Medical Device Recall Notice

**AUG2015

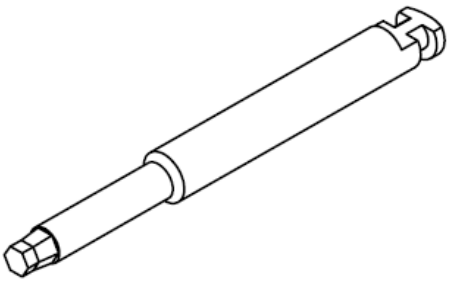
Insert Clinician
Acct. #
Name and
Address
here

Dear Valued Customer:

BIOMET ***3i*** wishes to inform you of a product recall affecting the items listed below:

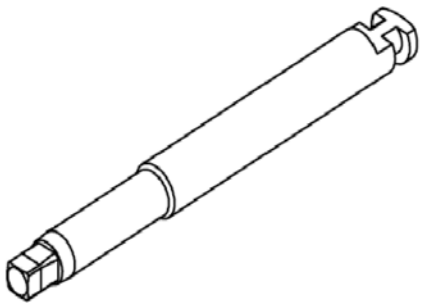
Affected Product:

Item: **RASH3N**
Description: **Narrow Right Angle Large Driver Tip (Hexed)**
Lot: **1184555**
Distributed: June 5 - July 15, 2015



RASH3N

Item: **RASQ3N**
Description: **Narrow Right Angle Square Driver Tip**
Lot: **1184554**
Distributed: June 5 - July 15, 2015



RASQ3N

We have discovered that the production documentation for the items listed above was inadvertently swapped during manufacturing. This caused the packaging labels to be created and applied incorrectly. Additionally, because of the swap, the RASQ3N received the RASH3N's laser marking, "RASH3N●" along the body of the driver tip.

Risks:

The use of either RASH3N or RASQ3N is not expected to result in any adverse health consequences:

- The attempted use of the RASQ3N driver tip with a hex drive screw (e.g. UNIHG) will result in no engagement of the square driver tip into a hexed screw head.
- The attempted use of the RASH3N driver tip with a square drive screw (e.g. UNISG) may result in slight engagement insufficient to torque the screw to 30 – 35 Ncm of torque as required in the BIOMET ***3i*** Restorative Manual. The slight engagement of the RASH3N driver tip will not affect the functioning of the square drive screw. It may be tightened or removed normally with an appropriate square driver tip.

As a medical device manufacturer, BIOMET ***3i*** takes patient safety and product quality very seriously. Therefore, we are recalling any unused quantities you may have.

Our records indicate that you've received one or more of the above listed items. These items were distributed both individually and in Surgical and Restorative Kits. Your affected order history is provided on the accompanying Recall Return Response Form in order to assist you in identifying the affected items you have received.

Responsibilities:

We ask that you respond to this notification at your earliest convenience by completing the accompanying Recall Return Response Form and returning any unused product to the address listed on the form. Returned product will be promptly replaced at no charge.

- **For individual RASH3N and/or RASQ3N—please return the item(s).**
- **For those who have received the affected items in Restorative or Surgical Kits, please only return the RASH3N and/or RASQ3N from the kits. DO NOT RETURN the kit(s).**

Health care professionals and consumers may report serious adverse events or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone:

- Online: www.fda.gov/MedWatch/report.htm
- Regular Mail: Use postage-paid FDA form 3500 available at www.fda.gov/Medwatch/getforms.htm mail to Medwatch, 5600 Fishers Lane, Rockville, MD 20852-9787.
- Fax: (800) FDA-0178
- Phone: (800) FDA-1088

We regret any inconvenience this may have caused and want to assure you that BIOMET ***3i*** is committed to ensuring the quality and efficacy of our products. We have given this matter the highest priority and are implementing corrective actions to prevent recurrence.

Thank you for your assistance. If you have any questions or concerns, please feel free to contact us at 1-800-342-5454.

Sincerely,

[redacted]
Mark Mashburn
Recall Coordinator
BIOMET ***3i***