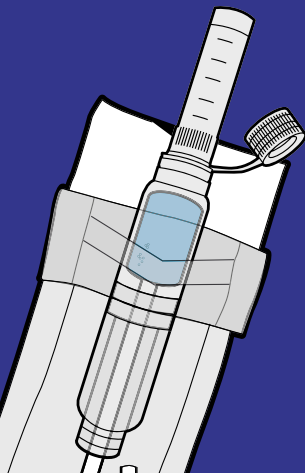


1

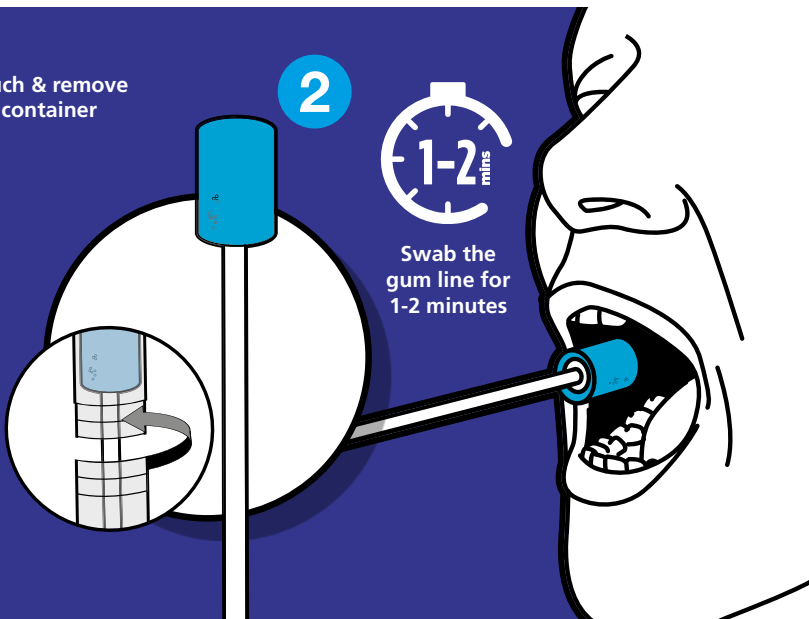
Open peel pouch & remove swab from it's container



2



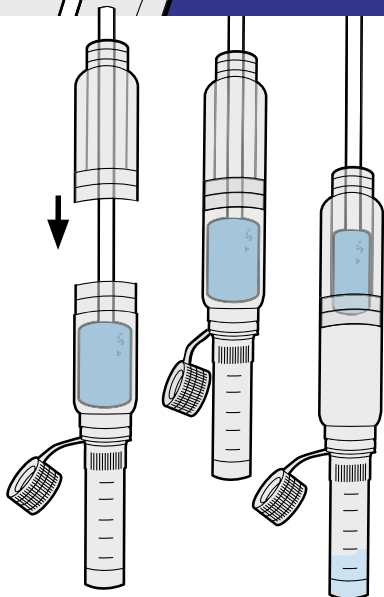
Swab the gum line for 1-2 minutes



3

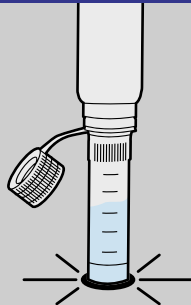
Re-insert the swab and re-assemble

Slowly pull the stick to express saliva into the microtube



4

Gently tap device on hard surface



5

Remove microtube & attach the cap to proceed with testing



ORACOL PRO INSTRUCTIONS FOR USE

Products Covered:

This IFU covers the Oracol (S20) saliva collection device.

Intended Use

Intended for use in the collection of saliva samples for use in In vitro diagnostic tests.

Intended User

The devices are intended to be used by medical professionals and members of the public.

Patient Population

Indicated for use in adults and paediatrics.

Packaging & Sterilisation

The devices are supplied sterile, for single use only. The devices are sterilised via gamma irradiation in accordance with ISO 11137.

Precautions/contraindications

- Not to be used if the patient has a bleeding gum.
- The device is single use only. Reuse may cause infection.
- Do not use the device if the device is damaged.
- Saliva may escape the top of the device when pulling the swab through the funnel.
- Pull the swab through the funnel slowly to maximise sample volume.

Storage

- To be stored under normal ambient conditions.
- The shelf-life of the product is stated on the label.

Disposal

Dispose of top section in regular household waste. Samples returned to the laboratory should be disposed of in accordance with local clinical disposal instructions.

Name and address of manufacturer

Malvern Medical Developments
Unit 10, Northbrook Close
Barbourne, Worcester
WR3 8BP, United Kingdom
Tel: +44 (0)1905 731343
Email: sales@malmed.co.uk



Name and address of EC Rep:

Advena Ltd.
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar
BKR 4013, Malta.