

Instructions for Use

UniGuide Core



- **Description**

UniGuide Core has a hollow titanium body that can accommodate a Braun Omnifix 3 mL syringe (length-compatible), but is also compatible with most other 3 mL syringes and some 2–2.5 mL syringes.

The device features a hand piece for improved operator control and a top rail guide, in which an endoscope up to 5 mm in diameter can be loosely inserted and supported. Pressure applied with the index finger allows controlled manipulation of the endoscope.

Core can be used for:

- Local anesthesia procedures (e.g., SPG block)
- Steroid injections and transtympanic procedures
- Local drug delivery using needle or topical administration

- Multi-site applications in ENT procedures
- No part of the device should contact the patient directly; users should wear gloves during handling.

- **Contents**

The packaging contains 2 Venteus UniGuide Core® devices. The Instructions for Use is available online.

- **Principle of Operation**

UniGuide Core is a syringe holder with a co-guiding feature for an endoscope by which it is possible to co-guide an endoscope together with a syringe for a single operator procedure.

- **Intended Use / Indications for Use**

Core is a reusable device designed to assist trained ENT specialists in the precise local drug administration in the nose, mouth, and ears using flexible or rigid endoscopes. It enables multi-instrument procedures by allowing the operator additional control during interventions.

- **Expected Clinical Benefit**

UniGuide Core is supportive only and does not have a clinical benefit in it-self.

- **Patient Target Group**

UniGuide Core is supportive only and does not have a target group.

- **Intended Users**

UniGuide ETD is intended for use by qualified medical professionals only

- **Contraindications**

Use only by trained medical professionals.

Do not use with syringes larger than 3 mL unless validated.

Do not use with endoscopes exceeding 5 mm in circumference.

Avoid use if the operator has known allergy to titanium or glove materials used; no patient contact is expected.

- **WARNINGS AND PRECAUTIONS:**

Inspect device and syringe/endoscope compatibility before use.

Do not use if device, syringe, or endoscope exceeds size specifications or is damaged.

Use only as described in the IFU.

Maintain aseptic techniques during all procedures.

Follow all local infection control regulations.

Keep out of reach of unauthorized personnel.

Single patient use per handling cycle; device does not require full sterilization post-procedure but should be washed thoroughly.

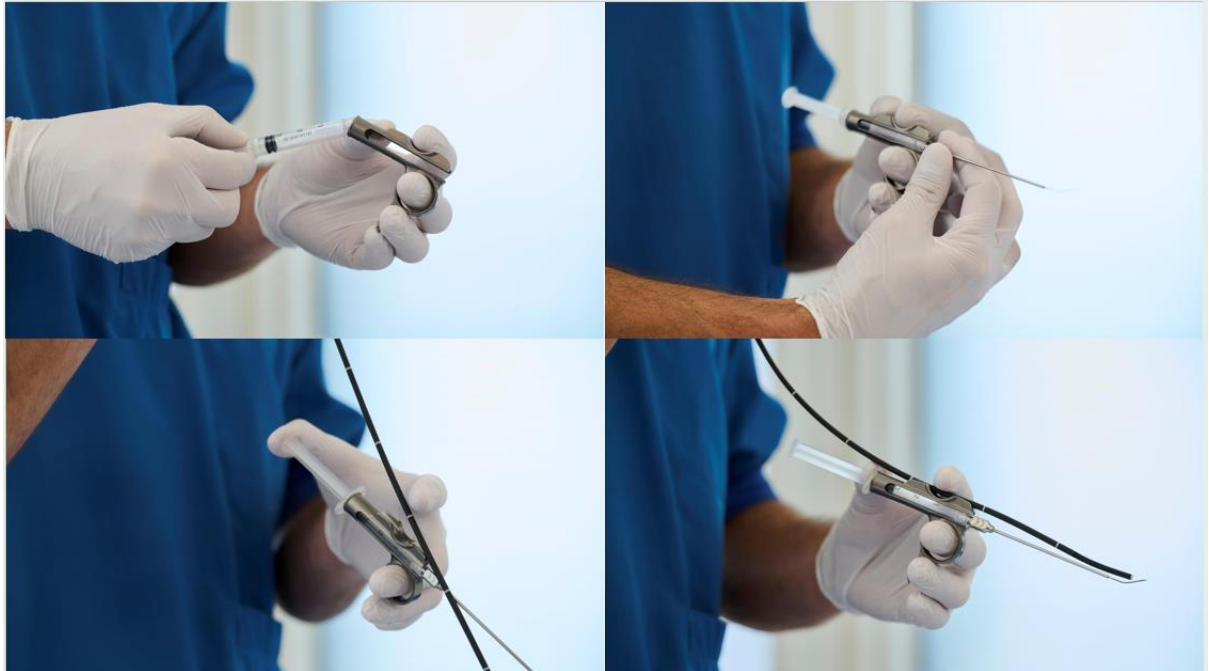
Gloves must be worn by the operator at all times.

Core is intended for use with needle or topical drug administration. Operators must follow standard clinical precautions for such procedures, including aseptic technique and patient safety. The procedural risks associated with injections or topical applications are not related to devices.

The core is made of titanium, a material with documented mechanical strength and corrosion resistance. Titanium can withstand washing and autoclaving up to 120°C without affecting its properties. Short-term contact with the operator's gloved hands presents minimal risk. Full sterilization is not required post-procedure, but autoclaving may be used if desired

Principles of Operation

- Inspect device for damage and ensure all components are intact.
- Insert a compatible syringe (Braun Omnifix 3 mL recommended; most 3 mL or some 2–2.5 mL syringes may also fit) into the hollow body.
- Connect device to a flexible or rigid endoscope up to 5 mm in circumference using the top rail guide.
- Apply controlled pressure on the endoscope using the index finger on the rail guide to manipulate and stabilize the scope.
- Prepare the local anesthetic or drug according to clinical guidelines.
- Insert device according to procedural protocol.
- Deliver medication precisely as intended for the procedure.
- Withdraw device carefully, maintaining aseptic technique and wearing gloves.












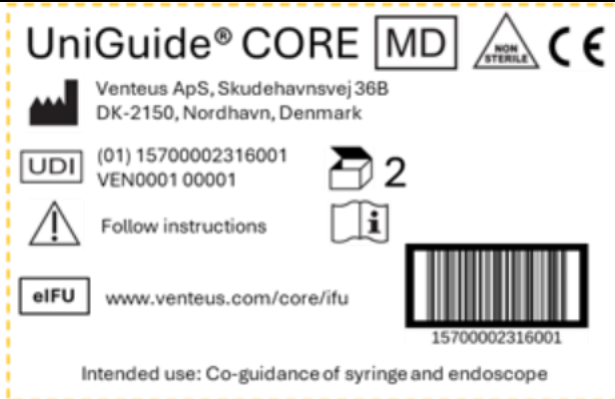
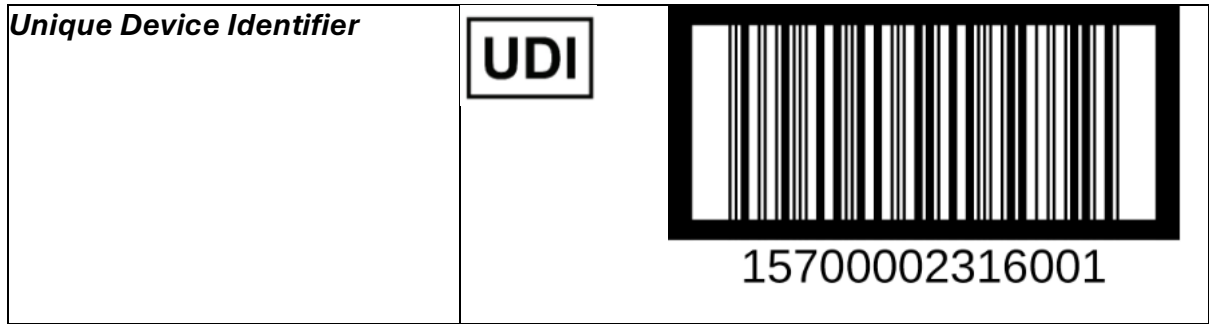
- **Combination with other Devices, Including Accessories**

There are no accessories to UniGuide Core.

The UniGuide Core® is intended to be used in conjunction with a standard medical endoscope (rigid or flexible)

- **Symbols**

Manufacturer:		Venteus Medical Devices ApS Skudehavnsvej 36b DK-2150, Copenhagen, Denmark Made in Denmark
REF – Catalogue number		UGC-002
LOT – Lot number		XXXXXX
CE mark		
Consult instructions for use eIFU	 eIFU indicator	
Temperature limitation (5 °C – 30 °C/ 41 °F to 86 °F) Symbol has an upper limit and lower limit, 5 °C – 30 °C this will also indicate “Do not freeze”	 5 °C/41 °F 30 °C/ 86 °F	
Keep dry		
Keep away from sunlight		
Medical Device		



- **Storage and Handling¹**

Store at 5°C to 30°C (41°F to 86°F); Do Not Freeze. Keep dry and protected from direct sunlight.

- **Maintenance and Repair**

Wash device thoroughly after use with appropriate cleaning agents.

Full sterilization is not required for post-procedure.

Inspect device for integrity before next use.

- **Manufacturer**

Venteus Medical Devices Aps

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