IRIX[®] MAX: THE NEW CERAMIC FILLED HYBRID COMPOSITE MATERIAL FOR PERMANENT RESTORATIONS

Irix[®] Max is a new photosensitive ceramic filled hybrid composite material (42% of ceramic in weight) for the customized production of permanent restorations such as: inlays, onlays, veneers, single crowns and bridges up to three elements by stereolithographic 3D printing.

Irix® Max is a Class IIa CE marked medical device*.

To meet aesthetic and functional requirements, Irix[®] Max is available in different monochromatic shades and the unique Photoshade adaptive gradient.

Restorations made with Irix[®] Max are characterized by excellent esthetics and high strength values. For perfect characterization, they can be customized with biocompatible products (lacquer, glaze, etc.) and/or light-curing colors.

The so-configured prosthesis is a bespoke disposable medical device.

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* Long-term invasive medical device in Class IIa according to Rule 5 of Annex IX, Dir. 93/42/EEC.

FEATURES

- High translucency
- Superior surface quality
- High dimensional stability
- Precise fit
- Available in six shades: N, A1, A2, A3, A3.5, B1
- Available in Photoshade adaptive gradient technology (DFAB Chairside and DFAB Desktop only)

ADVICE FOR USE

Irix® Max is specifically developed for the use in DWS dental 3D printers DFAB Chairside, DFAB Desktop and LFAB.

Exclusively for DFAB Chairside and DFAB Desktop, the Photoshade technology provides adaptive gradient feature.

In order to increase the mechanical performances of the restorations and to guarantee their proper stability, the use of the specifically designed DCURE curing device with its thermal/UV post-treatment is recommended.

TECHNICAL CHARACTERISTICS OF THE LIQUID MATERIAL

Valori ambientali di utilizzo	22°C - 27°C - max, RH 40% - 60%
Aspetto / Colore	Liquid / 6 shades available
Densità	1,36 g/cm ³
Viscosità	~ 6000 mPa•s at 25°C

TECHNICAL CHARACTERISTICS OF THE RESIN AFTER UV CURING

Flexural strength (MPa) (ISO 10477)	> 100
Water sorption (µg/mm3) (ISO 10477)	< 10
Water solubility (µg/mm3) (ISO 10477)	< 1.4
Application/use	Permanent restorations

Product	Test cycles	Simulated years	Test results
Irix Max	1200000	5	None fractures observed

From the microscope pictures, no fractures are observed*

*Internal data, chewing machine CS-4.4 SD Mechatronik

Technical specification subject to change without notice. This document contains informative addressed to healthcare professionals as it deals with information that may lead to serious damages for patient's health and safety if not properly understood and duly executed. Regulations under the Italian law (Legislative Decree dated February, 23rd 2006, Legislative Decree no. 219/2006 and in general by Legislative Decree no. 46/97 as amended by Legislative Decree no. 37 dated January, 25th 2010).

DWS

IRIX[®] MAX

Technical Data Sheet

ADVICE FOR USE

Follow the operating instructions for your 3D printer in the model specified by DWS.

RESTRICTIONS OF USE AND WARNINGS

Irix[®] Max is a medical device that must be strictly used by specifically trained personnel (dental technician, dentist).

The clinician must take an accurate anamnesis of the patient before proceeding with the placement of the prosthesis.

Configured following the polymerization process, the prosthesis must be placed on the patient in a proper hygienic environment. Clean the

CONTROINDICATIONS

An accurate anamnesis of the patient must be done, with the aim to identify potential intolerances or allergies to methacrylates.

SAFETY

Device in liquid form may cause skin irritation, eye irritation, and skin sensitization

Contact with the solidified material is not hazardous.

INFORMATION FOR ORDERS

PRODUCT
IRIX MAX N, DLTY 1-2 U SIZE S, SET 5
IRIX MAX A1, DLTY 1-2 U SIZE S, SET 5
IRIX MAX A2, DLTY 1-2 U SIZE S, SET 5
IRIX MAX A3, DLTY 1-2 U SIZE S, SET 5
IRIX MAX A3.5, DLTY 1-2 U SIZE S, SET 5
IRIX MAX B1, DLTY 1-2 U SIZE S, SET 5
IRIX MAX N, DLTY 3-4 U SIZE M, SET 3
IRIX MAX A1, DLTY 3-4 U SIZE M, SET 3
IRIX MAX A2, DLTY 3-4 U SIZE M, SET 3
IRIX MAX A3, DLTY 3-4 U SIZE M, SET 3
IRIX MAX A3.5, DLTY 3-4 U SIZE M, SET 3
IRIX MAX B1, DLTY 3-4 U SIZE M, SET 3

CODE	PRODUCT
10200449	IRIX MAX N, DLTY 5-6 U SIZE L, SET 3
10200450	IRIX MAX A1, DLTY 5-6 U SIZE L, SET 3
10200451	IRIX MAX A2, DLTY 5-6 U SIZE L, SET 3
10200452	IRIX MAX A3, DLTY 5-6 U SIZE L, SET 3
10200453	IRIX MAX A3.5, DLTY 5-6 U SIZE L, SET 3
10200454	IRIX MAX B1, DLTY 5-6 U SIZE L, SET 3
10200455	IRIX MAX PHOTOSHADE, DLTY 1-2 U SIZE S, SET 5
10200456	IRIX MAX PHOTOSHADE, DLTY 3-4 U SIZE M, SET 3
10200457	IRIX MAX PHOTOSHADE, DLTY 5-6 U SIZE L, SET 3

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device with a disinfectant solution prior to placement on the patient.

PRECAUTIONS AND PROTECTIVE MEASURES

Avoid direct contact with skin and eyes, use protective goggles and nitrile gloves when handling the device.

In case of skin contact, wash with plenty of water and soap. If skin irritation or rash occurs, contact the doctor.

In case of eye contact, carefully rinse eyes with water for several minutes. If irritation persists, contact the doctor.

Detailed safety information is available in the MSDS at www.dwssystems.com.

STORAGE

Store in a cool, dry place out of direct sun light or heat source. Store at 5° - 30°C.

DISPOSAL

Refer to local regulations.

DWS