

## ROTARY DEVICES

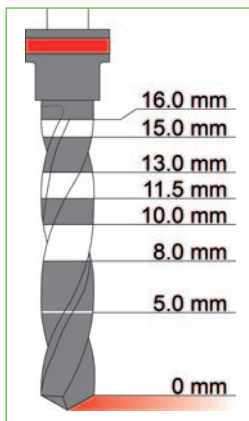
### Product

**Handpiece/hex key adapter, Mechanical clamping aid, Depth stop, Corer, Bone expander, Bur, Surgical bur, Bone tap, Countersink, Bur extension.** For full details of available components refer to the catalogue or website [www.tffsystem.it](http://www.tffsystem.it).

**Material:** medical steel, zirconium, tungsten or diamond.

**Type of connection:** for the contra-angle handpiece (bur, surgical bur, countersink, bur extension, adapter) or hex key fitted with O-ring to assure retention (bone tap, bone expander). All rotating devices are supplied nonsterile and are reusable.

- The **surgical bur** and the **countersink** are externally irrigated and designed for possible use with fixed height depth stops. Both can be used together with the PRF **bur extension**.
- The **depth stops**, should they be used for cylindrical surgical burs, must be selected based on bur diameter and depth required by the operator. The depth is indicated with laser coding on the outer diameter of the stop, expressed in millimetres.



- The **cylindrical surgical burs** in surgical steel have laser depth markings indicating the five heights of the Easy Grip® implants (see picture).
- The **bone tap** and the **bone expander** can be used both manually (with the digital key, the ratchet or the screwdriver handle for hexagonal inserts) and with the countersink handle by means of the AMFO **adapter**. They are fitted with O-rings to ensure retention (replace O-rings after 15-20 sterilisation cycles).

- The mechanical aid is used by connecting it to the torque handpiece, using the suitable optimal values.
- All the devices of the Easy Grip® CONE implant range are identified in the package with a product code and can be traced through a production lot number.
- Rotary devices may be fitted with colour O-rings and/or laser coding, for better identification of the devices found in the surgical kit.
- The Easy Grip® CONE implant range is continuously enhanced. T.F.I. System reserves the right to alter the design and production. Check for product updates on [www.tffsystem.it](http://www.tffsystem.it).

### Intended Use

- Intended only for qualified surgeons or dentists who have specialised knowledge and experience in dental implantology, and therefore are fully responsible for deciding on the actual use of the products in each individual case.
- The device is intended for the preparation of the maxillary or mandibular implant site where the dental implants will be inserted.
- Bur kits are available for specific purposes (bone crest regularization kits, abutment milling kits).

### Contraindications

- The device is contraindicated in cases where it is not possible to create an implant site (inadequate amount of bone, hard tissue lesions and lesions in anatomical structures).
- It is contraindicated to use rotating devices that do not belong to the Easy Grip® range to position implants.

### Handling precautions

- Assure plenty of cooling by means of irrigation with sterile saline solution, preferably cooled to 4°C in order to prevent irreversible damage to the bone and/or adjacent tissue. The cooling liquid should be distributed over the entire active surface of the surgical bur. Stop drilling if there is no irrigation, for any reason.
- The bone is drilled with an intermittent pumping action and an appropriate number of revs (as indicated in the table below) to assure maximum cooling and removal of bone debris.
- Before using the burs, the operator should always ascertain their optimal cutting efficiency. Devices with deteriorated cutting efficiency due to the thread being worn, those that are bent or with an eccentric rotation should be immediately removed and not reused as they are unsuitable (they may cause overheating, which in turn will result in bone necrosis and/or the operator and the patient being injured).
- Since the instrument's cutting ability decreases with use, **it is recommended to dispose of it after creating 15-20 sites** and in any case, when the cut of the bur is inadequate and/or impaired.
- The working pressure must be between 0.3 and 2 N/mm<sup>2</sup>. Strictly avoid excessive pressure as it generates bone overheating and damages the working part.
- Insert the rotating device only in a suitable micromotor drill with a contra-angle fitting in perfect condition, carefully and



without force. Incorrect insertion may cause the instrument to vibrate and rotate eccentrically.

- Do not wrap or lean on the device during the processing as it risks breaking.
- With regards to **burs** and **countersinks** comply with the maximum rotation speed of 500-1000 RPM and the recommended speeds (indicated in **diagram 1**), while taking care to use the bur only after it has reached the speed of use before applying it to the part to be treated. The recommended speed for all **bone taps** and **bone expanders** is 15 RPM. For the **crest bur** (RLO35) the recommended speed is 1000-1200 RPM.
- If use of the suitable **extension** is opted for, ensure the **surgical drill** is properly inserted and locked inside the extension. Proper housing of the drill on the extension is marked by a slight “click” when coupled.
- Due to the small size of the burs and instruments particular attention should be paid to make sure they are not swallowed by the patient.
- Take into account that measurement of the depth markings of the **surgical cylindrical burs** does not include the length of the tip, which varies depending on the bur (see **diagram 2**). Therefore, when drilling near vital anatomical structures, the extra length of the bur must be considered.
- If forced, depth stops may lose elasticity of the fins. In this case the position must be restored by tightening them slightly with a pair of tongs.
- Before tightening the prosthetic components, ensure the hex

of the **mechanical aid** is inserted properly in the hex head of the screws or the implant, in order to prevent hex deformation. If the hex is worn, it is recommended to replace the surgical device.

- If the rotating device is used, it must be disposed of as biological waste to all intents and purposes and handled in accordance with local regulations.

**Instructions for use**

- For the product’s operating procedures refer to the Technical Operating Manual of T.F.I. System srl - also available on [www.tfisystem.it](http://www.tfisystem.it) - and in the specific instructions provided in electronic format.

- The surgical and prosthetic procedures described are to be considered a standard set of guidelines that can be applied to the particular requirements and circumstances that arise in practice, depending also on the manual skills, the experience and diagnosis made by the legally qualified doctor.
- The manufacturer cannot be held liable for the use of the medical device and the procedure followed. The responsibility for the correct and proper use of the instruments and products is therefore borne by the user.

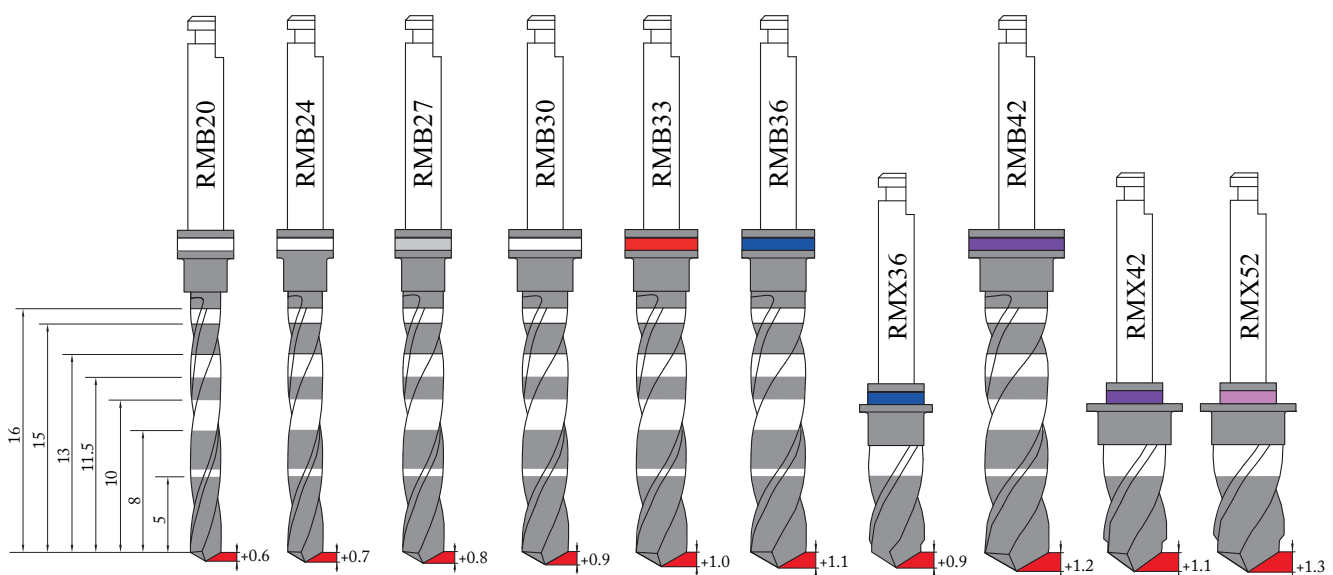
**Diagram 1**

**Rotation speed**

Code	Speed RPM
RLO18 RA018 RMB20 RMB24	850
RMB27 RMB30	750
RMB33 RMB36 RMX36	650
RMB42 RMX42 RMX52	550
AS2 AS3 - ASS AS4 - ASL AS5 - ASX	350

**Diagram 2**

Unit of measure: mm



- The surgical procedure decided by the implant dentist may range from being minimally invasive (using the mucotome) to lifting the total thickness of the sides and expose the bone.
- The positions of the implant sites are established using the **round bur** or the **cutter**.
- To create appropriate osteotomy for the position of the selected implant, a set of **burs** of increasing diameter are used.
- The implant dentist may also decide to use adequate **bone taps** or **bone expanders**, depending on the bone density found.
- The **countersink** is required to create the proper housing for the tapered neck of the Easy Grip® implants, thereby increasing the bone retention phenomenon at cortical level and preventing excessive compression of the microgrooves on the bone, which results in tissue necrosis.

### Maintenance and storage

- Prior to being used on the patient the rotating device must always undergo validated processes of cleansing, disinfection and/or sterilisation, taking care to disconnect any depth stops from the burs.
- Before cleaning the instruments, manually remove the impurities using only specifically designed nylon brushes.
- **To clean:** place the used instruments in a cleaning solution, specific for reusable medical devices, with the relative dilution and contact time, making sure that they remain sufficiently immersed.  
Pay particular attention that the cutting parts of the burs do not touch each other (use specific bur holder supports). Clean the instruments in an ultrasonic bath, where applicable. It is recommended to use enzymatic/neutral products (see “products that are incompatible with the instruments”). Immediately dry the instruments, otherwise there lies the risk of corrosion.
- **To disinfect:** place the used instruments in a special disinfectant solution, specific for reusable medical devices, with the relative dilution and contact time, making sure that they remain sufficiently immersed. Pay particular attention that the cutting parts of the burs do not touch each other (use specific bur holder supports). It is recommended to use products containing anti-corrosive additives (see “products that are incompatible with the instruments”). Immediately dry the instruments, otherwise there lies the risk of corrosion.
- **For sterilisation:** sterilise in steam autoclave for approx. 20 minutes at standard temperature of 121°C. Pay particular attention that the cutting parts of the burs do not touch each other (use specific bur holder supports). Once sterilisation is completed, store the sterile instruments in closed containers.

- Always keep the product clean and store in a dry place, avoiding impacts that might damage it.
- Do not use the device if the packaging is damaged.

### Products that are incompatible with the instruments

When choosing the products for cleaning and disinfecting ensure they do not contain the following chemical components, as they may corrode and/or oxidise the instruments, in particular in the area with laser marking:

- organic, mineral and oxidising acids (pH 5.5 is the minimum value allowed)
- strong alkaline solutions (pH 8.5 is the maximum value allowed; it is recommended to use a neutral/enzymatic cleaning agent)
- organic solvents (for example alcohols, ethers, ketones, gasoline)
- oxidants (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- halogenated / aromatic hydrocarbons

Never use harsh chemicals or ammonium-salt based chemicals.