

rs VIVO

RS VIVO C&B Ultimate

INSTRUCTIONS FOR USE

rapidshape

PACKAGING UNITS

RS VIVO C&B Ultimate A1, 500g [RS006202]
RS VIVO C&B Ultimate A2, 500g [RS006203]
RS VIVO C&B Ultimate A3, 500g [RS006204]
RS VIVO C&B Ultimate B1, 500g [RS006206]
RS VIVO C&B Ultimate Bleach, 500g [RS006205]

DESCRIPTION

RS VIVO C&B Ultimate is a flowable, light-curing, acrylate-based composite material for the additive manufacturing of permanent crowns, temporary crowns and bridges, monolithic full and partial dentures and artificial denture teeth. **RS VIVO C&B Ultimate** is intended to be cured by exposure to LED light with an intensity of 2mW/cm² at a wavelength of 385nm, using a 3D printer curing time of 3s for 100µm. **RS VIVO C&B Ultimate** has a compressive strength of >300 MPa, a flexural strength of >50 MPa and a depth of cure of >1.5 mm.

COMPATIBLE EQUIPMENT

RS VIVO C&B Ultimate is compatible with the following equipment:

1. Dental scanner: 7Series/Dental Wings; T-Series/Medit or suitable scanners with an accuracy of <15µm.
Design software: Straumann CARES® Visual; exocad DentalCAD; 3shape Dental System.
2. 3D printer: rapidshape® D-series D20 II, D30 II, D40 II, D20+, D30+, D50+, PRO 20, ONE with a wavelength of 385nm.
3. Post curing unit: rapidshape® RS cure, PRO cure with a light intensity of 25mW/cm² and appropriate parameter set; Otofash G171 Cure Box/NK Optik.

The user must follow all applicable labeling including Instructions for Use, installation guides, operating instructions, user manuals and other related labeling for any compatible devices listed that are used in conjunction with **RS VIVO C&B Ultimate** resin. For assuring a safe print result, strict adherence to all given instructions is crucial.

Ensure that the equipment is installed, maintained and calibrated in accordance with the manufacturer's operating instructions. Only use validated and approved devices as listed above.

COMPOSITION

Preparation consisting of acrylates, fillers (50%/wt., ø 0.7µm), initiators and pigments.

INDICATION

RS VIVO C&B Ultimate is a light-curing dental resin for restoring or improving chewing function by prosthetically reconstructing damaged or missing teeth using additively fabricated

- permanent full crowns, veneers, inlays, onlays
- temporary crowns and bridges (max. two consecutive pontics)
- monolithic full and partial dentures
- artificial denture teeth.

CONTRAINDICATIONS

Patient and user: Products made from **RS VIVO C&B Ultimate** should not be used in patients or by users who are known to be allergic to any of the ingredients.

ADVERSE REACTIONS

Patient and user: Product may cause allergic reactions. User: Observe warnings.

INTERACTIONS

Cements containing eugenol must not be used.

APPLICATION AND CONSTRUCTION PROCESS

CONSTRUCTION NOTES

- Minimum connector cross sections for temporary bridges: anterior 12 mm²/posterior 14 mm².
- Minimum wall thickness: Occlusal 1.5 mm in central fissure/1 mm circumferential.

PREPARE DATA

Build volume placement (Digital Device Design):

- Parts should be orientated as follows on the build platform:
Crowns, inlays, onlays, veneers, single artificial denture teeth: Occlusal/incisal, buccal/labial, lingual/palatinal, distal/mesial.
Bridges: Occlusal/incisal, buccal/labial, lingual/palatinal.
Monolithic dentures, connected artificial denture teeth: Occlusal/incisal.
- The distance between the parts should be at least 3 mm.
- Keep the parts at least 1 mm from the outer edge of the platform.

SUPPORT CONSTRUCTION

- It is recommended to support all parts, using support thickness of 0.3 mm, bar contour cross and a hexagonal grid as baseplate as described in printer manufacturer's operations instruction to achieve optimal results. Every unit has to be supported with at least 4 support structures.
- Supports must not be positioned on the preparation surfaces, since these will interfere with the fit.

JOB PREVIEW

- Examine each layer for problem features, especially overhangs that need support.
- Find and correct areas that are not effectively connected to the intended supports.

ESTABLISH VARIABLE PROCESS PARAMETERS

- The appropriate process print parameters are selected according to the system supplier's specifications. Ensure that the correct material-specific set of parameters is selected. Ensure

that only product-specific predetermined validated settings are used.

MATERIAL USE

General notes:

- Ensure that the resin is at an ambient temperature (20-25°C/ 68-77°F) prior to printing.
- Do not use after the expiration date.
- Do not mix different batches.
- Clean printer platform after every job.
- In case of a print failure filter the resin through a sieve with 190 µm pore size.
- It is recommended to sieve the material frequently.
- From initial filling, the material in the reservoir must be replaced completely after 30 print jobs or two months of storage at the latest.

INITIAL FILLING

- Ensure a clean material reservoir is used.
- Thoroughly stir material in the bottle with a spatula before filling the reservoir. Avoid bubbles and splashes.
- Let the resin rest for 10 minutes after filling before starting the print job.

REUSE OF MATERIAL

- Ensure that the printer material reservoir is free of residues from previous print jobs. If necessary, remove cured elements from the material reservoir with paper cards or use the "Clean Reservoir" function of the printer (refer to the printer manufacturer's operation instructions).
- Thoroughly stir material with a paper card in the reservoir. Avoid bubbles and splashes.
- Let the resin rest for 10 minutes before starting the job.

REFILL OF MATERIAL

- Ensure that the printer material reservoir is free of residues from previous print jobs. If necessary, remove cured elements from the material reservoir with paper cards or use the "Clean Reservoir" function of the printer (refer printer manufacturer's operation instructions).
- Thoroughly stir material in the bottle with a spatula and remaining material in the material reservoir with a paper card. Add the prepared material of the same batch to the material reservoir. Avoid bubbles and splashes.
- Let the resin rest for 10 minutes prior to starting the print job.
- Remaining material in the material reservoir can be refilled with fresh resin of the same batch up to 30 times from the initial filling of the printer (→ see also chapter "General Notes")

START PRINT JOB

CLEANING AND DRYING

Option 1

The built part is cleaned by removing the adherent resin using a centrifuge. The recommended rotational speed and time is 1500 rpm for two minutes.

- Recommendation 1: Laboratory centrifuge with tube holder, e.g.
 - SBS-LZ-4000/20-6 from Steinberg or
 - XC 2450, from Premiere
- Recommendation 2: Plate centrifuge e.g.
 - LMC 3000 from Biosan with R-2 swing-out rotor.
- Wrap objects in cellulose cloth, secure centrally on the plate holder of the rotor, then turn the tube through 180° and centrifuge again.

Option 2:

The built part is cleaned under flowing conditions with isopropanol for a maximum of 5 minutes. If necessary carefully clean the objects with a brush and a spray bottle filled with isopropanol.

Clean the part with compressed air and allow to dry for 30 minutes. Alternatively, the objects can be stored in a drying cabinet at a temperature of approx. 37°C [99°F].

POST CURING

Used printer	Curing Device	Post-curing
Rapidshape	Otoflash	2000 flashes each for top and bottom ¹
	RS Cure, PRO Cure	Selection of the corresponding material parameter set ²

¹Recommendation: Curing under exclusion of oxygen prevents the formation of the inhibition layer.

²Exposure time: 8 min / vacuum 50 mbar / without nitrogen / heater off / power 100 % / wave length 375+415 nm.

Ensure that the unit used is serviced and calibrated in accordance with the manufacturer's instructions.

FINAL CLEANING

- The component is cleaned under flowing conditions in isopropanol for max. 2 min. If necessary, carefully clean the objects with a brush and a spray bottle filled with isopropanol.
- Blow component with compressed air and leave to dry for 30 min. Alternatively, the objects can be stored in a drying cabinet adjusted to a temperature of approx. 37°C.

REMOVE SUPPORT STRUCTURE AND FINISH

- Remove supports and grind remains of the supports to a smooth surface.
- Sandblast inner and outer surfaces of the part with 50 µm corundum at 1.5 bar to remove the white layer.

CUSTOMIZATION, CHARACTERIZATION, POLISHING

- Restorations made from **RS VIVO C&B Ultimate** can be supplemented and customized with light-curing composites and stains. In such cases, the processing instructions of the materials used must be followed. Reductions in the vestibular or incisal areas should not exceed 0.3 mm.
- Restorations made from **RS VIVO C&B Ultimate** can be polished to a high gloss finish according to standard dental techniques.

PERMANENT CEMENTATION

- Restorations can be cemented with conventional self-adhesive cements (e.g. RelyX™ Unicem 2/3M ESPE) or resin based luting materials (e.g. Variolink Esthetic DC/Ivoclar Vivadent) with primer (Adhese Universal/Ivoclar Vivadent). Observe the processing protocol of the materials used, in particular the protocol for the pretreatment of the restoration.

TEMPORARY CEMENTATION

- Eugenol-free temporary cements are used for cementation. Observe the processing protocol of the materials used, in particular the protocol for the pretreatment of the restoration.

CONNECTING DENTURE TEETH WITH DENTURE BASE

- Printed teeth are cemented to the denture base using 3Delta Denture Bond and 3Delta Denture Fix (DeltaMed GmbH). Please respect the valid instructions for use → 3Delta Denture Base | 3Delta Denture Bond | 3Delta Denture Fix.

FURTHER PROCESSING INSTRUCTIONS

The fit of the printed restorations must be checked and evaluated by the dental technician (on the model) and the dentist (in the patient's mouth).

WARNINGS

Any deviation from the processing process described here can jeopardize the biocompatibility, functionality and safety of the final product.

Contains skin sensitizing substances (acrylates, phosphine oxide, TPO, Skin Sens. 1B > 0.1%), contains reproductive toxic substances (diboron trioxide, Repr. 1B > 0.1%).

Obtain special instructions before use.

Please always observe the current safety data sheet!

Applies to the uncured material: May cause allergic skin reactions. May damage fertility. May damage the unborn child. Avoid contact with uncured material. Wear protective gloves/protective clothing/eye protection. If on skin: Wash with plenty of water and soap. Do not breathe dust/ vapors/ spray. Switch on an extraction system during finishing. If exposed or concerned: Get medical advice/attention. The unpolymerized material is harmful to the environment. Avoid release to the environment. Collect any spillage.

Always observe the relevant country-specific health and safety regulations and legal requirements when handling hazardous substances.

STORAGE INSTRUCTIONS / SHELF LIFE

Protect from exposure to light. Keep container tightly closed. May polymerize spontaneously. Store between 4°C and 25°C (39°F – 77°F). Do not use after the expiration date. See imprint/label for expiration date.

DISPOSAL INSTRUCTIONS

Dispose of contents/container in accordance with local regulations.

IMPORTANT PRODUCT INFORMATION

R_x Federal (U.S.) law restricts the finished device to sale by or on the order of a dentist.

RS VIVO C&B Ultimate meets the performance requirements of DIN EN ISO 10477 Type 2/ Class 2 and DIN EN ISO 20795-1 Type 4.

The product has been developed for use in dentistry and must be used in accordance with the instructions for use. Serious incidents must be reported to DeltaMed GmbH and the responsible authority.



Batch code



Catalogue number



Medical device



Use-by date



Consult instructions for use



Temperature limit



Keep away from sunlight



Stir before use



Manufacturer



Manufacturing Date



Distributor



Exclamation mark



Environmental hazard



Health hazard



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