



RealGUIDE[®] Surgical Instruments

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INSTRUCTIONS FOR USE - RealGUIDE SURGICAL INSTRUMENTS

1. NAME AND TRADE NAME OF THE DEVICE

RealGUIDE surgical instrumentation for dental implantology, such as: pilot drill / start drill, bone leveller drill, calibrated drills, drill stop, tissue punch / mucotome, bone mill (drill) and bone mill screw, countersink, bone tap, fixation pin drill, fixation pin, implant mount, driver and connectors

2. MANUFACTURER – NAME AND ADDRESS HEADQUARTERS

Manufacturer: 3Diemme S.r.l. - Via Risorgimento 9 - 22063 Cantù (CO) - Italy - Tel: +39 031 7073353.

The RealGUIDE surgical instrumentation for dental implantology complies with the EU Regulation 2017/745.

The Manufacturer 3Diemme S.r.l. is equipped with ISO 13485 Certified Quality System.

3. STORAGE AND HANDLING CONDITIONS

The RealGUIDE surgical instrumentation for dental implantology is supplied in a plastic bag with a tear-open system. Each package is accompanied by product identification labels.

The RealGUIDE instruments must be kept intact in a dry and clean place.

Do not use the devices if the package is broken or damaged.

Once removed from the plastic bag, the instrumentation can be placed in the appropriate surgical box.

4. STERILE STATE AND STERILIZATION METHOD

The RealGUIDE surgical instrumentation for dental implantology is supplied NON sterile and must be cleaned, disinfected and sterilised before use, as indicated in this document.

Sterilisation must take place in a steam autoclave (prion cycle for 20 minutes at a temperature of 134°C).

The sterilisation process must be carried out by qualified personnel under the supervision of the implantologist, using autoclaves which are in perfect working order and periodically reviewed, to ensure the correct sterilisation (as indicated by the autoclave manufacturer).

5. REUSABLE DEVICE

The RealGUIDE surgical instrumentation are non-disposable devices, they can be reused, but only after having been cleaned, disinfected and sterilised as per the procedure indicated in this document. It is up to the user to check that the devices are not damaged or worn before use. Damaged and worn devices must not be used, these must be disposed of and replaced.

6. INTENDED USE

The RealGUIDE Surgical Instruments are intended for the creation of the implant site, the insertion and extraction of the dental implant and for the connection and disconnection of prosthetic components to the dental implant.

7. INDICATIONS

Surgical instrumentation suitable for creating the implant site, inserting a dental implant and screwing in the related prosthetic components.

The drills for guided surgery must be used ONLY in GUIDED SURGERY procedures since the length of the drills takes into account the presence and thickness of a surgical guide.

The tip of the drills has an overall dimension of 0.5 mm more than the declared length of the drill. This must be taken into consideration, especially in the case of preparations in the vicinity of sensitive structures (e.g. nerve, membranes, ...).

In further detail, the indications for use of each family is listed:

Device Family	Model	Device Indications for use
PILOT DRILL/ START DRILL	STRMTAGL-1	The pilot, start and bone leveller drill is intended to be used to start the preparation of the implant pocket. The starting sequence drills are intended to be used for drilling in the cortical bone.
BONE LEVELLER DRILL	STRMTAGL-2	
CALIBRATED DRILLS	STRMTAGL-1	Calibrated drills are intended to be used to prepare the pocket in the cancellous bone, to allow insertion of the dental implant screw.
DRILL STOP	STRMTAGL-1	Drill stop is intended to limit the drilling depth to a predefined value during the preparation of the implant site.
TISSUE PUNCH/ MUCOTOME	STRMTAGL-3	The tissue punch (mucotome) is intended to be used to perforate the gingival mucous membrane and uncover the implant in the second surgical phase (usually after osseointegration) and to create, according to its shape, a gingival tunnel that allows the connection of the healing screws and later the prosthetic components, to the implant.
BONE MILL (DRILL) &	STRMTAGL-4	Bone Mill drills are intended to be used to remove any bone overgrowth in the area around the

Device Family	Model	Device Indications for use
BONE MILL SCREW		implant head, especially if the implant needs to be assembled with a straight or angled base for immediate loading. The bone mill screw is intended to be used to stop the bone mill drill in depth. The screw is intended to be screwed on the implant and to connect (surface on surface) to the bone mill drill.
FIXATION PIN DRILL	STRMTAGL-6	Fixation pin drills are intended to be used to prepare the pocket in the bone at predetermined points for the fixation pin.
FIXATION PIN	STRMTAGL-6	The fixation pin is intended to be used for fixing the surgical guide to the patient's bone.
COUNTERSINK	STRMTAGL-7	Countersink is intended to create a conical hole in the cortical bone and form the base of the neck where the implant has to be inserted.
BONE TAPS	STRMTAGL-5	Bone taps are intended to pre-tap a thread into the bone when preparing the implant site to allow for optimal insertion of the dental implant.
IMPLANT MOUNT	STRMINSESTR-3	The implant mounts are intended to be assembled on the implants to allow insertion through the surgical guide.
DRIVER	STRMINSESTR-1	Drivers are intended to be used during the implant insertion phase in the bone and to secure prosthetic components or other devices (e.g. transfer or mounts) on implants.
CONNECTORS	STRMINSESTR-2	Connectors are intended to extend the connection between the handpiece and the endpiece, to transfer rotary motion.

8. CONTRAINDICATIONS

The use of Surgical Instruments has no contraindications if used for the purpose intended by the manufacturer.

The use of dental guided surgery instruments is contra-indicated where dental guided surgery and thus implant placement is contra-indicated, such as in vulnerable patients (e.g. pregnant women, pediatric and elderly patients).

9. TARGET PATIENT POPULATION

The device is intended for all patients requiring dental guided surgery, both males or females of any age.

10. INTENDED USERS

The use, handling and clinical application of the Surgical Instruments must be carried out by qualified professional personnel (implantologist, dentist or maxillofacial surgeon) who has the necessary qualifications required according to the legislation in force in each country. It is necessary to have adequate and specialised training on the guided surgery technique. The intervention must be performed in a protected environment which is considered adequate from a hygienic point of view and with appropriate instrumentation.

11. EXPECTED CLINICAL BENEFITS

Surgical instruments do not have a direct clinical benefit to the patient.

The use of the instruments, both cutting and for insertion/extraction, may have indirect clinical benefits on the patient, since dental implant placement is not possible without surgical instruments.

12. DEVICE PERFORMANCE CHARACTERISTICS

The RealGUIDE surgical instrumentation includes the following devices: initial drills, calibrated drills for guided surgery, countersinks, bone taps, tissue punches, bone mill drills and related screws, drills and fixing pins for surgical templates, implant mounts, drivers and connectors. The box that can be supplied with the RealGUIDE Surgical instruments is specially designed to be used as a stand for sterilising the instrumentation in an autoclave.

The indications possibly marked on the surgical tray enable the instrumentation to be stored neatly, therefore making it available in a sequential position at the time of surgery, to facilitate the clinician's work.

DRILLS

The drills (available for software guided surgery) are available in multiple diameters and lengths to be able to insert implants of different diameters and lengths.

All the drills have the portion of engagement with the micromotor handpiece made in compliance with international standards.

The drills for guided surgery also have a 7.5 mm long cylindrical portion which allows them to be guided precisely within the surgical guide sleeves. Between the connection area to the handpiece and the cylindrical area and the cutting portion, the drills have a "stop" area.

When this area comes into contact with the surgical guide sleeve, the desired depth has been reached, and it is then possible to proceed with the next drill or with the insertion of the implant.

The length and diameter of the cutting portion are laser marked on the cylindrical portion of the drill. The drills can be cylindrical or conical or have a double diameter in the apical portion in order to create a surgical alveolus that acts on one side as a guide for the next drill and on the other creates an alveolus with the suitable morphology for implants (precision research in the creation of the surgical alveolus and an optimal primary stability of the implant once inserted in the alveolus).

The drills and mucotomes are coated in DLC (which gives the devices their black colour) in order to increase their cutting power and duration over time and to minimise the friction coefficient with the bone and therefore reduce the risk of necrosis by overheating.

MOUNTS

The mounts are made with different types of connections in order to be available on the different implant connections.

All the guided surgery mounts have a diameter in the cylindrical portion which is specially designed to be able to accurately guide the implant during the insertion phase.

At a distance of 9 mm from the contact plane between the mount for guided surgery and the implant, a stop zone is created that allows the clinician to know when the implant has reached the planned depth. The stop zone must come into contact with the surgical guide sleeve.

Beyond the stop area, a square portion is made to allow the engagement of the instruments for the insertion of the implants.

The mounts are supplied with the dedicated mount screw. Inside the mount there is a threaded hole that prevents the screw from accidentally slipping out during surgery.

13. INFORMATION TO CHECK IF THE DEVICE IS SUITABLE

Before each use, it is necessary to check that the devices are not damaged or have any worn areas. It is important to check that the coating of the drills is uniform, that there is no oxidation or dirt on the instruments, that the tips and cutting edges of the drills and mucotome are not damaged or worn, and that the laser markings are clearly visible.

If a device is not in perfect condition, it must be disposed of and replaced. Devices that are not in perfect condition should not be used, as they could cause damage to the patient's health and compromise the success of implant rehabilitation.

14. UNDESIRABLE SIDE EFFECTS, RESIDUAL RISKS

The possible side effects that can occur following dental implant surgery are:

- Transient discomfort due to the surgery.
- Inflammation of the area which has undergone surgery.
- Localised infections.

If any other reaction occurs which is not described in this leaflet, please contact the Manufacturer or the distributor of the RealGUIDE dental instrumentation.

Work with abundant irrigation of pre-cooled physiological solution to avoid overheating and consequent bone necrosis and to maintain perfect visibility in the operating field.

15. SPECIFICATIONS REQUIRED BY THE USER

The surgical alveolus drilling system is sequential, and each calibrated drill has a laser marking of the diameter on the drill itself.

It is recommended to use the drills for up to 15 patients and to carefully check the cutting edge before each use. The use of worn drills could lead to overheating of the bone and compromise the osteointegration process of the implant.

It is recommended to use mounts for a maximum of 20 uses and to carefully check that the devices are in good condition before each use. The use of worn devices could lead to difficulties in the mount-implant assembly phase or in the positioning of the implant in the surgical alveolus.

The surgical instruments are supplied NON-STERILE and MUST be cleaned, disinfected and STERILISED BEFORE USE. Using or reusing a surgical instrument that has not been properly cleaned and sterilised exposes the physician, operators and patient to serious risk of infection and cross-infection.

Operate the micromotor only once the guided surgery drill is already inserted in the surgical guide sleeve and stop the rotation before removing the guided surgery drill from the sleeve to avoid vibrations and damage to the devices.

16. PREPARATORY TREATMENT, HANDLING, AND DISINFECTION LEVELS NECESSARY TO ENSURE PATIENT SAFETY

The preparation of the patient and the surgical field must guarantee the conditions of hygiene and sterility typical of any surgical intervention. Hygiene and sterility conditions must be ensured throughout the procedure.

All the surgical instruments must be cleaned, disinfected and sterilised before use.

After surgery all the instruments must be immediately treated to prevent traces of blood or other tissues from being encrusted on the instruments themselves. All the instruments must then be disinfected and sterilised according to the instructions provided in this document.

17. INFRASTRUCTURE, TRAINING AND USER QUALIFICATION

Oral implant surgery must be performed by implantologists with the qualification required in each country and at clinics or facilities which are authorised by the competent authorities in each country to perform oral implant surgery. Users must carry out surgery while correctly

wearing all the PPE required by their profession, e.g. mask, gowns, gloves and goggles. They must pay the utmost attention to avoid minor injuries from contact with devices with sharp or pointed ends, to prevent contamination with the patient's saliva or blood, and to avoid contaminating the patient themselves. The utmost importance must be given by users to the cleaning, disinfection and sterilisation of the environment in which the surgery is performed and of the instrumentation used, to prevent the onset of infections or the occurrence of cross-infections.

Any use, manipulation or application, in total or partial form, during any of the phases of the intervention with 3DIEMME devices by unqualified personnel or by those without the necessary qualifications can cause serious damage to the patient's health; this exempts the Manufacturer from liability for any damage or hazards caused by the conditions described in this document or by other facts not described. Likewise, the user is entirely responsible for any damage or hazards that could be caused by the incorrect handling or use of the system.

18. INFORMATION FOR CLEANING, DISINFECTION AND STERILIZATION

The sterilisation process must be carried out by qualified personnel under the supervision of the implantologist, using autoclaves which are in perfect working order and periodically reviewed, to ensure the correct sterilisation.

Before the first use and immediately after surgery, all steel and titanium instruments must be treated with the following validated procedure:

- 1) Pre-wash - manual procedure that uses an enzymatic detergent designed to remove organic contaminants from the medical device by chemical disintegration, while ensuring partial physical removal of the microbial contamination:
 - 1a. Immediately clean the blood residues, secretions and bone particles from the surgical instruments and the surgical tray. It is necessary not to let them adhere, in order to make cleaning easier. Remove the instruments from the surgical tray and immerse them completely in a container with a non-aggressive and non-corrosive cleaning solution (use a multi-enzymatic detergent, i.e. a neutral mixture of surfactants and protease, lipase and amylase enzymes. Avoid solutions containing chlorine. Prepare the solution by following the detergent manufacturer's instructions) and leave them to soak for the contact time indicated by the detergent manufacturer in the technical data sheet, making sure that they are not touching each other.
 - 1b. Remove from the bath and brush thoroughly with a soft sponge to remove all visible dirt. Pay special attention to the sharp edges of the surgical drills to avoid minor wounds.

- 1c. Thoroughly rinse all the material with running water for at least 3 minutes, moving the devices around slightly to allow the water to reach the whole surface area, to remove any detergent residue.
- 1d. Dry briefly with absorbent paper.
- 2) Cleaning - manual procedure necessary to complete the removal of organic contaminants:
 - 2a. Prepare the solution using a multi-enzymatic detergent (a neutral mixture of surfactants and protease, lipase and amylase enzymes) following the detergent manufacturer's instructions.

Fill the ultrasonic tank with the cleaning solution and activate the degassing phase as indicated in the equipment instructions (this phase is important as it releases the gas bubbles bound to the solution that could affect the cleaning action of the ultrasounds). At the end of the degassing phase, put the pre-washed devices in the ultrasonic tank, placing them in a special basket, completely immersed in the detergent solution. Set the working temperature (25°C) and, when this is reached, activate the ultrasounds (power 45 kHz). Place the devices in the bath individually to prevent them from being damaged by coming into contact with each other.

Leave the devices immersed for the contact time indicated by the detergent manufacturer in the data sheet.
 - 2b. At the end of the immersion time, remove the devices from the bathroom and carefully brush them with a soft sponge to remove all visible dirt.
 - 2c. Rinse all the material again for at least one minute under cold running water (6°C - 12°C), moving it around slightly to allow the water to reach the whole surface area, to remove any detergent residue.
 - 2d. Next, briefly dry the devices with a sterile cloth.
- 3) Disinfection – manual procedure necessary to break down the remaining microbial load on the devices:
 - 3a. Transfer the washed and dried devices as specified above into a clean basin and immerse them in a ready to use alcohol-based disinfectant solution with

low residual potential (70% alcohol) for a minimum contact time obtained from the disinfectant data sheet.

3b. After the contact time has elapsed, remove each device and dry it with a sterile cloth.

4) Sterilisation – process conducted in an autoclave to make the devices sterile:
All the new instrumentation of the 3DIEMME system is supplied non-sterile and must be removed from its original packaging for cleaning, disinfection and sterilisation prior to first use.
At the end of the cleaning and disinfection phases, the instrumentation must be sterilised.

4a. If you choose to sterilise the instrumentation inside the surgical box supplied by the Manufacturer:

1. Place all the clean instruments as indicated above in the surgical tray inside the surgical box.
2. Wrap the surgical box in a double bag for autoclaving.
3. Sterilise in a steam autoclave (prion cycle for 20 minutes at a temperature of 134 °C). At the end of the sterilisation process, check that the process parameters provided by the autoclave comply with the parameters required in this document.
4. Do not remove the surgical box from the autoclave until the end of the drying cycle.

4b. If you choose to sterilise the instrumentation individually:

1. Place the clean instrument as indicated above in a double bag for autoclave sterilisation.
2. Sterilise in a steam autoclave (prion cycle for 20 minutes at a temperature of 134 °C). At the end of the sterilisation process, check that the process parameters provided by the autoclave comply with the parameters required in this document.

19. USE IN CONJUNCTION WITH OTHER DEVICES

All RealGUIDE surgical instruments can be used in conjunction with RealGUIDE Surgical Guides, RealGUIDE Surgical Guide Sleeves and with the Universal RealGUIDE box.

The use of non-original devices, used individually or in combination with any original 3DIEMME product, will automatically void any full or partial warranty on original 3DIEMME products and could cause serious harm to the patient's health. The use of non-original

3DIEMME devices exempts the Manufacturer from liability for any damage or hazards caused to operators and patients.

The instruments intended to be motor driven are compatible with any handpiece designed in accordance to the ISO 1797 standard.

20. DIRECTIONS FOR USE

The instruments must be used according to the specific drilling sequence, as planned.

The motor powered tools must be inserted in a dental handpiece with ISO 1797 connection and must be constantly irrigated during use.

Each instrument should be used without exceeding the following, maximum, speeds:

- Fixation pin drills	1000 rpm
- Bone leveler, Start drill, Cylindrical and Conical bone mill	600 rpm
- Mucotome	100 rpm
- Calibrated drill	800 rpm
- Implant mount	20 rpm

Connection instruments such as Implant mount mustn't be stressed with a torque greater than 50 Ncm.

Connection devices such as the bone mill screw, and the implant mount must be used with the appropriate implant.

21. WARNINGS

The sterilisation cycles cause a progressive deterioration of the surgical instruments; therefore, it is necessary to periodically review all the instruments to check that they are in perfect condition (including unused instruments).

Before each use, check that each instrument is in good condition, replacing all instruments that show signs of defects.

Do not use in the case of allergy or sensitivity to the chemical components of the material from which the instruments are produced.

22. MATERIALS

The RealGUIDE surgical instrumentation is manufactured in stainless steel for surgical instruments AISI 420 (according to the ASTM F899 standard), AISI 303 stainless steel

(according to the ASTM A582M standard) and titanium grade 5 TiAl6V4 (according to the ASTM F136 standard), and could be coated with carbon based DLC coating.

23. PRECAUTIONS FOR DISPOSING OF THE DEVICE SAFELY

- INFECTIONS OR MICROBIAL RISKS - CONTAMINATION BY POTENTIALLY INFECTIOUS SUBSTANCES OF HUMAN ORIGIN

Carry out the surgery with 3DIEMME instrumentation by always wearing the appropriate personal protective equipment to avoid contaminating the staff with the patient's saliva or blood. Always carry out the surgery in a facility which is equipped for oral implant surgery, respecting the hygiene and sterility conditions required for an oral implant surgery. Get rid of any damaged or worn devices in the special waste, if they are disposed of after the surgery and therefore biologically contaminated or get rid of damaged or worn devices in the general waste, after having cleaned, disinfected and sterilised them correctly according to the procedure presented in this document.

- PHYSICAL RISKS - SHARP OR POINTED OBJECTS

The RealGUIDE surgical devices have sharp or pointed parts. It is therefore necessary to pay the utmost attention during their handling at all stages: surgery, cleaning-disinfection-sterilisation process, control and disposal.

24. REQUIREMENT TO REPORT ACCIDENTS TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE

The user is obliged to immediately report any adverse event or incident to the Competent Authorities of the State in which they have used the 3DIEMME devices and to the Manufacturer, through the distributor. An adverse event or incident is defined as any malfunction or deterioration in the characteristics and/or performance of the medical devices, as well as any inadequacy in the labelling or instructions for use which, directly or indirectly, could lead to or could have caused the death of a patient, of a user or other people or a serious deterioration in their state of health or in the event of any serious risk to public health.

25. SYMBOLS USED IN THE LABELLING

	Catalogue Number		Unique Device Identification (UDI) number
	Caution		Prescription only (USA market)
	Model number		Do not use if packaging is damaged

	Consult instructions for use (electronic)		Batch Code
	Manufacturer		CE Marking of Conformity and associated Notified Body number.
	Swiss Authorised Representative		Medical device
	Non sterile		Distributed by