

HAND-HELD DENTAL RETRACTORS (Basic UDI-DI 463003499DENREC6F)
retractors №№ 1.013, 1.019, 1.119
gingival cord packers №№ 1.016S
cotton roll holders №№ 1.010

Name of manufacturer

TOR VM Ltd.

Registered trade mark of manufacturer



Address of manufacturer

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The products are CE marked

PRECAUTION

Devices in plastic packages should be stored away from heating devices to avoid packaging damage.

INSTRUCTION FOR USE

Revision 9

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The devices contain no human or animal-derived tissues or cells. The devices are supplied non-sterile.

Hand held dental retractors are intended for professional use in dental clinic only. Operating with retractors is well known procedure. No special training needed.

The devices are for multiple use.

Target groups

No limitations for target treatment group – retractors can be used for all groups of patients without restrictions.

Benefits

Hand held dental retractors provide the following benefits:

- 1) Improved safety of restoration procedure due to:
 - minimizing the damage of the interdental gingival papilla;
 - exception of damage to cheeks and tongue by rotating tools;
- 2) Consistent high quality of restoration due to:
 - improved visibility for the dentist of the entire working field;
- 3) Reduction of restoration time due to:
 - operating reliability and simplicity of use;
 - easy adaptation and easy removal from the tooth.

Precautions

- 1) Prior to use the device make sure of its integrity and absence of rust on it.
- 2) The devices are supplied in non-sterile state and after each use are to be sterilized as follows:
 - submerge device in cleaning agent solution with neutral pH for 20 min;
 - rinse the device thoroughly with purified water for 3-5 min;
 - perform standard steam sterilization procedure following the sterilizer instructions.
- 3) Consider for gag reflex upon usage of the device.
- 4) The devices cannot be placed in the inflamed gingiva as it can cause bleeding.

STERILIZATION

The devices are multiple use and require sterilization after each use.

Presterilizing clearing

In order to remove any inorganic and organic contaminants (including protein, fat, mechanical and others), including drug residues from medical device and to decrease in general microbial contamination to facilitate subsequent sterilization presterilizing clearing is carried out.

The devices can be cleaned in two ways:

- a) mechanical cleaning;
- b) ultrasonic cleaning.

A. Mechanical cleaning

- 1) Soak devices with full immersion in the cleaning agent with filling the cavities and channels with cleaning agent right after the use;
- 2) Wash devices in the same cleaning agent in which it was soaked using a brush;
- 3) Rinse with running water (channels - using a syringe or electric suction);
- 4) Rinse with distilled water (channels - using a syringe or electric suction);

It is up to end user to ensure that cleaning agent is suitable for medical devices mechanical cleaning and use it in accordance with its instruction on use.

B. Ultrasonic cleaning

- 1) Fill the ultrasonic bath container with the devices (collapsible products were placed in disassembled form; products with locks - open), then the cleaning agent was added to at least 1/3 and not more than 2/3 of the volume of the container of the ultrasonic bath;
- 2) Process in an ultrasonic bath with the temperature of the cleaning agent at least 18°C;
- 3) Rinse with running water (channels - using a syringe or electric suction);
- 4) Rinse with distilled water (channels - using a syringe or electric suction);

It is up to end user to ensure that cleaning agent is suitable for use in ultrasonic baths and use it in accordance with its instruction on use.

Sterilization process:**Procedure:**

- 1) Disinfect your hands;
- 2) Put on disposable gloves;
- 3) Put the cleaned the devices in the autoclave bag;
- 4) Carry out the sterilization in accordance with the instruction of the autoclave manufacturer at 134°C for 5 minutes.

The user is responsible for inspecting the devices prior to each use and for the use of damaged and dirty devices. The life time of devices depends on the frequency of use, the care by the user and proper reprocessing methods.

Warning:

- 1) Do not use cleaning agents, detergents or disinfectants containing high percentage of chlorine and cleaners containing oxalic acid, strong alkalines (pH>9), strong acids (pH<4), phenols or iodophors, hydrogen peroxide, interhalogenic agents, halogenic hydrocarbons, strong oxidizing agents, organic solvents, aldehydes.
- 2) Do not keep instruments in liquid medium for more than 3 hours.
- 3) Dry the devices thoroughly before sterilization.
- 4) Follow instructions of autoclave (sterilizer) manufacturer.
- 5) To avoid corrosion of the metal due to electrolysis, do not place devices in autoclave together with products made of aluminum, brass and copper.
- 6) Do not use / sterilize the devices in case of presence of traces of rust on the surface or traces of surface damage.

Operating instructions**RETRACTORS №№ 1.013, 1.019, 1.119****Preparation:**

1. Open the packaging.
2. Make sure that there are no:
 - signs of violation of the integrity of the device(including cracks and chips)
 - traces of rust or dirt on the surface.
3. Carry out disinfection, pre-sterilization cleaning and sterilization according to current instruction for use (in case of re-use).

Operating procedure:**Retractor №1.013**

1. Orient the retractor axis parallel to the patient's nose line.
2. Compress the retractor in a direction perpendicular to its axis.
3. Insert the cylindrical grooves behind the cheeks, while moving the lips apart.
4. Slowly reduce the gripping force of the retractor, allowing the grooves to extend the cheeks and expand the area of the parted lips, allowing access to the working field.
5. Carry out the necessary manipulations.
6. Remove the retractor from the oral cavity.

Retractor № 1.119

1. Select the area of the dental arch that you want to isolate.
2. If necessary, close the excretory duct of the parotid salivary gland with a gauze swab.

3. Holding the retractor by the grip handle, place it on the selected area so that the teeth and gingival margin are between the lingual and buccal protective walls.
4. If necessary, install hygroscopic rollers between the protective walls of the device and the teeth.
5. Carry out the necessary manipulations.
6. Remove the retractor from the oral cavity.

Retractor №1.019

1. Align the retractor with the holding handle.
2. Select the area of the dental arch that you want to isolate.
3. If necessary, close the excretory duct of the parotid salivary gland with a gauze swab.
4. Holding the retractor by the grip handle, place it on the selected area so that the teeth and gingival margin are between the lingual and buccal protective walls.
5. If necessary, install hygroscopic rollers between the protective walls of the device and the teeth.
6. Carry out the necessary manipulations.
7. Remove the retractor from the oral cavity.

Warning:

Do not use the retractor in case of:

- the presence of traces of rust,
- identifying signs of cracking of the retractor.

When installing the retractor:

- avoid sharp compression of the retractor.

The criterion for the unsuitability of retractors for use is the violation of its integrity. For retractors №1.117 and №1.119, an additional criterion is the weakening of the thread in the handle and the impossibility of reliable fixation of the working part.

GINGIVAL CORD PACKERS №1.016S

Preparation:

1. Open the packaging.
2. Make sure that there are no:
 - signs of violation of the integrity of the device (including cracks and chips)
 - traces of rust or dirt on the surface.
3. Carry out disinfection, pre-sterilization cleaning and sterilization according to current instruction for use (in case of re-use).

Operating procedure:

1. Select the size of the cord packer according to the size of the tooth.
2. Moisten the floss with a solution such as 25% buffered aluminum chloride solution.
3. Cover the prepared tooth with the floss.
4. Select the appropriate side of the cord packer for the tooth position.
5. Using the cord packer, gently insert the floss between the tooth and the gum from the mesial surface.
6. Using the cord packer, continue to lay the floss from the distal and lingual sides.
7. Remove the cord packer from the oral cavity.

Warning:

Do not use the cord packer in case of:

- presence of traces of rust,
- identifying signs of cracking of the cord packer

When installing the retractor:

- avoid sharp compression of the cord packer.

COTTON ROLL HOLDERS № 1.010

Preparation:

1. Open the packaging.
2. Make sure that there are no:
 - signs of violation of the integrity of the device (including cracks and chips, rupture of arcs in any of the places)
 - traces of rust or dirt on the surface.
3. Carry out disinfection, pre-sterilization cleaning and sterilization according to current instruction for use (in case of re-use).

Operating procedure:

1. Outside the mouth, place two hygroscopic rollers in the cylindrical grooves of the cotton roll holder. The diameter of the rollers is from 8 to 12 mm.
2. Spread the grooves to the sides and place the cotton roll holder in the mouth, orienting the rollers on both sides of the dentition in the area of the transition fold. The bridge connecting the cylindrical grooves should be oriented towards the inside of the oral cavity.
3. Carry out the necessary dental procedures, controlling the degree of filling the rollers with saliva. If the rollers become saturated with saliva, remove the cotton roll holder from the oral cavity and replace the rollers.

The criterion for the unsuitability for use of cotton roll holder is the violation of its integrity.

Storage

Store *retractors* in a dry place. Devices in plastic packages should be stored away from heating devices to avoid packaging damage.

Product shelf-life

Shelf-life of *retractors* is unlimited.

Disposal

Unusable *retractors* are to be disposed as class 3a "other non-hazardous wastes" according to WHO-UNEP/SBC 2005 coding recommendations.

Warranty

Retractors are multiple-use devices and are to be sterilized after each use.

TOR VM will replace the product that is proved to be nonconforming.

It is up to user to ensure that the product is suitable for the intended process and purpose. The user is responsible for inspecting the devices prior to each use and for the use of damaged and dirty devices. The life time of devices depends on the frequency of use, the care by the user and proper reprocessing methods

Any serious incident or non-compliance that has occurred in relation to TOR VM *retractors* should be reported by e-mail torvm77@gmail.com and/or tor.vm.de@googlemail.com.

In case of emergency contact

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Language

IFU is available in English and can be provided in any official Union language on customer request.