November 30, 2016

To: Risk Managers and Surgeons

Subject: **URGENT FIELD SAFETY NOTICE – REMOVAL**
Affected Product: Gender Solutions PFJ Milling Handpiece

Item Number	Serial Number
00-5927-040-00	All

Figure 1: Handpiece

Zimmer Biomet is conducting a medical device field removal for all distributed Gender Solutions PFJ Milling Handpieces. Complaints have been reported that the handpiece is inoperable. The investigation found that the complaints were related to the lack of preventative maintenance contrary to what is recommended in the instructions for use included with the handpiece. As stated on page 6 of the instructions for use (Figure 2 below), preventative maintenance should be performed on each handpiece every six (6) months.

Repair Service

Brasseler USA recommends that all powered devices and accessories be returned for preventative maintenance every six (6) months. Brasseler USA warrants any service or repair work performed will be free from defects in material or workmanship for the period of six (6) months from date of service or repair. This warranty applies to the actual work performed.

Figure 2: IFU excerpt

Also, as stated on page 5 of the instructions for use (Figure 3 below), the handpiece is not to be immersed.

Cleaning Procedure

1. Leave hose attached or insert the cleaning cap (optional) into the hose connector of the instrument. Remove bur prior to cleaning.
2. Scrub, using a nylon brush, the instrument thoroughly with mild soap and water. Remove all traces of blood and debris.
3. With the air/nitrogen hose or cleaning cap(optional) still attached, rinse all traces of contaminants and detergent under running water.

Do NOT immerse. If accidental immersion occurs please see Accidental Immersion.

Figure 3: IFU excerpt

In the event that the handpiece is inoperable, there are additional options available to complete the surgery as detailed on page 17 of the Zimmer® Gender Solutions™ Patello-Femoral Joint (PFJ)

System Surgical Technique (97-5926-002-00 Rev1). This page can also be seen in Attachment. Please note that this page also describes the method for ensuring that the burr is fully inserted and locked for proper operation.

1. Use the second milling handpiece included in the instrument kit KT-5927-00-200 (Gender Solutions Handpiece Kit).
2. If the second handpiece is inoperable the 00-5927-050-00 PFJ Drill Milling Adapter can be used to join the PFJ Milling Burr to a standard surgical drill. The adapter utilizes the PFJ Milling Guide for accurate bone preparation. This option is further explained on page 32 of the Zimmer® Gender Solutions™ Patello-Femoral Joint (PFJ) System Surgical Technique (97-5926-002-00 Rev1). This page can also be seen in Attachment 2.

As described below an inoperable handpiece may result in surgical delay and or increased risk of infection.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	Delay in surgery less than 30 minutes	*Risk of infection due to delay of surgery*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	None	*Risk of infection*

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of September 2007 and August 2016.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow up schedule.
3. Your Zimmer Biomet Sale Representative can support you to test / check the functionality of the instrument. Please complete the Attachment 4 reporting the functionality test. If a handpiece is not functioning properly, return it to Zimmer Biomet on a Product Experience Report (PER). If a handpiece is functioning properly, please await further instructions for preventative maintenance.Complete Attachment 3 – Certificate of Acknowledgement.
    a. Return a digital copy via email to fieldaction.uk@zimmerbiomet.com or via fax to +41 52 244 86 76 within three (3) days or give it to your Zimmer Biomet sales representative.
    b. Retain a copy of the Acknowledgement Form with your field removal records in the event of a compliance audit of your documentation.
4. If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.

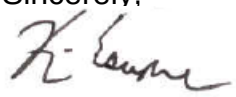
Vigilance/ Reporting Information

This voluntary notification will be reported to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local health authority in your country.

Please keep Zimmer GmbH informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

Sincerely,



Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Surgical Technique Excerpt

SECTION 6

Mill Femoral Trochlea

6.2 Perform the Milling Operation

- Open Collet on Milling Handpiece: Unlock the burr locking mechanism by rotating the locking collar into the "open" position (a click can be felt as the collet fully opens).
- Install PFJ Mill Burr (00-5927-050-00): Insert burr fully into collet until flush (Fig. 32).

TECHNIQUE TIP 6.B

If burr does not sit flush initially, make sure collet is unlocked and rotate burr while inserting.

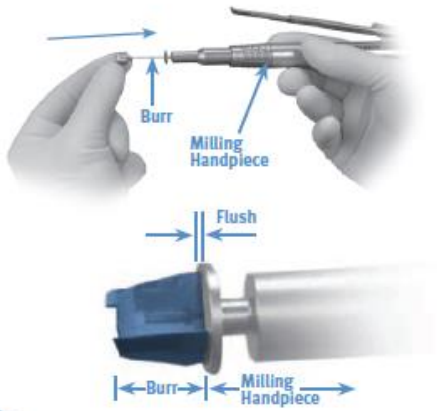


Fig. 32
Insert burr into collet.

- Lock Collet: Rotate the locking collar into the "lock" position (a click can be felt when fully secure, and the "red" dots will be aligned) (Fig. 33).

  - Tug slightly on burr to ensure it is fully locked.

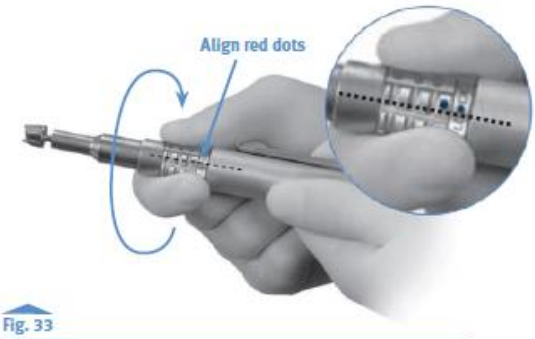


Fig. 33
Rotate locking collar into "Lock" position.

NOTE: If the Milling Handpiece is inoperable, refer to the Milling Handpiece operating instructions for trouble shooting (packaging insert or brasselerusamedical.com). If after trouble shooting the mill remains inoperable, use a second Milling Handpiece. Refer to Appendix A for the backup milling procedure if a second Milling Handpiece is not available.

- When operating the Milling Handpiece, take care to place the slotted end (burr guard) into the track before initiating power on the handpiece (Fig. 34).

WARNING: The Milling Handpiece should only be operated when engaged in the Milling Guide. Serious injury could occur if instructions are not followed.

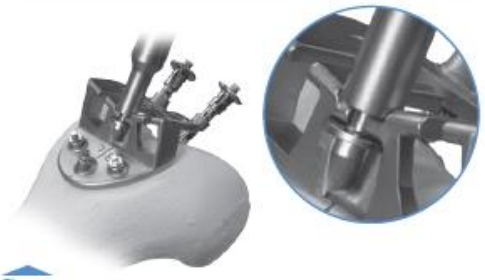


Fig. 34
Place burr guard into track before initiating power.

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ATTACHMENT 2
Surgical Technique Excerpt

Appendix A: Backup Milling Procedure Rationale:

The PFJ Drill Milling Adapter can be used to complete the milling operation in the event the Milling Handpiece is inoperable at the time of surgery. The Drill Milling Adapter joins the PFJ Mill Burr to a standard surgical drill via a Jacob's Chuck and utilizes a PFJ Milling Guide for accurate bone preparation. *The milling operation is more challenging when using this approach and should only be used as a backup to the Milling Handpiece.*

1. Assembly:

Insert new PFJ Mill Burr (00-5927-050-00) into the PFJ Drill Milling Adapter as shown in (Fig. 1).

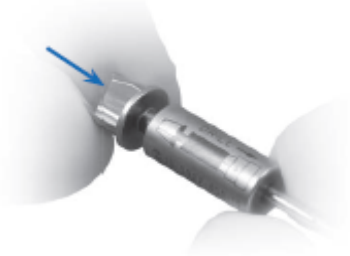

Fig. 1 Insert burr into adapter

With a 1/4 in. or smaller Jacob's Chuck facing upright, insert the shank of the PFJ Mill Burr with PFJ Drill Milling Adapter into the Jacob's Chuck until they both bottom out (Fig. 2). Tighten securely with chuck key (Fig. 3). Rotate assembly to visually verify that the burr is clamped straight and that the PFJ Drill Milling Adapter rotates independently from the PFJ Mill Burr.

Fig. 2 Burr and adapter in Jacob's Chuck

Fig. 3 Tighten Jacob's Chuck securely

Caution: To minimize the potential for over-resection, hold Jacob's Chuck vertically during tightening and ensure there is no axial play in the assembly (Figs. 4 & 5).

Fig. 4 Backup Milling Assembly (CORRECT)

Fig. 5 Backup Milling Assembly (INCORRECT)

Place Backup Milling Assembly into a standard surgical drill.

Caution: The use of a reamer/wire driver is not recommended. Ensure the standard surgical drill/Jacob's Chuck can achieve 7 50-25,000 rpm. Too slow/fast may result in poor bone preparation and/or damage to the instruments.

2. Secure the Milling Guide: Additional Fixation

In addition to the three (3) anterior fixation screws, it is recommended to utilize a 48mm MIS headless screw (00-5983-041-48) in the Milling Guide's posterior fixation hole when using this approach. This will help ensure adequate fixation (Fig. 6).

Fig. 6 Posterior screw insertion

ZFA 2016-163

ATTACHMENT 3

Certificate of Acknowledgement

FSN/FSCA: FA 2016-163

Affected Product: Gender Solutions PFJ Milling Handpiece

Please email or fax the completed form to your local Zimmer Biomet contact

Fax / Email _____ / _____

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Removal Notice.

[ ] **Hospital Facility** [ ] **Surgeon**

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date:**____/____/____

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and return it via email to fieldaction.uk@zimmerbiomet.com.

ATTACHMENT 4

Product Functionality Testing Form

ZFA 2016-163 PFJ Brasseler Handpiece

Country: _____Account Number: _____

Account Name: _____

Account Address: _____

Name of person completing this form (printed): _____

Signature of person completing this form: _____Date:_____

Title: _____ Telephone:_____

Part Number	Serial Number	Quantity	Functionality Testing Results	
			Functioning (Pass)	Not Functioning (Fail)

Note: If a handpiece is not functioning properly, return it to Zimmer Biomet on a Product Experience Report (PER). If a handpiece is functioning properly, please await further instructions for preventative maintenance.