

**stryker**

Endoscopy

**URGENT: DEVICE REMOVAL****Attention:** O.R. SUPERVISOR & RISK MANAGER**Re:** URGENT: DEVICE REMOVAL**Date:** February 8, 2005**Product:** Stryker Arthroscopic 5.5mm Bur**Part Numbers:** See Attachment**Lot Numbers  
Affected:** See Attachment

**Product Issue:** Stryker Endoscopy has received reports of patient burns resulting from certain 5.5mm Arthroscopy burs that have overheated during use. Our investigation has confirmed that overheating can only be caused if all of the following conditions exist:

1. Burs manufactured with an oversized bushing.
2. Excessive side loads (greater than 5 lbs) are applied during use.
3. The suction function is disengaged (in violation of the instructions for use accompanying the product).

Stryker has determined that certain raw material receipts of bushing material may be responsible for an oversized condition within the bushing housing. Although devices that are manufactured with this material are perfectly safe to use if suction is continuously employed, Stryker has decided to recall these devices as a conservative measure.

**Recommended Action:** Recipients of this letter are confirmed to have received the subject material. Only the lots listed are affected. Please take the following action.

1. If you are holding product affected by this notice, contact Stryker Endoscopy Customer Service at 1-800-624-4422 to arrange for a no-charge replacement product to be shipped to you. Return the affected part(s) to Stryker Endoscopy by contacting your Sales Representative or Stryker Customer Service 1-800-624-4422. Please send returns to "Attention: Josh Bates".
2. Complete and return the included notification card acknowledging that you have received this notice. Doing so will preclude further notices.

**Solution:** Stryker has instituted process controls to eliminate this condition from production. No product manufactured in 2005 is affected.

We sincerely apologize for any disruption this notice may cause you, however the well being of patients and continued confidence of our customers is our primary concern.

**Additional Information:** Please contact a Regulatory Affairs Representative at 408-754-2423 should you have any questions regarding this notice.

