

## **General instructions for use, sterilization and safety recommendations**

### **For professional dental application only**

**Product: Prophylaxis Cups, Brushes and Angles**

**Classification: Class IIa Medical Devices (Single use devices)**

#### **Correct usage**

- Instruments are strictly single use and must not be reused.
- Only use in an appropriate, correctly maintained slow speed handpiece (carefully following handpiece manufacturer's instructions).
- Insert shank correctly into handpiece and check instrument is correctly seated by pulling on prophylaxis cup/ brush/ angle to assure it does not dislodge.
- Tilting or levering the instruments leads to an increased risk of breakage and should therefore be avoided.
- Wear appropriate protective clothing, such as safety goggles, masks and gloves when sterilizing or using instrument.
- The recommended speed must be maintained in order to prevent thermal damage to the pulp or to the rotary instrument.



- Inspect all rotary instruments and discard any with visual imperfections.

#### **Recommended speeds for use**

- Use at a recommended speed of 2000-5000rpm (maximum speed 10,000rpm).

Ignorance of the maximum permissible speed leads to an increased safety risk.

Dental instruments may only be used for their intended purpose. Incorrect usage may cause damage or harm to the instrument, equipment, patient or user.

#### **Cleaning, disinfection and sterilization**

The instruments are to be disinfected with disinfectants designed with corrosion protection for rotary instruments or for instruments with plastic/ silicones/ nylon brush components. The recommendations for use (duration of exposure, concentration, suitability) for cleaning agents and disinfectants are as stated by the disinfectant manufacturers and should be closely followed.

Disinfected/ cleaned instruments should be visually inspected, and damaged instruments discarded.

#### **Recommended sterilization parameters**

- Sterilization temperature 134°C
- Holding time: 5mins
- Drying time: 10mins

Autoclave manufacturers recommendations for use should be closely followed.

It is the responsibility of the medical device operator to ensure that the disinfectant/ sterilization treatment is carried out with suitable protective equipment, suitable materials and suitably qualified staff.

#### **Security and liability**

The instruments may only be used for the specified purpose. Failure to follow these safety instructions may result in damage to the instrument or dental handpiece and may cause injury to the user or patient.

The user is obliged to independently check the product for suitability for its intended use before use.

Contributory negligence on the part of the user will lead to an exclusion of the liability of Premium Plus. This is especially the case if the user instructions or warnings are ignored or if the user accidentally misuses the device.