

Date: September 6, 2017

URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

Attention: Surgical Risk Management Department

Products:

- MBUR5060FRCV - Burr, 5mm Round Cutting, Variable Exposure, Standard Length
- MBUR6060FRCV - Burr, 6mm Round Cutting, Variable Exposure, Standard Length
- MBUR7060FRCV - Burr, 7mm Round Cutting, Variable Exposure, Standard Length

Lots: All product with an expiration date prior to August 3, 2022

Description of the problem:

Olympus has become aware of an issue that requires your attention. This letter pertains to the Olympus Round Variable Cutting Burrs ("Burrs") referenced above. Our records indicate that you may have purchased affected burrs.

We are in receipt of a number of non-injury-related complaints that has made Olympus aware of a possibility that the burr may "chatter" when drilling bone. Although this chatter phenomenon can occur with any type or brand of cutting burr, depending on technique and bone density, Olympus has become aware that the larger diameter variable exposure burrs listed above can exhibit more chatter than other similar devices in some situations, particularly when they are extended to longer lengths. After extensive testing, Olympus has determined that our variable exposure burrs of less than 5mm diameter, and all fixed exposure burr offerings, are not affected by this phenomenon.

Because of this, Olympus has elected to issue this field safety notice (FSN). Please refer to the enclosure with this letter that cautions of the possibility of the chatter phenomenon in the larger variable offerings. The FSN also recommends that surgeons exercise due caution in their usage of the devices accordingly to avoid inadvertently adversely affecting sensitive anatomical structures adjacent to the drilling site.

Olympus requires you to take the following action:

- Immediately assess any affected product you have in stock and attach the enclosed FSN to the IFU. Also ensure that any potential users of the devices are aware of the additional warning in the supplement. Future versions of the IFU will include the warning.
- If you need additional copies of the supplement, call your Olympus customer service representative at 1-XXX-XXX-XXXX to arrange for them to be provided.
- Please note on the enclosed questionnaire that you have received this information.
- Fax the completed questionnaire to XXX-XXX-XXXX regardless of whether you have any affected inventory at your facility.

In addition, if you may have further distributed this product, please identify your customers, inform them at once of this FSN, and appropriately document your notification process. Your notification to your customers may be enhanced by including a copy of this FSN letter.

Olympus regrets any inconvenience from this action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at XXX-XXX-XXXX or at email XXXX for any additional information concerning this matter.

Sincerely,

Name
title

Urgent Field Safety Notice - Olympus Round Variable Cutting Burrs,

Details on affected devices:

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Advice on action to be taken by the user:

Although use of the affected devices may continue, the medical practitioner must be aware that there is a potential for the burr to “chatter” during the drilling of bone. This phenomenon can be unpredictable and can damage adjacent anatomical structures. Therefore, the medical practitioner should exercise due caution using the affected product in close proximity to any sensitive or vital anatomical structures. Drilling in those areas can be completed using a less aggressive diamond cutting burr.