



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 and hospitals.

Intended Users

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

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.



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.

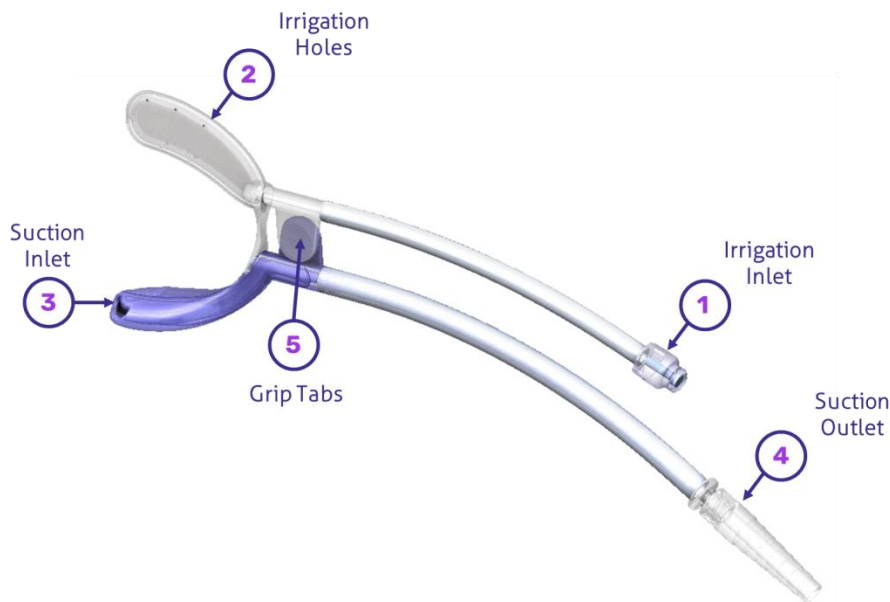


Note: provides other important information.

Cautions in this Manual

-  For use only by healthcare professionals trained to perform suctioning.
-  Ensure that suction line does not kink during use of device.
-  During suction with the SwishKit™ device, listen for suction and look for evidence of fluid in suction line. If suction is not apparent, halt the process and remove the mouthpiece.
-  Enteral feed should be stopped 15 minutes prior to SwishKit™ use.
-  SwishKit™ is single use; do not re-use SwishKit™
-  Use only 20 mL syringes with SwishKit™. 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.
-  The SwishKit™ is only for patients with endotracheal tubes.
-  Subglottic suctioning should be available as normal, if required
-  Oral care following standard protocols should continue, in addition to use of the SwishKit™.
-  Normal oropharyngeal suctioning should be performed in patients who are intubated with an endotracheal tube according to standard protocols.
-  Appropriate PPE to be worn while using SwishKit™; perform hand hygiene, don non-sterile gloves, facemask, and shield.
-  Ensure patient is well-oxygenated prior to suctioning.
-  Ensure the device does not dislodge or pinch the endo-tracheal tube.
-  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.
-  Dispose of SwishKit™ after use following hospital biohazards protocols.
-  Monitor for returning fluid through the suction tube; stop irrigation if no fluid is returning.
-  Inspect for damage before use.

Device Description



- 1 – Syringe Inlet**
Connects to 20mL 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

ROnly

This device is only to be used on the order of a physician.



The SwishKit™ is only for patients with endotracheal tubes



Subglottic suctioning should be available as normal, if required



Enteral feed should be stopped 15 minutes prior to SwishKit™ use.



Appropriate PPE to be worn while using SwishKit™; perform hand hygiene, don non-sterile gloves, facemask, and shield.



The SwishKit™ is to be used whenever oral care is performed on intubated patients, i.e., every 4 hours.



Irrigation must be performed with the patient turned to the opposite side the next time oral care suctioning is performed using the SwishKit™.

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.



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



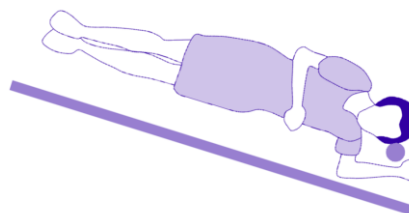
Inspect for damage before use.

Patient Positioning



Risk of fluid entering trachea if irrigation performed when patient is not positioned in lateral Trendelenburg.

Position patient laterally, with suction arm of mouthpiece on downward, lowest side of patient, with bed in Trendelenburg (15 degrees or greater).



During Use



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

1. Place device in patient's mouth.



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

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 (6) to keep mouthpiece flexed during placement.

3. Patient will be positioned laterally. Insert mouthpiece with suction arm (3) 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.

4. 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.

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 (5) on the mouthpiece.



Risk of fluid entering trachea if irrigation performed when patient is not positioned in lateral Trendelenburg.



Use only 20 mL syringes with SwishKit™. Larger syringes may result in excess fluid in the patient's mouth; smaller syringes may lead to inadequate oral irrigation.

7. Instill 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



Ensure that suction line does not kink during use of device.

8. Provide irrigation with the remaining fluid in the syringe. Continue monitoring suction line visually for signs of fluid evacuation.



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

9. Repeat irrigation with additional syringes 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 (6) and gently pulling outward.
2. Inspect SwishKit™ for any damage or missing parts.



Dispose of SwishKit™ after use following hospital biohazards protocols.

3. Perform oral inspection and verify that gums and cheeks in contact with the mouthpiece are free of abrasion.

4. Perform final oral suction using a Yankauer suction end piece as per standard procedure.
5. Reposition patient per clinician discretion.
6. Perform lip care.
7. Verify that the endotracheal tube is undisturbed after the mouthpiece has been removed and the patient repositioned, and that the ventilator is functioning normally.

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 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:

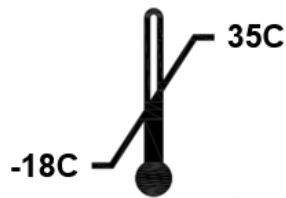
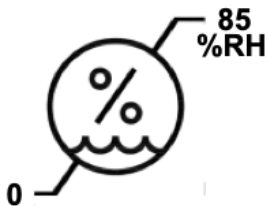
+1-888-375-5382

info@swiftsure.com



Swiftsure Innovations Inc.
36 Forest Road
Pasadena, Newfoundland
A0L 1K0
Canada

Environmental Conditions



Shelf Life

1 year

(from date of manufacture)

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Document Release Form

Document ID	Document Title
SK-LBL-003	Label, Operators Manual

Do other documents require update because of the change?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
Initial Release of DMR documents			
If revising QMS documents, has QMS-RSK-001 been reviewed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Approvals¹

Authority	Approved by	Signature	Approval Date (YYYY-MM-DD)
Director of Quality	Ide Moynihan	<i>ide moynihan</i>	2023-03-30

¹Release only, documents reviewed and approved through Design Review Process at IPD following IPD document control process



Revision History

Rev.	Description of Change / Reason for Change	Release Date (YYYY-MM-DD)
A	Initial Release of DMR Documents at SwiftSure,	2023-03-30