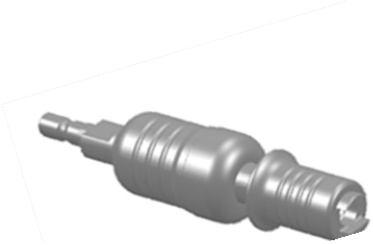
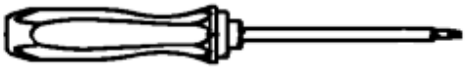
URGENT FIELD SAFETY NOTICE
Ref-3004976965-04/20/16-002-R
PLEASE READ THOROUGHLY

Greatbatch Medical – Torque Limiting Devices



Torque Limiting Adapter

Torque Limiting Handles



Torque Limiting Screwdriver

Torque Limiting Adaptors	
Catalog Number	**Model**
MAC21001	T112972
T116245	T116245
MAC21003	T116430
MAC21001	T13621

Torque Limiting Handles	
Catalog Number	**Model**
MCL120014	T14000

Torque Limiting Screwdrivers	
Catalog Number	**Model**
T14001	T14001
MTO35173507	T14378
MTO375173506	T14379
MTO35173505	T14380
MTO35175303	T8127

GREATBATCH MEDICAL TORQUE LIMITING DEVICES ARE AFFECTED BY THIS RECALL

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

April XX, 2016

Dear Valued Customer,

The purpose of this letter is to advise you that Greatbatch Medical has initiated a global Field Safety Corrective Action for the Recall of Torque Limiting Devices. Our records indicate you have received at least one of these devices since the product was first released in 2005.

REASON FOR FIELD SAFETY CORRECTIVE ACTION:

Greatbatch identified through laboratory testing that the required sterility assurance level (SAL) of 10^{-6} is not achieved on torque limiting devices steam sterilized according to the Instruction For Use (IFU) provided with the devices. Torque limiting devices are supplied non-sterile and require cleaning and steam sterilization prior to use and subsequent re-use. Although Greatbatch has not received any reports of deaths, illnesses, injuries, or other adverse effects associated with this issue, Greatbatch has initiated a recall of these devices.

This Field Safety Corrective Action is being performed with the knowledge of the appropriate regulatory authorities.

RISK TO HEALTH:

Torque-limiting devices are used in orthopedic and trauma surgeries to secure implants. When reprocessed according the IFU provided with the device, tests have shown that the torque limiting devices may not be sufficiently sterile and may be contaminated from previous use. Using a non-sterile device in surgery could lead to patient contamination and/or infection.

Frequency of failures:	Based upon the fact that Greatbatch has received zero complaints to date, the actual rate of occurrence is 0% of all Torque Limiting Devices. We have calculated a 0.2% probability of occurrence of patient harm.
Adverse events:	Greatbatch has received no reports of deaths, illnesses, injuries, or other adverse effects associated with this issue. This issue carries with it the possibility of patient infection.

INSTRUCTIONS TO CUSTOMERS:

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS FIELD SAFETY CORRECTIVE ACTION

1. Review the enclosed **Field Recall Response Form**. This Form contains important information about your specific account. It must be returned to us even if you do not have any impacted Torque Limiting Devices in your possession. For your convenience, we have pre-populated the Form with information we have in our records concerning the impacted Torque Limiting Device shipped to you by Greatbatch since the product was released in 2005.

2. Examine your inventory and identify all impacted Torque Limiting Devices that are in your possession and quarantine those devices immediately.

3. Complete the **Field Recall Response Form** indicating if you have the device or not and email it to Stericycle at Greatbatch4578@stericycle.com.

4. If you are returning affecting product please ensure that all devices are free of visible bodily fluids and debris. Once Stericycle receives your Field Recall Response Form they will send you a pre-paid UPS return label. If additional returned labels are needed please email Stericycle at Greatbatch4578@stericycle.com.

5. Adverse reactions or quality problems experienced with the use of this product may be reported to Greatbatch Medical at orthopm@greatbatch.com

6. You have concluded the actions to be taken in response to this Field Recall. We sincerely thank you for your assistance.

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure patient and customer satisfaction. If you have any questions or need help completing these actions, please contact your local Greatbatch Medical representative, contact us at 001 763-951-8235, or e-mail us at FieldActionCenter@Greatbatch.com and we will be happy to assist you.

Sincerely,

[redacted]
Greatbatch, Inc.
2300 Berkshire Lane North
Plymouth, Minnesota 55441, USA

Enclosures:

1) Field Recall Response Form