## REFERENCE DOCUMENT

### DO\_COM - 02 - vers 2.0

Date : 27/10/2020

Dental rotary instruments from DUMONT Instruments are for dental use and must be used by dentists, dental surgeons or other specialist who, through their formation and expertise, are competent to use these devices.

DUMONT Instruments develops a wide range of devices. The practitioner is responsible to use the appropriated device to the care he provides. Reference : ISO 17664

# 1. Labelling

INSTRUMENTS & CO

Labelling	Symbol	Description
Image: Second state sta	LOT	Lot number of the medical device
	NON STERILE	Medical device sold non sterile
	i	Read the instructions for use before use
		Manufacturer's address
	CE	CE marking : 0476
	REF	Medical device reference
		rpm – rotation speed

# 2. <u>General informations</u>

Before each use of the device, be sure to

- have devices and turbines not worn and sterilized
- firmly fix the device in the turbine
- start the turbine at low speed to ensure that the device rotates properly
- respect the recommended speeds
- wear safety glasses, a mask and gloves
- wash one's hands

After each use of the device, be sure to

- remove the soiled device in a closed container, containing a pre-disinfection solution
- clean, disinfect and sterilize soiled devices

**Warning** : Before the first use, the device will be removed from its packaging, cleaned and sterilized.

- 3. Rotation speed
- → Labelling

# 4. Working pressure

Excessive pressure on the tooth (greater than 2N) should be avoided. Such pressure may cause

- heating of the tooth and irreversible damage
- premature wear of the abrasive properties of the device
- damage or even destruction of the device in extreme cases

# 5. <u>Cooling</u>

To avoid overheating during dental work, the working area should be cooled with sufficient air or water flow (50mL/min). This flow must be adapted to the dimensions of the device, the rotation speed and the pressure exerted.

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#### INSTRUCTIONS FOR USE, CLEANING, DESINFECTION, STERILIZATION AND SAFETY

Additional cooling is essential when using devices longer than 22mm or with a head diameter greater than 2mm. Inappropriate cooling can lead to oral lesions.

# 6. Storage

Store the devices dry, out of direct sunlight, heat and dust

# 7. Number of uses

Information given below is given for information purposes, the life of a device depending mainly on dental care for which it is used and the conditions under which such care is practiced.

Tungsten carbide devices	~15 uses
Diamond devices	~25 uses

#### 8. Disposal of worn devices

Devices that cannot be used (damaged or having lost its abrasive efficiency) must be disposed of in accordance with local regulations. Before disposal, any device must be sterilized.

# 9. Sterilization process

# 9.1. Predisinfection

This step, which protects the staff, facilitates subsequent cleaning by lowering the level of contamination. After its use, immerse the device in a container containing a detergent-disinfectant solution, in order to prevent incrustations and reduce its level of contamination, and close the tray.

**Warning :** Be careful not to use products containing aldehydes that have the property of fixing proteins.

## 9.2. Cleaning

This step consists of taking off and removing all the dirt lying on the devices. This operation can be done as follows

- immerse the devices in an ultrasonic bath containing a detergentdisinfectant solution
- close the bath
- after removal of dirt, remove the devices from the bath
- manually brush the devices, using brushes that do not damage the device.

It will be necessary to ensure that the bath is of sufficient size to prevent the devices from touching each other and to comply with the supplier's recommendations.

### 9.3. Rinsing and drying

All devices that have been dipped in a detergent-disinfectant solution must be thoroughly rinsed and dried to prevent contamination.

#### 9.4. Sterilization

The devices will be placed on the sterilizer tray and sterilized according to the sterilizer supplier's instructions for use. The sterilizer shall meet the requirements of EN 13060 specifying general requirements and test methods for small steam sterilizers.

We recommend a sterilization cycle including evacuation of air, the rise of temperature by thermal plateau of 134  $^\circ$  C in 18min and the return to atmospheric pressure.

The tools will be stored free from contamination.

# 10. Manufacturer's address

DUMONT Instruments and Co Rue des Anciens Etangs, 42 - 1190 Bruxelles Tél : +32-2-343.65.30 E-mail : <u>info@dumont-instruments.com</u>

Note : Only the French version of this instruction of use was controlled and accepted by the notified body.