IT: CONTRA-ANGLE DRILLS AND INSTRUMENTS

PRODUCT IDENTIFICATION
Contra-angle burs and surgical instruments for implant systems manufactured by Bone System Srl are medical devices intended for use in the oral cavity, for temporary use (continuous use not exceeding 60 minutes), reusable, in NON-STERILE packaging.
The functions of the surgical instruments are:
- preparation of implant sites;
- insertion of implants into the sites;
- tightening and unscrewing all connection screws (surgical screws, healing screws, abutments, prosthetic screws, ball abutments, etc.).

Bone System surgical instruments are intended for use with dental implants manufactured by Bone System Ltd. The use of surgical instruments for procedures involving implants other than those manufactured by Bone System Ltd. limits the liability of Bone System Ltd. and voids the product warranty (see section "Liability for defective products and warranty terms").
We are not responsible for the use of non-original equipment.

DESCRIPTION AND USE
The information in these instructions for use supplements the information provided in catalogues and surgical manuals.
All instruments are marked with elements that allow the device to be uniquely identified (e.g. diameter or length) according to the diameter of the implant or the size of the platform. The instruments covered by these instructions for use (surgical burs and drivers) are intended for mechanical use, i.e. they have a shank with a standard contra-angle connection in accordance with ISO 1797:2017 and must be used with a suitable micromotor for implantology. Incorrect insertion of the instruments into the handpieces can lead to instrument vibration, eccentric rotation, premature wear and bending of the shank. It is recommended that only surgical micromotors suitable for use be used. It is recommended that micromotors be checked periodically by the manufacturers, according to their individual instructions, to prevent possible malfunctions (e.g. displacement of the drive shaft axis, worn or malfunctioning collets, etc.). Failure to comply with the instructions provided may cause surgical problems and damage to the patient's health.

Shoulder milling cutters and preparers
These are sharp instruments used to prepare surgical sites for specific dental implants. They have different shapes depending on the implant system to which they belong, feature depth markings to allow the working depth to be determined, and may or may not be designed to attach a depth stop. Please refer to the catalogues of the individual implant systems for detailed technical specifications. The drills produce a hole that is longer than the insertion depth of the implant. This greater length is related to the size of the tip of the instrument. The exact measurements of the depth of the holes determined by the drills are given in all implant system catalogues and surgical manuals. It is recommended to use the rotation speeds indicated in the individual catalogues or surgical manuals to avoid the development of bone necrosis. Lever movements increase the risk of instrument fracture and should therefore be avoided. In general, sudden changes in speed should be avoided. Pressure should never be applied to the point of forcibly stopping the rotation of the instrument. This could lead to excessive heat build-up in the tissues affected by the cut, resulting in bone necrosis, and damage both the instrument and the device used (micromotor). This could also cause the instrument itself to break. It is also recommended to work intermittently to avoid overheating and wear of the working part and undue heat increase in the tissues affected by the cut. The use of a suitable cooling liquid is recommended. In the absence of adequate irrigation, bone necrosis may occur.
The wear of the burs depends largely on the type and density of the bone being drilled: harder bone causes greater wear on the instruments. For greater safety and caution with regard to the wear resistance of the device, it is recommended that the burs be used for no more than 20 work cycles or sooner if the instruments lose their cutting capacity. The recommended 20 cycles represent an average figure. It is recommended to check the maintenance status of the residual cutting capacity after each operation. Bone System Ltd. accepts no responsibility in the event of excessive use. Cutters must never be resharpened. Do not use damaged, bent or worn instruments.
An extension for burs is available for use when the total length of the instruments is too short due to the presence of adjacent teeth that prevent the handpiece head from passing through. When using it, ensure that the bur shank is inserted correctly and completely. Incomplete insertion will cause the bur to rotate eccentrically.

RECOMMENDED SPEEDS

Initial cutters	Cutte	Final bur	Preparer
rs			
800-1,000 rpm	intermedia		shoulder
	te		
	200-600 rpm	200-300 rpm	100-200 rpm

Stop cutters
These devices are inserted onto the drills designed to receive them. They allow the working length of a drill to be limited to a predetermined height. The measurements are listed in catalogues and surgical manuals and screen-printed on surgical trays. It is recommended to always check that the stop is inserted at the desired height. Incomplete insertion may reduce the height of the preparation. Any insertion difficulties can be resolved by slightly activating the stop tabs. Also check that the stop provides sufficient retention. If retention is too weak, the instrument may fall off the bur during surgery. If the stops reduce the retention capacity, simply tighten the tabs slightly, either manually or with tweezers.

Drivers
These devices have a dual function: they act as carriers, allowing implants to be removed from their packaging without contaminating them, i.e. without touching their surface, and transported to the oral cavity without ever touching them; they also act as screw drivers, transmitting the rotary motion from the micromotor to the implants, allowing them to be screwed into the prepared sites. Lever movements should be avoided as they increase the risk of fracture. Drivers vary depending on the different implant systems. Technical details for each individual system can be found in the surgical manuals and catalogues. It is recommended that you read these before use.
Drivers used to tighten final abutment screws must be used with torque control:
- Surgical screws and healing screws: 10–15 Ncm
- Prosthetic screws for tightening abutments: 20-25 Ncm
- Direct screw-retained prosthetic components (e.g. straight mufas and ball attachments): 30 Ncm

INTENDED USE
For the purposes of Regulation (EU) 745/2017, Bone System Srl declares itself to be the manufacturer of Bone System contra-angle surgical instruments for dental implants and identifies their risk class as follows:
Surgical burs, bur stops and drivers: Reusable invasive surgical medical devices for temporary use, in NON-STERILE packaging, Risk Class IIa according to rule 6.
The use and handling of surgical instruments is reserved for dental medical personnel with the necessary qualifications and professional training.

IDENTIFICATION OF THE MANUFACTURER
Bone System Srl
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RAW MATERIALS USED
The materials used to manufacture contra-angle instruments have been selected on the basis of their properties for their intended use, in accordance with Regulation (EU) 745/2017.
Depending on the type of instrument, they are manufactured in:
- Cutters: AISI 630 (17-4 PH)
- Drivers: AISI 630 (17-4 PH)
- Bur stops: AISI 630 (17-4 PH)

It is recommended to check with patients for any allergies to the raw materials listed.
Detailed technical data sheets for all materials used can be requested from Bone System Srl to verify their chemical composition and physical-mechanical characteristics.

SIDE EFFECTS
When using contra-angle instruments, the following complications have been observed sporadically
following complications have been observed sporadically:
- Post-operative haemorrhages
- Necrosis due to overheating
- Infections
- Suture dehiscence
- Iatrogenic trauma
- Poor osseointegration/implant loss
- Insertion post jammed or torn due to excessive torque
- Seizing of the stem inside the contra-angle handpiece seat
- Breakage of the adjustment screw due to excessive torque

CLEANING / STERILISATION / STORAGE
All contra-angle surgical instruments are sold in a NON-STERILE condition.
Before use, they must be cleaned, disinfected and sterilised. These processes must be performed before first use and before each subsequent reuse. Repeating the processes described in this paragraph has a minimal effect on these devices. The correct functionality of the instruments must always be verified before use. If there are signs of wear, the instruments must be replaced immediately with new devices.
Failure to comply with these instructions may result in cross-infection and intraoperative complications.
Cleaning
Containers and transport to be used for washing: there are no special requirements.
For manual cleaning: use an ultrasonic tank with a suitable detergent-disinfectant solution.
For instrument disinfection, it is recommended to use washing liquids based on: N,N-didecyl-N-methylpoly(oxyethyl)ammonium propionate, chlorhexidine digluconate, enzyme system (amylase, carbohydrase, lipase, protease), synergised surfactants according to HLB grade, perfume, colouring, stabilising agents and purified water as required.
For warnings and mixing instructions, refer to the manufacturer's technical data sheet. Use demineralised water to prevent the formation of stains and marks.

At the end of the contact period, the devices are rinsed with water

sterile. The medical devices are then dried with a sterile cloth.

After rinsing, dry the devices thoroughly and place them in suitable sterilisation bags.

If a drying cycle is performed as part of the cycle of a washing and disinfection device, do not exceed 120°C. **Sterilisation**
For the sterilisation of reprocessed medical devices, the manufacturer recommends a moist heat process in a vacuum steam autoclave with cycles at 121°C for 18 minutes.
Storage
After sterilisation, the product must remain in the bags used for sterilisation. The bags must only be opened immediately before reuse. Sterilisation bags are normally able to maintain sterility inside them, unless the packaging is damaged. Therefore, take care not to use components if the bags in which they were stored are damaged and re-sterilise them in new bags before reuse. The storage period of sterilised products inside the bags must not exceed that recommended by the bag manufacturer.
The product must be stored in a cool, dry place, away from direct sunlight, water and heat sources.

REGULATORY REFERENCES
The design and manufacture of surgical components is carried out in accordance with the most up-to-date harmonised directives and standards concerning

CE 0425

the materials used, production processes, information provided and packaging.
The shank of contra-angle instruments complies with ISO 1797:2017 Dentistry - Shanks for rotary and oscillating dental instruments.

DISPOSAL PROCEDURES
Surgical instruments, if used, must be disposed of as biological waste in accordance with local regulations.

LIABILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS
Optimal patient care and attention to their needs are necessary conditions for successful implantology. It is therefore necessary to carefully select patients, inform them of the risks involved and the responsibilities associated with treatment, and encourage them to cooperate with the dentist to ensure the success of the treatment.
Patients must therefore maintain good hygiene, which is confirmed during check-ups and follow-up appointments; this must always be ensured and documented, just as the doctor's instructions and prescriptions must be observed and documented.
The instructions provided by Bone System Ltd. are available at the time of treatment and accepted by the dental practice; they must be observed and applied at all stages of treatment: from the patient's medical history to post-operative check-ups.
The warranty only covers proven manufacturing defects, subject to the item being sent with its item code and batch number within the warranty period.
Any serious incident occurring in relation to the medical device supplied by us must be reported to the competent authority of the Member State in which you are based.

DATE AND VALIDITY OF THESE INSTRUCTIONS FOR USE
These instructions for use are valid from 01/07/2025.

SIMBOLISM

	Caution! See instructions for use.
	Lot number
	Code
	Manufacturer
	Country of production
	UDI code, Unique Device Identifier
	Medical Device
	Consult the instructions for use.
	CE conformity marking Where applicable: the identification number of the notified body must follow this symbol
	Do not reuse, single-use product
	Do not use if the packaging is damaged.
	Non-sterile product

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