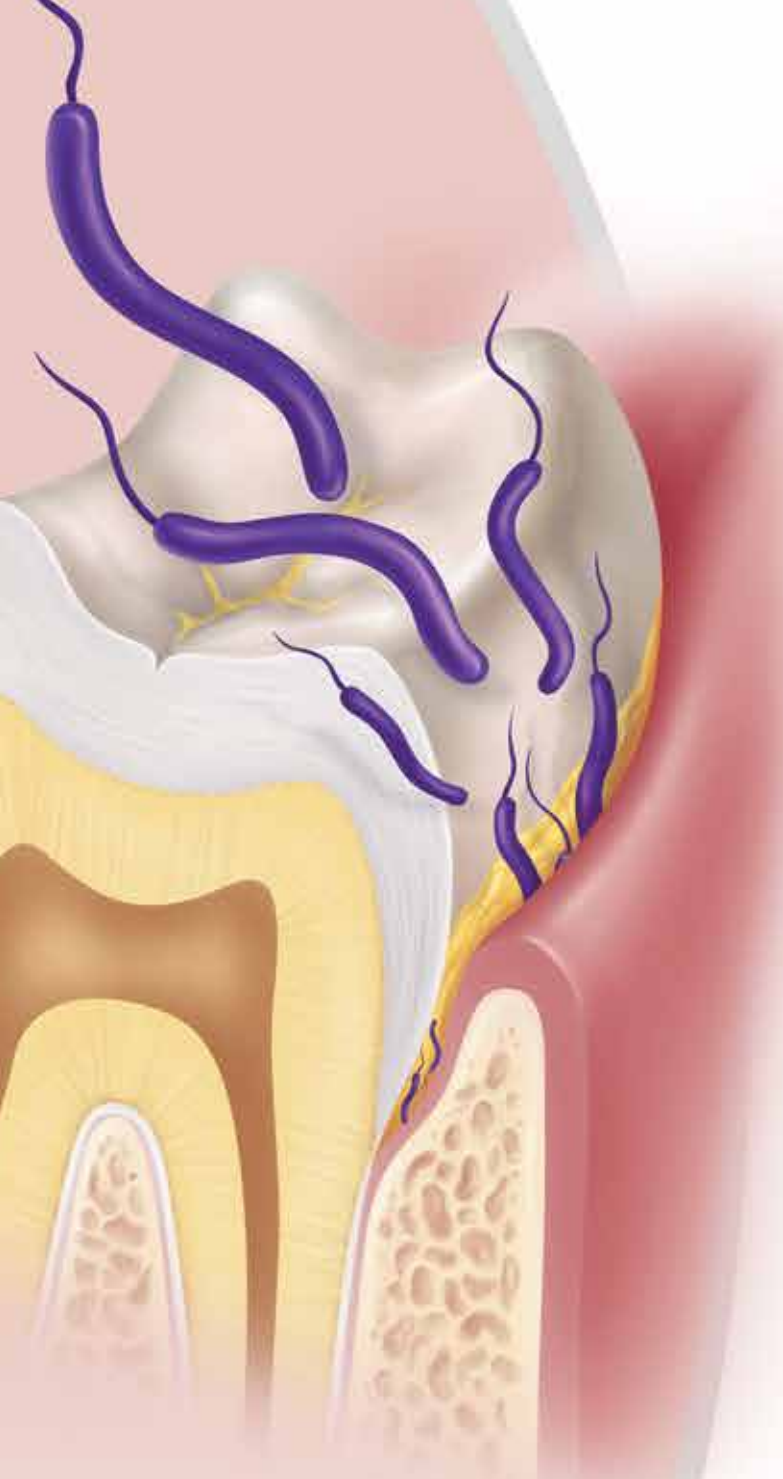


ORAL HYGIENE

Q•Care® Oral Cleansing & Suctioning Systems and
Toothette® Oral Care





THE IMPORTANCE OF ORAL CARE IN ADDRESSING HAP AND VAP RISK FACTORS

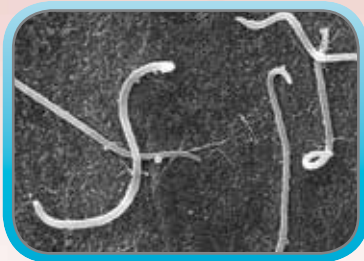
Hospital-acquired pneumonias (HAPs), including ventilator-associated pneumonia (VAP), often start in the oral cavity.^{1,2} Bacteria, including dental plaque, can colonize in the oropharyngeal area,³ and these pathogens can be aspirated into the lungs, causing infection.⁴ VAP is the most common infectious complication among ICU patients and accounts for over 47% of all infections.⁵ Non-vent patients with conditions including dysphagia, stroke, COPD and malignancy are also at risk for HAP.^{6,7}

IMPROVING SURVEILLANCE FOR VENTILATOR-ASSOCIATED EVENTS IN ADULTS

The Centers for Disease Control and Prevention (CDC) has proposed a change to the way VAP surveillance is reported through the National Healthcare Safety Network (NHSN). Under the proposal, hospitals would be required to publicly report VAPs, Ventilator-Associated Conditions (VACs) and Infections with Ventilator-Associated Conditions (IVACs).⁸

BIOFILM FORMING OVER A 24-HOUR PERIOD

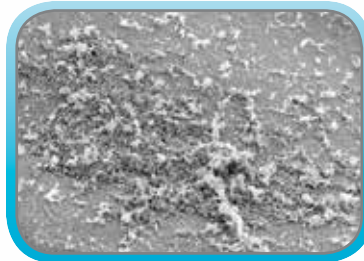
Photos courtesy of Center for Medical Biofilm Research, University of Southern California.



Bacteria beginning to form.



More and more bacteria adhere, and existing bacteria begin to multiply forming a microcolony.



Bacteria spread in all directions becoming a macrocolony; bacteria begin to grow in multiple layers.



Bacteria macrocolonies spread and overlap, resulting in full biofilm.

REFERENCES: 1. Schleder B, et al., J Advocate Health Care. 2002 Spr/Sum; 4(1): 27-30. 2. Tablan OC, et al., Guidelines for preventing health-care-associated pneumonia, 2003, Recommendations of CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC), 2003. 3. Scannapieco FA, J Periodontology. 1999 Jul; 70(7):793-802. 4. Fourrier F, et al., Crit Care Med. 1998;26: 301-8. 5. Cason, CL, et al., Am J Crit Care. 2007 Jan; 16 (1): 28-38. 6. Marik PE. N Eng J Med. 2001;344(9):665-71. 7. Kozlow JH, et al., Crit Care Med. 2003;31(7):1930-7. 8. Centers for Disease Control and Prevention, available at http://www.cdc.gov/nhsn/PDF/vae/CDC_VAE_CommunicationsSummary-for-compliance_20120313.pdf

BIOFILMS: A RISK FACTOR FOR PNEUMONIA

Biofilms are a thin, usually resistant layer of microorganisms (as bacteria) that form on and coat various surfaces.¹ Biofilms have been found to be involved in up to 80% of infections.² Dental plaque is one of the most common biofilms and is responsible for various periodontal diseases, including gingivitis.³

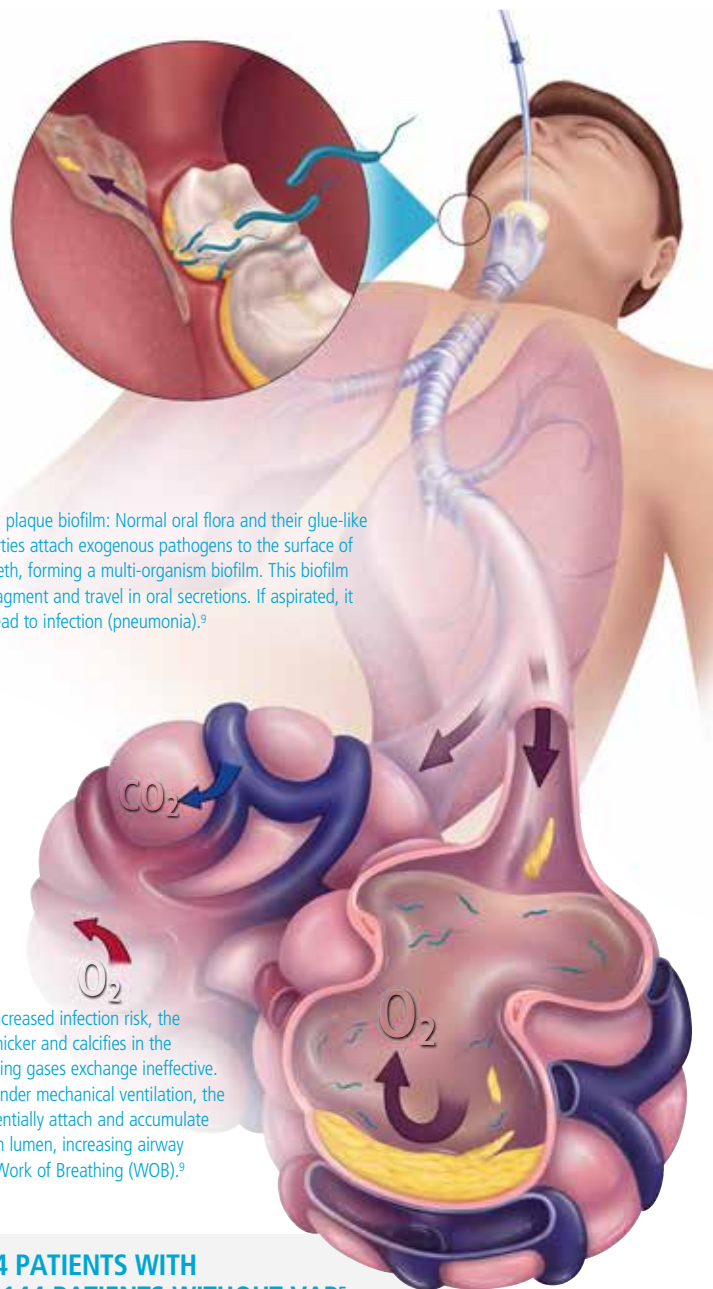
VAP CONSEQUENCES

- Mortality rate of up to 76%.⁴
- Mean hospitalization costs were \$99,598 for patients with VAP and \$59,770 for patients without VAP ($P < .0001$), resulting in an absolute difference of \$39,828.⁵
- Mean length of stay can reach 23 days.⁶
- 9.6 additional days on the vent, 6.1 extra days in the ICU and 11.5 more days in the hospital.⁷

COMPREHENSIVE ORAL HYGIENE ADDRESSES THREE KEY VAP RISK FACTORS:⁷

- Bacterial colonization of the oropharyngeal area.
- Aspiration of subglottic secretions.*
- Colonization of dental plaque with respiratory pathogens.

* Routine suctioning minimizes oral secretions which can migrate to the subglottic area.



Dental plaque biofilm: Normal oral flora and their glue-like properties attach exogenous pathogens to the surface of the teeth, forming a multi-organism biofilm. This biofilm can fragment and travel in oral secretions. If aspirated, it may lead to infection (pneumonia).⁹

In addition to increased infection risk, the biofilm grows thicker and calcifies in the alveolus, rendering gases exchange ineffective. Subsequently, under mechanical ventilation, the biofilm can potentially attach and accumulate in the endotracheal lumen, increasing airway resistance and Work of Breathing (WOB).⁹

COSTS IN A MATCHED COHORT OF 2,144 PATIENTS WITH VENTILATOR-ASSOCIATED PNEUMONIA (VAP) AND 2,144 PATIENTS WITHOUT VAP⁵

Outcome type	Cost, dollars, mean \pm SD ^a		P	Difference in dollars (%)
	With VAP	Without VAP		
Hospitalization	99,598 \pm 86,359	59,770 \pm 58,278	<.0001	39,828 (40.0)
Nursing time	3,369 \pm 16,487	2,980 \pm 14,109	.568	389 (11.5)
Pharmacy	14,345 \pm 16,992	8,547 \pm 14,497	<.0001	5,798 (40.4)
Antibiotic	1,947 \pm 4,095	1,011 \pm 2,039	<.0001	936 (48.1)
Vancomycin	327 \pm 564	248 \pm 420	<.0001	79 (24.2)
Propofol for sedation	947 \pm 1,768	585 \pm 1,202	<.0001	362 (38.2)
Ventilator	4,710 \pm 6,251	2,184 \pm 2,807	<.0001	2,526 (53.6)
Ventilator in ICU	3,716 \pm 4,479	1,909 \pm 2,304	<.0001	1,807 (48.6)
Respiratory therapy	2,650 \pm 4,007	1,496 \pm 2,539	<.0001	1,154 (43.5)
Chest x-rays	1,762 \pm 1,594	1,009 \pm 958	<.0001	753 (42.7)

NOTE. ICU, intensive care unit; SD, standard deviation.

^a Costs represent medical direct and indirect costs (not Medicare charges). Costs were not additive (eg, antibiotic and propofol costs were a subset of pharmacy costs).

BEATING BIOFILMS WITH COMPREHENSIVE ORAL CARE

Toothette® Oral Care addresses key VAP risk factors with a comprehensive approach based on cleaning, debriding, suctioning and moisturizing the entire oral cavity. The Toothette brand incorporates 24-hour systems, innovative tools and effective solutions, all while facilitating compliance to your oral care protocol. 88% of the oral care market is trusted to Toothette brand oral care.¹



88%

of the oral care market is trusted to the Q•Care and Toothette brands.¹

all other brands

BEATING BIOFILMS

"If oral care is not started upon admission, the mouth could become colonized with harmful bacteria within the first 48 hours. Plaque on the teeth can provide a breeding ground for this growth of bacteria... The most effective way to remove plaque is to use a brush."²



CLEAN

Brushing and suctioning with an antiseptic agent kills³ and mechanically removes bacterial biofilms (dental plaque) from teeth and oral tissues.



DEBRIDE

Swabbing and suctioning with Perox-A-Mint® solution helps remove dead, loosened biofilms.⁴



MOISTURIZE

Water-based formula soothes and moisturizes oral tissues.

REFERENCES: 1. GHX Trend Report (Dollars), 1st Quarter, 2012 Hospital; Annualized markets based on last 4 quarters data. 2. Campbell DL, Ecklund MM. Development of a research-based oral care procedure for patients with artificial airways. NTI News (a publication of AACN's National Teaching Institute). 7 May 2002. 3. Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph, Federal Register, 68(103):32232-87. 4. Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, Federal Register, 53(17): 2436-61.

PROFESSIONAL GUIDELINES

CDC GUIDELINES FOR PREVENTING HEALTHCARE-ASSOCIATED PNEUMONIA^{1*}

"...Develop and implement a comprehensive oral-hygiene program (that might include use of an antiseptic agent) for patients in acute-care settings or residents in long-term care facilities who are at risk for health-care-associated pneumonia (II)."

*In addition to other interventions

AACN PROCEDURE MANUAL FOR CRITICAL CARE—ORAL CARE INTERVENTIONS, 2010^{2*}

"Initiate oral hygiene with a pediatric or adult (soft) toothbrush, at least twice a day. Gently brush patient's teeth to clean and remove plaque from teeth."

"In addition to brushing twice daily, use oral swabs with a 1.5% hydrogen peroxide solution to clean mouth every 2 to 4 hours."

"After each cleansing, apply a mouth moisturizer to the oral mucosa and lips to keep tissue moist."††

"Suction oral cavity and pharynx frequently." ††

"Antiseptic oral rinses (chlorhexidine, cetylpyridinium chloride [CPC]), added after brushing or done in conjunction with comprehensive oral care did achieve elimination of VAP."†

*In addition to other interventions.

†Level B: Well-designed, controlled studies with results that consistently support a specific action, intervention, or treatment.

††Level C: Qualitative studies, descriptive or correlational studies, integrative reviews, systematic reviews, or randomized controlled trials with inconsistent results.

IHI PROTECTING 5 MILLION LIVES FROM HARM CAMPAIGN

Getting Started Kit: Prevent Ventilator-Associated Pneumonia How-To Guide³

Develop a comprehensive oral care process that includes the use of 0.12% chlorhexidine oral rinse.

APIC 2009 GUIDE TO THE ELIMINATION OF VENTILATOR-ASSOCIATED PNEUMONIA⁴

Key prevention strategies:

- Perform routine antiseptic mouth care

Example mouth care and documentation form includes the following:

- Brush teeth q12^o
- Provide oral care every 2 to 4 hours with antiseptic
- Apply mouth moisturizer to oral mucosa and lips
- Suction orally as necessary

PROVEN CLINICAL OUTCOMES

Reducing VAP

- A published 4-year study using an oral care protocol including Toothette® Oral Care Systems saw a 33% reduction in VAP, plus fewer vent days, shorter length of stay and decreased mortality rates.⁵
- One facility had a VAP rate of zero for three straight years after implementing an oral care protocol that included Toothette Q•Care® Systems.⁶
- Another study saw a 60% reduction in VAP after implementing comprehensive oral care with Toothette products.⁷
- A 4-year study found Toothette Oral Care helped achieve a statistically significant 42.1% VAP reduction—avoiding \$722,975 in costs.⁸

Reducing HAP

- A 2-year study at 11 nursing homes found pneumonia risk was significantly reduced in patients receiving oral care. In fact, mortality due to pneumonia was about half that of patients not receiving oral care.⁹
- The use of a comprehensive oral hygiene protocol including Q•Care Systems was effective in reducing one facility's HAP rates by 46%.¹⁰
- Comprehensive oral care lead to 3% reduction in NV-HAP, \$1.72 million in costs avoided and 500 extra hospital days averted in a 2014 study.¹¹

Cost Avoidance

- In 17 months, one 350-bed hospital reduced VAP over 75%, avoiding \$1.6 million in costs. Along with a ventilator bundle and head-of-bed elevation, they upgraded from swabs only to Q•Care cleansing and suctioning every 2 to 4 hours.¹²

REFERENCES: 1. Tablan OC, et al., Guidelines for preventing health-care-associated pneumonia, 2003, Recommendations of CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC), 2003. 2. Scott JM, Vollman KM, Endotracheal tube and oral care. In DJ Lynn-McHale Wiegand and KK Carlson (Eds.) AACN Procedure Manual for Critical Care, Fifth Ed., pp. 28-33, Elsevier Saunders, St. Louis, MO. 3. 5 Million Lives Campaign. Getting Started Kit: Prevent Ventilator-Associated Pneumonia How-to Guide. Cambridge, MA: Institute for Healthcare Improvement; 2010. 4. APIC 2009 Guide to the Elimination of Ventilator-Associated Pneumonia, pp. 38, 40. 5. Garcia R. Reducing Ventilator-Associated Pneumonia Through Advanced Oral-Dental Care: A 48 Month Study. AJCC, July 2009, Doi: 10.4037. 6. Lipke B, Carman V. Sustained Reduction in Ventilator-Associated Pneumonia (VAP) Using a Two-Hospital Multidisciplinary Approach that Includes Oral Care and Regular Staff Education. Poster presented at 2008 APIC Annual Conference: June 15-19, 2008. 7. Schlieder B, et al., J Advocate Health Care. 2002;5(3):434-8. 8. Orr Jean C, Mitchell M. Prevention of Hospital-Associated Pneumonia Using a Comprehensive Oral Hygiene Protocol. Poster presented at 2008 APIC Annual Conference: June 15-19, 2008. 9. Quinn, B. et al. Basic Nursing Care to Prevent Nonventilator Hospital-Acquired Pneumonia, Journal of Nursing Scholarship, 2014, 46(1), 11-19. 12. Sherman Hospital saves \$1.6 million on VAP-related costs. Case study, 2005 (available at <http://www.sageproducts.com/company/media2.asp?ArticleID=51>).

INNOVATIVE TOOLS AND SOLUTIONS PROVEN EFFECTIVE AGAINST VAP AND HAP RISK FACTORS

Toothette® Oral Care delivers a comprehensive approach based on cleaning, debriding, suctioning and moisturizing the entire oral cavity. With multiple products incorporating innovative tools and effective solutions, proven clinical outcomes and effective compliance programs, it's no wonder that Toothette is the market leader in oral care.

EASY BURST POUCHES DISPENSE SOLUTION IN SECONDS!

Premoistens swabs right in the package. Ready to use, no waste in product or nursing time due to mixing your own solutions.



REFERENCES: 1. DelWalt EM, Nurse Res. 1975 Mar-Apr;24(2):104-8. 2. Pearson LS, Hutton JL, J Adv Nurs. 2002 Sep;39(5):480-9. 3. Scannapieco FA, Stewart EM, Mylotte JM, Crit Care Med. Jun 1992;20(6):740-5. 4. Scannapieco FA, J Periodontology. 1999 Jul; 70(7):793-802. 5. Fournier F, et al., Crit Care Med. 1998; 26: 301-8. 6. Sole ML, et al., Am J Crit Care. 2002 Mar; 11(2): 141-9. 7. Schlieder B, et al., J Advocate Health Care. 2002 Spr/Sum; 4(1):27-30. 8. Schlieder BJ, Nursing Mgmt. 2003 Aug; 34(8):27-33. 9. Nisengard RJ, Dept of Periodontics & Endodontics, Sch of Dent Med, SUNY Buffalo, 2000 Dec. 10. Candida albicans, Streptococcus mutans and Actinomyces viscosus.

* Based on an independent study of 24 subjects comparing the plaque removal efficacy of toothbrushes



TOOTHETTE® SUCTION TOOTHBRUSH

Helps remove dental plaque,^{1,2} debris and oral secretions, all known to harbor potential respiratory pathogens.^{3,4,5,6}

- Available with sodium bicarbonate to mechanically cleanse.
- Swab on back of brush helps deliver cleansing solution.
- User-friendly thumb port provides easy suction control.
- Three suction ports to avoid clogging. Keeps open path for debris.



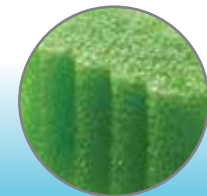
31 times more contact points and 25% more effective in plaque removal* than representative competitors' molded plastic bristle toothbrushes.



TOOTHETTE® SUCTION SWAB

Helps remove debris and oral secretions while stimulating oral tissues^{1,7,8} between brushings.

- Available with sodium bicarbonate to mechanically cleanse.
- Soft foam heads gentle on delicate oral tissues.
- User-friendly thumb port provides easy suction control.
- Non-suction swabs available.



Perpendicular ridges clean between teeth. Lifts debris and mucus from teeth and gums.



COVERED YANKAUER

Helps remove debris and secretions.

- Soft tip gentle on fragile oral tissues.
- User-friendly, one-piece design.

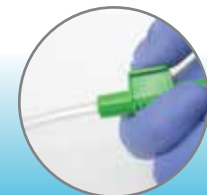


Exclusive retractable sleeve addresses infection control issues by helping contain oral secretions and protecting Yankauer from environmental debris.



OROPHARYNGEAL SUCTION CATHETER

Helps remove secretions from the oropharyngeal area above the vocal cords.



Longer, flexible design allows for suctioning of areas Covered Yankauer may not be able to reach.

Chlorhexidine Gluconate 0.12% Oral Rinse

- Indicated for the treatment of gingivitis, as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing.
- Single dose bottle is ready to use – no product waste due to measuring and mixing.
- Provides antimicrobial activity during oral rinsing.
- Prescription grade requires documentation on MAR and promotes better oral care compliance.

Perox-A-Mint® Solution

- Mechanically cleans and debrides with 1.5% hydrogen peroxide.

Antiseptic Oral Rinse

- Helps reduce chance of infection in minor oral irritation with 0.05% cetylpyridinium chloride (CPC).
- Promotes healing by reducing bacteria known to cause most oral dysfunction.^{9,10}

Anti-plaque Solution

- Helps remove and prevent plaque that leads to gingivitis with 0.05% cetylpyridinium chloride.
- Alcohol-free and non-irritating, with pleasant mint flavor.

Alcohol-Free Mouthwash

- Cleans and refreshes oral cavity with pleasant mint flavor.

Mouth Moisturizer

- Soothes and moisturizes with Vitamin E and coconut oil.
- Water-based formula can be used inside mouth.

Q CARE® 24-HOUR SUCTION SYSTEMS

For patients who cannot expectorate and cannot perform their own oral care

Take a comprehensive approach to oral hygiene and facilitate compliance to your protocol with Q Care Oral Cleansing and Suctioning Systems.

SYSTEMS INCLUDE:

Easy to use, sequential q2°, q4° or q8° packaging to lay out each step.

Minimal setup—less time opening packaging and more time for oral care.

Superior components and cleansing solutions.

Simple tools work with your existing suction equipment.

No mixing, no mess burstable solution packets.

Oral Check™ barcode on systems that contain over-the-counter drug solutions. Allows scanning of each product package for documentation on the MAR, further enhancing protocol compliance.

Available as Rx Oral Cleansing and Suctioning System with Chlorhexidine Gluconate 0.12% Oral Rinse

Features 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse in a convenient single dose bottle or burst pouch, which means no mixing and no mess. No wasted product and no wasted nursing time but provides essential antimicrobial activity during oral rinsing.



Q•CARE WITH THUMB PORT TOOLS



Length of Stay (LOS) Yankauer Holder provides easy access.



Space-saving Bedside Bracket helps increase compliance to protocol.



Suction handle provides variable suction control and allows quick tool changes.



Thumb port provides easy suction control.

INDICATIONS AND PHARMACOLOGY OF CLEANSING SOLUTIONS:

PRODUCT (ACTIVE INGREDIENT)	INDICATIONS	CLINICAL PHARMACOLOGY
Chlorhexidine Gluconate 0.12% Oral Rinse	0.12% Chlorhexidine Gluconate (CHG) Oral Rinse is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Peridex™ Oral Rinse has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS. ¹	0.12% Chlorhexidine Gluconate (CHG) Oral Rinse provides antimicrobial activity during oral rinsing. The clinical significance of 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse's antimicrobial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-97% through six months use. ¹
	FUNCTION/CLAIM	HOW ACTIVE INGREDIENT WORKS
Perox-A-Mint® Solution (1.5% hydrogen peroxide)	Oral Debriding Agent—aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth. ²	Mechanical Action—The release of bubbles of oxygen by enzymatic action when peroxide comes into contact with the tissues. ³
Antiseptic Oral Rinse (0.05% cetylpyridinium chloride)	Oral Antiseptic—helps reduce the chance of infection in minor oral irritation. ⁴	Chemical Action—The positive charge on the chemical reacts with the negative charge of the bacterial cell to cause cell death. ⁵
Antiplaque Solution (0.05% cetylpyridinium chloride)	Antiplaque/Antigingivitis—helps remove plaque that leads to gingivitis. ⁵	Chemical Action—The positive charge on the chemical reacts with the negative charge of the bacterial cell to cause cell death. ⁵
Alcohol-Free Mouthwash	Cleans and refreshes.	N/A

CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE

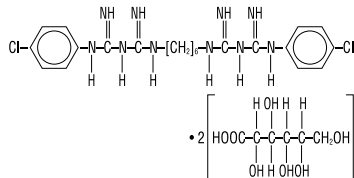
NDC 53462-003-15

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diostearate, flavor, sodium saccharin, and FD&C Blue No. 1.

Rx only

KEEP OUT OF REACH OF CHILDREN

DESCRIPTION: Chlorhexidine Gluconate is an oral rinse containing 0.12% chlorhexidine gluconate (1,11-hexamethylene bis[5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Chlorhexidine Gluconate is a near-neutral solution (pH range 5-7). Chlorhexidine Gluconate is a salt of chlorhexidine and gluconic acid. Its chemical structure is:



CLINICAL PHARMACOLOGY: Chlorhexidine Gluconate Oral Rinse provides antimicrobial activity during oral rinsing. The clinical significance of Chlorhexidine Gluconate Oral Rinse's antimicrobial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-97% through six months use.

Use of Chlorhexidine Gluconate Oral Rinse in a six month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after Chlorhexidine Gluconate Oral Rinse was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at baseline.

PHARMACOKINETICS: Pharmacokinetic studies with Chlorhexidine Gluconate Oral Rinse indicate approximately 30% of the active ingredient, chlorhexidine gluconate, is retained in the oral cavity following rinsing. This retained drug is slowly released in the oral fluids. Studies conducted on human subjects and animals demonstrate chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhexidine gluconate reached a peak of 0.206 µg/L in humans 30 minutes after they ingested a 300 mg dose of the drug. Detectable levels of chlorhexidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhexidine gluconate occurred primarily through the feces (~90%). Less than 1% of the chlorhexidine gluconate ingested by these subjects was excreted in the urine.

INDICATION AND USAGE: Chlorhexidine Gluconate Oral Rinse is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Chlorhexidine Gluconate Oral Rinse has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS.

CONTRAINDICATIONS: Chlorhexidine Gluconate Oral Rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula ingredients.

WARNINGS: The effect of Chlorhexidine Gluconate Oral Rinse on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing in Chlorhexidine Gluconate Oral Rinse users compared with control users. It is not known if Chlorhexidine Gluconate Oral Rinse use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Anaphylaxis, as well as serious allergic reactions, have been reported during postmarketing use with dental products containing chlorhexidine, see CONTRAINDICATIONS.

PRECAUTIONS:

GENERAL:

1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with Chlorhexidine Gluconate Oral Rinse should not be used as a major indicator of underlying periodontitis.

2. Chlorhexidine Gluconate Oral Rinse can cause staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in toothstaining. In clinical testing, 56% of Chlorhexidine Gluconate Oral Rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of Chlorhexidine Gluconate Oral Rinse users developed what was judged to be heavy stain, compared to 1% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque. Stain resulting from use of Chlorhexidine Gluconate Oral Rinse does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis. Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from Chlorhexidine Gluconate Oral Rinse treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these restorations.

3. Some patients may experience an alteration in taste perception while undergoing treatment with Chlorhexidine Gluconate Oral Rinse. Rare instances of permanent taste alteration following Chlorhexidine Gluconate Oral Rinse use have been reported via post-marketing product surveillance.

PREGNANCY: TERATOGENIC EFFECTS Pregnancy Category B. Reproduction Studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 3000 mg/kg/day and 40 mg/kg/day respectively, and have not revealed evidence of harm to fetus. However, adequate and well-controlled studies in pregnant women have not been done. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

NURSING MOTHERS: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Chlorhexidine Gluconate Oral Rinse is administered to nursing women. In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which would result from a person's ingesting 30 mL of Chlorhexidine Gluconate Oral Rinse per day.

PEDIATRIC USE: Clinical effectiveness and safety of Chlorhexidine Gluconate Oral Rinse have not been established in children under the age of 18.

CARCINOGENESIS, MUTAGENESIS, AND IMPAIRMENT OF FERTILITY: In a drinking water study in rats, carcinogenic effects were not observed at doses up to 38 mg/kg/day. Mutagenic effects were not observed in two mammalian in vivo mutagenesis studies with chlorhexidine gluconate. The highest doses of chlorhexidine used in a mouse dominant-lethal assay and a hamster cytogenetics test were 1000 mg/kg/day and 250 mg/kg/day, respectively. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.

ADVERSE REACTIONS: The most common side effects associated with chlorhexidine gluconate oral rinses are: 1) an increase in staining of teeth and other oral surfaces; 2) an increase in calculus formation; and 3) an alteration in taste perception; see WARNINGS and PRECAUTIONS. Oral irritation and local allergy-type symptoms have been spontaneously reported as side effects associated with use of chlorhexidine gluconate rinse. The following oral mucosal side effects were reported during placebo-controlled adult clinical trials: aphthous ulcer, grossly obvious gingivitis, trauma, ulceration, erythema, desquamation, coated tongue, keratinization, geographic tongue, mucocoele, and short frenum. Each occurred at a frequency of less than 1.0%. Among post marketing reports, the most frequently reported oral mucosal symptoms associated with Chlorhexidine Gluconate Oral Rinse are stomatitis, gingivitis, glossitis, oral, dry mouth, hyposthesia, glossal edema, and paresthesia. Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using Chlorhexidine Gluconate Oral Rinse. There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using Chlorhexidine Gluconate Oral Rinse.

OVERDOSAGE: Ingestion of 1 or 2 ounces of Chlorhexidine Gluconate Oral Rinse by a small child (~10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of Chlorhexidine Gluconate Oral Rinse is ingested by a small child or if signs of alcohol intoxication develop.

DOSE AND ADMINISTRATION: Chlorhexidine Gluconate Oral Rinse therapy should be initiated directly

following a dental prophylaxis. Patients using Chlorhexidine Gluconate Oral Rinse should be reevaluated and given a thorough prophylaxis at intervals no longer than six months. Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usual dosage is 15 mL of undiluted Chlorhexidine Gluconate Oral Rinse. Patients should be instructed to not rinse with water, or other mouthwashes, brush teeth, or eat immediately after using Chlorhexidine Gluconate Oral Rinse. Chlorhexidine Gluconate Oral Rinse is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED: Chlorhexidine Gluconate Oral Rinse is supplied as a blue liquid in single dose 0.5 fluid ounce (15mL) amber plastic bottles with child-resistant dispensing closures. **STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled room temperature].**

Rx only. KEEP OUT OF REACH OF CHILDREN.

WHAT TO EXPECT WHEN USING CHLORHEXIDINE GLUCONATE ORAL RINSE

Your dentist has prescribed Chlorhexidine Gluconate Oral Rinse to treat your gingivitis, to help reduce the redness, and swelling of your gums, and also to help you control any gum bleeding. Use Chlorhexidine Gluconate Oral Rinse regularly, as directed by your dentist, in addition to daily brushing. Spit out after use. Chlorhexidine Gluconate Oral Rinse should not be swallowed.

If you develop allergic symptoms such as skin rash, itch, generalized swelling, breathing difficulties, light headedness, rapid heart rate, upset stomach or diarrhea, seek medical attention immediately. Chlorhexidine Gluconate Oral Rinse should not be used by persons who have a sensitivity to it or its components.

Chlorhexidine Gluconate Oral Rinse may cause some tooth discoloration, or increase in tartar (calculus) formation, particularly in areas where stain and tartar usually form. It is important to see your dentist for removal of any stain or tartar at least every six months or more frequently if your dentist advises.

- Both stain and tartar can be removed by your dentist or hygienist. Chlorhexidine Gluconate Oral Rinse may cause permanent discoloration of some front-tooth fillings.
- To minimize discoloration, you should brush and floss daily, emphasizing areas which begin to discolor.
- Chlorhexidine Gluconate Oral Rinse may taste bitter to some patients and can affect how foods and beverages taste. This will become less noticeable in most cases with continued use of Chlorhexidine Gluconate Oral Rinse.
- To avoid taste interference, rinse with Chlorhexidine Gluconate Oral Rinse after meals. Do not rinse with water or other mouthwashes immediately after rinsing with Chlorhexidine Gluconate Oral Rinse.

If you have any questions or comments about Chlorhexidine Gluconate Oral Rinse, contact your dentist or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diostearate, flavor, sodium saccharin, and FD&C Blue No. 1.

STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled room temperature].

Manufactured by:

Sage Products LLC

Cary, IL 60013

1-800-323-2220

Revised: September, 2013

SAGE150R1811BLB

REFERENCES: 1. See complete package insert on page 10. 2. Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Federal Register, 53(17):2436-61. 3. Oral Health Care Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; Federal Register, 47(101):22760-930. 4. Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products; Federal Register, 59(27):6084-124. 5. Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph; Federal Register, 68(103):32232-87



Q•CARE® Rx ORAL CLEANSING AND SUCTIONING SYSTEM WITH CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE

24-HOUR SUCTION SYSTEMS

For mechanically ventilated patients

q4° Q•CARE® ORAL CLEANSING AND SUCTIONING SYSTEM WITH SAGE ORAL SOLUTION BURST PACKET* WITH THUMB PORT TOOLS

(Connects directly to standard suction lines)

- 2 Packages of 1 Untreated Suction Toothbrush, Sage Oral Solution Burst Packet and Applicator Swab
- 4 Packages of 1 Suction Swab with Sodium Bicarbonate, Perox-A-Mint® Solution, Mouth Moisturiser, and Applicator Swab

20 systems/case
Reorder #6934-BP

CE 0086

q8° Q•CARE® ORAL CLEANSING AND SUCTIONING SYSTEM WITH SAGE ORAL SOLUTION BURST PACKET* WITH THUMB PORT TOOLS

(Connects directly to standard suction lines)

- 2 Packages of 1 Untreated Suction Toothbrush, Sage Oral Solution Burst Packet and Applicator Swab
- 1 Package of 1 Suction Swab with Sodium Bicarbonate, Alcohol-Free Mouthwash, Mouth Moisturiser, and Applicator Swab

25 systems/case
Reorder #6938-BP

CE 0086



q4° Q•CARE® ORAL CLEANSING AND SUCTIONING SYSTEM WITH THUMB PORT TOOLS

(Connects directly to standard suction lines)

- 2 Packages of 1 Suction Toothbrush with Sodium Bicarbonate, Alcohol-Free Mouthwash, Mouth Moisturiser, and Applicator Swab
- 4 Packages of 1 Suction Swab with Sodium Bicarbonate, Perox-A-Mint® Solution, Mouth Moisturiser, and Applicator Swab

20 systems/case
Reorder #6404-X

CE 0086



q8° Q•CARE® ORAL CLEANSING AND SUCTIONING SYSTEM WITH SUCTION HANDLE TOOLS

(Tools connect directly to Suction Handle)

- 1 Covered Yankauer with Suction Handle and Y-Connector
- 2 Packages of 1 Suction Toothbrush with Sodium Bicarbonate, Alcohol-Free Mouthwash, Mouth Moisturiser, and Applicator Swab
- 1 Package of 1 Suction Swab with Sodium Bicarbonate, Alcohol-Free Mouthwash, Mouth Moisturiser, and Applicator Swab

25 systems/case
Reorder #6808-X

CE 0086



q4° Q•CARE® PETITE SIZE ORAL CLEANSING AND SUCTIONING SYSTEM WITH SUCTION HANDLE TOOLS

(Tools connect directly to Suction Handle)

- 2 Packages of 1 Petite size Suction Toothbrushes, Alcohol-Free Mouthwash, Mouth Moisturiser, and Applicator Swab
- 4 Package of 1 Petite Size Untreated Suction Oral Swabs, Alcohol-Free Mouthwash, Mouth Moisturiser, and Applicator Swab

15 systems/case
Reorder #6714-X

CE 0086

*Sage Oral Solution Ingredients: water (aqua), alcohol, glycerin, PEG-40 sorbitan diisostearate, aroma, chlorhexidine digluconate, sodium saccharin, Blue 1 (CI 42090).

SINGLE-USE SUCTION SYSTEMS

For patients at risk of aspiration pneumonia



UNTREATED SUCTION TOOTHBRUSH SYSTEM

(Tools connect directly to standard suction lines)

1 Untreated Suction Toothbrush

100 systems/case
Reorder #6577-X

CE 0086



UNTREATED SUCTION TOOTHBRUSH SYSTEM

(Tools connect directly to standard suction lines)

1 Untreated Suction Toothbrush with Alcohol-Free Mouthwash, Applicator Swab and packet of Mouth Moisturiser

100 systems/case
Reorder #6573-X

CE 0086



UNTREATED SUCTION TOOTHBRUSH SYSTEM WITH ALCOHOL-FREE MOUTHWASH

(Tools connect directly to standard suction lines)

1 Untreated Suction Toothbrush, Suction Swab, Alcohol-free Mouthwash and Applicator Swab

100 systems/case
Reorder #6576-X

CE 0086



UNTREATED SUCTION TOOTHBRUSH SYSTEM WITH SAGE ORAL SOLUTION BURST PACKET*

(Connects directly to standard suction lines)

1 Untreated Suction Toothbrush with Sage Oral Solution Burst Packet and Applicator Swab

100 systems/case
Reorder #6977-BP

CE 0086

*Sage Oral Solution Ingredients: water (aqua), alcohol, glycerin, PEG-40 sorbitan diisostearate, aroma, chlorhexidine digluconate, sodium saccharin, Blue 1 (CI 42090).



SUCTION SWAB SYSTEM

(Tools connect directly to standard suction lines)

2 Suction Swabs with Perox-A-Mint® Solution and Mouth Moisturizer

100 systems/case
Reorder #6513-X

CE 0086



SUCTION SWAB SYSTEM WITH PEROX-A-MINT® SOLUTION AND MOUTH MOISTURIZER

(Tools connect directly to standard suction lines)

1 Suction Swab with Sodium Bicarbonate, 7 ML Perox-A-Mint® Solution, 2g Mouth Moisturiser, and Applicator Swab

100 systems/case
Reorder #6519-X

CE 0086



UNTREATED SUCTION SWAB SYSTEM

(Tools connect directly to standard suction lines)

1 Suction Swab

100 systems/case
Reorder #6578-X

CE 0086

ORAL HYGIENE COMPONENTS



SUCTION HANDLE AND COVERED YANKAUER

- 1 Suction Handle, Covered Yankauer without Y-Connector

60 packages/case
Reorder #6629

CE 0086



SUCTION HANDLE AND COVERED YANKAUER

- 1 Suction Handle, Covered Yankauer and Y-Connector

60 packages/case
Reorder #6639

CE 0086



SINGLE USE ORAL SWAB SYSTEM WITH PEROX-A-MINT® SOLUTION

- 2 Swabs with Sodium Bicarbonate, Perox-A-Mint® Solution and packet of Mouth Moisturiser

100 systems/case
Reorder #6013-X

CE



TOOTHETTE® PLUS ORAL SWABS

With Sodium Bicarbonate, Individually wrapped

800/case or 200/box
Reorder #6075-X (S)

CE

Untreated, Individually wrapped

800/case or 200/box
Reorder #6070-X (S)

CE



BEDSIDE BRACKET

Bracket with Removable Adhesive Strip for wall-mounting near the bedside

25 brackets/case
Reorder #6697



LENGTH OF STAY (LOS) YANKAUER HOLDER

Bracket with Removable Adhesive Strip for mounting near the bedside

4 bags of 25 100/case
Reorder #6696



ADULT BITE BLOCK

Individually Wrapped

144/case
Reorder #4000

CE



MOUTH MOISTURIZER

14g Tube

144/case
Reorder #6083-X



ULTRA-SOFT TOOTHBRUSH

Individually Wrapped

72/case
Reorder #6082

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