URGENT FIELD SAFETY NOTICE
Ref-3004976965-10/10/16-003-R
PLEASE READ THOROUGHLY

Greatbatch Medical – Offset Reamer Handle

Offset Reamer Handle

Offset Reamer Handle	
Catalogue Number	**Model**
00-7804-080-00	T5766

GREATBATCH MEDICAL OFFSET REAMER HANDLE ARE AFFECTED BY THIS RECALL

NO OTHER GREATBATCH PRODUCTS ARE AFFECTED BY THIS FIELD SAFETY CORRECTIVE ACTION

Month xx, yyyy

To: **Risk Managers and Surgeons**

Subject: **URGENT MEDICAL DEVICE RECALL CORRECTION – LOT-SPECIFIC RECOMMENDATIONS FOR CLINICAL USE**

AFFECTED PRODUCT: GREATBATCH MEDICAL OFFSET REAMER HANDLE (00-7804-080-00)

This letter provides important information from Greatbatch Medical, the manufacturer of the 00-7804-080-00 Offset Reamer Handle. Greatbatch Medical initiated a Recall Notification for the 00-7804-080-00 Offset Reamer Handle (Figure 1), and Zimmer Biomet is a distributor of the device. Your assistance with the execution of the removal phase is now required. Greatbatch has re-designed the 00-7804-080-00 Offset Reamer Handle, and replacements are now available.

Figure 1: Representation of the 00-7804-080-00 Offset Reamer Handle

Description of the problem:

On June 14, 2016 Greatbatch Medical identified an issue with the 00-7804-080-00 Offset Reamer Handle, as field complaints were reported that the drive chain mechanism seizes during use. The function of the drive chain mechanism is to transmit rotational power from a mechanical drill to an acetabular reamer during a Total Hip Arthroplasty. During seizing, the device is rendered non-functional in the operating room.

The risks associated with this failure are:

1. The Offset Reamer Handle seizes and the surgery must be completed with an alternate device, leading to a delay of 30 minutes or greater from the scheduled surgery time.
2. The Offset Reamer Handle seizes and no replacement device is available in the hospital, leading to an interruption and rescheduling of surgery.

Replacement devices:

Greatbatch is re-designing the 00-7804-080-00 Offset Reamer Handle and will provide the newly designed device, upon availability, to Zimmer Biomet for ultimate delivery to end-users.

Your Responsibilities:

1. Review the notification and ensure all affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative with the quarantine of any affected product.
3. Your Zimmer Biomet sales representative will remove the recalled product from your facility.
4. Complete the Acknowledgment Form and return it to CorporateQuality.PostMarket@zimmerbiomet.com.

Available Assistance:

For questions related to this action, please contact your local Zimmer Biomet sales representative or call (574) 372-9672.

Other Information:

This recall is being conducted in cooperation with the relevant government agencies.

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.

It is very important that you keep Zimmer Biomet informed of any complaints or adverse events associated with this device. Adverse events may be reported to Zimmer.PER @zimmerbiomet.com.

Greatbatch Medical
10000 Wehrle Drive,
Clarence, NY 10431
USA

Greatbatch Medical SA
Bahnhofstrasse 15
2502 Biel/Bienne
Switzerland
Tel. +41 32 358 01 11
orthopaedicseurope@greatbatchmedical.com

ADDENDUM A

Part Number: 00-7804-080-00
Lot Numbers: See Table Below

56474947	56596272	56596333	56596429
56474941	56596276	56596334	56596430
56474943	56596277	56596335	56596433
56474944	56596292	56596366	56596434
56474945	56596293	56596368	
56474946	56596294	56596369	
56474974	56596295	56596370	
56474982	56596330	56596371	
56474983	56596331	56596372	
56474990	56596332	56596428	

Acknowledgement Form

Affected Product: Greatbatch Offset Reamer Handle (00-7804-080-00)

IMMEDIATE RESPONSE REQUIRED – TIME-SENSITIVE ACTION NEEDED

This acknowledgement form is to certify that I have read and understand the information and instructions contained in this **URGENT MEDICAL DEVICE RECALL**.

Acknowledgment:

By signing below, I acknowledge that I understand the required actions to be taken in accordance with the Recall Correction Notice.

Printed Name: _____ Signature: _____

Facility Name: _____

Facility Address: _____

Title: _____ Telephone: ( ) _____ Date: ___/____/____

Please email this form to CorporateQuality.PostMarket@zimmerbiomet.com, **and keep a copy of your completed form for your records.**

November xx, 2016

To: **Distributors, Sales Representatives, and Distribution Operation Managers**

Subject: **URGENT MEDICAL DEVICE RECALL**

AFFECTED PRODUCT: GREATBATCH MEDICAL OFFSET REAMER HANDLE (00-7804-080-00)

This letter provides important information from Greatbatch Medical, the manufacturer of the 00-7804-080-00 Offset Reamer Handle. Greatbatch Medical initiated a Recall Notification for the Offset Reamer Handle (Figure 1), and Zimmer Biomet is a distributor of the device. Greatbatch has re-designed the 00-7804-080-00 Offset Reamer Handle.

Figure 1: Representation of the 00-7804-080-00 Offset Reamer Handle

Description of the problem:

On June 14, 2016 Greatbatch Medical identified an issue with the 00-7804-080-00 Offset Reamer Handle, as field complaints were reported that the drive chain mechanism seizes during use. The function of the drive chain mechanism is to transmit rotational power from a mechanical drill to an acetabular reamer during a Total Hip Arthroplasty. During seizing, the device is rendered non-functional in the operating room.

The risks associated with this failure are:

1. The Offset Reamer Handle seizes and the surgery must be completed with an alternate device, leading to a delay of 30 minutes or greater from the scheduled surgery time.
2. The Offset Reamer Handle seizes and no replacement device is available in the hospital, leading to an interruption and rescheduling of surgery.

Replacement devices:

Greatbatch is re-designing the 00-7804-080-00 Offset Reamer Handle and will provide the newly designed device, upon availability, to Zimmer Biomet for ultimate delivery to end-users.

Your Responsibilities:

1. Review this notification and ensure all affected personnel are aware of the contents.
2. Place an order for your replacement devices. Credit will be issued upon receipt.
3. Locate and quarantine all affected unused product identified in Addendum A. Distributors previously received an individual list from Zimmer Biomet that constituted the fielded inventory in their respective territory based on a review of consignment inventory, as well as an individual list of direct sale (non-consigned) inventory delivered directly to hospitals in their respective territory.
4. You will receive a copy of the notification sent directly to hospital risk managers and surgeons in your respective territory. Review and facilitate understanding of this notification if necessary.
5. Complete the Distributor Acknowledgment form and return it via email to CorporateQuality.PostMarket@zimmerbiomet.com within three (3) days. Return a list of any hospital risk managers and/or surgeons in your territory who should also receive notification of this update, and supply the information to the entities you have identified.
6. Return the recalled product, along with a copy of the completed Distributor Acknowledgment Form. Clearly mark the outside carton of each product return shipment as "Recall." Upon receipt of the affected recalled product, Zimmer Biomet will ship replacements, as appropriate. Send returned product to:

[Enter Address]

Available Assistance:

For questions related to this action, please contact your local Zimmer Biomet sales representative or call (574) 372-9672.

Other Information:

This recall is being conducted in cooperation with the relevant government agencies.

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.

It is very important that you keep Zimmer Biomet informed of any complaints or adverse events associated with this device. Adverse events may be reported to Zimmer.PER @zimmerbiomet.com.

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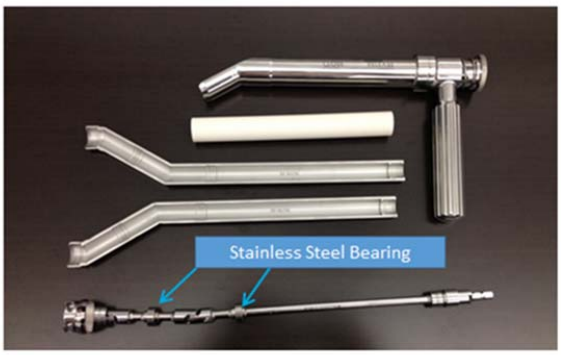
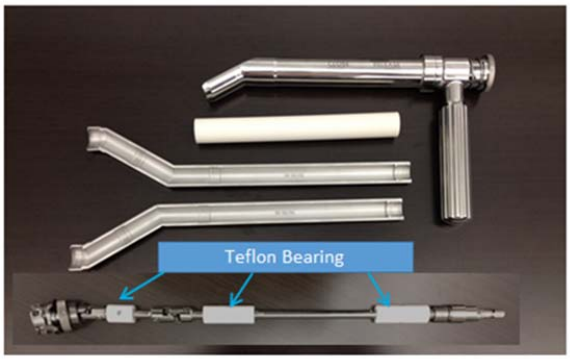
The new design uses Teflon bearings with the drive chain assembly. This design replaces stainless-steel ball bearings. With the exception of the drive chain bearings, all other components, including the part numbers, are the same.





Distributor Acknowledgement Form

Affected Product: Greatbatch Offset Reamer Handle (00-7804-080-00)

IMMEDIATE RESPONSE REQUIRED – TIME-SENSITIVE ACTION NEEDED

This acknowledgement form is to certify that I have read and understand the information and instructions contained in this **URGENT MEDICAL DEVICE RECALL**.

Territory Number: _____ **Account Number:** _____
Account Name: _____ **Phone Number:** _____
Account Address: _____ _____

An exhaustive search for the affected lots has been performed and all available affected products are being returned to Zimmer Biomet.

Yes ☐ **No** ☐

Item Number	Lot Number	Quantity Returned

Please return the affected products to the following address with a copy of this acknowledgment or spreadsheet containing the item number, lot number, and quantity to:

[Enter Address]

Acknowledgment:

By signing below, I acknowledge that I understand the required actions to be taken in accordance with the Field Notification.

Printed Name: _____ Signature: _____

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

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is your responsibility to complete this form, in addition to the Additional Accounts form, and email to CorporateQuality.PostMarket@zimmerbiomet.com. **Please keep a copy of your completed form for your records.**