Oxford MTA

Oxford Scientific

Handmix

Directions for Use

Endodontic Repair Cement

Product description
Oxford MTA is a biocompatible endodontic repair cement. Oxford MTA powder is consisting of very fine hydrophilic particles of several mineral oxides. After contact with Oxford MTA liquid it forms a gel that hardens to an impermeable barrier.

Indications/Intended use
- Repair of root perforations during root canal therapy
- Root-end filling (retrograde)
- Pulp capping
- Root-end filling (orthograde)

Performance features
The performance features of the product meet the requirements of the intended use.

Contraindications
None known

Patient target group
Persons who are treated during a dental procedure.

Intended users
This medical device should only be used by a professionally trained dental practitioner.

Side effects
None known

Application

1. Dispensing and Mixing
The **powder/liquid ratio** is **2.6/1.0.** This can be obtained by mixing **1 level (blue) scoop of powder and 2 drops of liquid.**
If a thinner or firmer consistency is desired, the mixing ration can be modified slightly:

Mixing ratio (by weight)	2:1	**2,6:1**	3:1
Working time (at 23 °C/74 °F)	3:00 min	**2:00 min**	1:00 min

For root end filling (orthograde) (see 5.4) the recommended mixing ratio is 2:1 (by weight). This can be obtained by mixing **3 level (blue) scoops of powder and 8 drops of liquid.** The mixed material gives a sufficient amount for apexification that can be applied optimally with a suitable application device into the root canal.

For mixing of Oxford MTA use a mixing pad that is impervious to water or a glass block of suitable dimension.

For accurate dispensing of Oxford MTA powder shake the bottle to loosen the powder. Overfill the spoon with the powder, level the powder with the mixing spatula and carry it onto the mixing pad.

For dispensing of Oxford MTA liquid turn the bottle vertically with the tip about 5cm above the mixing pad. Steady your hand and squeeze the bottle gently to dispense one drop at a time. If any bubbles are present, lightly tap the bottle with the fingers holding it. **Discount under-sized drops** that contain bubbles and are obviously not full-sized. **Discount over-sized drops**, usually resulting from holding the bottle too close to the mixing pad or squeezing the bottle too hard and/or for too long.

Use a small spatula to rapidly mix all the cement powder in portions into the liquid.. The mixed cement should be thixotropic and have a homogeneous consistency. Total **mixing time is 30 seconds.**
If desired, a more rigid consistency can be achieved by adding some more powder to the mixture, a more creamy consistency is attained by adding some liquid.

After use, tightly close both liquid and powder bottles to prevent exposure to moisture.

2. Application
2.1. Repair of root perforations
Place rubber dam and clean the root canal system using intracanal instruments and NaOCl solution. Dry the root canal with paper points and isolate the perforation.
Fill the apical canal space up to the perforation completely with a suitable root canal filling material.
Mix Oxford MTA as described under point 1.
Apply Oxford MTA with suitable instruments into the perforation site and condense it.
Check the position of Oxford MTA in the root canal by an X-ray. If an adequate barrier has not been created, rinse Oxford MTA out of the canal and repeat the procedure.
Remove excess moisture with a damp cotton pellet or a paper point.
Place a cotton pellet in the access to the root canal and apply a temporary filling material. Alternatively seal the root canal with a suitable root canal filling material and seal the cavity with a tight filling.
Both options can be done at the earliest 5 minutes after placement of the Oxford MTA.
Oxford MTA repair material remains as a permanent part of the root canal filling.

2.2. Root End Filling (retrograde)
Create a surgical access to the root-end and resect the root. Prepare an apical cavity to a depth of 3-5 mm.
Isolate the area and dry the root end cavity with paper points. Achieve hemostasis with suitable methods.
Mix Oxford MTA as described under point 1.
Apply Oxford MTA with suitable instruments and condense it using a small plugger.
Remove excess cement and clean the surface of the root with a moist piece of gauze.
Confirm placement of the Oxford MTA repair material with an X-ray. The Oxford MTA repair material remains as a permanent part of the root canal filling.

2.3. Pulp Capping
Place rubber dam and prepare the cavity. Rinse the cavity and exposed pulpal areas with a suitable disinfectant.
Mix Oxford MTA as described under point 1.
With a suitable instrument apply a small amount of Oxford MTA over the exposed pulp and remove excess moisture with a cotton pellet.
At the earliest 5 minutes after application of Oxford MTA place a small amount of a flowable light cure liner (e.g. Oxford Iono VLC) and light cure.
Etch the remaining cavity walls according to the total-etch-technique with Oxford Etch and apply a suitable bonding agent (e.g. Oxford Bond TE Mono) according to the corresponding instructions.
Place a light cure composite (e.g. Oxford Ceram NANO) according to the instructions and light cure.
Check pulp vitality and status regularly.

2.4. Root End Filling (orthograde)
Place rubber dam and clean the root canal system using intracanal instruments and irrigate with NaOCl. Dry the root canal with paper points.
For disinfection place calcium hydroxide paste in the root canal for one week. Seal the access opening with a temporary filling material.
Mix Oxford MTA as described under point 4..
With a suitable instrument apply a small amount of Oxford MTA into the apical region and condense it. Create a 3 – 5 mm barrier of Oxford MTA.
Check the position of Oxford MTA by an X-ray. If an adequate barrier has not been created, rinse Oxford MTA out of the canal and repeat the procedure.
Remove excess moisture with a damp cotton pellet or a paper point.
Place a damp cotton pellet in the access to the root canal and apply a temporary filling material.
Alternatively seal the access preparation with a suitable root canal filling material and seal the cavity with a tight filling.
Both options can be done not before 5 minutes after placement of the Oxford MTA.
Oxford MTA repair material remains as a permanent part of the root canal filling.

Additional remarks
- In the first hour after application handle the placed MTA cement carefully.
- Oxford MTA can cause discoloration.
- Keep away from children!

Composition
MTA, bismuth oxide

Storage
Oxford MTA protected from moisture at 10-25 °C (50-77 °F). Do not use after expiry date.

Disposal
Disposal of the product according to local authority regulations.

Reporting obligation
Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Note
The summary of safety and clinical performance of the medical device can be found in the European database on medical devices
(EUDAMED – https://ec.europa.eu/tools/eudamed).

Warranty
First Scientific Dental Materials GmbH warrants this product will be free from defects in material and manufacture. First Scientific Dental Materials makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusively remedy and First Scientific Dental Materials' sole obligation shall be repair or replacement of the First Scientific Dental Materials product.

Limitation of Liability
Except where prohibited by law, First Scientific Dental Materials GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Caution:
Federal law restricts the sale of this device to or by the order of a dentist

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