



OPERATOR'S MANUAL

REF

SK-001A

Intended Use

SwishKit™ is intended for the oral irrigation and subsequent suction of irrigating agent to promote oral hygiene in intubated adult patients or other adult patients unable to maintain proper oral hygiene.

SwishKit™ is intended to be adjunctive to existing means of oral hygiene and not replace current practices.

Intended Environment

SwishKit™ is intended to be used in professional medical care environments such as in the ICU, hospitals, acute and long-term care settings.

Intended Users

SwishKit™ is to be used by healthcare professionals who provide oral care.

Explanation of Symbols



Caution: indicates that caution is necessary when operating the device, the current situation needs operator awareness, or operator action is needed to avoid undesirable consequences.



Temperature Limit: temperature limits to which the medical device can be safely exposed.



Prescription-only: this device is only to be used on the order of a physician or licensed health care professional including Nurse or Respiratory Therapist.



Consult instructions for use: device is intended for one use, on a single patient.



Reference Number: manufacturer's number identifying the device.



Unique Device Identifier: information for identifying the device in the USA.



Do not re-use: device is intended for one use on a single patient.



Humidity Limit: range of humidity to which the medical device can be safely exposed.



Do not use if packaging is damaged: device is intended for one use, on a single patient.



Manufacturer Information: identification and contact information for the manufacturer.



Lot Number: code identifying the manufacturing lot.



Note: provides other important information.

Cautions in this Manual



SwishKit™ is single use; do not re-use SwishKit™



The SwishKit™ is for intubated adult patients or other adult patients unable to maintain proper oral hygiene.



Inspect for damage before use.



Instill only 20mL of fluid at a time. More than 20mL of fluid may result in excess fluid in the patient's mouth



Recommended syringe sizes for use are 20mL to 60mL. Larger syringes may result in excess fluid in the patient's mouth; smaller syringes may lead to inadequate oral irrigation.



Monitor ventilator for alarms during and after use of the device, if applicable.



Risk of fluid entering trachea if irrigation performed when patients nose is not parallel to the bed or pointed downwards



Oral care following standard protocols should continue, in addition to use of the SwishKit™.



For safe and effective use, the patient must be capable of maintaining lateral position with nose pointed downward for the duration of the procedure.



Ensure the device does not dislodge or pinch the endo-tracheal tube, if applicable.



Maximum wall suction pressure is 200mmHg. Higher than 200mmHg could result in damage to the device; lower than 150mmHg could result in poor suctioning of irrigation fluid from the patient.



Monitor for returning fluid through the suction tube; stop irrigation if no fluid is returning.



Risk of fluid entering trachea if irrigation performed when patient is not positioned in Lateral position with head parallel to bed.



Training is required for intended users prior to use of the SwishKit™

Device Description

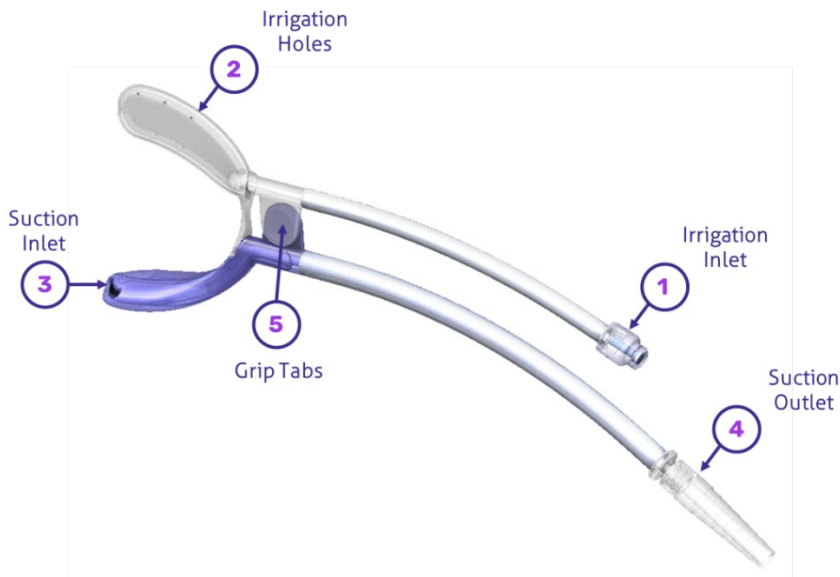


Figure 1

- 1 – **Irrigation Inlet**
Connects to 20mL – 60 mL syringe
- 2 – **Irrigation Holes**
Direct fluid into the oral cavity
- 3 – **Suction Inlets**
Collect fluid from oral cavity
- 4 – **Suction Outlet**
Connects to wall suction tube
- 5 – **Grip Tabs**
Place to hold mouthpiece

Instructions for Use

Before Use

Rx Only

This device is only to be used on the order of a physician or licensed health care professional including Nurse or Respiratory Therapist.



The SwishKit™ is for intubated adult patients or other adult patients unable to maintain proper oral hygiene



For safe and effective use, the patient must be capable of maintaining lateral position with nose pointed downward for the duration of the procedure



SwishKit™ is compatible with Hollister Anchorfast Guard or similar ET Tube securement device.



SwishKit is designed for use with an oral irrigation fluid, such as saline or sterile water.

1. Perform oral assessment and oral care according to standard protocol.
2. Perform oral inspection with a light source to ensure that there are no large pieces of debris that could occlude the suction inlets (3) of the SwishKit™ mouthpiece.
3. If large pieces of debris are found in the oral cavity, then remove the debris.
4. Unpack a new SwishKit™ device and inspect it for visible damage. If the packaging is not sealed, dispose of the SwishKit™ device.
5. Ensure subglottic suctioning is available for patients who have subglottic cuffs, as applicable for intubated patients.



SwishKit™ is single use. Do not re-use SwishKit™.



Inspect for damage before use.

Patient Positioning



Risk of fluid entering trachea if irrigation performed when patient is not positioned in Lateral position.



Risk of fluid entering trachea if irrigation performed when patients nose is not parallel to the bed or pointed downwards.

Position patient laterally with bed flat. Ensure the suction arm of the mouthpiece on lowest side of patient with the patients nose parallel to the bed or pointed down (0° - 15°). See Figure 2.



Figure 2

During Use



Monitor ventilator for alarms during and after use of the device, if applicable.



Face the patient during use of the device.

1. Insert the device in patient's mouth.



Ensure that the endotracheal tube is not dislodged by the placement and use of the SwishKit™, if applicable.

2. Flex the mouthpiece with fingers to decrease the width for ease of placement within the oral cavity.



Grasp the mouthpiece at the grip tabs (5) to keep mouthpiece flexed during placement.

3. Slide wide suction arm along the inner cheek of the patient and release tab when within oral cavity. Device is positioned correctly when the irrigation piece sits between the teeth and suction arm resides in the buccal pocket between the teeth and cheek.



Check for placement by flexing mouthpiece outward slightly until cheeks can be seen moving outward slightly.



Suction arm should not be between the teeth.



Ensure the device does not dislodge or pinch the endotracheal tube, if applicable.

4. Rotate the patient into lateral position with bed flat. Ensure the mouthpiece with suction inlet arm (3) is on the side of the cheek that will be lowest when patient is repositioned.



The irrigation fluid will drain down toward the suction inlets due to gravity.

5. Check wall suction pressure is set between 150-200 mmHg.



Using suction pressure lower than 150 mmHg could result in poor suctioning of fluid from the oral cavity.

Suction pressures higher than 200 mmHg could result in damage to the device.

6. Connect wall suction line to the suction outlet port (4) on the mouthpiece. Ensure to face the patient while using the device.



Risk of fluid entering trachea if irrigation performed when patient is not positioned in Lateral position with head parallel to bed.



Risk of fluid entering trachea if irrigation performed when patients nose is not parallel to the bed or pointed downwards.



Recommended syringe sizes are 20mL to 60mL. Larger syringes may result in excess fluid in the patient's mouth; smaller syringes may lead to inadequate oral irrigation.

7. TEST suction by instilling 3-5 mL of fluid to ensure that suction is functioning. Listen for suction and watch for fluid in the suction line.



Monitor for returning fluid through the suction tube; stop irrigation if no fluid is returning.



SwishKit is designed for use with an oral irrigation fluid, such as saline or sterile water.

8. Provide irrigation with up to 20mL fluid in the syringe. Continue monitoring suction line visually for signs of fluid evacuation.



Instill only 20mL of fluid at a time. More than 20mL of fluid may result in excess fluid in the patient's mouth.



Use a push-pause process to apply quick bursts of force to the syringe plunger.

9. Repeat irrigation with additional 20mL volumes of fluid until the fluid returning through the suction tubing appears clear and free of mucous/organic debris.
10. Cease instillation of fluid.

After Use

1. Remove the mouthpiece by grasping the tabs (5) and gently pulling outward.
2. Inspect SwishKit™ for any damage or missing parts.
3. Perform oral inspection and verify that gums and cheeks in contact with the mouthpiece are free of abrasion.
4. Perform final suctioning as per standard procedure.
5. Reposition patient per clinician discretion.
6. Perform lip care.
7. Verify that the endotracheal tube, if applicable, is undisturbed after the mouthpiece has been removed and the patient repositioned, and that the ventilator is functioning normally.
8. Dispose of SwishKit™ after use following facility and local regulations biohazards protocols.

Troubleshooting

SwishKit™ does not fit inside patient's mouth

Use a tongue depressor to create space in the mouth.

Before inserting, bend the SwishKit™ device at hinge.

Use a gloved finger to gently pull on the corner of the patient's lip to create space to slide the suction paddle inside of the cheek and on the outside of the teeth.

No fluid coming out of suction tube

Confirm that device and patient are properly positioned.

Confirm that the wall suction tube is connected to SwishKit™.

Confirm that wall suction tube is connected at the wall outlet.

Confirm that the suction pressure is set to 150-200 mmHg.

Confirm that the suction inlets are not obstructed.

Syringe is hard to depress

Check for obstruction on the irrigation tubing.



Contact Information

For all inquiries and assistance, contact the manufacturer:

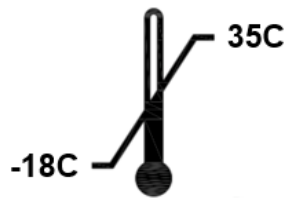
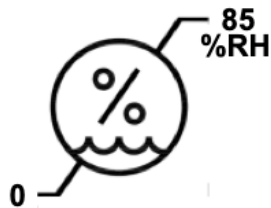
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Environmental Conditions



Shelf Life

1.5 years

(from date of manufacture)