Toothbrush Can Chip Teeth and Cause Choking

When using your electric toothbrush, you don't expect parts of the device to pop off and chip your tooth, fly into your eyes or get stuck in your throat.

But that's exactly what has happened to some users of the battery-powered Arm & Hammer Spinbrush—or the Crest Spinbrush, as it was called before 2009.

"It's important that consumers know how to avoid the risks associated with using the Spinbrush," says Shumaya Ali, M.P.H., a consumer safety officer at the Food and Drug Administration. "We've had reports in which parts of the toothbrush broke off during use and were released into the mouth with great speed, causing broken teeth and presenting a choking hazard."

FDA regulates toothbrushes—whether manual or electric—as medical devices that are intended to help prevent tooth decay. Safety precautions should be taken with all kinds of electric toothbrushes.

"Electric toothbrushes can be very effective in removing dental plaque, and so they can help prevent dental decay and gum disease," says Susan Runner, D.D.S., chief of FDA's dental devices branch. "At the same time, it's important to supervise children when they use these brushes, and to look out for any malfunctions of the toothbrush that might cause an injury."

Injuries reported from using the Spinbrush powered toothbrush include

- chipped or broken teeth
- cuts to the mouth and gums
- swallowing and choking on broken pieces
- injury to the face and eyes



Two models of the Spinbrush are shown here. To help prevent injury, inspect the Spinbrush for damage or loose bristles before each use, and always supervise children and adults who may need assistance when using it.

FDA is alerting the public about the potential for injury while using the following models of Spinbrush:

- Spinbrush ProClean
- Spinbrush ProClean Recharge
- Spinbrush Pro Whitening
- Spinbrush SONIC
- Spinbrush SONIC Recharge
- Spinbrush Swirl
- Spinbrush Classic Clean
- Spinbrush For Kids
- Spinbrush Replacement Heads

"It's important that consumers know how to avoid the risks associated with using the Spinbrush."

Parts Popping Off

The Spinbrush handle contains batteries and a motor that operates the brushes, which are attached to a brush head. In the models of Spinbrush made for adults, the brush head is removable and can be replaced.

But the brush head should not pop off during normal use, says Ali. "In some cases, the brush head popped off to expose metal pieces underneath that can—and have—poked individuals in the cheek and areas near the eyes, causing injuries."

The "Spinbrush for Kids" models, which have different handle designs, such as Spiderman and Thomas & Friends, do not have removable brush heads. Nonetheless, problems with the Spinbrush for Kids have also been reported, such as cut lips, burns from the batteries, and bristles falling off and lodging in a child's tonsils.

"FDA's concern is that the unexpected release of any part of this battery-powered toothbrush during use poses a risk of injury," says Steven Silverman, director of the Office of Compliance in FDA's Center for Devices and Radiological Health. "And the risk is higher in children or adults who may need assistance but are not supervised while using the toothbrush."

FDA Actions

FDA's inspection last year of Church & Dwight Co. Inc., which manufactures the Spinbrush, uncovered evidence that there had been numerous consumer complaints that had not been reported to the agency. On May 16, 2011, FDA warned the company (www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm258325.htm) of its violations of the Federal Food, Drug, and Cosmetic Act, including failure to report—within a reasonable

time frame—serious injuries.

After further discussions with Church & Dwight about the risks of the battery-powered Spinbrush, the company has taken some actions:

- improved the labeling to caution consumers to change the brush head every three months or sooner if the brush is worn or parts are loose
- added bristles that change color with wear to give consumers a visual reminder of when to replace the brush head
- issued a safety notice about Spinbrush in television and print ads; the safety notice also appears on the Spinbrush website and the interactive voice response to consumers who call the company's toll-free telephone numbers.

Safety Notice: Please remember to replace your brush head after 3 months of use, or if the brush is damaged, or if parts become loose. Extended usage, loose parts or excessive wear could lead to brush head breakage, generation of small parts and possible choking hazard. Inspect brush for loose parts before use.

Advice to Parents, Caregivers and Consumers

- Before using the Spinbrush, inspect it for any damage or loose brush bristles. If you find any, do not use the brush. Report it to Church & Dwight, which can be reached toll-free at 1-800-352-3384 or 1-800-561-0752.
- Make sure the brush head is connected tightly to the brush handle, and test the brush outside

- of your mouth before using. If the connection feels loose or the brush head easily detaches from the handle, *do not use the brush*. Report it to Church & Dwight.
- Use care not to bite down on the brush head while brushing.
- To prevent injuries, always supervise children and adults who may need assistance when using the Spinbrush.
- Follow the instructions and recommended replacement guidelines included with the Spinbrush.
- Report injuries or problems with the Spinbrush to MedWatch—FDA's Safety Information and Adverse Event Reporting Program—either online (www.fda.gov/MedWatch), by regular mail, by fax or by phone.
 - o Regular Mail: Use postage-paid, pre-addressed FDA form 3500 (www.fda.gov/MedWatch)
- o Fax: 800-FDA-0178
- o Phone: 800-332-1088

Find this and other Consumer Updates at www.fda.gov/ ForConsumers/ConsumerUpdates

Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html