



## Endoscopy Mouthpieces



REF 207



STERILE EO



## Endoscopy Mouthpieces

### Intended Use

- Used when performing an upper gastrointestinal (GI) tract endoscopy to protect the patient's teeth and lips from the endoscope.
- Upper GI Tract Endoscopy (a.k.a Esophagogastroduodenoscopy: EGD): is a procedure in which a doctor uses an endoscope - a long, flexible tube with a camera - to see the lining of your upper GI tract: (the esophagus, stomach, and duodenum: first part of the small intestine).
- A gastroenterologist, surgeon, or other trained health care provider performs the procedure, most often while you receive light sedation.
- During an upper endoscopy, an endoscope is easily passed through the mouth and throat and into the esophagus, allowing the doctor to view the esophagus, stomach, and upper part of the small intestine.
- A camera at the end of the tube transmits the lighted image before the tube to a 'TV' screen so the examiner can see the inside of the upper gastrointestinal tract as the tube advances. At the examiner's end of the instrument, there are controls that direct the other end, pump air into the stomach, clear the view with water, or suck out unwanted content. Used for:
  - Stomach pain/Upper abdominal pain (dyspepsia )
  - Persistent heartburn
  - Nausea and vomiting
  - Difficulty swallowing
  - Digestive tract bleeding
  - Unexplained weight loss
  - In addition, your doctor may use an endoscope to take a biopsy: (removal of tissue) to look for ulcers or the presence of diseases such as cancer, celiac disease and gastritis.

### Product Description

- Endoscopy Mouthpiece is used in procedures that performed with endoscope.

### Indications

- It provides the operation to be done in a comfortable way, the products allows comfortable breathing during the process and endoscopy mouthpiece prevents the endoscope piece in the mouth from being bitten by the patient.

### Contradictions

- There are no known contradictions reported with the performance of the devices.

### Warnings

- The product is for 'single-use" only. The product should not be used again even after sterilized because, re-sterilization may cause cross-infection.

### Instructions For Use

#### Endoscopy Mouthpiece without strap / Econobite

- Put endoscopy mouthpiece between the patient's teeth in his/her mouth

#### Endoscopy Mouthpiece with strap

- Assemble the given strap using the holes on the strap.
- After placing the mouthpiece between the patient's teeth.
- Pass the strap over the patient's head and adjust it to the desired position.
- Use the holes to tighten the mouthpiece.

#### Endoscopy Mouthpiece with Oxygen Entry

- Use the outlets and inlet to supply the oxygen.
- Use tubes with a suitable length.

### Indications

- Endoscopy mouthpiece is used in procedures performed by the endoscope (gastroscope). For comfortable handling of the procedure ensures that the patient does breathe during the procedure and prevents the endoscope bitten by the patient during operation.
- An Endoscopy Mouthpiece is placed between the patient's teeth so that the patient can comfortably breathe and the gastroscope can be comfortably advanced through the mouth during the procedure.

### Product Features

- Smooth edges and smooth passing surface.
- Silicone tooth protective.
- Strap to secure comfortably in place during the procedure.
- Compatible with mouth anatomy.
- Fits different sizes of endoscopes. (Pediatric and Adult versions.)
- Endoscopy Mouthpiece with Oxygen Entry port allows oxygen to be given through the oxygen entrance.

## Endoscopy Mouthpieces

### Harmonized Standards used for Endoscopy Mouthpiece Manufacturing Process

- EN ISO 13485; Medical devices - Quality management systems - Requirements for regulatory purposes.
- TS EN 556-1; Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
- ISO 15223-1; Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.
- ISO 10993-1; Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-7; evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.
- ISO 11135; Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO 14971; Medical devices - Application of risk management to medical device.
- ISO 14644-1/2/3/4/5; Cleanrooms and associated controlled environments.

### Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.
- Manufactured under ISO 13485 Quality Management System standard.
- Notified Body: UDEM LTD A.Ş. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 10405

### Biocompatibility

- The product does not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, latex, radioactive material and electromagnetic waves.

### Sterilization

- Sterilized with Ethylene Oxide.

### Storage Conditions

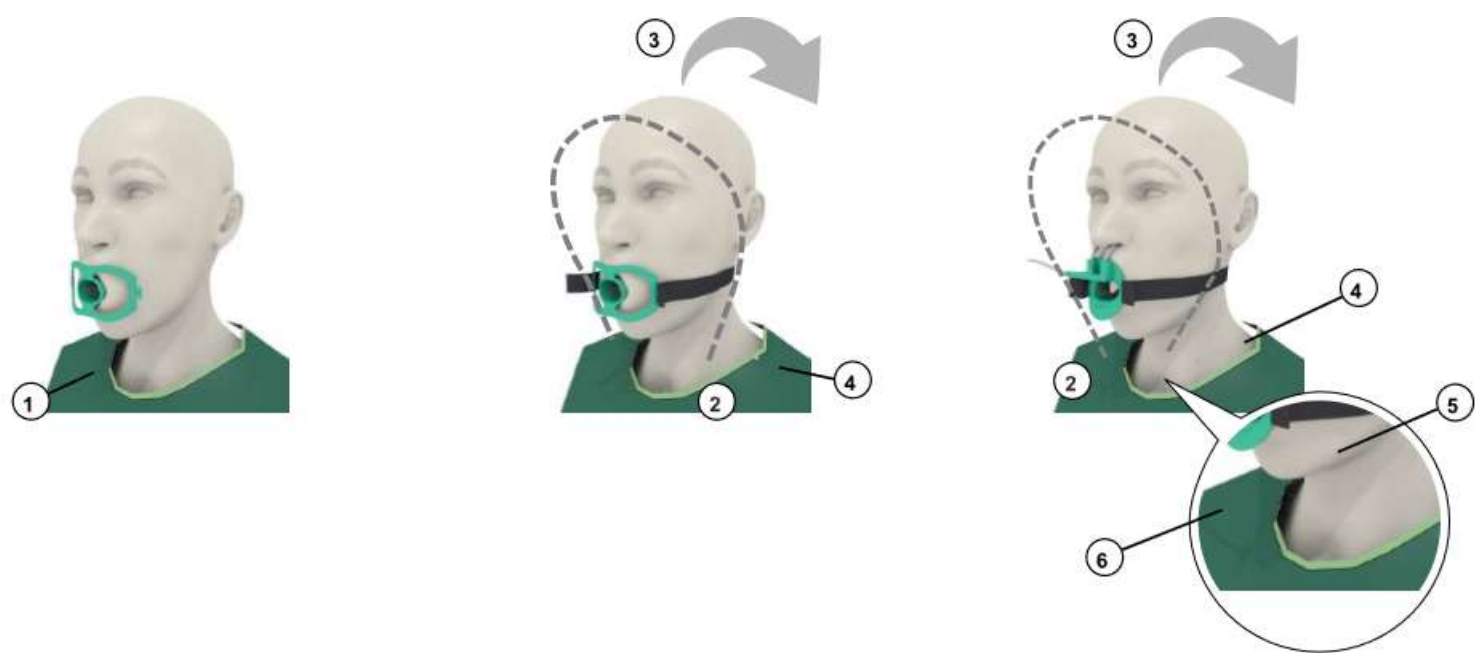
- Must be stored in dry, ventilated environments, away from direct sunlight.

### Shelf Life

- 5 years.



Endoscopy Mouthpieces



REF NO	PRODUCT NAME	STERILIZATION
207 01	Endoscopy Mouthpiece with Strap (Adult)	EO
207 02	Endoscopy Mouthpiece with Strap (Pediatric)	EO
207 03	Endoscopy Mouthpiece without Strap (Frameless)	EO
207 04	Endoscopy Mouthpiece with Oxygen Entry Port	EO
207 06	Econobite without Strap and without Tooth Protector	EO
207 07	Endoscopy mouthpiece with Oxygen Entry and Strap	EO
207 08	Endoscopy Mouthpiece without Strap (with Frame)	EO

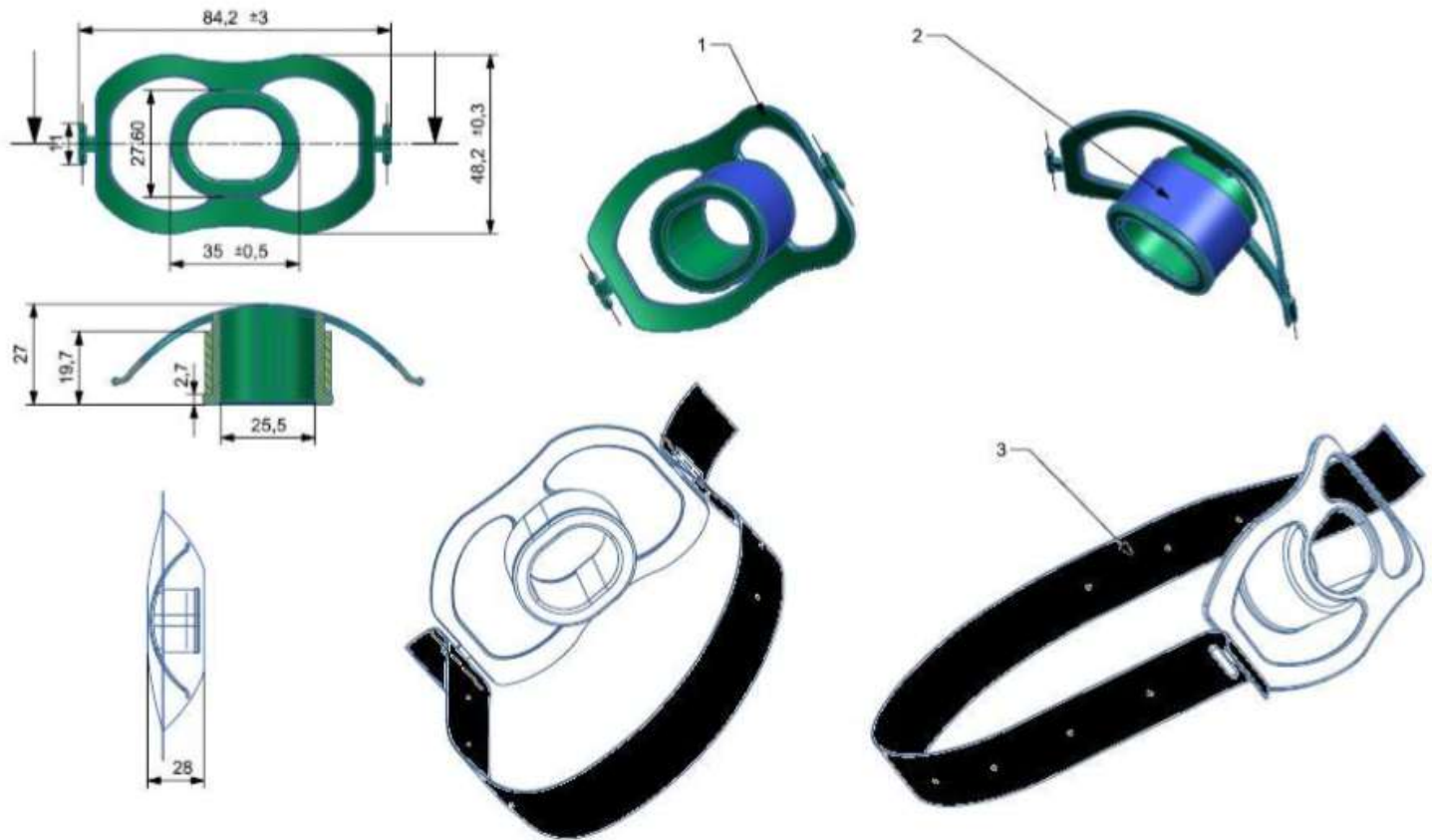
Packaging Specs	Primary Package	Secondary Package	STERILIZATION
207 01	Sterilization Pouch	Carton Box	Parcel
207 02	125x74 mm	27,5 x 20 x 35 cm	42x38x56 cm
207 03	1	100	400

## C-Arm Cover with Clips

## Technical Drawing

## C-Arm Cover with Clips

## Endoscopy Mouthpiece with Strap for Adults



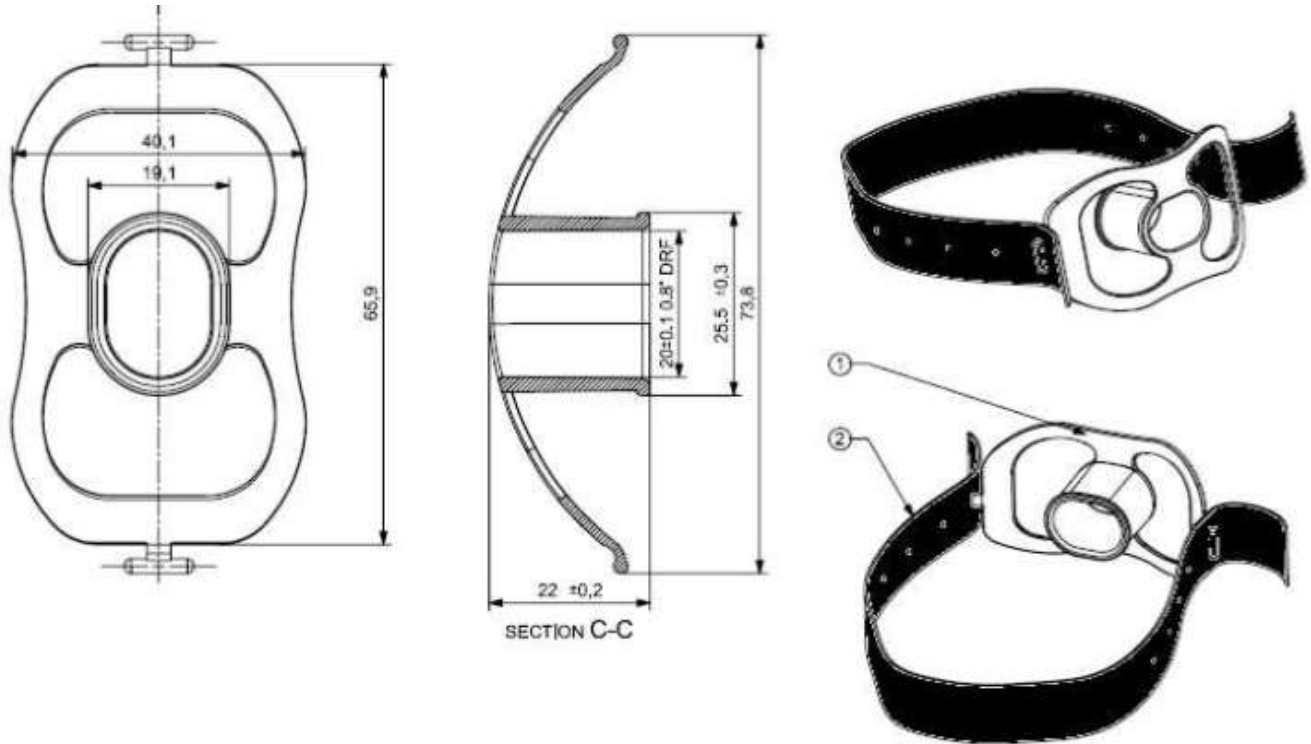
1-Body (HDPE) 2-Teeth Protection (TPE) 3-Strap (TPE)

## C-Arm Cover with Clips

## Technical Drawing

## C-Arm Cover with Clips

## Endoscopy Mouthpiece with Strap for Pediatrics



1-Body (HDPE)    2-Strap (TPE)



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