+EBRE009690EX10/$$720250519R

EN

Instructions for use

009690EX *// digital.connect – digital.bond*

CE
0483

Please read these instructions for use carefully before using the product. The products must only be used by appropriately trained specialist staff in accordance with their intended purpose. The manufacturer will not accept any liability for damage resulting from non-compliance with these instructions for use.

1 Product description

digital.connect is a light-curing bonding agent and digital.bond is a dual-cure luting resin. digital.connect and digital.bond can be used to bond pre-fabricated teeth (e.g. neo.lign), milled teeth, or crowns (made of e.g. breCAM.multiCOM⁺ or breCAM.HIPC) onto milled or printed PMMA denture bases.
The manufacturer's instructions for use (package insert) must be followed in the case of treatments that require medication and in the case of alternative healing procedures. This is because therapeutic measures may affect the prosthetic restoration (e.g. discolouration or increased plaque affinity).

2 Intended purpose

The medical device produced by bredent is used to manufacture a custom-made dental device.

The product is intended to restore and correct the function, phonetics and aesthetics of existing teeth and lost teeth as an integral part of a dental restoration.

The product is intended for fixed, removable or partially removable implant and/or natural tooth-based restorations.

The product is intended for extraoral use.

Indication and patient population:
The indication is a partially edentulous and/or implant-restored jaw or a gap tooth or a completely edentulous jaw.

User profile:
Only doctors, dentists, dental technicians and suitably trained dental staff may use this product.

Use environment:
Dental laboratories and dental surgeries and clinics.

2.1 Contraindication

The product must not be used if the patient is known or suspected to be intolerant to any of its components. If intolerance is suspected, the product must not be used until allergy tests that confirm the absence of an allergy have been carried out.

The expected benefits of the product can be negatively affected due to patient-related factors, such as medication, bruxism, osteoporosis, radiotherapy, addictive behaviour (e.g. heavy smoking, alcohol abuse) and metabolic diseases such as diabetes.

If different materials are used, an interaction may occur, which may cause mucosal irritation or peri-implantitis, for example.

3 Warnings and precautions

Further safety information on the product can be found in the safety data sheet (see technical product documents at https://bredent-group.com).

The batch numbers for all products used must be recorded to ensure traceability and for the purpose of handling complaints.

Hazard statements:

digital.bond:

Signal word: Attention

H315 Causes skin irritation.
H319Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.

digital.connect:

Signal word: Danger

H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.

3.1 Prevention

Read and understand all the safety information and product-accompanying documents before use. More detailed information can be found on the safety data sheet.

Use personal protective equipment as required. Protective equipment includes:
- Protective gloves
- Safety goggles

digital.bond:
P261 Avoid breathing vapours.
P264 Wash thoroughly after handling.
P273 Avoid release to the environment.

digital.connect:
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 Avoid breathing vapours.
P273 Avoid release to the environment.
P280 Wear protective gloves/eye protection.

3.2 Reaction

digital.bond:

P304+P340	IF INHALED: Take individual out into fresh air and ensure they are able to breathe freely.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if worn and easy to remove. Continue rinsing.

digital.connect:

P303+P361+P353	IF ON SKIN (or hair): Remove all contaminated clothing immediately. Rinse skin with water/shower.
P304+P340	IF INHALED: Take individual out into fresh air and ensure they are able to breathe freely.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove any contact lenses if possible. Continue rinsing.

3.3 Ingredients

digital.bond:
Product contains: Bisphenol A ethoxylated dimethacrylate, 7,7,9-(or 7,9,9-)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diol dimethacrylate, N,N-bis(2-hydroxyethyl)-p-toluidine, dibenzoyl peroxide, 2-(dimethylamino)ethyl benzoate

digital.connect:
Product contains: Dipentaerythritol pentaacrylate, methyl methacrylate, phenyl-bis(2,4,6-trimethylbenzoyl)-phosphine oxide, 2-(dimethylamino)ethyl benzoate.

4 Storage and shelf life information

P403+P233	Store in a well ventilated place. Keep container tightly closed.
P403+P235	Store in a well ventilated place. Keep cool.

The product is delivered in a non-sterile condition and must be stored in its original packaging in a dry and dust-free environment, at a temperature between 15°C und 23°C .
The product must be protected from sunlight.

For the purpose of identification and protection of the product, the product must be stored in its original outer packaging (delivery condition).

The product must not be used after the expiry date (see label).

5 Processing/application

Attention:
As a general principal, we recommend thorough surgical and prosthetic planning and selection of the prosthetic components based on the specific situation and restoration.

We recommend only using bredent products for the production process to ensure biological compatibility with our products.

All parts should be protected against aspiration and swallowing during insertion as they could otherwise lead to infections and physical injury.

All non-sterile parts intended for disinfection must be prepared before use. To do so, all assembled parts must be disassembled into their individual parts. According to the German Working Group for Hygiene in Dentistry (DAHZ) hygiene guidelines, dental workpieces should be subjected to immersion or spray disinfection (e.g., Dentaclean impression and prosthesis disinfection) and then rinsed under tap water before being inserted into the patient's oral cavity.

5.1 Preparation

When constructing the prosthesis base, care must be taken to maintain an adequate all-round tooth socket height in order to guarantee sufficient adhesive bonding.

Mechanical retentions can also be milled manually or by machine to improve the adhesive bond between the prefabricated teeth and the base.

The components are discharged from the double cartridge by hand or using a suitable discharge device (e.g. REF 32000441).

5.2 Processing

The prefabricated teeth (e.g. neo.lign) or milled teeth or tooth crowns (made of e.g. breCAM.multiCOM⁺ or breCAM.HIPC), as well as the tooth slots in the milled or printed denture base (e.g. breCAM.base) are blasted with 110 µm aluminium oxide at 2-3 bar (roughen, increase surface area).

Attention:
Do not steam-clean the object. If it is soiled, remove it using a clean brush or alternatively oil-free compressed air.

The surfaces to be conditioned are wetted with digital.connect using a brush. The material is cured for 180 seconds in a suitable light-curing device or alternatively with a suitable hand lamp according to 5.3 for 20 seconds per tooth socket.
If a hand lamp is used, final curing in a light-curing device is mandatory after gluing.

Attention:
Apply digital.connect thinly. Only apply digital.connect once! Polymerize digital.connect immediately after application.

Smoothly apply digital.bond into the tooth sockets of the cooled denture base and, if necessary, to the retentive areas of the tooth, and adapt the pre-fabricated teeth to the tooth socket.

We recommend gluing the prosthesis in two steps in each quadrant.
First, remove the cartridge cap by twisting it and discard the material until both pastes are evenly dispensed.
To ensure optimal mixing of the material, only the supplied mixing cannulae may be used.
The processing time is approx. 3 to 5 minutes at 20°C.
The curing time of digital.bond is 30 minutes at room temperature.
Leave the mixing cannula on the cartridge to act as a lid, until next use.

Attention:
To achieve optimal product performance, curing for 180 seconds after bonding in a suitable light-curing device according to 5.3 is recommended.

Then process the restoration and polish it to a high lustre.
The plastic surface can be cleaned with crea.lign surface cleaner.

5.3 Light-curing devices

Different light sources are used in light-curing devices (laboratory & practice). Light sources that cover the wavelength range from 370 to 500 nm are required. (E.g. bre.Lux PowerUnit 2, bre.Lux LightPen)
Pure UV light-curing devices with wavelengths from 320 to 400 nm are not suitable. Suitable light-curing devices and curing times on request.

6 Technical data

REF	Name	Packaging unit	Material	CE 0483
VLDDLSET	Luting System	1 set	see below	CE 0483
VLDDCONN	digital.connect	10 ml	see below	CE 0483
VLDDBOND	digital.bond	8 g	see below	CE 0483

Composition of digital.connect	
Acrylate	~ 95%
Initiators, stabilisers, pigments	~ 5%

Composition of digital.bond	
Acrylate	~ 61%
Filler	~ 37%
Initiators, stabilisers, pigments	~ 2%

Properties in accordance with DIN EN ISO 4049	
Flexural strength	≥ 50 MPa
Elasticity modulus	> 1500 MPa
Water absorption	≤ 40 µg/mm^3
Solubility	≤ 7.5 µg/mm^3
Layer thickness	≤ 50 µm

In order to guarantee our products function correctly, we recommend manufacturing exclusively with bredent GmbH & Co. KG and bredent medical GmbH & Co. KG products.

7 Other information

These instructions for use correspond to the current state of the art and our own experience. The product must only be used for the indication described in Section 2. The users themselves are responsible for how they use the product. No liability is accepted for incorrect results since the manufacturer has no control over how the product is handled.

Before using the product for its intended purpose, it is the user's responsibility to check that the latest instructions for use are used in accordance with the eIFU portal (http://ifu.bredent-group.com/).
A printed version is available from the manufacturer within 7 days (for shipment to the EU).

Important:
A check must be carried out during the restoration and at the patient's annual recall appointment to ensure that the prosthetic restoration and the retaining elements are correctly positioned.

In the case of extraoral bonding, the surface must be carefully cleaned and polished to prevent plaque from accumulating.

The contents/container must be disposed of in accordance with the local/regional/national/international regulations.

The user must report any serious incidents that occur in relation to the product to the manufacturer and/or the relevant authority of the EU Member State.
An incident is defined as a malfunction/deterioration in the properties or performance of the product, including application errors due to ergonomic features, as well as an inadequacy in the instructions for use or an undesirable side effect. This incident is considered serious if there has been or could have been, directly or indirectly, a temporary or permanent deterioration in the state of health of the patient, the user or third parties.