

Disposable Saliva Ejectors Instruction For Use



Huanghua Promisee Dental Co., Ltd.
Mould Industry Garden, Empolder Section,
Huanghua, 061100 Hebei, P.R. China
Tel: +86-317-8882702
www.promiseedental.com

EU REP MedNet EC-REP GmbH
Borkstrasse 10, 48183 Muenster, Germany

Product Name: Disposable Saliva Ejectors
ET01 ET02

Brand: COTISEN

Product Description

As dental chair supporting supplies, disposable saliva ejectors is now essential for oral treatment. This product can be independent plastic pipe structure. ET01 and ET02 are made of an independent long tube, with separate holes and no holes on the tube wall. Compared to weak suction, the holes on the tube wall can reduce the adsorption of oral soft tissue during suction operations.

Intended Use

The disposable saliva ejectors are used to be linked to strong suction handle of the dental chair device to deliver controlled fluids during dental treatment. Under the control of suction device, it can effectively absorb blood, saliva and other foreign matter in the patient's mouth. It is non-sterile, users need to disinfect the device before use, and it is single-use.

Intended user

The intended users are professional medical staffs, includes physicians, nurses, therapists and other relevant staffs with medical science.

Patient Population

1. Age group: non-limited, the person who need dental treatment.
2. Weight range: No limit.
3. Health: person who have dental disease
4. Country: all.

Indications

The Disposable Saliva Ejectors is used in dental unit. Keep the patient's mouth dry by aspirating fluids. Blood, saliva and other impurities can be removed. Improve dental professional productivity and patient comfort.

Limitation

The device can only be used by professional medical staffs. Please use the device within the expire date. Contraindications: No contraindication is identified by now. Adverse Reactions: Not found

Usage Method

(a). Disinfect the product before use.

For details, please refer to *Processing Instruction before use (Single-Used Medical Devices)*

(b). Installation of disposable saliva ejectors. Take out the disposable saliva ejectors and make sure the strong suction handle matches this specification. (It is recommended to use the standard HVE vacuum valve size: 7/16). Fully insert one end of the long tube into the strong suction handle interface.

For details, refer to *Installation Instructions as below*;

(c). After the installation is completed, gently pull the disposable saliva ejectors to ensure that the saliva suction tube is firmly installed.

(d). Control the switch of the dental chair suction device and the strong suction handle switch valve, and test the suction power of the disposable saliva ejectors and whether the suction is smooth.

Installation Instructions



a. The disposable saliva ejector ET01 ET02 and the corresponding strong suction handle.

b. Insert the long end of the disposable saliva ejectors into the strong suction port until it stops moving by gently pulling forward.

c. The picture above shows the connection status of disposable saliva ejectors and strong suction.

d. During treatment operation, manual operation can be performed as needed.

Warning and Precaution

1. The product is only used by qualified medical staff.
2. It's forbidden to use when the products are deformed or damaged. And it cannot be used when the package is damaged.
3. The disposable saliva ejectors are single use. Please dispose after use according to local regulation required.
4. It is provided in non-sterile, the user needs to disinfect the device before use.
5. Use a pair of tweezers or a gloved hand to take the disposable saliva ejectors to avoid cross-infection. The disposable saliva ejectors cannot touch the hair or the human body. If the disposable saliva ejectors falls to the ground, it must be discarded.

Storage Condition

1. This product should be stored in a clean, dry, ventilated, room temperature 10°C - 35°C, relative humidity not greater than 80%, atmospheric pressure 50 kPa - 106 kPa, and no corrosive gas.
2. Avoid direct sunlight.
3. Prevent external extrusion and deformation during transportation and storage.

Shelf Life

3 years.

Symbols

CE 0197	CE certified by TÜV Rheinland		Consult instructions for use	#	Model number
EU REP	European union representative		Non-sterile	II	Keep upwards
	Caution	MD	Medical device		Use-by date
	Keep dry	LOT	Batch code		Made In China
	Keep away from sunlight		Date of manufacture		Do not re-use
	Manufacturer		Importer	UDI	Unique device identifier
ISO 13485	ISO 13485 certification				

Processing Instructions before use (Single -Used Medical Devices)

Manufacturer: Huanghua Promisee Dental Co., Ltd.
Device(s): Disposable Saliva Ejectors
Model: ET01 ET02

INSTRUCTIONS

Cleaning	Not Applicable. Because it's processing before use for single used medical device.
Disinfection	Soak in 2% glutaraldehyde for 1 hour before use, and then rinse repeatedly with distilled or demineralized water.
Drying	Dried with low-linting wipes.
Storage	1. This product should be stored in a clean, dry, ventilated, room temperature, relative humidity not greater than 80%, and no corrosive gas. 2. Avoid direct sunlight. 3. Prevent external extrusion and deformation during transportation and storage.
Manufacturer contact	Mould Industry Garden, Empolder Section, Huanghua, 061100 Hebei, P.R. China Tel: 0086-317-8881708 www.promiseedental.com Email: info@promiseedental.com