



Urgent Field Safety Notice

Recommendation for the Surgical Technique

Attention: Hospital Director, Risk Management, Medical Device Vigilance Coordinator

January 12th, 2012

Name of the Medical Device	Reference
Vanguard ROCC – Reamer	A08V0073 A08V0074
Vanguard ROCC – Finned Punch Tower	A08V0072

Dear Biomet Customer,

This Field Safety Notice is to inform you of a recommendation for the Surgical Technique to be applied during keel preparation (paragraph "Keel preparation and trial stem" on page 20 of the Vanguard ROCC Knee System Surgical Technique: DOC GEN 098_French Version or DOC FLK 220_English Version).

The instrument Vanguard ROCC Reamer is used for bone preparation before implantation of a Vanguard ROCC Knee Prosthesis. It is used for keel preparation to implant the Vanguard ROCC Tibial Baseplate.

Since the introduction of the Vanguard ROCC Knee System in 2008, it has been reported that metal debris may produced while using Vanguard ROCC- Reamers and Vanguard ROCC - Finned Punch Tower.

Investigations confirmed that the instruments meet pre-defined specifications: the Vanguard ROCC reamers were initially designed to act both as compactor and as reamer. However, in case of extramedullary surgery and with any other technique not including "hole" preparation, there might be insufficient guidance of the reamer in the punch tower without pre-drilling. As a consequence, reamer might be slightly misaligned, creating wear between the reamer and punch tower forming metallic debris.

Additionally, even though rare, inadequate bone preparation may also occur due to insufficient reaming.

As a result of the metallic debris formation, a slight delay in surgery may occur to rinse the bone area with saline solution. If the surgeon does not recognize the issue, the consequences might be a possible inflammation and/or metallosis.

In case of inadequate bone preparation, it might result in instability of the baseplate or fracture of the tibia while impacting the baseplate, which may possibly result in a revision surgery.



To avoid such events, it is recommended to use the Vanguard Premier Starter Reamer (Reference 32-487271) and drill a pre-hole before using the Vanguard ROCC reamer. The Vanguard ROCC reamer will then act as a compactor/reamer whilst inserting the baseplate.

As a result, we recommend you to follow the attached detailed procedure: "Recommendation of Use".

What you need to do:

- 1- Kindly assist us with this action, please distribute this Field Safety Notice immediately to the appropriate people within your hospital and maintain it with the documentation related to the Vanguard ROCC Knee System Surgical Technique.
- 2- Please sign and return the "Fax-back form" enclosed, on which you will confirm that you have received, read and that you will fully comply with this notice.

Please accept our apologies for any inconvenience caused by this matter.

Should you have any further questions regarding this communication, please do not hesitate to contact your Biomet Local Contact.

Yours sincerely,

Morgane Grenier
Quality and Regulatory Affairs Director

Urgent Field Safety Notice
Recommendation of Use
Tibial bone preparation during implantation of a Vanguard ROCC Knee Prosthesis
January 2012

Background

In case of extramedullary surgery and with any other technique not including “hole” preparation, there might be insufficient guidance of the reamer in the punch tower without pre-drilling. As a consequence, reamer might be slightly misaligned, creating wear between the reamer and punch tower and creating metallic debris. Additionally, even though rare, inadequate bone preparation may also occur due to insufficient reaming.

Recommendation of Use

To avoid the above risks, we recommend that all users of the Vanguard ROCC Knee System take due notice of the instructions for the surgical technique stated below. Specific attention should be given to the Keel preparation with the Vanguard ROCC Reamer (A08V0073, A08V0074) and Vanguard ROCC - Finned Punch Tower (A08V0072): paragraph “Keel preparation and trial stem” on page 20 of the Vanguard ROCC Knee System Surgical Technique (DOC GEN 098_French Version or DOC FLK 220_English Version).

To ensure that the keel preparation is adequately performed, you must drill a pre-hole by reaming with the Vanguard Premier Starter Reamer before using the Vanguard ROCC reamer.

1. Insert the pins into the posterior holes of the trial tibial tray and fix the punch tower (A08V0072) onto the trial tibial tray using the appropriate pins (Figure 1).



Figure 1

2. Use the Vanguard Premier Starter Reamer (Ref 32-487271) and perform a pre-hole, as the first step of keel preparation (Figure 2).



Figure 2

3. Use the appropriate Vanguard ROCC reamer (A08V0073 or A08V0074) to prepare for the finned keel (Figure 3).



Figure 3

Please distribute this Field Safety Notice to the appropriate people within your hospital and to include and maintain this recommendation within the documentation related to the Vanguard ROCC Knee System Surgical Technique.

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Yours sincerely,

Morgane Grenier
Quality and Regulatory Affairs Director

