



Oral Health: True Innovation

Why the toothbrush requires innovation vs. renovation

A whitepaper by HydraBrush, Inc.

EXECUTIVE SUMMARY

In this whitepaper, we compare traditional toothbrush design to the patented innovation of HydraBrush/30 Second Smile (30SS). We do this by defining the challenges presented to manufacturers and distributors, explaining the opportunities available in the global market for toothbrushes, examining current technology, and presenting a truly innovative approach to toothbrush design. HydraBrush/30SS has taken the leap to designing a toothbrush with true innovation vs. classic renovation.

We will present independent clinical studies showing that HydraBrush/30SS is able to not only match the competition, but exceed the competition when placed in side by side testing. With the clinical evidence shown, HydraBrush/30SS has proven to be a product with enormous competitive value.

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BACKGROUND

HISTORY

The history of the toothbrush extends back to 3000 BC, but the modern day brush as we know it was designed in 1938 with the addition of nylon bristles instead of boar bristles. The first electric toothbrush, the Broxodent, was introduced in 1960. Interestingly enough, the only functional difference between the Broxodent and the toothbrush from 1938 was that the Broxodent vibrated. To this day, most mass produced toothbrushes all have the same single headed brush design, with minimal functional differences.

NEED

The need to maintain oral health is greater than ever since recent research has shown a connection between periodontal disease and diabetes, cardiovascular disease, and preterm low birth weight. The exact cause and effect relationships are still being investigated, but more and more data emphasize that having a healthy mouth is important to preserving systemic health. Technology that makes it possible for patients to be more effective in their personal oral hygiene is welcomed by the dental profession and the lay community. (Cohen 2007)

PURSUIT

The pursuit to truly design an innovative toothbrush was the goal of HydraBrush, Inc. CEO Ken Hegemann. Based on his own dental concerns, he was determined to find a way to defeat periodontal disease. His years of research and development determined that the most defining factor in the development of periodontal disease was improper home care, not to say that people do not brush their teeth, but the problem lies in the method they use to brush their teeth. The goal was to replace the flawed method with a truly error free approach to brushing, resulting in clean, healthy teeth and gums.

BRAND

The technology developed is currently branded under two names: HydraBrush and 30 Second Smile. For the purpose of this document, the technology will be referred to as HydraBrush/30SS. The slogan (Little Effort...Big Results) is a promise that encompasses the objective of the brand.

Little Effort... **Big Results**[®]

ADVANTAGES OF HYDRABRUSH, INC.

CERTIFICATION

In today's global marketplace, many organizations are utilizing the British Standards Institute's quality system as a platform to build their business management systems. Specifically, the ISO 13485:2003 is the international quality system for manufacturing medical devices. Registration to ISO 13485: 2003 is paramount to ensuring product quality. Additionally, registration is essential to securing and maintaining global business, becoming more cost-effective and improving efficiency and internal communication. Maintaining certification includes constant monitoring, evaluating, updating, learning and improving.

This arduous process elevates HydraBrush, Inc. above other companies that are not ISO 13485: 2003 certified. HydraBrush, Inc. received certification in early 2009 and has maintained good standing. The certification allowed HydraBrush, Inc. to also be awarded a medical license from Health Canada which reflects the company's adherence to the requirements of the Canadian Medical Devices Conformity Assessment System.

The ISO 13485:2003 certification shows without question that HydraBrush, Inc. is not just another company manufacturing electric toothbrushes. This certification shows our commitment to quality above everything else. We are very proud to have attained this certification, recognition of our years of work in developing our products and systems to the highest level.

GROWTH

Established in 2000, HydraBrush, Inc. has taken its premier consumer product line of HydraBrush/30SS and developed a positive consensus amongst many dental professionals and consumers alike.

HydraBrush/30SS has the opportunity to grow through the development of additional products to supplement the main product line. In addition, the patented brush heads can be used in a manual method to support further market share.



ISO 13485 / CMDCAS
FM 541462

CHALLENGE AND OPPORTUNITY

MANUFACTURERS

Most multinational companies launch new oral care products in an effort to fulfill the increasing desire of individuals to achieve good dental hygiene. The demand for these products coupled with population growth, drives the global market. Most personal care product growth is influenced by price, history, promotion, and advertising. Oral care products are atypical because bad oral health exhibits social stigma, therefore consumers are often willing to pay a premium price to resolve their oral care issues. The image conscious consumer as well as the health conscious consumer is constantly shopping for new and improved oral hygiene solutions. Which product they purchase may depend on price, new technology, brand loyalty, or packaging. With continual product launches, companies must ask themselves: Is this true innovation, or just another product to sustain a particular sector?

In the toothbrush sector, manufacturers have attempted to propel the evolution of the toothbrush by adding features including rubber grips, timers, lights, colored bristles, and rechargeable batteries. In addition to cosmetic features, the actual brush heads themselves have evolved into rotating, vibrating, or sonic bristles. While all of these attributes have increased the appeal of tooth brushing to consumers, none of them are truly innovative and instead just a minimal renovation of the original design.

“Product development in toothbrushes really seems to have reached an impasse. Even private label operators are offering battery-powered products as standard, and market growth has largely come from persuading users of manual products to trade up to electric ones, as well as trying to build consumer awareness of regular replacement” (GCI Magazine, 2009.)

How can manufacturers reach new and existing consumers without completely saturating the market essentially with products having minimal variables?

Innovation is the answer. Hydrabrush/30SS is the technology.

“Product development in toothbrushes really seems to have reached an impasse.”

GLOBAL MARKETPLACE

The global rise in awareness of the necessity of proper prevention in the approach to oral health has seeded a great opportunity for manufacturers to expand to markets generally untouched. With power toothbrushes becoming a growing trend in emerging markets such as Venezuela, South Africa, Egypt, and India, accurate price positioning is essential.

Opportunity lies in existing and emerging markets by using an interchangeable technology whereby a manufacturer can produce a product line to reach entry level markets to high end markets. The intellectual property of HydraBrush/30SS can offer a manufacturer the ability to capitalize on entry level products as well as high end lines, through minimal changes to how the technology is delivered.

HydraBrush, Inc. currently has ten (10) issued patents on its innovative toothbrush technology. Additionally there are five (5) pending patent applications. These provide the foundation and opportunity for development and sales in the global marketplace. The current product line reaches both the high-end market and the mid-range market. There is room for expansion into emerging and developing markets by use of the technology in a non-electrical approach.



“HydraBrush™ brand has given a whole new dimension to complete homecare oral cleaning systems. Under this brand, the company has launched highly innovative product offerings in the market for electronic oral cleaning systems.”

**-Frost & Sullivan
Research Analyst
Vaishnavi
Ananthanarayanan**

HYDRABRUSH TECHNOLOGY

HOW IT CAN IMPROVE ORAL HEALTH

CURRENT TECHNOLOGY

The toothbrush can be considered one of man's first innovations. History shows the evolution of the toothbrush has gained tremendous strides cosmetically but not functionally. True, there are sonic brushes, rotational brushes, and a multitude of other electric toothbrushes, but they all rely on the user to actually use them properly: brush for two minutes with correct positioning and action. What all of these brushes fail to do is eliminate human error.

Unlike dentists who are extensively trained in the art of tooth brushing, the average person may receive a brief reminder 1-2 times per year at their check-up. Unfortunately, there are thousands of people who do not receive regular exams and rely on their daily brushing as the only method of consistent oral care. In the interim of providing adequate dental care for all populations, why not instead offer them a toothbrush that will provide the reliability, the precision, and the proper execution of tooth brushing automatically?

HydraBrush/30SS offers reliability, precision, and proper execution.... automatically.

“As a dentist, one of the most difficult things to do is to try to show someone how to brush appropriately. No matter how hard you try, no matter how much time you spend patients just sometimes just can't get the hang of proper tooth care. Therefore it is so wonderful to have a device like 30 Second Smile that does it automatically.”

Dr. Michael Pruett, DMD

COMPARE		30 Second Smile™	OTHER LEADING POWER TOOTHBRUSHES
Recommended time to brush your teeth		30 seconds	2 minutes
Cleans top & bottom teeth simultaneously		YES	NO
Cleans INNER, outer, and chewing surfaces simultaneously		YES	NO
Completely surrounds each and every tooth		YES	NO
Teeth automatically position bristles for optimal cleaning		YES	NO
Automatically massages gums		YES	NO

HYDRABRUSH / 30 SECOND SMILE TECHNOLOGY

HOW IT WORKS

HydraBrush/30SS technology virtually eliminates human error and assures dental providers that their patients are brushing accurately and effectively by encompassing the following critical components:

6 Brush Heads in One

HydraBrush/30SS offers the user automation of proper brushing. To use HydraBrush/30SS, one simply turns on the unit, opens their mouth and gently bites down into the 6 micro-brushes. The dual sided brush head includes 6 micro-brushes, whereas most other technologies are based on a single brush head. The multiple heads ensure complete and thorough brushing in 30 seconds versus the recommend 2 minutes with a standard single-headed brush. Why is 30 seconds so significant?

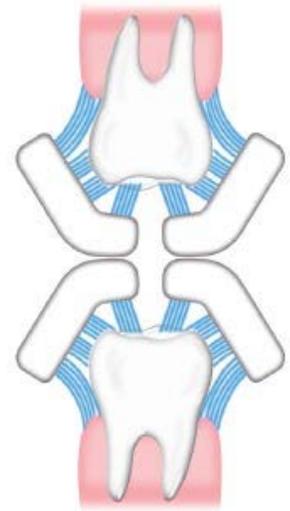
Because, the marketing outlook for anything that saves time is invaluable. The simplicity of the technology allows for the consumer to easily bite into the brush heads and guide the brush around their arch. The teeth are surrounded by micro-brushes which make it impossible to miss a spot, even in the back “hard to reach” areas.

Proper alignment and brush head angle

The 6 micro-brushes perfectly simulate the Bass Brushing Technique (the dentist recommend technique for proper brushing) with accurate alignment and angle of bristles. This technique is widely accepted as a very effective method for bacterial plaque removal adjacent to and directly beneath the gingival margin. This area is the most significant in the control of gingivitis and periodontitis.

Appropriate pressure on teeth and gums

HydraBrush/30SS accurately delivers the appropriate amount of pressure on teeth and gums due to the flexible brush head arms and the fact the user is exerting zero force. The advanced, wrap around head configuration provides automated, equalized gentle pressure on the inner and outer surfaces. The brush head arms flex to provide the proper amount of pressure for both the narrow front teeth as well as wide molars.



How It Works

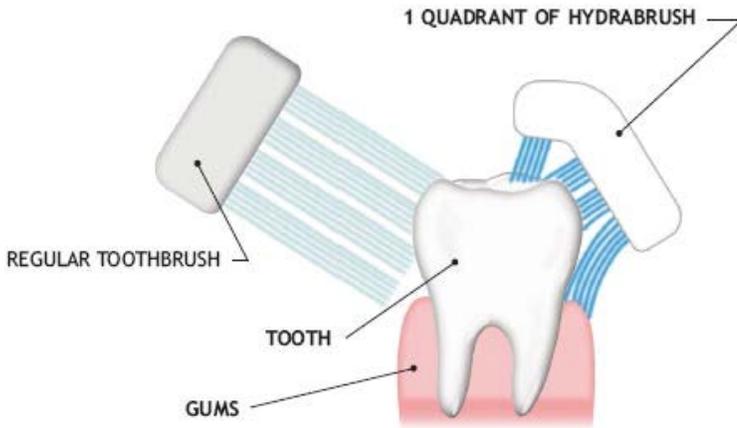
www.hydrabrush.com/animation

“It feels great when I help someone have a healthy mouth and then I give them the 30 SS so they can keep that mouth healthy. I think they appreciate that they make an investment in their mouth and then they have a tool that can protect their investment and keep that mouth happy.”

Dr. David Scharf, DMD

Short – Quick back and forth strokes

Short, quick back and forth strokes are also paramount in the Bass Technique. HydraBrush/30SS simulate this with two speeds: Low: 790-860 RPM and High: 1070-1140. Users of HydraBrush/30SS initially use Ultra-Soft Red brush heads and do not graduate to the blue bristles until their gums become accustomed to the brushing action. In addition, they begin using the product at the low speed and eventually their gums become healthy enough to graduate to the higher speed. The result: no chance of gum or tooth abrasion.



PRODUCT LINE

HydraBrush/30SS – AA Alkaline Battery Unit – Replaceable Batteries (DISCONTINUED)

HydraBrush/30SS – AA NiMH Battery Unit – Rechargeable Batteries (DISCONTINUED)

HydraBrush/30SS – Induction Model – Launched January 2012

HydraBrush/30SS – Brush Heads (Ultra Soft, Soft, Extra Reach, Kids)

HydraBrush Ultra – Dentifrice Delivery System

HydraBrush/30SS – Orthodontic Specific Brush Head

HydraBrush/30SS – Induction Model with UV Sanitizer – Available January 2013

“Our patients that have had periodontal disease or gum disease, we’ve seen a reduction in inflammation in the tissues, we’ve seen a resolving in the pocketing depths... it’s been fantastic, the healing that has actually occurred with the 30 Second Smile since I have introduced it into my practice.”

Dr. Andrew J. Hamilton Jr.,
DMD



Induction Model



Induction Model with UV Sanitizer

BENEFITS OF USE

Not only are there clinical studies to back up the effectiveness of HydraBrush/30SS, there is a large compilation of positive testimonials from users, dental professionals, caregivers, and product reviewers. HydraBrush/30SS solves the problem of brief brushing times (average person brushes 38 seconds vs. recommended 2 minutes) and resolves the erratic brushing patterns of most people.

The automated HydraBrush/30SS allows the user, regardless of dexterity level, to properly brush their teeth. In the case of a user with limited mobility, HydraBrush/30SS is often the answer to their dental woes. Whether they are now able to brush on their own or a caregiver is guiding the brush along their arch, many testimonials have shown that HydraBrush/30SS has become a great benefit to their home dental care.

SAFE

More than 300,000 Hydrabrush/30SS units have been in use without a single claim of injury or damage.

AWARDS

Arthritis Foundation

HydraBrush/30SS was awarded the Ease-of-Use commendation from the Arthritis Foundation. HydraBrush/30SS was tested at Georgia Tech Research Institute – Accessibility Evaluation Facility. The test determined the accessibility and ease-of-use of the product for people with arthritis. The favorable results showed that users were generally impressed with the ease-of-use and many remarked about the effectiveness.

Frost & Sullivan

Frost & Sullivan, a Growth Partnership Company, awarded HydraBrush/30SS with the prestigious Oral and Dental Care Product of the Year in 2005 in recognition of outstanding contribution to oral hygiene through its comprehensive oral care product range.

"I've been using the Hydrabrush for about six months. Prior to using the Hydrabrush, I had some symptoms that signaled the onset of gum disease that have now completely cleared up. I'm very pleased with the results."

Jeanne W., McLean, Virginia

"I have been using the Hydrabrush for nearly 2 years and every day I use it I feel like I have had a professional dental office cleaning. When my dentist has performed my six month dental exams he has stated that my gums have improved and look very healthy and this is fully attributable to my use of the Hydrabrush product."

Keith S., Dublin, CA



FROST & SULLIVAN

Oral & Dental Care
Product of the Year Award

CLINICAL STUDY 1:

As published in the Journal of the International Academy of Periodontology:

Comparison of the Hydrabrush powered toothbrush with two commercially-available powered toothbrushes

Abstract

INTRODUCTION:

An examiner-blinded, randomized, parallel, three-cell, controlled clinical trial was conducted to compare the efficacy of a new powered toothbrush (Hydrabrush) to that of two presently marketed power brushes (Oral-B and Sonicare) in reducing stain, supragingival plaque, gingivitis and the signs of periodontitis while monitoring safety.

CONCLUSIONS:

With the exception of clinical attachment loss, all subject groups were balanced for all measured clinical parameters at baseline. **Tooth stain became significantly less in the Hydrabrush group compared with the Sonicare group at 8 and 12 weeks. At all examinations, the Hydrabrush group had statistically significantly less plaque than the Sonicare group. At 4 weeks, the Hydrabrush group had statistically-significantly lower mean probing depth than both the Oral-B and Sonicare groups, and at 8 and 12 weeks, the Hydrabrush group had statistically-significantly lower mean probing depth than the Sonicare group. With regard to mean percentage of sites with probing depth > or =4 mm, the Hydrabrush group had statistically-significantly fewer sites > or =4 mm when compared to the other two tested brushes at all examinations.** No differences were seen among the treatment groups with regard to gingival recession and bleeding on probing and none of the tested brushes caused any adverse reactions.

J Int Acad Periodontol. 2005 Jul;7(3):80-9

Full Clinical Study: http://www.hydrabrush.com/clinicals/clinical_journal-IAP_Dr-Patters_Hydrabrush_july-2005.pdf

CLINICAL STUDY 2:

As published in the Journal of Contemporary Dental Practice:

Efficacy of the HydraBrush Oral Health System in Irrigating Periodontal Pockets.
Penetration of Fluids into Periodontal Pockets Using a Powered Toothbrush/Irrigator Device

Abstract

INTRODUCTION:

This study was a single-blind, randomized, controlled clinical trial. The researchers evaluated a powered brush/irrigating device (HydraBrush Oral Health System™; OHS) for its safety and ability to deliver a solution to the bottom of 5-6 mm pockets, compared to rinsing alone with a solution following brushing with a powered toothbrush (Sonicare Elite™ 7800; SE). An evaluation technique to measure the quantity and quality of solution able to enter the pocket was also introduced in this project.

CONCLUSIONS:

The experimental device is more efficient in delivering a solution to the base of 5-6 mm pockets than rinsing following use of a control powered toothbrush. Both devices have demonstrated they are safe and well accepted by patients. The technique developed provides a useful method for quantitative and qualitative studies of solutions from the base of periodontal pockets.

J Contemp Dent Practice. 2006 Jul;7(3):030-039

Full Clinical Study: http://www.hydrabrush.com/clinicals/MCG_clinical.pdf

CASE STUDY: Hygienetown Magazine

This study bridges the gap between randomized, blinded, controlled, clinical trials and personal experience.

Effects of the 30 Second Smile Power Toothbrush on Plaque Removal

A Clinical Practice Study

Townie Researchers selected patients in their practices who showed high plaque levels despite repeated instructions in oral hygiene. Townie Researchers provided the 30 Second Smile power toothbrush to a total of 12 patients. Data collection included baseline plaque scores and intra-oral photographs. Plaque scores were repeated approximately two weeks later, and in some cases further follow-up visits were scheduled. Both children and adults were included in the study.

A null hypothesis was proposed for this study stating that no changes in plaque scores would be seen with the use of the 30 Second Smile toothbrush compared to previous brushing. Results demonstrated that a majority of patients in this study showed lower plaque scores after two weeks or more of using the new brush. Some showed no difference and none showed increased plaque scores using the 30 Second Smile toothbrush. Thus, the null hypothesis was disproved in this study.

Based on these findings, the 30 Second Smile power toothbrush provides better plaque removal when used instead of a manual toothbrush for those who are ineffective with daily plaque removal. For patients who are not effectively removing plaque with a manual or power toothbrush, the 30 Second Smile brush promises to provide an effective alternative. The unique design and ability to reach all areas without depending on the manual dexterity of the user makes the 30 Second Smile ideal for those who need a new way to effectively clean their teeth.

By Trisha E. O'Hehir, RDH, MS

Full Case Study:

http://hydrabrush.com/clinicals/townies_FINAL_REPORT_30SS.pdf

Patient 1: Before: 58 percent



Patient 1: After: 25 percent



Patient 2: Before: 82 percent



Patient 2: After: 21 percent

Before photos of the study reveal high baseline plaque levels. After using the 30 Second Smile toothbrush for two weeks, plaque levels were reduced. Patient 1 Plaque scores dropped from 58 percent to 25 percent . Patient 2 began with a plaque score of 82 percent and returned two weeks later with a 21 percent plaque score.

TECHNICAL SPECIFICATIONS

Specification	Description
810 Strokes/min	The low strokes per minute actually : <ol style="list-style-type: none"> 1. Make the brushing action more comfortable; not like a vibrating jackhammer 2. More effective, enabling interproximal brushing
.005 bristle	Softer than industry standard for “soft”
BassTek	Head configuration insures Bass Technique is automatically executed.
6 micro-brushes	Surround teeth to cleanse all surfaces
Dual Speed	<ul style="list-style-type: none"> • Restoration Speed I [790-860 strokes per minute] Restores gingival health by removing harmful biofilm to provide patients with a brighter, healthier smile. • Maintenance Speed II [1070-1140 strokes per minute] Maintains and raises oral health to a new level of home oral care. Gums are healthy, pink and stipple; teeth are whiter/ brighter, breath is fresher.
Induction Charging	<p>Advantage- There are no exposed contacts that can become corroded. The ability to fully enclose the charging connection also makes the approach attractive, when water impermeability is required; such as toothbrushes that are frequently used near water.</p> <p>More convenient -Charging is accomplished by simply placing the unit in the charging stand.</p>
ISO 13485	Assurance of Quality products and Customer Service
Smart Pressure Sensor	Unit shuts off if the user bites too hard, and will not continue brushing until the biting pressor is correct.

CREATIVE MARKETING

EDUCATING CONSUMERS

The appearance of HydraBrush/30SS is exceedingly different from its counterparts in the industry. This transformative approach to design has initiated a creative marketing tactic intended for private dental offices as well as retail stores.

A free standing pedestal displays a demonstrative model enabling consumers to interact with the toothbrush before purchase. The interactive display provides the consumer with a sensory experience while presenting exactly how the product operates and effectively brushes teeth. In private dental offices, the display is stand alone on a pedestal. In the retail setting, the display sits on a POP display that holds twelve units.

The Interactive display does the following:

- 1) Shows people exactly how 30 Second Smile works
- 2) Shows clearly that it is brushing upper, lower, inside and out, all at the same time.
- 3) Clearly shows the “can’t miss” theory behind the product
- 4) Clearly shows full tooth contact as well as gingival massage
- 5) It shows how fast 30 Second Smile can brush the entire oral cavity
- 6) Clearly shows the brush has two brushing speeds; patient can actually change the speed during the demo.
- 7) Allows the interested patient to engage three (3) of his/her senses while interacting with the display; they can see it, they can hear it, they can touch the demo activation buttons.
- 8) Allows the patient to order the product and have it delivered directly to their home; the dental office does not collect money from the patient/buyer, or invest in and keep inventory at their dental office. (Dental office displays only.)
- 9) Signage on the display guides the patient to www.bestbrush.com where they can watch a 16 minute informative video, receive a discount due to the dental office visit, and place their order. Note: You will not be able to view this website because a dental office discount code is required for entry into the site. That’s our way of tracking sales and compensating the dental offices. (Dental office displays only.)

Interactive Display



Retail Display



Watch It

www.bestbrush.com/display

ENHANCED PRODUCT LINE

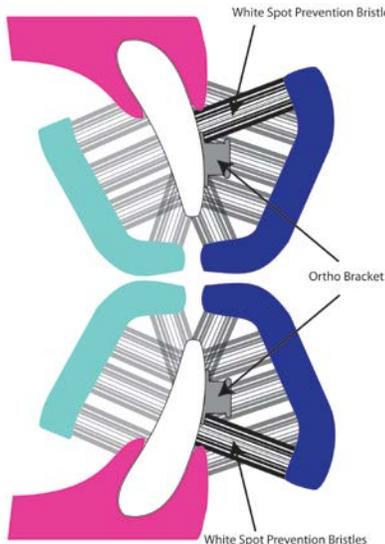
ORTHODONTIC SPECIFIC BRUSH HEAD

PROBLEM

Many people are overjoyed to have their braces removed, only to be greeted with the sight of white spot damage all over their newly straightened teeth. Plaque can remain undisturbed quite easily for 3 weeks or longer in small patches that just can't be seen. The most common source of white spots is from the acid produced by dental bacteria that live in plaque long enough so that it starts leeching out the calcium from the enamel - a process called "decalcification". These white spots are typically discovered when brackets are removed, and is one of the largest problems that exists today in orthodontics industries. White spot lesions on teeth can be an early sign of tooth decay formation.

SOLUTION

This notoriously difficult area is often neglected by a traditional toothbrush. To prevent this, the makers of 30 Second Smile developed the innovative Orthodontic Specific Brush Head, which has a special bristle configuration to not only clean the teeth and gums like our standard heads, but also clean the hard to reach areas around dental brackets. The result is peace of mind that these difficult areas are being cleaned automatically. That is the simple solution to preventing white spots, keeping the teeth free of plaque. As you can see in the illustration, the Orthodontic Specific Brush Head is equipped with an additional row of bristles, angled to automatically ensure that those areas are cleaned.



How White Spots Form

White Spots form in those regions where dental plaque has been allowed to remain on a tooth's surface for extended periods of time. When dental plaque accumulates on the enamel surface of a tooth, the bacteria that live in the plaque excrete acid waste products that can dissolve away a portion of the enamel's mineral content. This loss in mineral content causes a visible change in the enamel's appearance. It loses its gloss and shine and instead appears chalky. The challenge is consistently removing plaque and stain that accumulates around the dental brackets.

GUM CARE

The Orthodontic Specific Brush Head also provides beneficial gum care while patients wear braces.

VIDEO LINK

www.bestbrush.com/ortho

ADDITIONAL TESTIMONIALS & LINKS

How it Works Animation

www.hydrabrush.com/animation

User Testimonials

www.hydrabrush.com/testimonials/testimonials.pdf

Dental Professionals Testimonials

www.bestbrush.com/testimonials

Clinical Trials & Case Study

hydrabrush.com/clinicals/clinical_journal-IAP_Dr-Patters_Hydrabrush_july-2005.pdf

hydrabrush.com/clinicals/MCG_clinical.pdf

www.hydrabrush.com/clinicals/townies_FINAL_REPORT_30SS.pdf

Marketing /Display Videos

Display: www.bestbrush.com/display

16 Minute Infomercial: www.bestbrush.com/infomercial

Orthodontic Brush Head Video

www.bestbrush.com/ortho

SUMMARY

HydraBrush, Inc. has developed a revolutionary technology that is truly innovative to the toothbrush as a product. Some challenges facing manufacturers/distributors of dental care products can be faced head on with our technology because it is innovative, advanced, and it truly benefits the user as compared to the current leading electric toothbrushes.

The benefits of HydraBrush/30SS should be available to people in all global markets. With this technology, the opportunity for advancing into those sectors is possible with both electric and manual versions of the product.

As compared to other manual and electric toothbrushes, HydraBrush/30SS is the only toothbrush that simultaneously brushes all surfaces of the user's teeth. With HydraBrush/30SS, the user is cutting down on actual time spent brushing while actually improving their overall oral health.

The clinical studies provide evidence that HydraBrush/30SS exceeds the current market leaders in plaque removal and stain removal. With this evidence, HydraBrush/30SS is equipped to compete with market leaders and successfully appropriate the toothbrush market.



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