



Health Santé  
Canada Canada

Health Products and Food Branch  
Direction générale des produits de santé et des aliments

The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **The Gillette Company**.  
Contact the company for a copy of any references, attachments or enclosures.

**PUBLIC ADVISORY**

**Health Canada Endorsed Important Safety Information on  
Oral-B CrossAction Power and PowerMax Toothbrushes and refills.**



October 27, 2004

**Subject: URGENT PRODUCT REMOVAL ORAL-B CROSSACTION POWER AND  
POWERMAX TOOTHBRUSHES AND REFILLS**

Dear Consumers:

We want to inform you about reports we have received concerning instances where the brush head of an Oral-B CrossAction Power or PowerMAX toothbrush has become loose in the mouth during brushing.

**A. Special Instructions to Caregivers**

There have been three reported incidents that occurred while consumers were using our Oral-B CrossAction Power and PowerMAX toothbrushes and refills to assist in brushing the teeth of persons with special needs, such as cerebral palsy or autism. During brushing, the head of the toothbrush became unlatched, and the loose brush head was caught in the throat or swallowed. This may have occurred when the release latch was bitten or hit by front teeth. None of the consumers suffered any permanent injury, but medical assistance was required.

**We therefore recommend that consumers stop using the CrossAction Power or PowerMAX toothbrushes and brush refills to assist in brushing the teeth of people with special needs.** No other Oral-B product is affected.

If you are currently using a CrossAction Power or PowerMAX to assist in brushing the teeth of a person with special needs, Oral-B will replace it -- at no charge -- with our Oral-B Advance Power 400, which is better suited for use in assisted-brushing environments because it has a brush head without a latch.

Please call 1-800-496-6557 between the hours of 9:00 AM and 5:00 PM (EST) on Monday through Friday and Oral-B will send you a prepaid mailing envelope to return your CrossAction Power or PowerMAX toothbrush to us. Once received, we will send you an Oral-B Advance Power 400 battery toothbrush.

Also, caregivers can find helpful information about brushing the teeth of people with special needs on the website of the American Dental Association:

[http://www.ada.org/public/topics/special\\_needs.asp](http://www.ada.org/public/topics/special_needs.asp)

and on the website of the Canadian Dental Association:

[http://www.cda-adc.ca/english/your\\_oral\\_health/caring\\_teeth/dental\\_care\\_seniors/caring.asp](http://www.cda-adc.ca/english/your_oral_health/caring_teeth/dental_care_seniors/caring.asp)

#### **B. Information for Other Consumers**

In addition, among consumers without special needs, there have been a small number of reports of brush heads being loose in the mouth. None of these consumers swallowed the brush head, no medical assistance was needed, and there were no reports of any permanent injury. **We recommend that all consumers use care not to bite down on the brush head during brushing.**

#### **C. General Information**

Gillette is redesigning the brush heads for these toothbrushes to eliminate issues related to the unlatching of the brush head. The new brush head refills, when available, will fit into the current CrossAction Power and PowerMAX toothbrushes. The new Oral-B CrossAction Power and CrossAction PowerMAX toothbrushes and brush refills are scheduled to be available in stores in January 2005.

You can call 1-800-496-6557 as noted above if you have any questions regarding the use of these products or this notice.

Please note that we are taking these actions because consumer safety is the number one concern at Oral-B. This action is being conducted with the knowledge of Health Canada.

Thank you for your continued support of Oral-B products.



CrossAction



CrossAction



CrossAction

The identification, characterization, and management of medical device-related adverse incidents are dependent on the active participation of health care professionals and consumers in adverse reaction reporting programmes. Any occurrences of serious and/or unexpected adverse incidents should be reported to Health Canada at the following address:

**Any suspected adverse incident can also be reported to:**

Health Products and Food Branch Inspectorate

HEALTH CANADA

Address Locator: 3002C

Ottawa, Ontario K1A 0K9

Tel: The Inspectorate Hotline at 1-800-267-9675

For other inquiries: please refer to contact information.

The [Medical Devices Problem Report Form](#) and [Guidelines](#) can be found on the Health Canada web site.

[http://www.hc-sc.gc.ca/hpfb/inspectorate/md\\_pro\\_rep\\_form\\_tc\\_e.html](http://www.hc-sc.gc.ca/hpfb/inspectorate/md_pro_rep_form_tc_e.html)

[http://www.hc-sc.gc.ca/hpfb/inspectorate/man\\_vol\\_pro\\_rep\\_md\\_entire\\_e.html](http://www.hc-sc.gc.ca/hpfb/inspectorate/man_vol_pro_rep_md_entire_e.html)