



OralKleen™

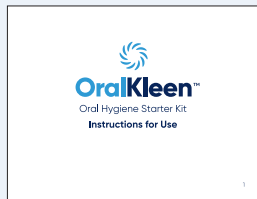
Oral Hygiene Starter Kit

Instructions for Use

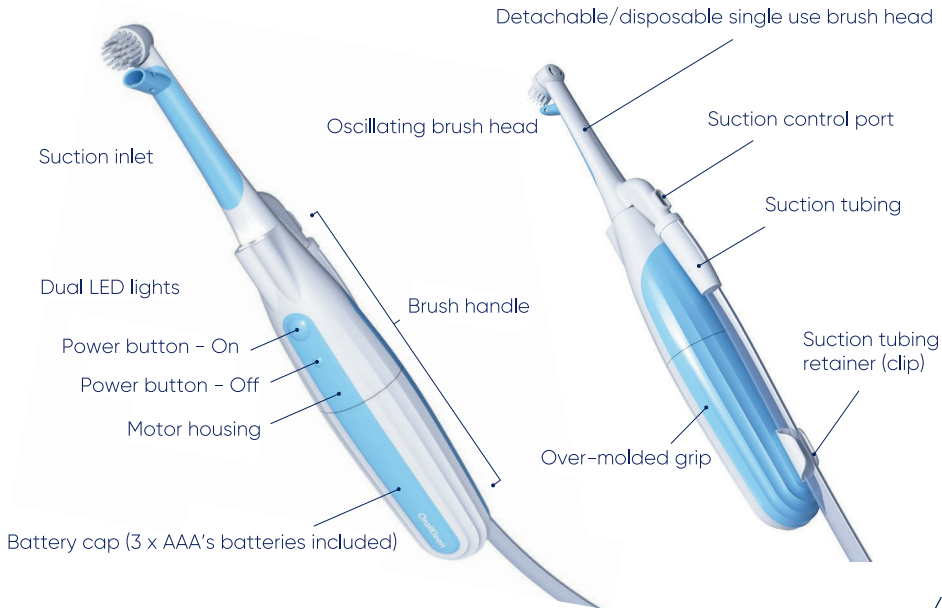


Kit Contents

- | | |
|----------------------------------|--|
| A. Brush handle | F. Mouth gel (moisturizer) |
| B. Tongue scraper | G. Lip balm |
| C. 6 Brush heads | H. Instructions for use Booklet |
| D. 3 Swabs | I. Storage tray |
| E. Non-foaming toothpaste | J. Storage Lid |

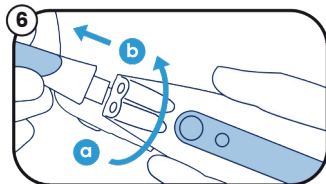
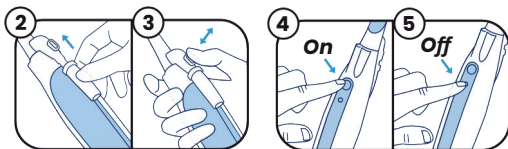
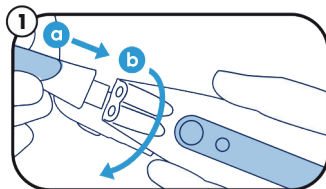


OralKleen's Patented Electric Toothbrush



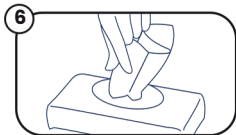
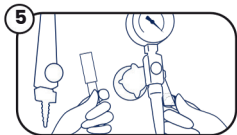
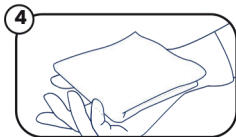
Operating Instructions for Electric Toothbrush

1. Install brush head:
 - a. Insert and push brush head on to post of brush handle
 - b. Twist clockwise to secure the lock
2. Connect suction tubing as shown and secure the suction tubing in the retainer clip
3. Check suction function by opening/closing the control port with finger
4. Depress large power button to turn on and activate lights and brush head
5. Depress small power button to turn off
6. Remove brush head:
 - a. Twist brush head counterclockwise while holding the handle to unlock the brush head
 - b. Remove brush head from handle post and discard



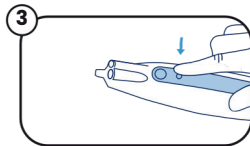
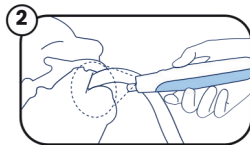
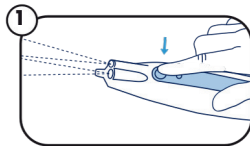
Comprehensive Oral Care Step 1: Prepare Supplies

1. Affix patient label to clear plastic cover on OralKleen Starter Kit for initial use
2. Verify patient label for each use
3. Don personal protective equipment: Face mask, gloves & eye protection (per facility policy)
4. Obtain clean towel
5. Ensure suction is set up and on to 80-120 mm Hg
6. Obtain facility approved disinfectant wipes



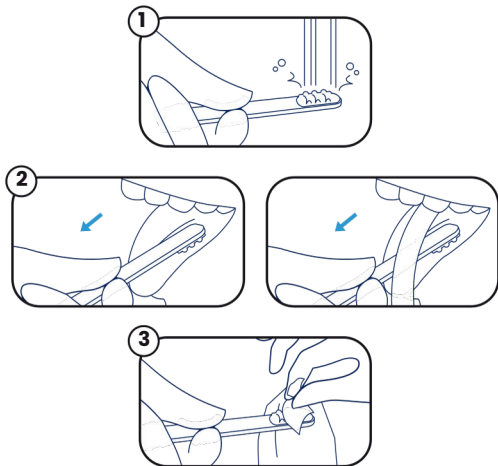
Comprehensive Oral Care Step 2: Assessment

1. Press large button to power brush handle ON to activate LED lights
2. Use LED lights to assess the general condition of patient's mouth per facility protocol
3. Press smaller button to power brush handle OFF when assessment complete



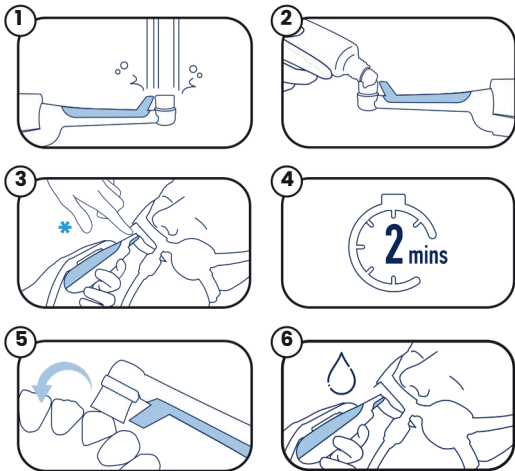
Comprehensive Oral Care Step 3: Tongue Scraping

1. Moisten tongue scraper
2. Use ridged surface and gently scrape tongue from back-to-front
3. Wipe debris off with a clean towel after each pass prior to reinserting
4. Set tongue scraper aside when complete, do not discard
5. Rinse and clean thoroughly, pat dry, and return to kit to air dry



Comprehensive Oral Care Step 4: Brushing

1. Moisten brush head
2. Apply pea-size amount of non foaming toothpaste to bristles
3. Insert toothbrush inside mouth*, then turn ON to prevent splatter of toothpaste
4. Brush teeth: 2 minutes total
5. Use gentle pressure, brush the inside and outside surfaces of all teeth. Move the toothbrush slowly, 1-2 seconds per tooth until complete. **DO NOT SCRUB BACK AND FORTH**, let the brush do the work
6. Use suction to remove residue and /or liquids at any time by covering the suction control port with your thumb or finger. Rinse toothpaste. Use suction to remove rinse

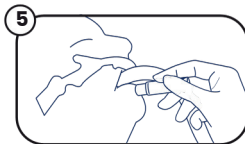
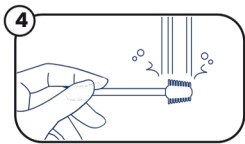
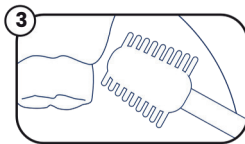
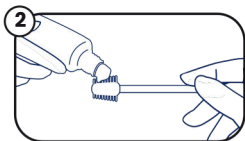
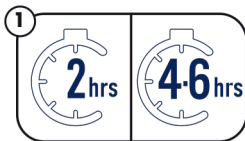


*If needed, retract cheek with gloved finger to improve access.

Comprehensive Oral Care Step 5: Moisturizing/Mucosal Care

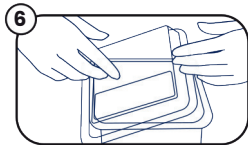
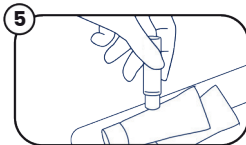
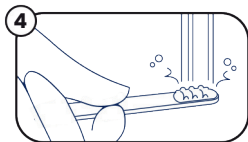
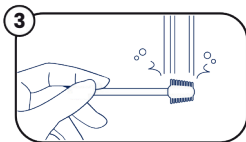
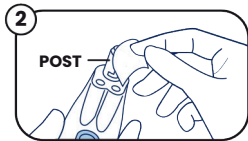
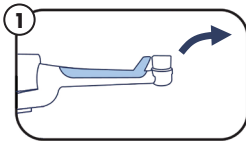
Perform immediately after brushing and between brushing to keep oral mucosa moist

1. Frequency:
 - a. Intubated: Every 2 hours or per facility protocol
 - b. NOT intubated: Every 4-6 hours or per facility protocol
2. Apply mouth gel (moisturizer) to swab stick
3. Swab tongue, gums, and inside of cheeks
4. Rinse swab stick and return to storage tray
5. Apply thin layer of lip balm to lips*
*Lip balm contains beeswax. Avoid use in case of known allergy to bees.



Product Cleaning

1. Remove brush head and discard after each use.
2. Wipe the post and top of brush handle with facility approved disinfectant wipes after each use to remove secretions. Return to storage tray to air dry
3. Rinse and clean 24-hour swab and return to storage tray to air dry
4. Rinse and clean reusable tongue scraper and wipe clean of secretions with a towel. Return to storage tray to air dry
5. Return toothpaste, mouth gel (moisturizer), and lip balm to storage tray
6. Close tray with vented plastic lid



Product Replacement

3 day kit: Single-patient use device

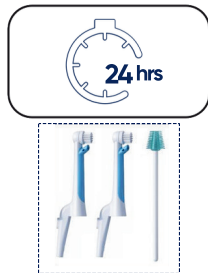
Do not replace kit until batteries in handle depleted

Discard brush head after each use

Reuse 1 swab for 1 day (24 hours) and discard

Day 4-15 replacement supplies:

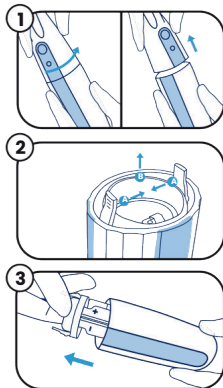
1. Obtain daily replacement pack from unit storage:
contains two brush heads and one swab
2. Individual components of brush handle, brush head, swab, tongue scraper, toothpaste & mouth gel (moisturizer) can be obtained separately from unit storage as needed
3. Brush handle: Obtain new kit once batteries depleted



Brush Handle & Battery Disposal

Remove Batteries for Disposal:

1. Twist the motor housing of the handle counterclockwise from the battery cap and pull apart to divide the handle in half
2. A. Push in on both tabs to release battery carrier spring
B. The battery carrier will elevate from battery cap
3. Pull battery carrier up and out of battery cap. Remove the batteries and dispose per facility protocol
4. Dispose brush handle per facility protocol



Troubleshooting

Problem	Possible Reason	Solution
Lights do not turn on when power button compressed	Power button not fully depressed End of battery life Motor malfunction	Recompress power button Replace brush handle Replace brush handle
The brush head oscillating stops or slows while brushing teeth	Excessive pressure exerted on brush head Improper use of device Patient closes mouth and/or bites on brush head during brushing	Remove brush head pressure from teeth and allow brush head to resume oscillation before resuming brushing Decrease the amount of pressure during brushing. Do not scrub. Allow brush head to glide across the teeth and gums Use bite block to prevent mouth closure and biting. Replace brush head if stops completely
Suction not working	Wall suction off or set too low Brush head not properly secured to handle Debris/obstruction noted in wall suction tubing	Turn on wall suction 80–120mm Hg Remove and reattach brush head Rinse and/or replace wall suction tubing
Handle powers on (lights on) but bristles do not oscillate	Dried secretions at post of brush handle Brush head not properly secured	Remove brush head and wipe post and top of brush handle. Replace with same brush head. If still not oscillating, replace with new brush head. If not working, replace handle Remove and replace brush head. Ensure seal locks in place between brush head and handle. If does not work or seal broken (stripped), replace with new brush head. Replace handle if brush head still not working

Technical Specifications

Expected battery life up to 15 days with recommended patient use

Recommended suction settings 80–120 mm Hg

Intended Use

FDA Class II medical device (510K exempt) designed specifically by nursing and dental professionals to be used by trained healthcare professionals in acute care hospitals, long-term care acute care hospitals, and rehabilitation settings to safely and effectively clean the teeth of patients.

Contraindications for use of the electric toothbrush

Orofacial trauma

Mouth wired shut

Children under 10 years of age











Adverse events

Follow facility protocol

Call: 1-877-ORALKLEEN (1-877-672-5553)

Email: contact@oralkleen.com

Glossary of Symbols

Symbol	Symbol Title	Definition	Standard Ref. #
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1 Ref. #5.1.4 ISO 7000 Ref. #2607
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 Ref. #5.1.6 ISO 7000 Ref. #2493
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1 Ref. #5.2.7 ISO 7000 Ref. #2609
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 Ref. #5.2.8 ISO 7000 Ref. #2606
	Single Patient Multiple Use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.	ISO 15223-1 Ref. #5.4.12 ISO 7000 Ref. #3106
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1 Ref. #5.4.3 ISO 7000 Ref. #1641
	Unique Device Identification	Indicates a carrier that contains Unique Device Identifier	N/A – From new revision of ISO 15223-1:2020 Ref. #5.7.10
	Quantity	Indicates the number of units per package	N/A – Not derived from Standard
	Not made with Natural Rubber Latex	Indicates the medical devices are not made with natural rubber latex	Negation of (ISO 15223-1 Appendix B.2) ISO 15223-1 Ref. #5.4.5 ISO 7000 Ref. #2725
	Recyclable and biodegradable packaging	Packaging is 100% recyclable and biodegradable	N/A – Not derived from Standard

**Warning:**

- This device is to be used by trained healthcare professionals.
- Use this product only for its intended use as described in this manual. Do not use attachments which are not recommended by the manufacturer.
- Use with caution in agitated patients. Biting down on the brush head may result in detachment of the bristle disc which may present a choking hazard.
- Use with caution in agitated patients. Biting down on the swab may result in detachment of the swab tip which may present a choking hazard.
- Use with caution in patients with genetic or acquired coagulopathy. May cause bleeding. Consult with medical team prior to use.

**Caution:**

- Do not submerge the handle in fluids (i.e. water etc.)
- Clean per the manufacturer and facility recommendations.
- Failure to clean the post of the handle may cause motor malfunction.
- Failure to keep patient's mouth open during brushing may cause brush head and/or motor malfunction.
- Device has no serviceable parts. Do not open and disassemble device except when disposing of the batteries.
- Device shall only be powered by the recommended battery type: 3 x AAA alkaline batteries (3VDC).
- Lip balm contains beeswax. Avoid use in case of known allergy to bees.

Residual Risks:

- The following are potential residual risks and side effects that could require medical intervention: Sensitization/irritation/ulcers/bleeding etc.

Disposal:

- Prior to brush handle disposal, remove and dispose of batteries per facility protocol.



OralKleen™



Instruction for Use:
Comprehensive
Oral Care Protocol



System Components
Overview

If you should require user
assistance, please call our
customer service line or email:

OralKleen, LLC

1 North 1st St. Suite 7200
Phoenix, Arizona 85004
(877) ORALKLEEN
(877) 672-5553

contact@oralkleen.com
<https://oralkleen.com>

OralKleen Electric Suctioning
Toothbrush, 3.7V
PN 715-0080



(01) 0 0850030 08112 4
(10) MH4454BP1625

FDA Registered Medical Device (Class-2)

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