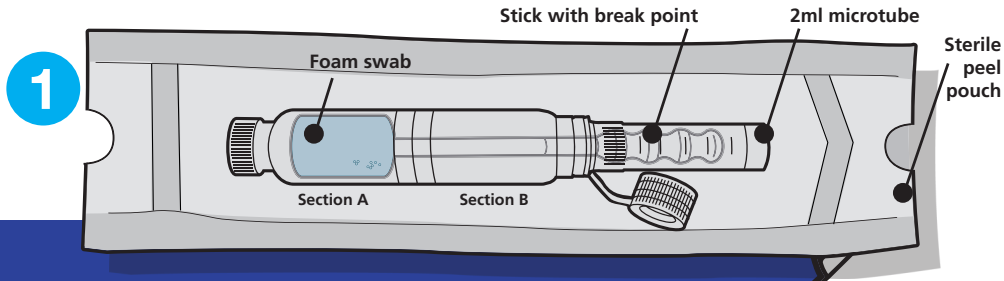
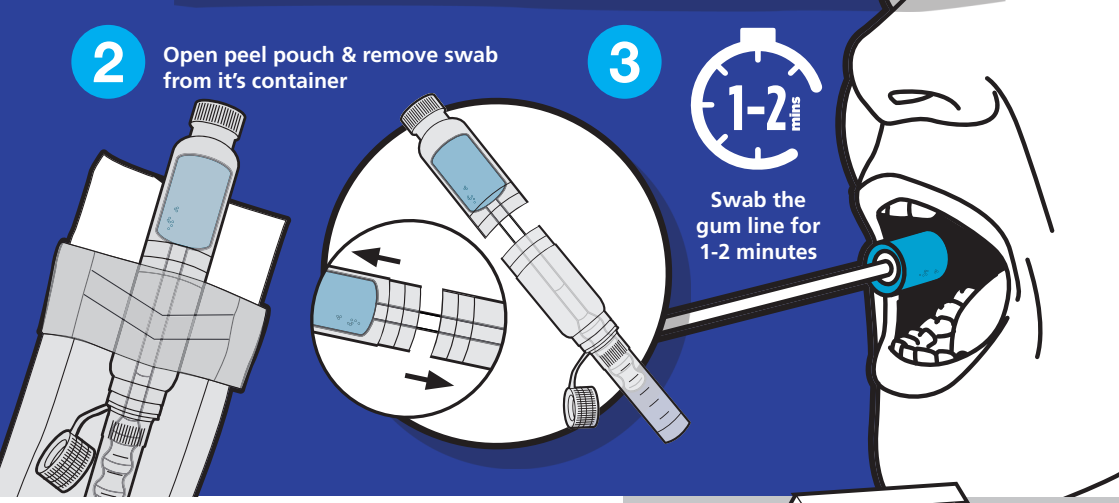
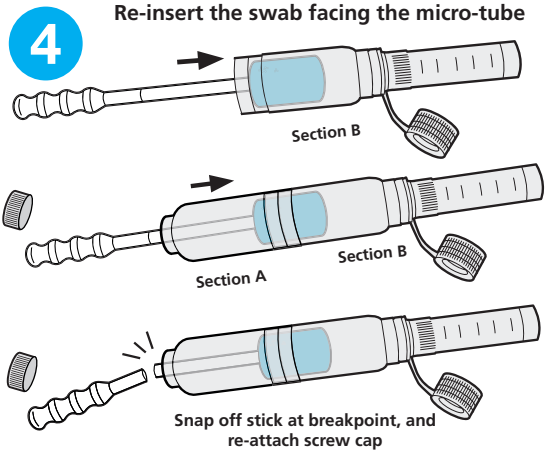
MALVERN MEDICAL DEVELOPMENTS

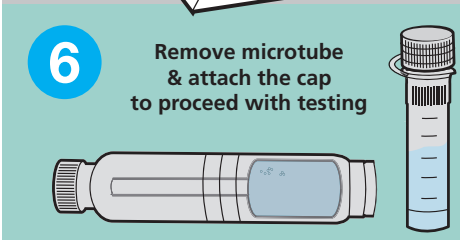
INSTRUCTIONS FOR USE

ORACOL+ Saliva Collection Device









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ORACOL+ INSTRUCTIONS FOR USE

Products Covered:
This IFU covers the Oracol+ (S14) saliva collection device.

Intended Use:
Intended for use in the collection of saliva samples for use 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. Each device is 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.

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

Disposal:
Dispose of the device in accordance with local clinical disposal instructions.

Instructions:
Refer overleaf for the instructions.

Name and address of manufacturer:
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Unit 10, Northbrook Close
Barbourne, Worcester
WR3 8BP, United Kingdom
Tel: +44 (0)1905 731343
Email: sales@malmed.co.uk

CE 1639

Name and address of EC Rep:
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BKR 4013, Malta.