INSTRUCTIONS FOR USE

Product: G-CAM

Raw Material: PMMA (polymethyl methacrylate) doped with graphene.

Please read this instruction sheet carefully before using the product.

1. What is G-CAM?

G-CAM is a thermoplastic acrylic disc made by a principal base of polymethyl methacrylate (PMMA) resin doped with graphene (allotropic form of carbon), suitable for the creation of dental prostheses using CAD/CAM technology.

G-CAM is available in different format, thicknesses, colors and anchors, having all the variations the same physicochemical characteristics.

G-CAM disc is available in 2 different formats: **G-CAM MONOCHROMA** and **G-CAM MULTICHROMA.** Monochrome and Multichroma discs may be both used for full anatomical monolithic restorations. When machined, G-CAM Monochroma and G-CAM Multichroma present a different visual effect:

- **G-CAM Monochroma**, is made of a pure VITA Classic guide's colour.
- **G-CAM Multichroma**, it has a chromatic spectrum based in natural colour imitating the optical effects of the natural pieces.

The more suitable choice between monochrome and multichrome disc will depend on the final application given to the device. G-CAM is presented as a compacted resin disc offered in two different anchor dimensions. There are two different discs variants base on the specified type of anchor used by the CAM device:

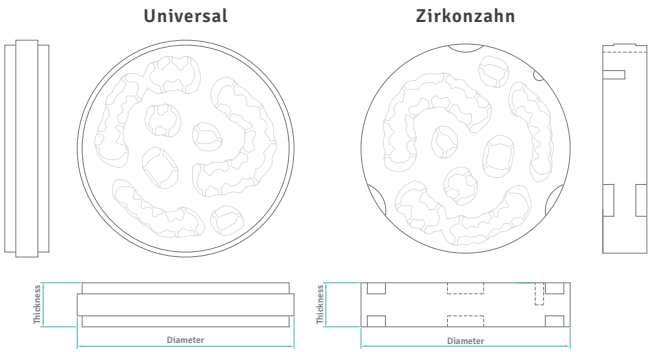
- **UNIVERSAL** anchorage: disc of 98.5mm (3.878in) diameter
- **ZIRKONZAHN** anchorage: disc of 95mm (3.740in) diameter

Both variants are presented in different thicknesses:

Thickness

mm	14	16	18	20	22	24	26	28	30
in	0.551	0.630	0.709	0.788	0.866	0.945	1.024	1.102	1.181

G-CAM is available in the following colours (according to the VITA classic guide):
A1, A2, A3, A3.5, B1, B2, BL1, BL2, C2, PINK, TRANSPARENT.



2. Intended Use/ Indications for Use

G-CAM discs are intended to be used for the manufacture of full and partial removable dentures, implant overdentures as well as permanent and temporary restorations such as anterior or posterior crowns and bridges, inlays, onlays, veneers, copings and substructures.

3. Contraindications

There are no recognised contraindications, except in the cases of adverse reactions to polymethyl methacrylate.

The existence of residual monomers, which could cause allergies, are tested. Remaining quantity of residual monomer is far below of 2.2% limit required by ISO 20795:2013 (see Technical Characteristics section)

4. Risk and safety indications

G-CAM is a thermoplastic solid material, so additional curing steps are not needed which prevents improper fabrication due to varying curing or working times. In addition, each production is subjected to an exhaustive quality control to check that the product is in accordance with its technical specifications.

The device was designed according to the applicable to its intended use standards to reduce the risk of mechanical failure.

The biocompatibility testing showed that G-CAM is biocompatible.

G-CAM labeling is designed to reduce the risk of improper use.

4.1 Working with CAM

The G-CAM disc can be used either wet or dry. In case of dry operation, it will be necessary to suction any debris resulting from the drilling operation. The drills may break if improper tools are used. Although graphene helps to dissipate the heating of materials, an inappropriate strategy may cause the overheating and deformation of the material.

4.2 Work in the laboratory

· To reduce the risk of mechanical failure cause by milling errors, specific information is given to the professional clients in documents like Instructions for Use, Work process, Design Parameters Sheet and Labelling.

· The occupational safety measures indicated in the regulations which are currently in force will be applicable.

· A protective mask and suction equipment must be used to prevent the inhalation of dust.

Safety goggles should be worn to avoid eye's damages caused by foreign particles.

· The information contained in this instruction sheet should be followed to in order to safeguard the quality and safety of the material.

5. Indications regarding storage and expiration

G-CAM should be stored at room temperature in its original packaging, in dry storage and avoid exposure to direct sunlight.

PMMA polymer from which the G-CAM disc is made is stable and can be stored for an extended period of time having a calculated 5 years shelf life (real-time testing method).

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6. Processing and application

G-CAM is a single use device provided non-sterile which should be processed selecting the PMMA milling strategy on the CAM software.

For specific applicability requirements review all the stablished G-CAM design parameters set for the different dental treatments on our website.

As a general requirements apply the following:

· G-CAM must be used only by professionals as dental lab technicians and / or dentist.

· Only original tools may be used for processing.

· The minimum wall thickness for natural teeth reconstructions should be 0.6 mm (0.236in) in occlusal and 0.4 mm (0.016in) in cervical areas.

· The cross-sections of connectors in the anterior area should not be less than 9 mm^2 (0.014in^2) or less than 13 mm^2 (0.020in^2) in posterior areas.

· There should be no more than three elements between the two pillar pieces.

7. Technical Characteristics

· Elastic modulus:	3200 ± 7% MPa (1)
· Flexural strength:	140 ± 7% MPa (1)
· Compressive strenght:	155 ± 5 MPa (4)
· Surface hardness:	88 Shore D (2) 19,5 KHN (3)
· Filler particle size distribution:	21,5µ (5)
· Solubility:	0,5 µg/mm3 (1)
· Water absorption:	4 µg/mm3 (1)
· Residual monomer:	<0,004 % (1)

(1) UNE-EN ISO 20795-1: 2013 | (2) ISO 48-4:2018 I (3) ASTM E384 (4) ISO 5833:2002 I (5) ISO 13320:2020

8. Other observations

· The product may only be applied for the indications described in point 2.

MD Medical Device

UDI Unique Device Identification

SN Serial Number

LOT Lot Number

REF Reference Number

ES Manufacture Date
Country of manufacture

Manufacturer

CE 1984 CE: EC conformity marking
1984: notified body number

Protect from sunlight

Store in a dry area

230°F Upper limit of temperature

Do not reuse

Check the instructions of use

Take into account the documentation that accompanies the product

℞ only Caution: Feredal law restricts this device to sale by or on order of a dentist/dental lab technician