DEMO — Fictional product. This is a sample IFU prepared to demonstrate the eIFU.one platform; it does not belong to a real medical device, its content and values are examples, and it is not for clinical use.

Carotid Shunt Set — Electronic Instructions for Use

Sample Medical Ltd. · REF KM-CS-2210 · MDR Class IIb · Sterile (EO) · Single use

GTIN / UDI-DI	09506000134000
Catalogue no. (REF)	KM-CS-2210
Regulation	MDR 2017/745 · EU 2021/2226
Intended user	Healthcare professional trained in vascular surgery
Manufacturer	Örnek Medikal A.Ş., Örnek Cad. No: 1, 34000 İstanbul, TR
EU authorised representative	Muster EU-Rep GmbH, Musterstraße 1, 12345 Musterstadt, DE

1. Intended purpose

The carotid shunt set is a temporary intraluminal shunt used to maintain blood flow from the common carotid artery (CCA) to the internal carotid artery (ICA) while the artery is clamped during carotid endarterectomy. It is for short-term (intraoperative) use only and is not a permanent implant.

Patient population: Adult patients scheduled for carotid endarterectomy.

> eIFU.one: This section is taken from the manufacturer's approved IFU; approval by an authorised person is required before publishing.

2. Device description

The set contains the following components in a single sterile package:

- Clear silicone shunt tube with radiopaque markers (example size: 10 Fr, 33 cm)
- One low-pressure silicone balloon at the distal (ICA) and one at the proximal (CCA) end
- An inflation line with a one-way valve and a colour-coded cap for each balloon (distal: white, proximal: blue)
- A side arm with T-port and three-way stopcock for flushing and pressure monitoring

Materials: Medical-grade silicone, polycarbonate (stopcock). Contains no latex or DEHP.

> eIFU.one: Each revision is archived as a separate version; the address of this page never changes.

3. Contraindications, warnings and precautions

Contraindications

- Long-term or permanent implantation
- Where the shunt diameter does not suit the vessel lumen
- Where severe intraluminal calcification or dissection prevents safe insertion

Warnings

- Single use only. Do not reuse or resterilise; reuse carries a risk of infection and device failure.
- Do not inflate the balloons beyond the specified volume; over-inflation may damage the intima.
- Inflate the balloons with saline only; do not use air.
- Make sure all air has been removed before inserting the shunt; there is a risk of air embolism.
- Do not use if the package is open or damaged or if the expiry date has passed.

Precautions

- Shunt flow should be checked throughout the procedure with Doppler or pressure monitoring.
- Advance the shunt slowly and under control to avoid dislodging plaque particles.

> eIFU.one: Healthcare professionals can ask the AI assistant about this section; answers draw only on this IFU.

---

4. Directions for use

1. Check the package and expiry date; open in the sterile field.
2. Flush the shunt and side arm with heparinised saline to remove air.
3. Test each balloon with the specified volume and deflate fully (example values: distal 0.3 mL, proximal 0.5 mL).
4. After the arteriotomy, insert the distal end into the ICA and inflate the distal balloon with the specified volume.
5. Back-bleed the proximal end to remove air, then insert it into the CCA and inflate the proximal balloon.
6. Close the stopcock and confirm shunt flow with Doppler.
7. When the endarterectomy is complete, deflate the proximal and then the distal balloon, remove the shunt and close the arteriotomy using standard technique.

> eIFU.one: Scanning the GS1 DataMatrix on the label via /01/{GTIN}/10/{lot} opens the version for that lot.

---

5. Storage and disposal

- Store dry, away from direct sunlight, at room temperature.
- Sterilised with ethylene oxide (EO); sterile until the expiry date provided the package is unopened and undamaged.
- Dispose of the used product according to the hospital procedure for infectious medical waste.

This IFU remains available at this address for the expected device lifetime (36 months).

---

6. Paper copy request

You can request a paper copy of these instructions free of charge. Under EU 2021/2226, requests are dispatched within 7 calendar days at the latest.

Request channel: destek@eKT.one (DEMO — fictional product; not a real request channel)

---

7. Symbols

Symbol	Meaning (ISO 15223-1)
	Manufacturer
	Date of manufacture
	Use-by date
REF	Catalogue number
LOT	Batch code
UDI	Unique device identifier
MD	Medical device
EC REP	Authorised representative in the European Union

STERILE EO	Sterilised using ethylene oxide
	Do not re-use
	Consult instructions for use (electronic IFU)
CE	CE marking; the number next to it identifies the notified body (example: XXXX)