Clamps (Basic UDI-DI 463003499RUBCLAD7)
№№ 0, 00, W00, 1, 1T, 2, 2A, 2AD, 2AT, 2T, W2, W2A, W3, 7, W7, 8, 8A, 8AD, W8A, W8A-M, 9, 9M, 9T, W9, 12A, 13A, 14, 14A, 14T, 22, 23, 24, 25, 26, 27N, 51, W56, U67, 138, 139, 201, 202, 210, 212, 215, P-1, P-2, G-1, G-2, OC, S-G, 54, 55, 64, 65, 74, 75, 84, 85, B1, B2, B3, B4, B1-M, B2-M, B3-M, B4-M, B5, B6,
№№ 0-B, 00-B, W00-B, 1-B, 1T-B, 2-B, 2A-B, 2AD-B, 2AT-B, 2T-B, W2-B, W2A-B, W3-B, 7-B, W7-B, 8-B, 8A-B, 8AD-B, W8A-B, W8A-M-B, 9-B, 9M-B, 9T-B, W9-B, 12A-B, 13A-B, 14-B, 14A-B, 14T-B, 22-B, 23-B, 24-B, 25-B, 26-B, 27N-B, 51-B, W56-B, U67-B, 138-B, 139-B, 201-B, 202-B, 210-B, 212-B, P-1-B, P-2-B, G-1-B, G-2-B, S-G-B, 54-B, 55-B, 64-B, 65-B, 74-B, 75-B, 84-B, 85-B, B1-B, B2-B, B3-B, B4-B, B1-M-B, B2-M-B, B3-M-B, B4-M-B, B5-B, B6-B

Clamp organizers (Basic UDI-DI 463003499RUBORGFZ)
№ 3.909, № 3.912

Rubber dam frames (Basic UDI-DI 463003499RUBFRAE8)
№ 3.401B, № 3.402B, № 3.403B, № 3.401A

Rubber dam forceps (Basic UDI-DI 463003499RUBFOREZ)
№ 3.991, № 3.992, № 3.993

Rubber dam punchers (Basic UDI-DI 463003499RUBPUNGV)
№ 3.999

Name of manufacturer

TOR VM Ltd.

Registered trade mark 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 10
Revised July 30, 2025

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

Rubber dam clamps, clamp organizers, rubber dam frames, forceps, punchers (*devices*) are intended for professional use in dental clinic only. Operating with *devices* is well known procedure. No special training needed.

The devices are for multiple use.

Target groups
No limitations for target treatment group – the *devices* can be used for all groups of patients without restrictions.

Benefits
Rubber dam clamps, clamp organizers, rubber dam frames, forceps, punchers (*devices*) provide the following benefits:

1) Improved safety of restoration procedure due to:
- protection from accidental swallowing of fragments of teeth, small tools, medicines;
- minimizing the damage of the interdental gingival papilla;
- exception of damage to cheeks and tongue by rotating tools;
- reliable and atraumatic clamping of the matrix to the neck of the tooth;

2) Consistent high quality of restoration due to:
- creation of proper tight contact point;
- providing right anatomy of the proximal surface of the teeth;
- 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;
- prevention of the release of the filling material beyond the side edges of the cavity;
- achievement of maximum dryness of the working field.

Warnings and 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) The devices cannot be placed in the inflamed gingiva as it can cause bleeding.
4) When operating with clamps:
- use only with rubber dam;
- all manipulations on clamp opening perform outside patient mouth;
- open clamp jaws for a width not more than 10 - 12 mm;
- fix clamp with floss to avoid clamp swallowing by the patient.

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 they were 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 add cleaning agent (neutral detergent) 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 for 10 minutes at a temperature of 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.

Cleaning inspection
Inspect all devices before sterilization or storage to ensure the complete removal of soil from surfaces, holes, joints, moveable parts.
If ANY soil or fluid is still visible return the device for repeat decontamination.
If areas are difficult to inspect visually check for blood by immersing or flushing the device in 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse the device thoroughly after using hydrogen peroxide solution.

Disinfection
Perform thermal disinfection in an automated washer /disinfector.

Drying
Carefully dry the devices with a lint free surgical wipe or blow the devices dry with micro filtered forced air.

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 134ºC for 5 minutes.
Use a validated, properly maintained and calibrated steam sterilizer.

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. Ensure that the sterilizer manufacturer's stated maximum load is not exceeded.
5) The devices should be processed through a complete sterilization drying cycle as residual moisture from autoclaves can promote staining and rust.
6) Devices processed in a wrapped instrument tray should be placed within the tray in a manner that allows steam to contact all surfaces of the device. Do not overload the tray.
7) To avoid corrosion of the metal due to electrolysis, do not place devices in autoclave together with products made of aluminum, brass and copper.
8) Do not use / sterilize the devices in case of presence of traces of rust on the surface or traces of surface damage.

OPERATING INSTRUCTIONS

Clamps №№ 0, 00, W00, 1, 1T, 2, 2A, 2AD, 2AT, 2T, W2, W2A, W3, 7, W7, 8, 8A, 8AD, W8A, W8A-M, 9, 9M, 9T, W9, 12A, 13A, 14, 14A, 14T, 22, 23, 24, 25, 26, 27N, 51, W56, U67, 138, 139, 201, 202, 210, 212, 215, P-1, P-2, G-1, G-2, OC, S-G, 54, 55, 64, 65, 74, 75, 84, 85, B1, B2, B3, B4, B1-M, B2-M, B3-M, B4-M, B5, B6,
№№ 0-B, 00-B, W00-B, 1-B, 1T-B, 2-B, 2A-B, 2AD-B, 2AT-B, 2T-B, W2-B, W2A-B, W3-B, 7-B, W7-B, 8-B, 8A-B, 8AD-B, W8A-B, W8A-M-B, 9-B, 9M-B, 9T-B, W9-B, 12A-B, 13A-B, 14-B, 14A-B, 14T-B, 22-B, 23-B, 24-B, 25-B, 26-B, 27N-B, 51-B, W56-B, U67-B, 138-B, 139-B, 201-B, 202-B, 210-B, 212-B, P-1-B, P-2-B, G-1-B, G-2-B, S-G-B, 54-B, 55-B, 64-B, 65-B, 74-B, 75-B, 84-B, 85-B, B1-B, B2-B, B3-B, B4-B, B1-M-B, B2-M-B, B3-M-B, B4-M-B, B5-B, B6-B

Operating procedure
1. Choose a clamp, taking into account the type and features of the structure of the tooth.
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. Outside the oral cavity, insert the retention spikes of rubber dam forceps into the holes on the clamp.
4. Squeeze the handles of rubber dam forceps and lock them apart.
5. Insert the rubber dam forceps with the clamp into the oral cavity.
6. After installing the clamp on the neck of the tooth, release the handles of the forceps, while the clamp should cover the tooth.
7. Disengage the forceps tines from the clamp and remove the forceps from the oral cavity.
8. Carry out the necessary manipulations.
9. Remove the clamp from the oral cavity using the rubber dam forceps. The sequence of actions for removing the clamp is the reverse of the described sequence of actions for staging.

Recommendations for choosing a clamp:
When working with a microscope, it is recommended to use anti-glare clamps (black and matte).

When choosing a clamp, it must be borne in mind that the clamp should tightly cover the neck of the tooth - not balance.
With the simultaneous introduction of the curtain and the clamp, it is more convenient to use clamps that do not contain the letter "W" in the number.
In the case of installing a clamp before introducing the curtain into the oral cavity, it is recommended to use clamps with the letter "W" in the number.

The criterion for the unsuitability of the device for use is a violation of its integrity and / or a significant increase in the distance between the cheeks of the clamp, at which its reliable fixation on the tooth is impossible.

Warning:
When installing the clamp:
- use only with rubber dam;
- carry out all dilution manipulations outside the patient's oral cavity,
- avoid sharp dilution of the clamp,
- do not allow the jaws of the clamp to be diluted at a distance of more than 10-12 mm,
- tie the clamp with floss to avoid swallowing by the patient.

It is not recommended to push apart the cheeks of the clamp at a distance more than 1.5 mm greater than the width of the tooth. Excessive force applied to the clamp can cause premature valve failure due to metal fatigue.

Clamp organizers № 3.909, № 3.912

Operating procedure
1. Open the packaging.
2. Make sure that there are no:
- signs of violation of integrity (including chips and cracks),
- traces of rust or dirt on the surface.
3. Place the clamps on the organizer using the forceps
4. Place the organizer with the clamps installed on it into the sterilizer.
5. After the end of the sterilization process place the organizer with clamps in the storage area or on the dentist's work table.

Warning:
When installing the clamps on the organizer:
in order to avoid premature decrease in the spring properties of the clamps, the installation of the clamps on organizer should be carried out on the cylinder of the smallest diameter, which ensures the stable position of the clamp on the pyramid.

Rubber dam frames № 3.401B, № 3.402B, № 3.403B, № 3.401A

Operating procedure
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. Place the frame over the curtain so that the curtain is located between the frame and the face of the patient, and the curved bar that connects the right and left of the frame is located below.
4. Slightly stretch the curtain and fix on the upper and lower thorns of the frame.
5. Turn the upper edge of the curtain to the outside.

6. Pull the bottom corners of the curtain to the corresponding upper edges of the frame.
7. Slightly pull the middle of the side parts of the curtain and also pull them to the upper edges of the frame.
8. Fold the sections of the curtain hanging over the operational area and fix them on the bottom studs of the frame.
9. Carry out the necessary dental procedures.
10. Remove the rubber dam system.

Warning:
To prevent maceration of the skin around the mouth in case of saliva leakage, as well as in patients with hypersensitivity to latex, it is necessary to use absorbent wipes under the rubber dam.

Rubber dam forceps № 3.991, № 3.992, № 3.993

Operating procedure
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. Outside the oral cavity, insert the retention spikes of the forceps into the holes on the clamp.
4. Squeeze the handles of the forceps and lock them apart.
5. Insert the jaws of the forceps with the clamp into the oral cavity.
6. Place the clamp on the neck of the tooth and release the handles of the forceps, while the clamp should cover the tooth.
7. Disengage the forceps jaws from the clamp and remove the forceps from the oral cavity.
8. Carry out the necessary dental procedures.
9. Remove the clamp from the tooth using the same forceps, observing the sequence of actions opposite to the described sequence of actions for setting.

Warning:
In order to avoid premature failure of the forceps and clamps, the opening of the clamps with the forceps must be performed to the minimum required level, which ensures the installation and removal of the clamp.

Rubber dam punchers № 3.999

Operating procedure
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. Mark with a marker the location of the holes in the latex curtain using a template (for ease of superposition, it is recommended to mark the upper edge of the curtain with a stroke).
4. Straighten the curtain on the weight without pulling it, and punch holes in the curtain with a punch.
5. Check the quality of the holes obtained. The edges of the holes must be even and the hole cut is complete.

Warning:
To avoid premature failure of the rubber dam puncher, it is necessary to apply a minimum force to the handles, sufficient to obtain a hole in the insulating curtain.

Storage

Store *rubber dam clamps, clamp organizers, rubber dam frames, forceps, punchers* (*devices*) 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 *rubber dam clamps, clamp organizers, rubber dam frames, forceps, punchers* (*devices*) is unlimited.

Disposal

Unusable *rubber dam clamps, clamp organizers, rubber dam frames, forceps, punchers* (*devices*) are to be disposed as class 3a "other non-hazardous wastes" according to WHO-UNEP/SBC 2005 coding recommendations.

Warranty

Rubber dam clamps, clamp organizers, rubber dam frames, forceps, punchers (*devices*) 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 *rubber dam clamps, clamp organizers, rubber dam frames, forceps, punchers* 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.