal labial-lingual angle should be 0.5-1.5 mm. Keep the preparation of the margins above the gingival tissues. Rounded shoulder or chamfer preparation with no undercuts should be used for all preparations.

Surface treatment/modification

Before further processing of the ENA CAD Disks & Bloks restoration, such as colouring or veneering, the surface involved must be treated as a composite surface, which is to be repaired or corrected. For this, we recommend initial powder-bla-sting of the surface or light abrasion with a milling tool. Then, oil-free pressurised air should be used to remove the lightly adhering dust. An absolut anhydrous processing is important. Before further processing, it must be ensured that the surface is clean, dry and free of grease. Then a composite bonding should be applied and light-cured. Please consult the manufacturer's recommendations. Do NOT fire for finishing or additional build-up.

Veneering
The surface, activated as described under "Surface treatment/-modification", can be veneered with conventional light-cu-
red K+B composite. Please consult the manufacturer's recommendations.

Attachment

Cleaning: clean the polished restoration in an ultrasonic cleaner or with a steam cleaner. Dry gently with an air syringe.
Contouring – Try the fit of the restoration to the preparation with light finger pressure. Adjust contacts and occlusion, contouring with the appropriate rotary instruments. Before attachment the ENA CAD restoration, the surface to be bonded must also be pretreated in the same manner as described under “Surface treatment/-modification: Adhesive light- or chemically-cured attaching material must be used when securing the restoration. Light curing is recommended (Ena Cem HF / Ena Cem HV – Micerium). When doing so, be sure to adhere to the User Information of the appropriate product manufacturer.

Notes about storage

- Store at around 10 °C to 30 °C.

Storage life
The maximum storage life is printed on the label of each packaging unit and is valid for storage at the prescribed storage temperature.

Warranty

Our technical advice, whether given verbally, in written form or through practical guidance relate to our own experiences and therefore, can only be taken as guidance. Our products are subject to continuous further development. Therefore, we reserve the right to make possible modifications.

Note
During processing dusts are released, which can damage the respiratory tract and irritate the skin and the eyes. Therefore, please only process the material while running an adequate extractor system. Wear gloves, protective goggles and a face mask. Do not inhale the dust.

Adverse effects
Undesirable side effects of this medical device are extremely rare when properly processed and applied. Immunoreactions (e.g. allergies) or localised discomfort can, however, not be fully excluded as a matter of principle. Should you observe any undesired side effects – even in cases of doubt – please inform us. Any serious incidents arising in connection with the use of this product must be reported to the manufacturer indicated below and to the relevant competent authority.

Contraindications / Interactions
This product must not be used if the patient is hypersensitive to one of the components, or should only be used under the strict supervision of the attending doctor/dentist. In such cases, the composition of the medical device supplied by us can be obtained on request. Known cross-reactions or interactions of the medical device with other materials already present in the mouth must be taken into consideration by the dentist during use.

Troubleshooting list

Error	Cause	Remedy
Milling/grinding procedure delivers uncl ean results/surfaces	Use of the incorrect tool	Suitable tool (specially produced tools for hybrid materials)
Milling/grinding procedure delivers uncl ean results/surfaces	Incorrect choice of template	Checks the templates and readju st if necessary
Milling/grinding procedure delivers impr ecise surfaces and dimensions (fit)	Disk/Block not fitted planar in the clamp. Impurities in the clamp, we ar to the tool	Remove the impurities, fit the Di sks & Blocks planar in the clamp, replace tools
Workpiece becomes hot	Tool rotation too great/fast	Observe the templates
Milling tool/grinder breaks off	Advance is too high /too great.	Observe the templates

ENA CAD is exclusively for use by dental technicians or dentists.
Please supply the dentist with the above information, if this medical device is used to produce a special model.

Waste treatment methods
Smaller quantities can be disposed of with household waste. Observe any existing safety data sheets for the product during processing.

Distributor
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Tom-Mutters-Str. #4 a
D-35041 Marburg, Germany

FAQ

Q: What should I do if I observe any undesired side effects?
A: Any undesired side effects should be reported to the manufacturer and relevant authorities immediately.

Q: How should I store ENA CAD Disks & Blocks?
A: Follow the storage temperature indicated on the label of the packaging unit for maximum storage life.

Documents / Resources

	**ENA CAD Composite Disks and Blocks** [pdf] Instructions Composite Disks and Blocks, Disks and Blocks

References

- User Manual