CE 2797

i-ZOE[N]

EN	Resin modified zinc oxide-eugenol cement
LT	Derva modifikuotas cinko oksido-eugenolio cementas
DE	Harzmodifizierter Zinkoxid-Eugenol-Zement
BG	Смола модифициран цинков оксид-евгенолов цимент
CS	Pryskyřice modifikovaný oxid zinečnatý-eugenol cement
DA	Harpiks modificeret zinkoxid-eugenol cement
ET	Vaiguga modifitseeritud tsinkoksiid-eugenooltsement
FR	Ciment oxyde de zinc-eugénol modifié à la résine
EL	Τσιμέντο τροποποιημένο με ρητίνη οξειδίο ψευδαργύρου-ευγενόλη
HU	Gyantával módosított cink-oxid-eugenol cement
IT	Cemento modificato con resina all'ossido di zinco-eugenolo
LV	Sveķu modificēts cinka oksīda-eugenola cements
NO	Harpiksmodifisert sinkoksid-eugenolsement
PL	Cement modyfikowany żywicą na bazie tlenku cynku i eugenolu
PT	Cimento de óxido de zinco-eugenol modificado com resina
RO	Ciment oxid de zinc-eugenol modificat cu rășină
SK	Živicou modifikovaný oxid zinočnatý-eugenol cement
SL	Cinkov oksid-eugenol cement, modificiran s smolo
ES	Cemento de óxido de zinc-eugenol modificado con resina
SV	Hartsmodifierad zinkoxid-eugenolcement
TR	Reçine modifiye çinko oksit-öjenol çimentosu
RU	Цемент на основе оксида цинка и эвгенола, модифицированный смолой
UA	Смоломодифікований оксид цинку-евгеноловий цемент

EN ISO 3107, Type I, Type II

INSTRUCTION FOR USE EN

DESCRIPTION

i-ZOE[N] is chemical curing, high strength, resin modified cement.

COMPOSITION

Powder: zinc oxide 90-99%, polymers 1-5%, excipients 1-5%. Liquid: eugenol 99-100%.

i-ZOE[N] does not contain medicinal substance, including human blood or plasma derivate; tissues or cells, or their derivates, of human origin; tissues or cells of animal origin, or their derivates, as referred to in Regulation (EU) No. 722/2012; substances which are carcinogenic, mutagenic, toxic to reproduction or having endocrine-disrupting properties.

PERFORMANCE CHARACTERISTICS

compressive strength	34 ± 4.0 MPa

INTENDED PURPOSE AND CLINICAL BENEFITS

i-ZOE[N] restores/improves aesthetic appearance of restorable tooth; restores/maintains dental function of restorable tooth; protects biological structures of restorable tooth and adjacent tissues.

CLINICAL INDICATIONS

- **For bases and linings under amalgams and glass ionomers; for temporary fillings; for temporary fixing crowns and bridges.**

CONTRA-INDICATIONS

Patients who have a history of severe allergic or irritation reactions to product or to any of the ingredients.

RESTRICTIONS TO COMBINATIONS

i-ZOE[N] should not be used with polymer-based restorative materials as eugenol may disturb polymerization process.

UNDESIRABLE SIDE EFFECTS

In susceptible individuals, i-ZOEN may cause allergic or irritation reactions (skin, eye, mucosa, respiratory tract).

RESIDUAL RISKS

Risk control measures have been implemented and verified, risk is reduced as far as possible, the overall residual risk is judged to be acceptable.

PATIENT TARGET GROUP

No restrictions known regarding patient population, their age and general health conditions. There may be children, middle aged or elderly patient.

INTENDED PART OF THE BODY OR TYPES OF TISSUES OF BODY FLUIDS

Part of the body – mouth. Tissues or body fluids contacted by the device – tooth, oral mucosa, saliva.

INTENDED USER

i-ZOE[N] is developed for professional use in dentistry only. Its user only licensed doctor who has knowledge how to use common dental cements. There is no need for specific training.

STERILITY

i-ZOE[N] is delivered non-sterile. There is no need of any preparatory sterilization, cleaning or disinfection, preventive, regular maintenance or calibration to ensure that the device operates properly and safely during its intended lifetime. However, do not use if primary package is damaged.

USE ENVIRONMENT

i-ZOE[N] is designed to be used in dental office where ambient temperature is 18-25°C. Dispensed amount of cement is suitable for single use (only for one patient). Do not re-use. Dispensed amount kept not in original package may lead to loss of function.

CONSUMABLE COMPONENTS AND ACCESSORIES

No accessories are supplied with the device. Consumables, such as measuring scoop, mixing pads, are supplied with the device.

INSTRUCTION FOR USE

1. Prepare surface as always. For deep cavities use calcium hydroxide liner.
2. Mix powder and liquid just before application.
3. Mixing ratio: 2 level spoons of powder / 3 drops of liquid.
   NOTE! Mixing proportions variations may affect the strength and durability of the material.
4. For mixing use metal spatula and glass slab. The powder should be added to the liquid in 2 portions (at least), until exact consistency is reached. Total mixing time is 60-90 seconds.
5. The working area must be kept dry.
6. Apply the mixed cement with suitable instrument into cavity. Total working time is 2-3 minutes including mixing.
7. After 8 minutes from start of mixing restoration / cementation is ready for finishing.

WARNINGS

Do not use in direct contact with pulp tissue. Higher amount of powder or higher temperature, higher humidity shorten the working / setting time and lower temperature, or higher amount of liquid prolong the working/setting time. Do not use i-ZOE[N] for patients who have a history of severe allergic or irritation reactions to product or to any of the ingredients. i-ZOE[N] does not emit radiation and does not cause any electromagnetic interferences.

PRECAUTIONS!

It is recommended to use cofferdam during application of the product. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF ON SKIN OR MUCOSA: Wash with plenty of water. If skin/mucosa irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. IF SWALLOWED: Rinse mouth. Call a Poison Center or doctor/physician if you feel unwell. IF INHALED: Remove person to fresh air and keep comfortable for breathing.
Wash hands thoroughly after handling. Avoid contact with eyes. It is recommended to wear protective gloves/protective clothing/eye protection/face protection for doctor and patient.
Precautions to be taken in the event of changes in the performance of the device:
If during the use of the product, after all the components are well mixed, product consistency is non-homogenous, or product does not harden or does not adhere to the applied surface while setting or any by-products/phases are released during the time of curing, or sudden acute pain occur on application site, or if any other abnormal behavior of the product is noticed while manipulating the device, that is not mentioned above, discontinue to use immediately. Remove the restoration from the tooth cavity with suitable dental instrument do not let the product to be swallowed. Ask patient how she/he is feeling. If patient noticed any undesirable side-effects, immediately call to a local poison center. Collect all available remaining supplies, do not use them again and keep them out of reach in a safe place until further notice. Contact the manufacturer immediately and report of any noticed changes in the performance of the product.

SHELF-LIFE

Shelf-life of i-ZOE[N] is 3 years of powder / 3 years of liquid from the date of manufacture. Do not use after the expiry date. The batch number should be quoted in all correspondence. See packaging for batch and expiry date.

STORAGE

Keep product tightly closed in dry well-ventilated place at 4-28°C. Protect from moisture, direct sunlight and heat sources. Do not freeze. Keep out of the reach of children!

DISPOSAL

Dispose of contents/container to as required by national regulatory requirements.

VIGILANCE

If any serious incident that has occurred in relation to the device report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

i-ZOE[N] is safe and performs as intended if it is used in accordance to manufacturer's instruction for use. Summary of safety and clinical performance is available through manufacturer's website www.i-dental.lt/sscp/ until European Database on Medical Devices (EUDAMED) comes online.

MANUFACTURERS RESPONSIBILITY

Our products have been developed for professional use in dentistry. As the application of our products is beyond our control, the user is fully responsible for the application. Of course, we guarantee the quality of our products in accordance with the applied standards.

VALIDITY

Upon publication of this instruction for use, all previous versions are superseded.

PACKAGING

REF ICEKP	20g powder, 6g liquid, measuring scoop, mixing pad
REF ICETP	2x20g powder, 12g liquid, measuring scoop, mixing pad

NAUDOJIMO INSTRUKCIJA LT

APRAŠYMAS

i-ZOE[N] yra cheminio kietėjimo derva modifikuotas cementas, pasižymintis dideliu stiprumu.

SUDĖTIS

Miltai: cinko oksidas 90-99%, polimerai 1-5%, pagalbinės medžiagos 1-5%. Skystis: eugenolis 99-100%.

i-ZOE[N] sudėtyje nėra vaistinių medžiagų, įskaitant žmogaus kraują ar plazmos darinį; žmogaus kilmės audinių ar ląstelių arba jų darinių; gyvūninės kilmės audinių ar ląstelių arba jų darinių, nurodytų Reglamente (ES) Nr. 722/2012; medžiagų, kurios yra kancerogeninės, mutageninės, toksiškos reprodukcijai ar turinčių endokrininę sistemą ardančių savybių.

VEIKSMINGUMO CHARAKTERISTIKOS

gniuždymo jėga	34 ± 4.0 MPa

NUMATYTA PASKIRTIS IR KLINIKINĖ NAUDA

i-ZOE[N] atkuria/pagerina restauruojamo danties estetinę išvaizdą; atkuria/palaiko atkuriamo danties funkciją; apsaugo atkuriamų dantų ir gretimų audinių biologines struktūras.

KLINIKINĖS INDIKACIJOS

- **Skirtas bazėms ir pamušalams po amalgamomis ir stiklo jonomerais; laikiniems užpildams; laikinam karūnėlių ir tiltų fiksavimui.**