ANTEEA
COMPONENTISTICA MADE IN ITALY

INSTRUCTIONS FOR USE
SURGICAL INSTRUMENTS

www.anteea.com

1.PRODUCT IDENTIFICATION
The surgical instruments designed by Anteea SRL are reusable medical devices intended for temporary use in the oral cavity (no more than 60 minutes at a time), supplied in NON-STERILE packaging, and are not designed for connection with an active medical device.
The surgical instruments manufactured by Anteea SRL can be used to prepare implant sites and are designed to be used with dental implants.

2. DESCRIPTION AND USE
The information provided in these operating instructions supplements the information provided in the catalogues/manuals. If you are not in possession of this documentation, a copy can be requested from Anteea SRL.
All devices are identified by an instrument code laser engraved on the body of each instrument. If the space is not sufficient to enter the complete code, the elements for unambiguous identification of the device are provided (e.g. diameter or length).
During surgical procedures, the operator must implement all the necessary actions to prevent patients from ingesting them.
Some tools are equipped with O-rings to allow a grip between different tools and ensure transport and use inside the mouth without the risk of falling. As these O-rings are made of plastic, their wear and gripping ability should be checked regularly. It is recommended to replace the O-rings whenever necessary and in any case no more than every 20 uses of the tools. Worn O-rings can be removed using a simple probe. New O-rings should be fitted to the tool and gently pushed into place. Check that they are positioned correctly and are not twisted.
Failure to comply with the instructions provided may cause surgical problems and damage to the patient's health.

a. Osteotomes / Expanders
These are hand-operated impact wrenches and are not connected to a micromotor or power sources. They are used to fix the cover screws, the transgingival healing screws, the fixing screws of the restoration posts, etc. They are very practical during the various phases of the intervention because they are ready to use and no assembly of the different parts is necessary, therefore, they are quick and easy to use and are available in various lengths: short, to facilitate access to the sectors distal, and long for use in the presence of anatomical obstructions related, for example, to the presence of adjacent teeth.

b. Drivers
These are hand-operated impact wrenches and are not connected to a micromotor or power sources. They are used to fix the cover screws, the transgingival healing screws, the fixing screws of the restoration posts, etc. They are very practical during the various phases of the intervention because they are ready to use and no assembly of the different parts is necessary, therefore, they are quick and easy to use and are available in various lengths: short, to facilitate access to the sectors distal, and long for use in the presence of anatomical obstructions related, for example, to the presence of adjacent teeth.

c. Screw tappers
These sharp instruments are used to prepare the bone to accept the implant thread. These are manually operated tools and are not connected to a micromotor or power source. They are normally used in the presence of very compact or cortical bone to reduce the compression and the implant insertion torque.

d. Drivers / Mounters
These devices have two functions. They act as a carrier to extract the implants from the package without contaminating them, i.e. without touching their surface, and transport them into the oral cavity without touching them and they also act as screwdrivers. They are manually operated tools and are not connected to a micromotor or power sources. Lever movements should be avoided as they increase the risk of breakage. Various drivers are available, depending on the implant system used. Technical details of each system are provided in surgical manuals and catalogues. Please read these details carefully before use. There are also drivers who have the same function as those mentioned above, but do not act as carriers. They are manually operated tools and are not connected to a micromotor or power sources. Caution is needed when using them to insert implants in place of special mounters or drivers, as excessive torque can fray the edges of the hex drivers and cause irreversible deformations to the sides of the internal connections. They are usually used to unscrew implants with internal connections, when an implant needs to be removed. Lever movements should be avoided as they increase the risk of breakage.

e. Digital connector
Manual devices for facilitated use of surgical kit instruments.

f. Depth gauges
Hand instruments used to verify the depth of insertion achieved by drills or osteotomes.

g. Parallelism pin
Instruments normally supplied with two round-tipped cylindrical sections, one narrower and one wider, which are normally inserted into prepared holes with burs, to allow the practitioner to verify that the preparations are parallel. Depending on the diameter of the hole, they can be inserted narrow end first or wide end first.

h. Mounter stop key
Hand wrenches used to hold the implant fitters in a stable position while the fixation screws are loosened. They are normally used to prevent the implants from coming loose when the screws holding the mounters are removed.

i. Guide sleeves
They are small steel cylinders that are normally inserted into special silicone or transparent resin supports made by dental technicians on the dentist's instructions and used to guide the insertion axis of the first drill used to prepare the implant site.

3. INTENDED USE
Anteea Srl declares to be the manufacturer and identifies the risk class as follows:
• Osteotomes/Bone Expanders, Drivers/Screwdrivers, Taps, Drivers, Allen Keys, Digital Connector, Depth gauges, Parallelism Pins, Mounter stop key and Dimes: Reusable surgical instruments, for temporary use (less than 60 minutes at a time), supplied in NON-STERILE packaging, not designed for connection to active medical devices, Class of risk 1.

4. MANUFACTURER IDENTIFICATION
The manufacturer of the surgical instruments for dental implants referred to in these Instructions for Use
Anteea Srl
Viale Europa 126 O/P - 55012 loc. Lammari (Lu) Italy
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www.anteea.com - info@anteea.com

5. RAW MATERIALS USED
The materials used by Anteea SRL for the production of surgical instruments have been selected on the basis of the properties indicated for their intended use pursuant to Regulation (EU) 2017/745, Annex I - Essential Requirements, point 10.1.
They are made, depending on the type of component, using:
• Titanium Grade 5 (Ti6Al4V)
• Stainless steel - KLEINOX 4305 (DIN EN X8CrNiS18-9 – AISI 303 – EN 10088-3)
Remember to ask patients if they are allergic to any of the raw materials. Go to www.anteea.com for detailed datasheets of all the materials used, to check their chemical compositions and physical and mechanical properties.

6. WARNINGS
Anteea SRL surgical instruments are sold in NON STERILE packs. Before use, they must be cleaned, disinfected and sterilized according to the instructions below. Failure to observe these warnings may expose the patient to infection.
It is recommended to collect and archive all clinical, radiological and radiographic documentation.
Each pack bears the code, the description of the contents and the lot number. The doctor should communicate these details if necessary. When handling the devices, both during use and during cleaning and sterilization, the use of surgical gloves is recommended for personal protection against bacterial contamination. The packaging complies with European standards.

7. CONTRAINDICATION
In evaluating the patient, in addition to his suitability for implant-prosthetic rehabilitation, it is usually necessary to consider the contraindications that apply to oral surgery procedures in general. These include:
• Coagulation disorders, anticoagulant therapy.
• Bone healing or regeneration disorders such as:
• decompensated diabetes mellitus
• metabolic or systemic diseases that compromise tissue regeneration with a particular influence on healing and bone regeneration
• alcohol abuse, smoking and drug use
• Immunosuppressive therapy, such as: chemotherapy and radiotherapy • Infections and inflammation, such as: periodontitis, gingivitis
• Poor oral hygiene
• Inadequate motivation
• Occlusion and/or articulation disorders as well as inadequate interocclusal space
• Inadequate alveolar process
• Bone expanders should be used instead of drills when preparing sites in poor quality bone.
It is contraindicated to place implants and implant restorations in patients with poor general or oral health, those who are unable to adequately monitor their general condition, or those who have undergone organ transplants. Psychologically unstable patients, alcoholics or drug addicts, poorly motivated or uncooperative patients should also be considered unsuitable for this type of treatment. Patients with poor periodontal health should first be treated and allowed to recover. In the presence of lack of bone substance or poor quality of the recipient bone, such as to compromise the stability of the implant, it is necessary to perform an adequate guided tissue regeneration before implant treatment.
Contraindications also include: titanium allergy, acute or chronic infectious diseases, subacute chronic maxillary osteitis, systemic diseases, endocrine disorders, diseases resulting from microvascular disorders, pregnancy, breastfeeding, previous radiation exposure, haemophilia, neutropenia, use of steroids, diabetes mellitus, renal insufficiency and fibrous dysplasia. Implants supporting restorations are medical devices which are introduced into the mouth during surgical procedures and as such entail further limitations of use, the details of which are given in the Instructions for use of the implant fixtures.

8. SIDE EFFECTS
The following may occur after surgical procedures:
• Temporary local swelling, edema and hematoma.
• Temporary changes in sensitivity.
• Temporary chewing restrictions.
• Post-operative micro-haemorrhages in the following 12-24 hours.

9. CLEANING / DISINFECTION / STERILIZATION / STORAGE
All surgical accessories for dental implants are sold NON STERILE. Before use, they must be cleaned, disinfected and sterilized. These processes must be performed before use and before any subsequent reuse. Repeating the processes described in this paragraph has a negligible effect on the devices. Tools should always be checked before use to ensure they are working properly. Any tools showing signs of wear must be replaced immediately with new ones. it is particularly important to check that the drivers grip correctly inside the connection wells on the heads of the screws to be lifted and tighten with them. Failure to follow these instructions may result in cross-infection and intraoperative complications.

a. Cleaning
Containers and transport to be used for washing: there are no particular requirements.
In case of automatic cleaning, use an ultrasonic bath with a suitable cleaning solution. Use only neutral detergents. Follow the manufacturer's instructions regarding concentrations and wash times. Use demineralised water to avoid the formation of stains and streaks.
When discharging, check for device recesses, holes, etc. to make sure all residue has been completely removed. If necessary, repeat the cycle or clean manually.
For manual cleaning, use a suitable neutral detergent and follow the manufacturer's instructions for use. Brush the products with a soft bristle brush under plenty of running water. Use the brush to apply the cleaner to all surfaces. Flush with distilled water for at least four minutes. Make sure plenty of running water runs through all holes.
For drills with internal irrigation, use the appropriate pins supplied with the handpieces to ensure that the irrigation holes are completely clean and free of bone fragments or biological tissue.
After rinsing, carefully dry the devices and place them inside special sterilization bags.
Do not exceed 120°C when performing a drying cycle in a washer-disinfector.

b. Sterilization
For sterilization, the kits must be packaged in autoclavable pouches.
Sterilization can be performed as follows:
• Method 1: Autoclave (Gravity Steam) temperature of 121-124°C, exposure for 20 minutes and drying for 15 minutes;
• Method 2: Autoclave (Dynamic Cycles-Air-Pre-Vacuum Removal) temperature of 134°C, exposure for 4 minutes and drying for 20 minutes.

c. Storage
After sterilization, the product must remain in the sterilization bags. Bags should only be opened immediately before re-use. Under normal conditions, sterilization pouches maintain the sterility of the contents unless the wrapping is damaged. Therefore, do not use the components if the bags they were stored in are damaged and re-sterilize in new bags before using them again. The storage time of the sterilized products inside the bags must not exceed that recommended by the manufacturer of the bags.
The product must be stored in a cool, dry place, away from sunlight, water and heat sources.

10. REFERENCE STANDARDS
The surgical components are designed and manufactured according to the most recent directives and harmonized standards relating to the materials used, the production processes, the information provided and the packaging.

11. DISPOSAL PROCEDURES
If used, dispose of surgical accessories as biological waste, according to local regulations.

12. RESPONSIBILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS
Optimal patient care and attention to patient needs are necessary conditions for the success of an implant procedure and, therefore, patients must be carefully screened and informed of the risks and obligations associated with treatment and encouraged to cooperate with the physician in the interest of the success of the treatment itself.
The patient must therefore maintain good hygiene, which must be confirmed during follow-up appointments, ensured and recorded, and the doctor's instructions and orders must be observed.
The instructions provided by Anteea SRL are available at the time of treatment and are accepted as normal dental practice. They must be followed and applied at all stages of treatment: from collecting the patient's history to post-operative check-ups.
The warranty only covers manufacturing defects provided that the defective part is identified by the article number and lot number and returned within the warranty period. The warranty terms are available on the website www.anteea.com.

13. DATE AND VALIDITY OF THESE USER INSTRUCTIONS
These user instructions are valid and effective from January 2021.

EXPLANATION OF THE SYMBOLS		
	Attention! See instructions for use	✓
	Lot number	✓
	Code	✓
	Manufacturer	✓
	Country of the manufacturer	✓
	UDI code, unique identification of the device	✓
	Medical Device	✓
	Consult the instructions for use www.anteea.com	✓
	CE mark The identification number of the notified body must follow this symbol	✓
	Do not use if the packaging is damaged	✓
	Non-sterile product	✓

manufactured by Anteea Srl
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