BIOMET
One Surgeon. One Patient.

Customer
Address 1
Address 2

Medical Device – Advisory Notice

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

May, 07th 2015,

Name of the product	Reference	Batch
OPTIGUN RATCHET	4195	0101296012
OPTIGUN RATCHET US	419500	0101296012

Dear Sir, Madam,

This Advisory Notice is to inform you of an issue Biomet France is facing with the pin which maintains the knob button in relation to the following products :

OPTIGUN RATCHET Ref: 4195 Batch: 0101296012
OPTIGUN RATCHET US Ref: 419500 Batch: 0101296012

Our records indicate that we may have shipped certain products from this batch to your hospital.

Biomet France has initiated this action after having receiving a number of complaints indicating that the pin which maintains the knob button felt down and the knob button was disconnected from the axis of the Optigun (see pictures below).

Picture 1

Picture 2

The investigation performed by Biomet France revealed that the diameter of some Optiguns rack holes in which the pin is inserted is out of specification.

Biomet France is issuing this advisory notice to make users aware of this potential issue.

Biomet France ask you to check the maintaining of the pin before using of the Optigun with applying light pressure on pin. If you identified any item with defective pin from the affected item/lot combination, please contact your local Biomet Distributor as soon as possible for replacement.

In the remote event of the loss of the pin occurred during surgery, care should be taken that the pin does not fall into patient body.

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What we kindly request you to do:

1. Ensure all relevant Hospital staff are given relevant awareness training relating to this matter to ensure they are fully informed.

2. To assist us with this action, please ensure that the operating staff are made aware of this matter without delay and that all the affected instruments are identified. Any damaged instruments should be withdrawn from use and a replacement Optigun will be made available.

3. Complete and return the attached "Response Form" to Biomet France or to tour local Biomet distributor. This confirms the fact that you have received and understood the attached advisory notice informed relevant theatre staff and have physically checked all inventory and hospital locations.

4. If you identified any item with defective pin from the affected item/lot combination, you will need to indicate the quantity you have available for return, the items then need to be returned to Biomet France or to your local Biomet Distributor as soon as possible, you must ensure you complete the attached Fax-Back response form and return it to Biomet France or to your local Biomet Distributor as soon as possible.

We thank you in advance for your attention to this matter.

We would like to apologize for this issue and any inconvenience caused by this matter.

If you have any questions regarding this communication, we kindly ask you to contact your local Biomet representative.

Yours sincerely,

Christophe Mironneau
Quality and Regulatory Director

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