

DENTAL HAND INSTRUMENTS

(Basic UDI-DI 463003499HNDINS9E)

Explorers № 8.0102, № 8.0105

Probe № 8.0121

Pluggers № 8.0215, № 8.0216

Mini spatulas № 8.0306, № 8.0705, № 8.0709

Pluggers / mini spatulas № 8.0401, № 8.0402, № 8.0405, № 8.0406, № 8.0408, № 8.0409, № 8.0410, № 8.0411

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.

INSTRUCTIONS FOR USE

Revision 2

Revised July 30, 2025

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

Dental hand instruments are intended for professional use in dental clinic only. Operating with *dental hand instruments* 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

The benefit of using the devices is to help dentist to perform diagnostics and do perfect dental filling including:

- 1) Ensuring perfect diagnostics and treatment of oral cavity including the most hard-to-reach areas;
- 2) Reduction of restoration time due to:
 - operating reliability and simplicity of use;
 - perfect preparation of tooth area before restoration;
 - easy and quick operating with filling material and/or liquid rubber dam.

Warnings and precautions

- 1) Prior to use dental hand instruments (devices) make sure of integrity of the device and absence of rust on it.
 - 2) The devices are supplied in non-sterile state and 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 moist heat / steam sterilization procedure following the sterilizer instructions;
 - avoid holding instrument handle in a fist for applied effort increase;
- visually control instrument edge position to exclude uncontrolled slipping of its working part towards oral tissues and / or uncontrolled full-length deepening of its working part into oral tissues

Do not use the device in case of any defect or presence of rust traces on device surface.

Upon sterilizing:

- 1) do not use cleaning agents with high percentage of chlorine and cleaners containing oxalic acid;
- 2) do not keep instruments in liquid medium for more than 3 hours.

Operating procedure

Preparation and sterilization

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

Explorers № 8.0102, № 8.0105

1. Insert explorer tip into carious cavity.
2. Perform diagnostic manipulations – determine the depth and tenderness of the cavity, stomatomalacia character, topography of tooth canal orifice.
3. Withdraw the explorer from patient oral cavity.

Probe № 8.0121

1. Insert probe tip into carious cavity.

2. Move the probe tip with slight pressing in gingival sulcus between the tooth and tissues. While moving hold the probe in parallel to the tooth root contour shifting it towards pocket foundation.
3. Determine the pocket depth using marks on the probe.
4. Withdraw the probe from patient oral cavity.

Pluggers № 8.0215, № 8.0216

1. After application of filling material insert plugger into patient mouth.
2. Perform the necessary procedures on filling modelling and / or correction of elements of operation field isolation system.
3. Withdraw the plugger from patient oral cavity.

Mini spatulas № 8.0306, № 8.0705, № 8.0709

1. Introduce spatula with filling material or drug into pretreated tooth cavity.
2. Perform the necessary procedures on filling modelling.
3. Withdraw the spatula from patient oral cavity.

Pluggers / mini spatulas № 8.0401, № 8.0402, № 8.0405, № 8.0406, № 8.0408, № 8.0409, № 8.0410, № 8.0411

1. Introduce plugger / mini spatula with filling material or drug into pretreated tooth cavity.
2. Perform the necessary procedures on filling modelling.
3. Withdraw the plugger / mini spatula from patient oral cavity.

Precautions

- avoid holding instrument handle in a fist for applied effort increase;
- visually control instrument edge position to exclude uncontrolled full-length deepening of its working part into oral tissues.

Storage

Store *dental hand instruments* 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 *dental hand instruments* is unlimited.

Disposal

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

Warranty

Dental hand instruments 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 *dental hand instruments* should be reported by e-mail torvm77@gmail.com and/or tor.vm.de@googlemail.com.

In case of emergency contact**TOR VM**

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Language

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