U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Ongoing Safety Review of Arthroscopic Shavers: FDA Safety Communication

FDA has become aware of instances in which pieces of tissue have remained within certain arthroscopic shavers, a device used in some orthopedic surgical procedures, even after the cleaning process was believed to have been completed according to the manufacturer's instructions. Reports submitted to FDA suggested that the tissue retained was not evident to the naked eye. Multiple manufacturers of these devices recently informed their customers of this situation and reiterated the importance of proper cleaning procedures.

We are concerned about this because retained tissue in these devices can compromise the entire sterilization process. We are actively working with the manufacturers of these devices to gather more data about this situation and to understand its potential public health impact. As the FDA obtains more information that better defines the situation and determines whether there are specific risks, we will provide that information to facilities, health care providers and the public.

The FDA encourages facilities that use any of these types of devices to evaluate the adequacy of their cleaning procedures. Hospitals should consider taking the following steps to minimize any potential risk to patients:

- Be sure that all personnel responsible for device cleaning and sterilization at your facility are aware of and comply with all steps in the manufacturer's instructions for thoroughly cleaning these devices prior to sterilization. Please refer to the specific instructions provided in the labeling or user manual for each brand and/or model of shaver your facility uses.
- Consider inspecting the inside of the devices following cleaning to ensure that they have been cleared of any tissue or fluids. There may be multiple ways to accomplish this. As one example, the facility that brought this situation to our attention uses a 3mm video scope to inspect the channels of the shaver handpiece.

If you discover retained tissue in arthroscopic shavers at your facility after following the manufacturer-recommended cleaning procedures, you may file a **voluntary report (https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm)** with

MedWatch, the FDA Safety Information and Adverse Event Reporting program (OMB Approval No. 0910-0291). You can report directly to MedWatch by phone at 1-800-FDA-1088, or obtain the **fillable form online (/Safety/MedWatch/HowToReport/DownloadForms/default.htm)**, print it out and fax to 1-800-FDA-0178 or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787. These voluntary reports will help us gather additional information related to this problem and assess its public health impact.

This reflects FDA's current analysis of available information concerning these devices, in keeping with our commitment to inform the public about its ongoing safety reviews of devices. The nature, magnitude and possible public health impact of this situation are not yet clear, and at this point FDA is not recommending that healthcare professionals stop using the device. FDA is considering, but has not reached a conclusion about whether future regulatory action may be warranted. We will update this document when additional information or analyses become available.

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at **DSMICA@CDRH.FDA.GOV (mailto:DSMICA@CDRH.FDA.GOV)** or 800-638-2041.