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SYNERGY D6 Flow

Instructions for use **EN**

Please read the instructions for use carefully before using the product.

PRODUCT DESCRIPTION
SYNERGY D6 Flow a radiopaque, light-curing dental composite for permanent restoration. The clinical benefit of the dental composite is (re-)construction of tooth morphology or aesthetics.

INTENDED USE
- direct filling therapy of small defects
- shape and shade corrections to improve aesthetics
- repairs of ceramic and composite restorations
- adhesive luting, if light penetration is possible

COMPOSITION

Component*	**wt %**
Methacrylate derivates	35-50
Barium aluminium boron silicate glass	40-50
Amorphous silica	2-12
Ytterbium fluoride	5-10

* Components present in very low concentrations (<1.0%) are not listed

INDICATIONS
Permanent restoration of hard structures in the mouth.

CONTRAINDICATIONS
Contraindicated in the case of hypersensitivity to any of the ingredients.

SAFETY INSTRUCTIONS
Safety
- Keep out of the reach of children!
- For hygienic reasons, the application needles are intended for single use only.
- SYNERGY D6 Flow is light sensitive and should not be left too long under intensive light before curing, especially surgical lighting or sun light. If possible, protect exposed material with a blue light blocking filter.
- Close syringes after use.
- Always wear gloves.
- For repairs, the treated surface must be roughened first.
- In case of direct contact with the oral mucosa, rinsing with tap water is sufficient. In the case of contact with the eyes, rinse thoroughly with water (10 min) and consult an ophthalmologist showing these instructions for use.
- Contains nano materials (bonded particles).

Residual risks
Users should be aware that any dental intervention in the oral cavity involves certain risks. Some of these risks are:
- Chipping / fracture / decementation
- Postoperative sensitivity / irritation of gingiva / secondary caries / endodontic complications
- Discoloration / wear / loss of gloss

SIDE EFFECTS / INTERACTIONS
No systemic side effects are known. Contact allergies with products of similar composition have been reported in isolated cases.
Agents containing eugenol and / or oil of cloves may affect the polymerization of SYNERGY D6 Flow. The use of zinc-oxide-eugenol cements in combination with SYNERGY D6 Flow should therefore be avoided. Discolorations may occur when using cationic mouth rinses as well as plaque indicators or chlorhexidin.

USER- / PATIENT GROUP
The product shall be used by qualified dental professionals only. Suitable for all patient groups.
Note: This product has not been specifically tested in vulnerable patient groups such as children or pregnant or lactating women.

PREPARATION
Cleansing the tooth
Cleanse tooth to be treated and the adjacent teeth using a brush and prophy paste which does not contain fluoride.

Selection of shade
Selection of shade should be made before isolation. The shade is ideally determined in broad daylight using the SYNERGY D6 shade guide or the VITA shade guide. Shades reach their final tone 24 hours after curing.

Isolation of the cavity (rubber dam)
Adequate isolation is absolutely necessary for achieving optimum results. The use of dental dams (e.g. from COLTENE) are recommended.

Preparation of the cavity
When preparing the cavity, every effort possible should be made to use a technique that preserves tooth structure (principle of the Adhesive Restoration Technique). Beveled enamel margins are recommended to increase the area of adhesion between tooth and filling material and thereby optimize the marginal seal.

Matrix and inter-dental wedges
When working approximally, apply a thin matrix band. Fix the matrix proximally using interdental wedges.

Pulp Protection
Apply appropriate pulp protection in regions close to the pulp. Procedure according to manufacturer's instructions for use.

Adhesive system
Apply adhesive system (e.g. from COLTENE) according to the corresponding instructions for use.

PROPER USE
a) Application of SYNERGY D6 Flow for direct restorations
Apply the material using the mounted application needle directly into the cavity.

b) Application of SYNERGY D6 Flow for indirect restorations

Conditioning the inner surfaces/contact surfaces of the restoration
Always condition the contact surfaces of the restoration according to the manufacturer's instructions for use.

Application of SYNERGY D6 Flow
Dispense the material using the mounted application needle directly into the restoration or cavity preparation. Position restoration in place using gentle pressure.

Removal of excess material
Remove coarse excess material (e.g. brush or spatula). Afterwards, hold restoration with pressure in position and remove additional excess material with a spatula or a suitable instrument.

Polymerization
Cure SYNERGY D6 Flow intra-orally with the blue light of any light curing unit (450 - 490 nm).

Maximum layer thickness 2 mm
SYNERGY D6 Flow must be cured layer by layer. The inhibition layer may not be removed for bonding. Insufficient exposure bears the risk of incomplete polymerization. For safety concerns and to avoid overexposure the instructions for use of the curing light has to be respected.

Recommended curing time for direct restorations:
Cure for 20 s with at least 500 mW/cm^2

Recommended curing time for luting indirect restorations:
Cure each side for 40 s with at least 800 mW/cm^2

Finishing
Use appropriate rotary instruments and polishers (e.g. from COLTENE) for shaping and polishing the occlusal and approximal surfaces. Fluoridate all surfaces after completion.

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE
For the syringe, the use of a disposable sleeve is recommended. In case of suspected or identifiable contamination, dispose of the syringe as described below.
Disinfection in a washer-disinfector or steam sterilization in an autoclave is not possible.

SHELF LIFE / STORAGE
Expiry date and LOT number: see primary packaging
Storage temperature: 4 - 23 °C / 39 - 73 °F
Shelf life after first opening: expiry according the expiry date
Protect against exposure to heat and sun. Avoid extreme temperature fluctuations. Close syringes immediately after use.

DISPOSAL
Dispose of cured or uncured waste according to applicable legislation. Special country-specific regulations may apply. Dispose only of completely emptied packages together with household waste in compliance with official regulations.

TECHNICAL DATA
Complies with ISO 4049 Type 1, Class 2, Group 1
Average filler particle size: 0.6 µm
Range of dimensions of inorganic filler particles: 0.04 - 2.5 µm
Inorganic filler content by volume: 33 %
Inorganic filler content by weight: 54 %
Radiopacity: 2.5 mm Al*
*Radiopacity of 1 mm aluminum (Al) is equivalent to that of dentin, 2 mm (Al) is equivalent to enamel.

REPORTING OBLIGATION
All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.
In the unlikely event of inhalation, ingestion, eye contact, or similar incidents seek immediate medical attention from an appropriate medical specialist to mitigate potential harm.

SAFETY DATA SHEET (SDS) / SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)
www.coltene.com

CE 0123

Glossary

Consult instructions for use
Keep away from sun light
Single use only
Temperature limitation
Marking of Conformity Europe
Identification for Ukraine
Legal Manufacturer
Expiry Date
LOT **Batch Code**
Rx ONLY **RX only**
MD **Medical Device**
Manufacturing Date
UDI **Unique Device Identifier**
EU REP **European Authorized Representative**
REF **Reference Number**
Importer

COLTENE International Dental Group

Dent4You AG
Bahnhofstrasse 2
CH-9435 Heerbrugg

Made in Switzerland by
Coltène/Whaledent AG
Feldwiesenstrasse 20
CH-9450 Altstätten

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COLTENE