

**Instructions for use (IFU) for Carmex dental products**

**General precautions** Before using Carmex Dental product, the operating surgeon/practitioner in charge should carefully study the indications, contraindications, recommendations, warnings and instructions, as well as all other product specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) and fully comply with them. The manufacture, the importer and the suppliers of Carmex products are not liable for complications, other negative effects or damages that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on. The operating surgeon is responsible for any such complications or other consequences.

**Cautions and Warnings**

- Carmex Implant Drills are to be used only by a licensed dentist who has the specializations, skills and the appropriate training in dental implants and restoration in order to assure successful treatment. Rx Only.
- Always wear Gloves when handling contaminated instruments.
- Eye protection must be worn to protect against ejected particles.
- Surgical mask must be worn to avoid inhalation of aerosol or dust generated.
- Inspect the drill for damage or wear before each use and discard/return to manufacturer defective drills.
- Ensure that the drill is fully seated and gripped in the handpiece collet before use.
- Maintain handpiece in good working order and correctly lubricated.
- Do not exceed the maximum speeds indicated in this leaflet.
- Avoid excessive drilling speed and/or drilling duration in order to avoid overheating and associated complications.
- Move the drill continuously when in use to avoid localized heating.
- The products are provided non-sterile. Clean and sterilize the drills in accordance with the directions below before first use and before each reuse, in order to avoid contaminations.

**Introduction – Intended Use** Carmex Implant Drill is for preparation of the jawbone for dental implant. The Implant Drill Accessories assist the Implant Drill in its use. The drills and accessories shank meets the requirements of ISO 1797-1.

**General Information** All instruments must be cleaned and sterilized prior to use. The drills have been marked with sizes and color coded for ease of identification. Size marking and color coding should be used to select proper drill for each surgical procedure.

Implant Drills are susceptible to damage and wear and should be inspected before use.

The number of uses per drill will vary and depends on a variety of factors including bone density encountered, proper handling and cleaning. Over time, repeat sterilizations may affect cutting efficiency and color appearance. Cutting edges should present a continuous edge and appear sharp. Check the latch lock shank for wear to ensure the connection is not damaged. If inspection reveals signs of wear, damage, or unrecognizable color identification, replace the drill accordingly. We advise 6 – 10 uses at the maximum.

**Cleaning and sterilization** Correct and careful maintenance of Carmex Implant Drills is extremely important. Cleaning can be done manually or by using automated washer unit.

*Manual cleaning*

1. Before use, soak the drills in a mild, pH-neutral (Action 201 or equivalent) detergent for 2.5 minutes or until cleaning can be performed. Avoid contact with phenol alcohol, chlorine, acid or quaternary ammonia.
2. Rinse the drills under a hard stream of water. Avoid water with high concentration of chlorine.
3. Flush the drill lumen with a hypodermic needle.
4. Use a nylon brush to rid the drill of additional debris caught in the irrigation channel.

*Automatic cleaning (using automated washer unit)*

1. Flush the drill lumen with a hypodermic needle.
2. Use a nylon brush to rid the drill of additional debris caught in the irrigation channel.
3. Run the automatic wash cycle – minimum cycle parameters:
  - 3.1. 4 minutes cold prewash at 30 ±5°C.
  - 3.2. 10 minutes cleaning wash at 55 ±5°C.
  - 3.3. 1 minute rinse at 30 ±5°C (tap water).
  - 3.4. 10 minutes rinse at 30 ±5°C (distilled water).






*Sterilization*

1. Wrap the drills for sterilization with wraps washed in pH-neutral detergents or disinfectants.
2. Sterilize the drills by steam according to the autoclave's instructions. 134°C/275°F for up to a maximum 6 minutes followed by a 30 minutes dry cycle. Distilled water should be used in order to avoid surface stains. Make sure before use that the elements, inside the autoclave, are not rusted. Chemclave is NOT recommended.

**The drilling technique** All drilling procedures should be performed at maximum 800 – 1300 RPM with copious irrigation. The use of sharp drills, sufficient irrigation, an in-and-out drilling motion, short cutting cycles, waiting for the bone to cool, and use of pilot drills in successively increasing sizes are essential.

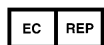
**Storage** The user must avoid all effects that could affect the product marking or shelf-life of the drills, the drill surface or the drill geometry such as unnecessary commotion, strains, heat, UV radiation, moisture, etc.

**Symbols**

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|--|---|
|  - Lot number / batch number    |  - Catalogue number        |
|  - Manufacturer                 |  - European representative |
|  - Consult instructions for use |   |

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