Patient and User Burns from Rotary Surgical Handpieces

As of March 31, 2003, FDA has received 265 reports of injuries and malfunctions involving over heating of pneumatic and electric powered rotary surgical handpieces. The following event summary is representative of the 265 reports received:

During a surgical osteotomy, the rotary handpiece driving the bone saw overheated and burned soft tissues in the incision. Patient required cosmetic surgery to correct scarring from the burn.

Rotary handpieces are used in a variety of orthopedic and general surgical procedures to cut, shape or drill tissue. Almost all rotary surgical handpieces have some form of bearings that permit the cutting tools to spin at high speeds. Poorly lubricated bearings can cause over heating of various components of surgical handpieces. Failure to regularly replenish bearing lubrication can lead to binding, over heating, scoring and eventually to disintegration of a handpiece's nose bearings.

What Went Wrong?

Of the 265 reports FDA has received, 62 reports describe burns to patients or medical personnel using the devices. Scoring (marking), seizing (bearings no longer rotating), failing or fragmenting of the nose bearings was reported in 177 of the 265 reports. In 101 of the 177 cases of bearing malfunction, manufacturers' examinations of the returned handpieces found that the bearings were scored, degraded, seized or disintegrated. Furthermore, in 76 of the 101 cases the manufacturer found that the handpiece had not been fully serviced since its original purchase over a year prior to the over heating incident. In routine use, the bearing lubricant is slowly removed by repeated cleaning and sterilization. Servicing instructions accompanying new handpieces recommend that the units be returned to manufacturers for preventative maintenance on a annual basis. If the rotary surgical handpieces are not returned to the manufacturer for annual servicing, the bearings still require lubrication by whoever is performing the regular service.

What Precautions Can You Take?

To reduce the incidence of handpiece overheating, you should familiarize yourself with the rotary surgical handpieces used in your facility and:

1. Check to determine when the rotary surgical handpieces were last serviced and lubricated.
2. Inspect and test rotary surgical handpieces regularly to look for evidence of overheating
3. Inspect rotary surgical handpieces before every use for evidence of overheating of the bearings.
4. Follow the manufacturer's instructions for servicing and lubrication.