Properties:
1. SavDen™ MTA can replace the sound dentin both in the crown and in the root, without any preliminary conditioning of mineral tissue.
2. SavDen™ MTA is indicated for root canal fillings to build reactionary dentin. The dentin bridges represent the necessary condition for good pulp healing.

Indications:
- A root filling material.
- For the repair of root canals as an open apical plug during speciation.
- For repair of root perforations during root canal therapy or as a consequence of internal resorption.
- As a pulp capping material.
- Pulpotomy of primary teeth in the child (ages >2 years) pediatric patient.

Contraindications:
None known

Limits of use:
Restoration of large loss of tooth substance subjected to high stresses.
Esthetic restoration of anterior teeth.
Treatment of teeth with irreversible pulpitis.

Side effects:
No known side effects.

Instructions for use (for each indication):
SavDen™ MTA mixing instructions:
1) Open a pack of SavDen™ MTA and dispense the powder onto a mixing pad.
2) Pull off the end of a SavDen™ MTA liquid-micro-dose ampoule and squeeze out contents onto morterosure onto the mixing pad next to the MTA powder.
3) The SavDen™ MTA was mixed at a proposed ratio of 5 g powder per 0.1 ml liquid (2) for models without liquid micro-dose ampoules, please use distilled, deoxygenated water.
4) Gravically incorporate the liquid into the powder using the MTA mixing stick.
5) Mix the powder with the liquid for about three minute to ensure all the powder is hydrated.

Immediate enamel restoration:
Access to the pulp chamber: SavDen™ MTA is not indicated for the treatment of teeth with irreversible pulpitis.
1) Isolate the tooth with a rubber dam.
2) Remove the infected dentin with a round bur and/or a hand excavator. Leave the affected dentin.
3) Prepare SavDen™ MTA as indicated above (SavDen™ MTA mixing instructions).
4) Insert SavDen™ MTA in the cavity avoiding trapping air bubbles. Ensure good adaptation of the material to the cavity walls and margins. Do not apply excessive pressure on the material.
5) Model the surface of the restoration.
6) Wait until the end of the initial setting time (15 minutes) before performing the permanent enamel restoration. SavDen™ MTA is compatible with all direct crown restoration techniques and particularly with all types of bonding systems.

Non-immediate enamel restoration:
Access to the pulp chamber: SavDen™ MTA is not indicated for the treatment of teeth with irreversible pulpitis.
1) Isolate the tooth with a rubber dam.
2) Remove the infected dentin with a round bur and/or a hand excavator. Leave the affected dentin.
3) Prepare SavDen™ MTA as indicated above (SavDen™ MTA mixing instructions).
4) Insert SavDen™ MTA in the cavity avoiding trapping air bubbles. Ensure good adaptation of the material to the cavity walls and margins. Do not apply excessive pressure on the material.
5) Model the surface of the restoration.
6) Wait until the end of the initial setting time (15 minutes) before removing the matrix.
7) Check occlusion.
8) Within one week to six months after placement of SavDen™ MTA, prepare the cavity according to the criteria recommended for the selected restorative material. The remaining SavDen™ MTA material can be considered as sound artificial dentin and permanently left in deep areas of the cavity and in areas adjacent to the pulp chamber. SavDen™ MTA is compatible with all direct or indirect crown restoration techniques (Inlay/Onlay), and particularly with all types of bonding systems.

Pulp capping:
Access to the pulp chamber by the usual tests: SavDen™ MTA is not indicated for the treatment of teeth with irreversible pulpitis.
1) Isolate the tooth with a rubber dam.
2) Remove the infected dentin with a round bur and/or a hand excavator. Leave the affected dentin.
3) If there is bleeding in the pulp, hemostasis must be achieved before applying SavDen™ MTA.
4) Prepare SavDen™ MTA as indicated above (SavDen™ MTA mixing instructions).
5) Place SavDen™ MTA directly in the pulp chamber and ensure good adaptation to the cavities walls and margins. Model the surface of the restoration.
6) Wait until the end of the initial setting time (15 minutes) of the material before removing the matrix.
7) Check occlusion.
8) Within one week to six months after placement of SavDen™ MTA, prepare the cavity according to the criteria recommended for the selected restorative material. The remaining SavDen™ MTA material can be considered as sound artificial dentin and permanently left in deep areas of the cavity and in areas adjacent to the pulp chamber. SavDen™ MTA is compatible with all direct or indirect crown restoration techniques, and particularly with all types of bonding systems.

Repair of root perforations:
1) Isolate the tooth with a rubber dam.
2) Prepare the root canal alternately using suitable endodontic instruments and a solution of sodium hypochlorite.
3) Dry the canal with paper points and use calcium hydroxide paste for disinfection between visits. Tighten the seal acuity with a temporary cement to protect the temporary filling.
4) At the next visit (usually after one week), place a rubber dam and remove the temporary cemenation. Clean the canal alternately using a solution of sodium hypochlorite and suitable endodontic instruments. Dry the canal with paper points.
5) Prepare SavDen™ MTA as indicated above (SavDen™ MTA mixing instructions).
6) Dis pense SavDen™ MTA over the perforation site using a suitable instrument.
7) Condense SavDen™ MTA with a plunger.
8) Take an X-ray to check that the material is correctly positioned.
9) Remove excess material and place a temporary filling.
10) Complete root canal treatment at the next visit according to current recommendations.

Repair of pulpal chamber perforations:
1) Isolate the tooth with a rubber dam.
2) Rinse the cavity with a solution of sodium hypochlorite to disinfect the area.
3) If there is bleeding, hemostasis must be achieved before applying SavDen™ MTA.
4) Dry the pulp chamber.
5) Prepare SavDen™ MTA as indicated above (SavDen™ MTA mixing instructions).
6) Dis pense SavDen™ MTA and condense. Perforation repair and crown restorations are performed in a single step.
7) Take an X-ray to check that the material is correctly positioned.
8) Remove excess material.
9) At a subsequent visit, if all clinical signs of a successful treatment are present, the possibility of a permanent restoration can be considered.

Repair of perforating internal resorptions:
1) Isolate the tooth with a rubber dam.
2) Prepare the root canal alternately using suitable endodontic instruments and a solution of sodium hypochlorite.
3) Dry the canal with paper points and use a calcium hydroxide paste for disinfection between visits. Tighten the seal acuity with a temporary cement to protect the temporary filling.
4) At the next visit (usually after one week), place a rubber dam and remove the temporary cemenation. Clean the canal alternately using a solution of sodium hypochlorite and suitable endodontic instruments. Dry the canal with paper points.
5) Prepare SavDen™ MTA as indicated above (SavDen™ MTA mixing instructions).
6) Dis pense SavDen™ MTA over the perforation site using a suitable instrument. Condense SavDen™ MTA with a plunger.
7) Take an X-ray to check that the material is correctly positioned.
8) Remove excess material and place a temporary filling.
9) Complete pulpal chamber treatment at the next visit according to current recommendations.

Aphrification:
1) Isolate the tooth with a rubber dam.
2) Prepare the root canal alternately using suitable endodontic instruments and a solution of sodium hypochlorite.
3) Dry the canal with paper points and use a calcium hydroxide paste for disinfection between visits. Tighten the seal acuity with a temporary cement to protect the temporary filling.
4) At the next visit (usually after one week), place a rubber dam and remove the temporary cemenation. Clean the canal alternately using a solution of sodium hypochlorite and suitable endodontic instruments. Dry the canal with paper points.
5) Prepare SavDen™ MTA as indicated above (SavDen™ MTA mixing instructions).
6) Dis pense SavDen™ MTA over the perforation site using a suitable instrument. Condense SavDen™ MTA with a plunger.
7) Take an X-ray to check that the material is correctly positioned.
8) Remove excess material and place a temporary filling.
9) Complete root canal treatment at the next visit according to current recommendations.

Root-end filling in endodontic surgery:
1) Dry and adapt the operative field following the current recommendations in endodontic surgery (3 mm apicoectomy).
2) Using a specific ultrasonic tip, prepare a root-end cavity, 3 to 5 mm deep in the apical area of the root canal.
3) Isolate the area. Achieve hemostasis. Dry the cavity with paper points.
4) Prepare SavDen™ MTA as indicated above (SavDen™ MTA mixing instructions).
6) Remove excess material and clean the surface of the root.
7) Take an X-ray to check that the material is correctly positioned.

Root-end filling in non-surgical endodontic treatment:
1) Isolate the tooth with a rubber dam.
2) Cleaning and shaping following the current recommendations in nonsurgical endodontic treatment.
3) Dry the canal with paper points.

Description of symbol:
Symbol | Tall of symbol | Description of symbol
LOT | Batch code | Indicates the manufacturer's batch code so that the batch lot can be identified.
| Date of manufacture | Indicates the date when the medical device was manufactured.
Consult instructions for use | Indicates the need for the user to consult the instructions for use.
Do not use if package is damaged | Indicates a medical device that should not be used if the package has been damaged or opened.
Keep away from sunlight | Indicates a medical device that must be protected from light sources.
Keep dry | Indicates a medical device that must be kept in a dry place, for use, or for storage in a single air-tight container.
Do not use | Indicates a medical device that is not intended for use, or for use in a single patient during a single procedure.
Devices for prescription use only | Indicates a medical device that is for “prescription use” only.