

<b>TRATE</b>	<b>Technical Documentation</b>	Instruction	<b>No. INS-GA.01</b>
	Subject: General application and safety instructions for the medical device produced by TRATE AG		
<b>Developed by:</b>	Director of Quality Vladlena Shulezhko	<b>Approved by:</b>	Member Siarhei Shulezhka
			01. October 2013

**General application and safety instructions for the medical device  
produced by TRATE AG**

<b>Document Status:</b>	<i>Original document</i>
<b>Approved by:</b>	<i>Director of Quality</i>
	<i>Vladlena Shulezhko</i>
<b>Date:</b>	<i>2013.10.01</i>
<b>Place:</b>	<i>Bach</i>
<b>Signature / Stamp</b>	

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TRATE AG medical products (Dental Implant, Dental superstructures, Surgical Instruments) must only be used by dentists, doctors and/or the respective experts who, due to their training and experience, are intensely familiar with the use of these products and who have the corresponding expertise in the respective specialist fields. The use of surgical products requires relevant expertise and experience in dental implantology.

It is the sole responsibility of the doctor in charge who, depending on the respective situation (indication), decides on the actual use of the TRATE AG products for each individual case.

All TRATE AG products have been developed for specific applications. Therefore, inappropriate use can result in the premature wear and tear of the products and put patients and users at risk.

### **Application**

In order to avoid damaging the instruments, they must be removed from the blister pack individually.

It is essential to only use turbines as well as hand and angle pieces that are technically and hygienically faultless, maintained and cleaned.

Rotating instruments need to be clamped as far down as possible with their speed set before applying them on the object are used with the rotary instruments.

Using the instruments for canting or leveraging should be avoided as it increases the risk of breakage.

Inappropriate use of the products leads to badly executed work and increased risk.

In particular, user of hand tools should take care to use them gently and with consideration.

The user must at all times avoid touching the instruments and parts without protection (protective gloves should be worn).

Thermal bone damage caused by rotating and oscillating tools (e.g. pilot burr, conical burr, expansion burr) must at all times be avoided (user training, working at low speed and with sufficient cooling).

During intraoral application attention has to be made to the fact that the products are protected against aspiration or falling on the floor.

### **Use of pressure**

Users of the instruments should at all times avoid applying excessive pressure. This can damage the working part of the instruments and cause the cutting edges to break off. At the same time, it generates excessive heat.

### **Cooling**

In order to avoid excessive heat generation during preparation, a sterile water/sodium chloride solution supplied via a permanent feeding device should be used to ensure sufficient cooling during use of the instruments.

When using FG instruments that are more than 22 mm long or whose head diameter exceeds 2 mm, additional external cooling is required.

Insufficient cooling will lead to irreversible damage to the bone and/or the adjacent tissue.

### **Storage, disinfection, cleaning and sterilization**

Unless there is explicit information to the contrary, all instruments and superstructures TRATE AG products are supplied in non-sterile packaging and, depending on the application, they need to be sterilized prior to use. Prior to their first use on the on the patient and immediately after each use, all products need to be disinfected and sterilized. Inappropriate cleaning and sterilizing of the instruments can result in the patient being infected with harmful bacteria.

You will find detailed instructions for the disinfecting, cleaning and sterilizing of products in the Instructions for the reprocessing of medical devices produced by TRATE AG. We would be happy to provide you with these instructions at your request. They are also available on the internet at [www.trate.ch](http://www.trate.ch).

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The products should be stored in appropriate, hygienically maintained containers. The same applies to sterilized instruments. The stored products must be protected from dust, humidity and recontamination. Instructions as to maximum storage duration must be adhered to.

### **Speed recommendations for rotary instruments**

Following the instrument-specific speed recommendations produces the best results.

Exceeding the maximum admissible speed (rpm) when using long and pointed instruments tends to produce vibrations that can lead to the destruction of the instrument.

When using working parts with diameters exceeding the thickness of the shaft, excessive speed can release great centrifugal forces that may cause the shaft to bend and/or the instrument to break. Therefore, the maximum admissible rpm must be exceeded.

Generally, the following rules apply:

- The larger the working part of an instrument the lower the speed
- The larger the working part of an instrument the greater the force of pressure
- Instruments with a maximum speed of 300.00 rpm are for micromotor hand pieces and turbines with stable ball bearings. Not to be recommended for turbines with air bearings.
- Instruments with a maximum speed of 30.000 of 160.000rpm are suitable for micro-motor hand pieces or technical hand pieces up to the indicated rpm.

Not to be recommended for turbines.

-Surgical instruments: suitable for geared down micro-motor hand and angle pieces 10:1 with stable ball bearings. Speed 600 to 800 rpm with physical and, possibly, sterile external cooling or internal cooling when using the respective hand piece.

### **Discarding worn instruments and parts**

As a rule, TRATE AG medical products (instruments) are re-usable there is explicit proof and information to the contrary. It is the sole responsibility of the doctor using the devices to decide on the possibility of and the justification for multiple use as well as on the frequency of use, based on the respective case and the potential wear and tear of the products. If in doubt, it is always best to discard the products early and to replace them.

- Instruments are subject to wear and tear. This is particularly true for rotating tools. Therefore, our warranty for all rotating tools expires after their fifth use. If the tools are used more frequently, the manufacturer, TRATE AG, can no longer guarantee a faultless cutting performance combined with minimum temperature change.
- Broken off cutting edges of instruments cause vibrations and great forces of pressure, which, in turn, leads to broken preparation corners and rough surfaces.
- Instruments that are bent and/or do not run true should be discarded forthwith.
- With the reuse of disposable products the risk of infection cannot be excluded and risk-free functional safety cannot be guaranteed.

### **Further comments:**

Due to statutory regulations, returned goods can, on principle, only be accepted if the complete batch number is provided. This number can be found on the product packaging.

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This medical product is CE marked in accordance with Directive 93/42/EEC on medical devices

**Manufacturer**

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