URGENT MEDICAL DEVICE RECALL

April 25, 2019

Product Field Action Number:	1958828
Description (Catalog #):	2.7 Degree Angled Sagittal Saw attachment (Mako Total Knee Application Only) 2.7 Degree Straight Sagittal Saw attachment (Mako Total Knee Application and Partial Knee Application 3.0)
Affected Catalog Number(s):	212480 212186
Affected Lot(s):	35040918 35051018, 35050918

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Department

Stryker has initiated a voluntary, lot-specific recall for the Mako System's 2.7 Degree Straight Sagittal Saw attachments and 2.7 Degree Angled Sagittal Saw attachments. The intent of this letter is to list known hazards and harms potentially associated with the above referenced products and list any risk mitigation factors.

Issue:

Stryker has discovered that the bearings in a subset of saw attachments in the three affected lots listed above for the 2.7 Degree Straight Sagittal Saw attachments and 2.7 Degree Angled Sagittal Saw attachments were ungreased. The 2.7 Degree Straight Sagittal Saw attachments are used in Mako Total Knee and Mako Partial Knee procedures with the Mako TKA 1.0 and PKA 3.0 applications. The 2.7 Degree Angled Sagittal Saw attachments are used in Mako Total Knee procedures with the TKA 1.0 application. Both saw attachments connect to the MICS handpiece to aid in performing bone resections.

Potential Hazards:

In the event that a 2.7 Degree Straight or Angled Sagittal Saw attachment with an ungreased bearing is used during a Mako TKA or PKA 3.0 procedure, the following potential hazards may occur:

- Reduced or no motion from the blade, resulting in limited or no output/functionality.

Potential Harms:

The aforementioned hazards may result in the following potential harm(s):

- Complications associated with extended surgery time of ≤30 minutes while retrieving a replacement 2.7 Degree Sagittal Saw attachment or converting to a manual TKA.

Risk Mitigation:

A mitigating factor which would increase the detectability of the pending bearing failure would be increased noise coming from the attachment. The user may identify this increased noise and replace the attachment prior to failure.

Actions Needed:

1. Please inform users of this Urgent Medical Device Recall and forward this notice to all those individuals who need to be aware within your organization.
2. Hospitals/Branches/Agencies: Complete and sign the enclosed Urgent Medical Device Recall Business Reply Form and fax a copy to 1-877-496-5040 or email to Stryker10077@stericycle.com
3. Hospitals/Branches/Agencies: Return all affected instruments available at your location to the following address.

Stryker Orthopaedics/PFA Product Returns
Attn: Distribution Inventory Team
325 Corporate Drive
Dock M-East
Mahwah, NJ 07431
Ref. PFA 1958828

Our records indicate that you have received the above referenced instrument. It is our responsibility to ensure that customers who may have received this affected instrument also receive this important communication. **Please assist us in meeting our regulatory obligation by faxing back the attached Urgent Medical Device Recall Business Reply Form within 5 days.**

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact me at (954) 628-0502.

Sincerely,

Clayton Odor
Senior Director, Quality Assurance
Stryker
Joint Replacement Division
2555 Davie Road
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URGENT MEDICAL DEVICE RECALL
BUSINESS REPLY FORM

April 25, 2019

Product Field Action Number:	1958828
Description (Catalog #):	2.7 Degree Angled Sagittal Saw attachment (Mako Total Knee Application Only) 2.7 Degree Straight Sagittal Saw attachment (Mako Total Knee Application and Partial Knee Application 3.0)
Affected Catalog Number(s):	212480 212186
Affected Lot(s):	35040918 35051018, 35050918

I have received the Urgent Medical Device Recall letter from Stryker dated April 25, 2019 providing information on the voluntary, lot-specific recall of the above referenced device.

_____ _____

Hospital or Stryker Branch Name Date

_____

Hospital/Agent/Risk Rep or Stryker Branch Rep
(Signature)

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL OR FAX LISTED BELOW:

Fax: 1-877-496-5040 or email to Stryker10077@stericycle.com