

# Z-Rinse

## DIRECTIONS FOR USE

### 1) PRODUCT NAME

Z-Rinse (Dental Irrigation Needles)

### 2) STRUCTURAL COMPOSITION

The Dental Irrigation Needles are composed of a needle tube (stainless steel or nickel-titanium material), a gasket and a needle seat.

### 3) PRODUCT DESCRIPTION

A passive product for rinsing the mouth. It is provided non-sterile.

### 4) INTENDED USE

The Dental Irrigation Needles are used to remove debris or debris in the oral cavity.

### 5) SCOPE OF APPLICATION

This product is suitable for dental oral rinsing in clinical.

### 6) INSTRUCTION FOR USE

- 1) Used in conjunction with washing equipment, the washing liquid is used to reach the oral cavity by pressure, and the concealed positions such as the gaps on the side of the teeth and the gaps between the gums and the teeth are cleaned by the washing liquid, so as to achieve the purpose of cleaning the oral cavity.
- 2) The Dental Irrigation Needles must be cleaned, disinfected and sterilized before use according to the method described in this manual.

### 7) CONTRAINDICATIONS

Z-Rinse is not recommended for use in patients with a known allergy to stainless steel and nickel-titanium.

## 8) PRECAUTIONS

- 1) Please read the contents of this IFU carefully before using it. When the product is contaminated or damaged, it is strictly prohibited to use it.
- 2) This product is a disposable product, please handle it safely and immediately after use.

**Notice: Inform the manufacturer and the competent authority of the Member State in which the user and/or patient is established in case that any serious incident has occurred in relation to the device.**

## 9) CLEANING, DISINFECTION AND STERILIZATION PROCESSING

1	<b>Device</b>	The device is supplied non-sterile but is intended to be used in a clean, disinfected and sterile state and therefore will require processing prior to use.
2	<b>Advise</b>	<ul style="list-style-type: none"><li>• The devices have to be cleaned, disinfected and sterilized prior to the use.</li><li>• Processing procedures have only limited implications to these dental devices.</li><li>• The devices are only for single use. The devices must not be reprocessed after clinical use. Re-use may result in infection, patient injury or death.</li></ul>

### Processing Instructions

3	<b>Preparation prior to processing</b>	The product is supplied in clean, but non-sterile state. Remove the packaging material of the products and put the products onto a cleaning tray for cleaning and disinfection.
4	<b>Pre-Cleaning</b>	Prior to automated processing of the Dental Irrigation Needles, ensure that the lumen of the needle is "open" and unclogged. Connect a syringe to the needle via Luer-Lock connector. Inject water into the needle lumen to ensure the patency of the needle. If the patency of the needle cannot be ensured, do not process the needle.
5	<b>Cleaning</b>	<p>Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated processing methods. Preference is to be given to automated processing methods, especially due to the better standardizing potential and industrial safety.</p> <p><b>Automated Cleaning:</b> Use a washer-disinfector meeting the requirements of the ISO 15883 series. Connect the Dental Irrigation Needles to the WD via Luer-Lock connector as per the WD manufacturer's instructions.</p>



5	Cleaning	<p><b>Start the program:</b></p> <ul style="list-style-type: none"> <li>• 4 minutes pre-washing with cold water (&lt;40°C).</li> <li>• Emptying.</li> <li>• 5 minutes washing with a mild alkaline cleaner at 55°C.</li> <li>• Emptying.</li> <li>• 3 minutes neutralising with warm water (&gt;40°C).</li> <li>• Emptying.</li> <li>• 5 minutes intermediate rinsing with warm water (&gt;40°C).</li> <li>• Emptying.</li> </ul> <p>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).</p> <p><b>Note</b> Acc. to EN ISO 17664 no manual processing methods are required for these devices. If a manual processing method has to be used, please validate it prior to use.</p>
6	Disinfection	<p>Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to AO value (see EN 15883).</p> <p>A disinfection cycle of 5 minutes disinfection at 90°C has been validated for the device to achieve an AO value of &gt; 3000. Here we suggest a disinfection cycle of 5 minutes disinfection time at 93 °C.</p>
7	Drying	<p>Automated Drying:</p> <p>Drying the instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.</p>
8	Functional Testing, Maintenance	<p>Visual inspection for cleanliness of the instruments. After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use.</p> <ul style="list-style-type: none"> <li>• Check that the product has no dents, cracks, deformations, scratches or corrosion.</li> <li>• Check the patency of the lumen.</li> <li>• Check all markings on the product for clear visibility.</li> </ul> <p>Defective device should be immediately discarded. The defects include: material deformation and corrosion, as well as patency of the lumen for Dental Irrigation Needles.</p>
9	Packaging	<p>Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.</p>







10	<b>Sterilization</b>	<p>Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.</p> <p><b>Minimum requirements:</b> 5 minutes at 134° C  <b>Maximum sterilization temperature:</b> 137° C  <b>Drying time:</b></p> <p>For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use.</p> <p><b>After sterilization:</b></p> <ol style="list-style-type: none"> <li>Remove the product from the autoclave.</li> <li>Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling.</li> <li>Check that the sterilization wraps or pouches are not damaged.</li> </ol> <p>Flash sterilization is not allowed on lumen instruments!</p>
11	<b>Storage</b>	<p>Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.</p>
12	<b>Processing validation study information:</b>	<p>The above-mentioned processing (cleaning, disinfection, sterilization) has been successfully validated. Refer to test reports:</p> <ul style="list-style-type: none"> <li>United Dental_Cleaning Disinfection Validation Report, Report No.: RDS-RECD-210730-0084, Revision No.: 00</li> <li>United Dental_Sterilization Validation Report, Report No.: RDS-RES-210730-0085, Revision No.: 00</li> </ul>














**Additional Instructions: None**

It is the duty of the user to ensure that the processing including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

## 10) SIGNS AND SYMBOLS USED ON LABELS AND MARKS AND THEIR DESCRIPTIONS

Symbols	Identification
	Expiry date
	Batch number
	Date of manufacture
	Do not reuse



Symbols	Identification
	Nickel Titanium
	Stainless Steel
	Non-sterile
	Sterilizable in a steam sterilizer (autoclave) at 134°C
	Catalogue number
	Manufacturer
	Model Number
	Medical device
	Caution
	Consult instructions for use
	CE marking of conformity
	Authorized representative in the EU
	Do not use if packaging is damaged. Consult directions for use.

## 11) STORAGE

The device should be stored in a clean environment with a relative humidity of no more than 80%, no corrosive gas and good ventilation.

## 12) SHELF LIFE

5 years.

## 13) PACKING SPECIFICATIONS

20 pieces/box, 50 pieces/box, 100 pieces/box.



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