

ENGLISH - Instructions for use DYNA CASTING MATERIAL

Warning

The descriptions given are insufficient to allow immediate use of all Dyna Systems. Guidance in the handling of the Dyna (Direct) System by an experienced dental professional is strongly recommended. Dyna (Direct) System must only be used by properly trained dental professionals and in combination with original components. In case of multiple use the following dangers could occur: cross infection and/or damaged products. This can result in loss of function and wrong identification of products. For more detailed information please refer to the Dyna Manuals as well as Dyna Terms of Guarantee – available on request. With the publication of this instructions for use all previous versions are no longer valid.

Product description

The Dyna EFM Alloy and Dyna keeper are parts of the Dyna (Direct) System, a magnetic retention system. Dyna EFM alloy is a ferromagnetic alloy to be casted as root keeper for magnets whereas the Dyna keeper is a pre-fabricated, ferromagnetic alloy keeper to be used directly on endodontically treated roots.

Materials

Dyna EFM Alloy, is a white precious alloy consisting of Pd 60,0%, Co 38,0%, Ga 1,2%, Pt 1,0%

Further specifications:

Specific gravity	: 10,0 g/cm3	0,2% yield strength	: 500 N/mm2
Elongation	: 15%	Total investment expansion:	1,9%
Preheating temperature	: 850°C (1562°F)	Melting range	: 1195-1210°C
Casting temperature	: 1350°C (2462°F)	Hardness	: 295 kg/mm2
Tensile strength	: 80 daN/mm2	Specific gravity	: 10,00 g/cm3
Solder	: 1060° - 1070°C		

Magnetic data

Magnetic permeability	: UM 240	Flux density	: B 10,0 kg
Coercitive force	: HC 5,7 Oersted		

The pre-fabricated Dyna OFM keeper is made of Stainless Steel Alloy 444.

Content package

See label on packaging.

Indications

Dyna magnetic systems are intended for increasing retention of (partial) overdentures, supported on implants and natural roots. Magnets are specially indicated for overdentures in patients with manual dexterity deficiency and/or sever reduced alveolar bone.

Contraindications

All contraindications associated with elective prosthetic rehabilitation on endodontically compromised teeth should be noticed. The use of Dyna Magnetic systems is additionally contraindicated in situations where:

- proper articulation can not be restored
- proper alignment of the magnet and keeper can not be guaranteed
- patients are known to be allergic to one or several of the elements contained in the attachment materials. In case of doubt perform preliminary allergological testing

The use of Dyna magnetic systems is contraindicated in situations where it is not indicated.

Laboratory procedure

The Dyna EFM alloy is castable with every casting machine or gas/oxygen torch. Use a clay crucible (non carbon) and flux. Oxidation layer remains on molten alloy. Alloy does not shine at casting temperature.

Remove around 0,1mm of upper layer of the keeper while finishing.

Recasting : use at least 30% of new material

Soldering : as all palladium alloys, see manual for details

Each product has its special clinical and laboratory procedure. See Dyna Magnet Manual for detailed information.

Clinical application

Whenever working with overdenture attachments take the following into consideration:

- allowing the patient 2-4 weeks of wear-in time
- type of implant/root-overdenture connection (resilient vs. non-resilient)
- alignment of the male and female parts

For details see the Dyna Magnet Manual.

Disinfection

Dyna EFM alloy is a dental alloy. Follow the usual pattern of disinfection/sterilization for dental alloys and castings. Dyna keepers are supplied not sterile in a blister packaging, and intended for single use only.

They must be sterilized or disinfected in an appropriate manner before clinical use. Do not use when the packaging is damaged.

Precautions

When damaged exchange products immediately.

Improper technique can contribute to treatment failure and/or bone loss. Check the overdenture/attachments regularly (every 6 months).

Use only the original instruments.

Denture cleaning agents should be used with care. Overnight cleaning solutions should be avoided.

Magnets must not be heated above 120°C / 248°F and may only be used in combination with Dyna EFM alloy, Dyna Keepers or Dyna Medical (magnet) abutments.

Facilitate safe disposal of devices according to safety precautions in the general dental practice or hospitals.

In case of any doubts concerning the use of Dyna products contact Dyna Dental Engineering BV or your local dealer.

Please note:

It is the user of Dyna products who is obliged to determine whether or not any products are suitable for a particular clinical situation. It is the user of Dyna products who is obliged to document in appropriate manner the products used for each patient. Dyna Dental Engineering BV disclaims any liability, express or implied and shall not be responsible for any damages arising from or in connection with any errors in professional judgement or practice in the use or installation of Dyna products. It is the users duty to study the latest developments in dental implantology as well as Dyna Implant Systems and its applications, and to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The user and/or patient should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority. When using our product intra-orally take proper care to prevent them from being inhaled or ingested.

Handling and Storage

Store in clean, dry, dust-free, dark room at room temperature.

Delivery

Federal law restricts these devices to be sold by or on the behest of a dentist or a physician.

Traceability of serial/lot numbers

It is the end users responsibility by law to record the serial and/or lot numbers of all products for traceability purposes. The Health Industry Bar Code (HIBC) on the label contains information for traceability purposes (the Labeler Identification Code (LIC) "EDYN", the reference number, the lot number and, if available, the serial number and date of manufacture). Read the human-readable interpretation of the bar code symbol printed below for verification.

Training

Dyna Dental Engineering BV arranges regular training courses for beginning and advanced implantologists. The courses are obligatory and are meant to provide the Dyna user with practical and theoretical expertise concerning the use of the Dyna Implant System.

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