INSTRUCTIONS FOR USE – DUAL RINSE® HEDP

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FOR DENTAL USE ONLY

INSTRUCTIONS FOR USE – Dual Rinse® HEDP

1) REFERENCES

Dual Rinse® HEDP			
References	08.660.00.001.FK	08.660.00.002.FK	08.660.00.003.FK
Quantities	10	30	100
Sterile	NO		
Reusable	NO		
Visual			

2) INTENDED USE

Dual Rinse® HEDP is intended to be added to chemically neutral or sodium hypochlorite irrigating solutions. Is intended for use as an irrigant during root canal treatment.

3) INDICATIONS FOR USE

1) USE: Dual Rinse® HEDP is an additive for endodontic irrigating solutions.
   a. Dual Rinse® HEDP should be added to chemically neutral or sodium hypochlorite rising solutions.
   b. The dentist will decide on the indication and use of Dual Rinse® HEDP.
2) CONTRAINDICATIONS: Do not use DUAL RINSE® HEDP in patients with reported sensitivity to the product.

4) WARNINGS

None known.

5) CONTRAINDICATION

Do not use Dual Rinse® HEDP in patients with known sensitivity to the product.

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6) ADVERSE REACTIONS

None known.

7) WARNINGS AND PRECAUTIONS

1) PRECAUTIONS
   a. Discard opened capsules.
   b. Observe the expiration date.
   c. Store in a cool and dry place.
   d. Do not swallow or allow contact with eyes or mucous membranes.
   e. The powder is corrosive (pH>12).
   f. Wear protective gloves, safety goggles, and work clothing.
   g. Do not use together with chlorhexidine and EDTA.
   h. Do not use together with <5% sodium hypochlorite.
   i. Do not heat together with sodium hypochlorite.
   j. Do not flush above the apex with the endodontic irrigation solution.
2) FIRST AID MEASURES:
   a. Skin contact: Rinse immediately with water.
   b. Eye contact: Rinse eyes with eyelids open under running water for several minutes and seek medical attention.
   c. Ingestion: Do not induce vomiting; drink plenty of water and consult a physician.

8) PROTOCOL FOR USE

a. A cup (mixing cup) should be sterilized in the autoclave in accordance with dental specifications ("Preparation of sterile medical products").
b. Place 10 ml of sodium hypochlorite (NaOCl) into the sterilized cup.
c. Open a capsule and place the powder from the capsule of Dual Rinse® HEDP into the sterilized mixing cup with NaOCl.
d. Stir the NaOCl/Dual Rinse® HEDP powder with a sterile instrument until it has completely dissolved.
e. Use the NaOCl / Dual Rinse® HEDP solution in accordance with the endodontic rinsing protocol.
f. The prepared solution is intended for single and immediate use only.

9) CONDITIONS AND TERM OF STORAGE, SHELF-LIFE

1) PRECAUTIONS FOR SAFE HANDLING:
   Ensure good ventilation/suction at the workplace.
   Wear suitable respiratory protective device when decanting larger quantities without extractor facilities.
   Handling: Product is intended for dental use only.
   Information about fire- and explosion protection: No special measures required.
2) Conditions for safe storage, including any incompatibilities
   Storage requirements to be met by storerooms and receptacles: Store only in the original receptable.
   Information about storage in one common storage facility: Do not store together with acids.
   Further information about storage conditions: Store in cool, dry conditions in well-sealed receptacles.

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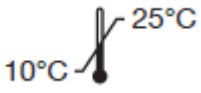
10) DISPOSAL

Small quantities may be disposed of with household waste, do not pour into the sewage system.

For questions or incidents, please contact info@medcem.ch or info@medcem.eu.
Report any serious incidents (death, serious deterioration of health, major public-health hazard) associated with this product to the manufacturer and to the competent authority of the EU Member State where you are established.

11) SYMBOLS

Information concerning the symbols used for labeling, packaging, and instructions for use:

Symbols	Designation	Description	Reference/ISO registration number
	Manufacturer	Identifies the manufacturer of the medical device (name and address). Note: If a date is next to this symbol, this corresponds to the date of manufacture. Date format: YYYY-MM-DD.	ISO 15223-1 (ISO no. 7000-3082)
	CE marking	European conformity marking for Class I medical devices.	(EU) 2017/745 Annex V and 93/42/EEC Annex XII
 fkg.ch/ifu	Operating instructions	Indicates the need for the user to consult the operating instructions and/or the processing instructions for FKG devices, as well as this document, made available on FKG Dentaire's website.	ISO 15223-1 (ISO no. 7000-1641)
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions to be taken that cannot be presented on the medical device itself.	ISO 9687 (ISO no. 7000-0434A)
	Keep Dry	Indicates a medical device that needs to be protected from moisture	ISO 15223-1 (ISO no. 7000-0626)
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1 (ISO no. 7000-0632)
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 (ISO no. 7000-1051)
	Medical device	Indicates that this is a medical device.	(EU) 2017/745 Annex I, Article 23.2(q)
	Authorized representative (authorized representative in the European Union)	Identifies the manufacturer's European authorized representative (name and address).	ISO 15223-1

Symbols	Designation	Description	Reference/ISO registration number
	Importer	Identifies the importer of the medical device (name and address).	ISO no. 7000-3725
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 (ISO no. 7000-2493)
	Batch code	Indicates the manufacturer's batch code so that the batch can be identified.	ISO 15223-1 (ISO no. 7000-2492)
	UDI code (Unique Device Identification)	Indicates the UDI code and UDI carrier specific to the device.	(EU) 2017/745 Annex I, Article 23.2(h)
	Quantity	Indicates the quantity contained in the packaging.	Not applicable
	Use-by date	Indicates the date after which the medical device is not to be used. Date format: YYYY-MM-DD.	ISO 15223-1 (ISO no. 7000-2607)
	Date of manufacture	Indicates the date on which the medical device is manufactured. Date format: YYYY-MM-DD.	ISO 15223-1 (ISO no. 7000-2497)
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 (ISO no. 7000-2606)
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1 (ISO no. 7000-2620)

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