

<b>TRATE</b>	Technical Documentation		Instruction	No. INS-IM.08
	Subject: Instruction for use			
Developed by:	Director of Quality Vladlena Shulezhko	Approved by:	Member Siarhei Shulezhka	13. July. 2015

**Instruction for use**  
**Dental Implant System ROOTT**  
**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>2015.07.13</i>
<b>Place:</b>	<i>Bach</i>
<b>Signature / Stamp</b>	

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## IMPORTANT Information!

### READ CAREFULLY!

#### Instruction

ROOTT implants placement should be performed by a specialist with a higher university degree in implant dentistry. Practitioners must have knowledge of dental implantology and instruction in the handling of the ROOTT product described herein for using the ROOTT product safety and properly in acc. with these instruction for use.

A thorough planning of treatment is necessary, even if further surgical situation requires making changes to the plan.

#### Description

ROOTT Dental Implant System is intended for surgical placement in the maxillary and / or mandibular arch to support crowns, bridges, or overdenture in edentulous or partially edentulous patients. For single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. ROOTT Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. The ROOTT Dental Implant System is composed of a solid titanium alloy root form, compressive, basal types of implants and solid abutments (for root form type) with associated instruments.

#### Material components

Item	Material
Dental Implants ROOTT	Titanium Alloy: Titanium Grade 5 (Ti6Al4V)
ROOTT Dental Superstructures	Titanium Alloy: Titanium Grade 5 (Ti6Al4V) POM-C
ROOTT Dental Instruments	Stainless Steel 1.4197 Titanium Alloy: Titanium Grade 5 (Ti6Al4V)
Instrument trays	Radel Plastic

#### Warnings

- Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury. If you want to protect it, to use rubber dam!

**If patient cannot breathe:** If this incident happens, immediately call to Emergency! If the instrument has entered the airways and patient cannot breathe, try to discharge part from the respiratory track. In critical situation it should then be necessary to perform a bronchoscopy. A special case describes the need to even perform a tracheotomy.

**If patient can breathe and situation not critical:** In the event an object entered the digestive system, it would require carrying out a series of post-operative controls with the help of radiological imaging. A rich diet in fiber will also help solve this problem sooner.

A gastroscopy or colonoscopy could also be mandatory in those cases in which the object remains stationery in the intestinal tract, while a proper medical follow-up will help see any progress of the object, or objects, through the digestive tract.

- Avoid approaching the proximity of the mandibular nerve channel during implant bed preparation and implant insertion. Nerve damage may result in anaesthesia, paraesthesia and dyesthesia.

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- Only the implants in the original packaging are sterile in the period of validity. If implants resterilized by the end user, in this case - regardless of the method of sterilization - the responsibility is removed. Sterile products are marked with symbol STERILE. The expiration date is designated by the symbol of hourglass. Specification LOT denotes the number of the lot. Implants can be used only once.
- Do not use damaged or blunt instrument. Note, that force for implant insertion as maximum recommended under 35 Ncm.

#### **Cautions / Precautions**

- S8 it is clinical fixing screw (colour: grey). S8 you have to use into the mouth of patient. SL8 it is laboratory fixing screw (colour: green). SL8 you have to use in dental technician laboratory only!
- Covering screw for the implant are delivered sterile and ready for use. All other ROOTT screws are delivered non-sterile and must be sterilized prior to use
- Avoid any contact of the implant with foreign substances prior to their use. Do not touch the endossal part of the implant.
- Gingiva formers and abutments are delivered non-sterile and must be sterilized prior to use
- Implants should be used according to their expiration date
- Do not use holder as standard insertion tool! Green part (holder) purpose – just to keep implant inside of blister without touching of blister or lid surfaces and to make first insertion to avoid contamination of implant by gloves.
- To avoid damage to the bone tissue you should promptly remove the non-osteointegrated or infected implants. The time when this should be done, is determined by the dentist.
- It is desirable to specify in the contract with the patient the fact that he should inform the doctor about the installed implants if he will do MRI.
- If implants not assembled any more with holder and just moving into the blister, DO NOT USE this implant because surface already contaminated by plastic particles
- If during the surgery, implant falling down do not use this implant
- If implants blister damaged, do not use this implant because it may be not sterile anymore.
- Because of the reduced surface area for anchorage in the bone, these implants are to be used safely for the following indications: as an additional implant together with longer implants to support implant-bone reconstructions and / or as an auxiliary for implant-bone bar construction supporting dull denture in a seriously atrophied mandible.

#### **Intended Use**

ROOTT Dental Implant System is intended for surgical placement in the maxillary and / or mandibular arch to support crowns, bridges, or overdenture in edentulous or partially edentulous patients.

ROOTT Dental Implant System is packed in a radiation sterilizable package. The implant is delivered in a sterile package with a multifunctional carrier, a two-component holder and a cover screw. A blister label has three peel-off stickers: for clinical documentation and implant passport

All implants delivered with Multifunctional holder and Plastic holder. Multifunctional holder is used with insertion tool for external platform ITE. Maximal torque should not exceed 40 N/cm. Can be used as a temporary abutment, as a transfer for open / closed tray or as a healing abutment. Surface is polished and anodized in green. Plastic holder is developed for initial implant insertion. If access is restricted, upper part of the holder can be dismantled.

#### **Side effects**

Temporary symptoms: pain, swelling, difficulty phonetic and gingival inflammation.

More persistent symptoms: chronic pain in connection with implants, permanent paraesthesia, and dysesthesia, loss of maxillary / mandibular ridge bone, localized or systemic infection, oroantral or oronasal fistulae, unfavorably affected adjacent teeth, fracture of implant, jaw, bone or prosthesis, aesthetic problems, nerve damage, exfoliation, hyperplasia.

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### Indications

**ROOT FORM Implants:** prominent alveolar process, single restorations, aesthetically important area.

**COMPRESSIVE Implants:** atrophied alveolar process, immediate loading, complete edentulation, replace multiple teeth.

**BASAL Implants:** tooth socket, bone tissue deficit, resorbed ridges, immediate loading.

### Contraindications

Preoperative diagnosis is necessary in order to identify threats to the patient, related to the procedure of the implant placement, as well as factors that may affect the possibilities of healing of the bone and surrounding soft tissues. Dental implants should not be set for patients with medical contraindications related to oral and maxillofacial surgery.

**Absolute contraindications** (*Implants cannot be placed in these situations*):

#### 1.1. Heart:

- Heart diseases affecting the valves (valvulopathy)
- Recent infarcts
- Severe cardiac insufficiency, cardiomyopathy

#### 1.2. Miscellaneous:

- Active cancer, certain bone diseases (osteomalacia, Paget's disease, brittle bones syndrome, etc.),
- Certain immunological diseases, immunosuppressant treatments, clinical AIDS, awaiting an organ transplant,
- Certain mental diseases,
- Strongly irradiated jaw bones (radiotherapy treatment),
- Treatments of osteoporosis or some cancers by bisphosphonates, even several years before.

#### 1.3. Age:

- Children: not before the jaw bones have stopped growing (in general 17-18 years). On the other hand advanced age does not pose problems if the patient's general condition is good.

**Relative contraindications** (*The indication to place implants will be evaluated on a case-by-case basis, with the greatest caution*):

- Diabetes (particularly insulin-dependent),
- Angina pectoris (angina),
- Seropositivity (absolute contraindication for clinical AIDS),
- Significant consumption of tobacco
- Certain mental diseases,
- Radiotherapy to the neck or face (depending on the zone, quantity of radiation, localisation of the cancerous lesion etc.),
- Certain auto-immunes diseases,
- Drug and alcohol dependency,
- Pregnancy.

**Relative local contraindications** (*The indication to place implants will be evaluated on a case-by-case basis, with caution*):

- An insufficient quantity of bone.
- Certain diseases of the mucous membranes of the mouth.
- Periodontal diseases (loosening of the teeth); it is necessary to clean up the gums and stabilize the disease first.

Prepared by: Director of Quality Vladlena Shulezhko

Updating Date: 13.07.2015

Page 4 of 11

- Severe grinding or clenching of the teeth.
- An unbalanced relationship between the upper and lower teeth.
- Infections in the neighboring teeth (pockets, cysts, granulomas), major sinusitis.
- Poor hygiene of the mouth and teeth.

Although various information regarding the implants treatment contraindications for the patient have to be gained via an intimate communication with the doctor in charge of the patient, it is the role of the dental practitioner to analyze the gathered information, grasp the patient condition in order to judge the suitability of the implant treatment.

The knowledge and understanding of the values of basic systematic analysis that frequents the scene of blood tests are essential. I will not go into depth, but these numerical values act as important indicators, not only for the suitability of the implant treatment, but also the postoperative infections, and predict any problems to arise with the wounding healing process. The Table shows the risk classifications for the invasive procedures. In the risks classed in terms of likeness of infection and bleeding, Class I, indicate normal level, and Class II required caution, but where there are no other abnormal signs, surgery can be performed. Whereas with the Class III should be dealt with the possibility of delaying the surgical procedure. The ranges of the values should be interpreted such that the reduction in the level of total protein or albumin should indicate decrease in the rate of wound healing, or diabetes should be suspected where an abnormal level of HbA1c has been presented.

Analysis	Contents	Normal Level
Hematologic test	White blood count (WBC)	3,000~8,000 / $\mu$ l
	Neutrophil	42~74%
	Red blood count (RBC)	3,700,000~5,400,000 / $\mu$ l
	Hematocrit (Ht)	34.0~49.0%
	Hemoglobin (Hb)	11.0~17.0 g/dl
	Blood platelet count (PLT)	150,000~350,000 / $\mu$ l
Biochemical test	GOT	8 ~38 U/l
	GPT	4~44 U/l
	$\gamma$ -GTP	16~73 U/l
	LDH	106~211U/l
	Total protein	6.6~8.2 g/dl
	Albumin (ALB)	4.0~5.2 g/dl
	Urea nitrogen	8.0~22.6 mg/dl
	Creatinine	0.6~1.1 mg/dl
	Blood sugar	60~110 mg/dl
Coagulation test	HbA1c	4.3~5.8%
	PT-INR (PT: Prothrombin Time)	1.0 $\pm$ 0.1
	Activated partial thromboplastin time (APTT)	30.0 $\pm$ 5.0 seconds
	FDP	< 4.0 $\mu$ g/ml

Contents	I	II	III
White blood count	> 2000	2000-1000	<1000
Neutrophil count	> 1000	999-500	< 500
Red blood count	> 150	149-50	< 50
Hb	Male	> 12	12-10
			< 10

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	female	> 10	10-8	< 8
	PT-INR	< 1.2	1.2-1.5	< 1.5
	(APTT)	Normal	Delay < 30 %	Delay > 30 %
	FDP	Normal	Slight outlier	High outlier
	Hepatorenal function	Normal	Slight outlier	High outlier

### Preoperative planning

The implant diameter, implant type, position and number of implants should be selected individually taking the anatomy and spatial circumstances into account. Before implant treatments should be done:

Blood test, Mouth examination, X-ray examination, CT examination.

#### Method

Under local anaesthesia for the implant bed is created with the use of drills. For the preparation of the appropriate bed for the implant it is recommended to use drills of dental implant system ROOTT and observe the technology of preparation of the bone bed:

1. Initiating drilling (1200-1500 rev/min)
2. Pilot drilling (900-1200 rev/min)
3. Check of the depth and direction
4. Form drilling for Rootform type of Implant (200-800 rev/min), for Basal and Compressive type of Implant (1200-1500 rev/min) with drills of increasing diameter. In cases of insufficient bone density it is recommended to use the previous diameter of the forming drill or even installation after the pilot drilling.

During the preparation of the bone bed attention should be given to the need of substantial cooling of the implant bed and fraises (eg using chilled (degree-sterile), normal saline). Continuing to use only sharp burs (max. 10 uses). Use intermittent drilling technique.

5. Implant placement

The implant is removed from the sterile packaging immediately prior to the introduction and stably installed in the bone bed. Be sure to install it securely immediately. ROOTT Implant can be placed either manually with the ratchet or with the aid of the handpiece.

For more information on the use of a dental implant ROOTT refer to the clinical guidance available on the website [www.roott.ch](http://www.roott.ch) and in any TRATE office

#### After treatment:

- After implantation the patient record must include the types of the used implants and lot number (put inside of card special label what located into the box with implant)
- ROOTT Products must be used in according with the instructions for use provided by manufacturer. It is the practitioner responsibility to use device in accordance with these instructions and determine if the device fits to the individual patient situation.

### Shelf life / storage of implants

The shelf life of implants is 5 years after sterilization; see the expiration date on the package.

Store in a dry place, protect from the sun.

### Courses and training

Continuing education ensures long-term success. Please, ask your ROOTT representative directly for information on the ROOTT Dental Implant System courses and training.

Further information at [www.roott.ch](http://www.roott.ch)

Prepared by: Director of Quality Vladlena Shulezhko

Updating Date: 13.07.2015

Page 6 of 11

<b>TRATE</b>	<b>Technical Documentation</b>		<b>Instruction</b>	<b>No. INS-IM.08</b>
	<b>Subject: Instruction for use</b>			
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Form of delivery

**Delivery set for the customer:**

ROOTFORM	COMPRESSIVE	BASAL
Transportation box (for 20, 40, 80, 160, 240, 320 pcs)* Group Box B20* with group label Individual box B1* with individual label Gammatex indicator Blister with lid and product label on blister Additional label for Medical Card Implant Implant holder Holder for implant holder Covering screw	Transportation box (for 20, 40, 80, 160, 240, 320 pcs)* Group Box B20* with group label Individual box B1* with individual label Gammatex indicator Blister with lid and product label on blister Additional label for Medical Card Implant Implant holder	Transportation box (for 20, 40, 80, 106, 240, 320 pcs)* Group Box B20* with group label Individual box B1* with individual label Gammatex indicator Blister with lid and product label on blister Additional label for Medical Card Implant Implant holder

TRATE Company reserves the right to change the design of the products and components or their packaging, respectively, to agree on the instructions for use, as well as to re-negotiate the price and delivery terms. The guarantee applies only for the replacement of defective goods. Other claims are excluded.

## Hygienic requirements and requirements for the preparation of reusable medical device

The medical devices produced and sold by TRATE AG are re-usable unless their label contains explicit information to the contrary. However, as a rule, it is the sole responsibility of the doctor/expert using the devices to decide whether, depending on the respective case and the potential wear and tear of the products, he can re-use the products and how frequently he uses them. In case of doubt, it is always advisable to discard the products early and to replace them. The manufacturer TRATE AG cannot guarantee the faultless function and performance of the products combined with a maximum degree of safety if the products are overused.

Regarding the previously mentioned products, the following legal regulations and guidelines are applied:

- Law on Medical Products
- Resolution on users of medicine products
- Federal Health 2001:44:1115-1126: Hygienic requirements for medicine products preparation (Recommendations of the Commission on the compliance with the requirements of hygiene in hospitals at the Robert Koch Institute and the Federal Ministry of medicines and medical products)
- ISO 17664
- DIN EN ISO/ANSI AAMI ISO 11607
- DIN EN 13060 and/or DIN EN 285
- DIN EN ISO 17665

### Pre-treatment:

- Abrasive impurities need to be removed from the products directly after use (within two hours maximum)

Prepared by: Director of Quality Vladlena Shulezhko

Updating Date: 13.07.2015

Page 7 of 11

<b>TRATE</b>	<b>Technical Documentation</b>		<b>Instruction</b>	<b>No. INS-IM.08</b>
	<b>Subject: Instruction for use</b>			
<b>Developed by:</b>	Director of Quality Vladlena Shulezhko	<b>Approved by:</b>	Member Siarhei Shulezhka	13. July. 2015

- To do so, use running water or a disinfectant solution; the disinfectant must not contain aldehydes (which could fix blood residues to the instrument surface), its effectiveness should be established (e.g. it should be certified by the VAH (German Association for Applied Hygiene), the DGHM (German Society for Hygiene and Microbiology) or the FDA or have CE marking)
- It should be suitable for the disinfection of the products and compatible with the products (see chapter on 'Material resistance'). For the manual removal of impurities, only use nylon brushes intended for the purpose (also see the chapter on 'Special Instructions') or clean soft and lint-free cloths that you only use for this purpose.
- Do not use metal brushes or steel wool.
- As to products with lumen (cavities): rinse all cavities three times by using a disposable syringe (minimum volume 5-10 ml) and a cannula. Please note that the disinfectants used during pre-treatment only ensure personal protection and can be no substitute for the disinfection procedure to be used later - after completion of the cleaning process.

#### **Mechanical cleaning/disinfection (disinfector/RDG (cleaning and disinfection device):**

When choosing a disinfector you will have to ensure:

- that the effectiveness of the disinfector has been certified (e.g. it has been licensed by the DGHM or the FDA or has CE marking according to DIN EN ISO 15883)
- that, if at all possible, a programme is used that has been certified for thermic disinfection (A0-value > 3000 or – with regard to older devices – at least 5 minutes at 90 °C (194 °F)) (chemical disinfection runs the risk of disinfectant residues remaining on the instrument)
- that the used programme is suitable for the products and has a sufficient number of rinsing cycles
- that only sterile water or water with low levels of germs (max. 10 germs/ml) and endotoxins (max. 0.25 endotoxin units/ml) is used for the post-purge cycle (e.g. purified water/highly purified water)
- that the air used for drying is filtered and that the disinfector is regularly maintained and checked.

When choosing an appropriate cleaning system you need to ensure:

- that it is generally suitable for the cleaning of products made of metal and plastic
- that, in addition, – When no thermic disinfector is used, the disinfection detergent should be certified by the VAH (German Association for Applied Hygiene), the DGHM (German Society for Hygiene and Microbiology) or the FDA or have CE marking)
- the detergent should be compatible with the products.

It is essential that the concentrations recommended by the manufacturer of the cleaning and the disinfectant agent (if required) are adhered to at all times.

#### **Procedure:**

1. Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components.
2. When using products with lumen: ensure that all lumens are rinsed effectively as part of the pre-treatment process.
3. Place the disassembled products in the disinfector.
4. Start the programme.
5. Remove the products from the disinfector after the programme has finished.
6. Check and wrap the products straight after removal if possible (see chapters on 'Checking', 'Maintenance' and 'Packaging') if necessary, after they have been dried off completely in a clean place.

*Proof of the general suitability for effective mechanical cleaning and disinfecting has been provided by an independent certified test laboratory using the washer - disinfector G 7892 CD (thermic disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent Neodisher Mediclean forte, Dosiersystem DOS 1 (Dr. Weigert GmbH & Co. KG, Hamburg). As part of the testing the laboratory used the above described procedure*

#### **Manual cleaning and disinfection:**

Prepared by: Director of Quality Vladlena Shulezhko

Updating Date: 13.07.2015

Page 8 of 11



<b>TRATE</b>	Technical Documentation		Instruction	No. INS-IM.08	
	Subject: Instruction for use				
Developed by:	Director of Quality Vladlena Shulezhko		Approved by:	Member Siarhei Shulezhka	13. July. 2015

When choosing an appropriate cleaning and disinfecting agent you need to ensure

- that they are generally suitable for the cleaning and/or disinfection of products made of metal and plastic
- that the cleaning agent, where used, is suitable for ultrasound cleaning (no production of foam)
- the disinfection detergent should be certified by the VAH (German Association for Applied Hygiene), the DGHM (German Society for Hygiene and Microbiology) or the FDA or have CE marking) and that it is compatible with the used cleaning agent
- that the used chemicals are compatible with the products (see chapter on 'Material resistance')
- Only use freshly made solutions and water that is either sterile or low in germs (max. 10 germs/ml) and endotoxins

(max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water) and only use filtered air for drying or a lint free cloth before packaging

Ideally, combined cleaning/disinfecting agents should not be used. Combined cleaning/disinfecting agents can only be used in cases where there is a very low degree of contamination (no visible soiling).

It is essential that the concentrations and contact times recommended by the manufacturer of the cleaning and the disinfectant agents are adhered to at all times.

#### **Procedure:**

##### **Cleaning**

##### **Pre-treatment for the ultrasonic treatment:**

1. Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components.
2. Place instrument into a suitable disinfectant with active cleaning properties so that all surfaces, inner cavities, lumens and openings come into contact with the solution. Follow the disinfectant manufacturer's instructions.
3. Remove the device from the disinfectant solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to reach areas.

##### **Ultrasonic treatment:**

1. Before placing instruments into the ultrasonic unit, turn on the ultrasonic machine and let it run for 30 minutes to de-gas the solution. Use the suitable disinfectant with active cleaning properties and follow the disinfectant manufacturer's instructions. This process removes any gas or air bubbles in the solution. As with all types of cleaning, multi-component instruments should be disassembled. Make sure instruments have plenty of room. Don't overload your ultrasonic cleaner. Don't mix dissimilar metals (such as titanium and stainless steel) in the same cycle to prevent cross-plating.
2. Set the control panel per manufacturers' instructions and start the cleaning process
3. Upon completion of the cycle, rinse instruments after ultrasonic cleaning with water to remove ultrasonic cleaning solution. Take the products out of the cleaning bath and rinse at least three times thoroughly with water. Final rinsing to be done with distilled or deionized water. With regard to products with lumen: rinse all instrument lumens five times at the beginning and or at the end of the contact time using a disposal syringe (minimum volume 5-10ml) and a cannula.
4. Dry with soft and lint free cloth before packaging. Dry lumens and conduits with compressed air.
5. Check the products (see chapters on 'Checking' and 'Maintenance').

##### **Disinfection:**

1. Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components.
2. Immediately after use, immerse all instruments in a cleaning or disinfecting agent or in combined cleaning and disinfecting agent to serve as own security and to prevent the contaminants from drying. Always adhere to the manufacturer's instructions regarding concentration and reaction time of the cleaning or disinfecting agent or combined cleaning and disinfecting agent. With regard to products with lumen: rinse all instrument lumens five times at the beginning and or at the end of the contact time using a disposal syringe (minimum volume 5-10 ml) and a cannula.

Prepared by: Director of Quality Vladlena Shulezhko

Updating Date: 13.07.2015

Page 9 of 11

<b>TRATE</b>	<b>Technical Documentation</b>		<b>Instruction</b>	<b>No. INS-IM.08</b>
	<b>Subject: Instruction for use</b>			
<b>Developed by:</b>	Director of Quality Vladlena Shulezhko	<b>Approved by:</b>	Member Siarhei Shulezhka	13. July. 2015

- Afterwards, take the products out of the disinfecting bath and rinse them thoroughly with water at least three times. With regard to products with lumen: rinse all instrument lumens five times at the beginning and or at the end of the contact time using a disposal syringe (minimum volume 5-10 ml) and a cannula.
- Dry the products by blowing them dry using filtered pressurised air or with a lint free cloth before packaging.
- Wrap the products, if possible, straight after removal (see chapter on 'Packaging', if necessary, after they have been dried off completely in a clean place).

*Proof of the general suitability for effective manual cleaning and disinfecting has been provided by an independent certified test laboratory using the ultrasonic bath Powersonic P 2600 D ultrasonic system (Martin Walter Ultraschalltechnik AG, Straubenhardt) and cleaning agent Neodisher Z, Dosiersystem DOS 3 (Dr. Weigert GmbH & Co. KG, Hamburg) and the disinfectant Stammopur DR 8 (Dr. Weigert GmbH & Co. KG, Hamburg). As part of the testing, the laboratory used the above described procedure.*

### **Sterilisation**

We only recommend the use of the sterilisation procedures listed below!

#### **Steam sterilisation**

- Use of a fractional vacuum process or a gravitation process\* (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060 and/or DIN EN 285
- Validated according to DIN EN ISO 17665 (up to now: DIN EN 554/ANSI AAMI ISO 11134) (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ)))
- Maximum sterilisation temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665 (up to now: DIN EN 554/ANSI AAMI ISO 11134))
- Sterilisation time (exposure time at the sterilisation temperature) at least 20 min at 121 °C (250 °F) and/or at least 5\*\* min. at 132 °C (270 °F)/134 °C (273°F)

\* Use of the less effective gravitation procedure is only admissible if the fractional vacuum process is unavailable.

\*\*or 18 min (prion deactivation).



*Proof of the general suitability of the products for effective steam sterilisation has been provided by an independent certified test laboratory using the Autoclave Euro - Selectomat (MMM Münchener Medizin Mechanik GmbH, Planegg / München) as well as the fractional process and the gravitation process. During the testing, the laboratory took into account the typical hospital and practice conditions as well as the procedure described above.*

As a rule, the flash sterilisation procedure is not admissible. Furthermore, do not use hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation or plasma sterilisation. In order to avoid stains and corrosion, the steam must be substance-free (see limit values included in DIN EN 13060). When sterilising several devices, the maximum load of the sterilising apparatus must not be exceeded (observe the manufacturer's instructions).

When it comes to products that are re-used, the end of their useful life tends to depend on their wear and tear as well as the use-related damage. Therefore, it is necessary to check the instrument after or prior to each re-use (see section on 'Checking'). Independently of this, it is the sole responsibility of the physician using the instrument to decide upon re-use based on the respective case as well as the potential wear and tear of the instrument. In this context, known restrictions as to the frequency of instrument use need to be observed.

The above instructions have been validated by the manufacturer of the medical devices who found them to be SUITABLE for preparing a medical device for re-use. It is up to the person in charge of the reprocessing to ensure that, based on the use of the correct equipment, material and personnel in the reprocessing facility; the actual reconditioning process produces the desired results. Normally, this requires the validation and routine monitoring of the procedure. Equally, each deviation from the instructions provided should be carefully checked for effectiveness and potential adverse consequences by the person in charge of reprocessing

### **Signs explanation**









	Consult instructions for use
	Catalogue number

Prepared by: Director of Quality Vladlena Shulezhko

Updating Date: 13.07.2015

Page 10 of 11

<b>TRATE</b>		Technical Documentation	Instruction	No. INS-IM.08
		Subject: Instruction for use		
Developed by:	Director of Quality Vladlena Shulezhko	Approved by:	Member Siarhei Shulezhka	13. July. 2015

	Batch code
	Use by
	Sterilized using irradiation
	Do not use if package is damaged
	Do not reuse
	Keep away from sunlight
	Keep away from water
	Manufacturer



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

**Notes!**

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Page 11 of 11