RA2024-3598242:
Urgent Medical Device Correction

May xx, 2024

Affected product

Product Name:	**Total Knee Arthroplasty (TKA) 2, Total Knee Arthroplasty (TKA) 1, Partial Knee Arthroplasty (PKA) 3, Total Hip Arthroplasty (THA) 4.0, 4.1 on Mako 3.0, 3.1.**
Identification of the Affected Products:	**Table 1**

Application Part Number	Product Description	GTIN
700001590415	TKA 2.0 + TKA 1.0.1 + THA 4.0.0.1 + PKA 3.0.2	7613327566468
700001590414	TKA 2.0 + TKA 1.0.1 + THA 4.1 + PKA 3.0.2 + MGO 1.2.2	7613327566444
700002190743-04	TKA 2.0.fr.1+TKA 1.0.1.fr.1+PKA3.0.2.fr.	07613327629095
700002190743-01	TKA 2.0.it.1+TKA 1.0.1.it.1+PKA3.0.2.it.	07613327629118
700002190743-03	TKA 2.0.de.1+TKA 1.0.1.de.1+PKA3.0.2.de.	07613327629132
700002190743-05	TKA 2.0.es.1 + PKA 3.0.2.es.1 + THA 4.0.	07613327599633

Dear Customer,

Stryker has initiated a voluntary correction for the application software listed in Table 1, intended to be deployed on Mako 3.0, part number 209999, and Mako 3.1, part number 219999, systems. The intent of this letter is to list all known hazards and harms potentially associated with the below noted issue and list the risk mitigation workflow to eliminate the potential hazards.

Issue

Stryker has discovered specific to the applications listed in Table 1 an increase in the Software Error #3 (SE3) error code when a Mako System shutdown or a Mako System restart is not performed prior to switching between applications (i.e. TKA to THA).

Potential Hazards

In the event of the Mako System generating 'Software Error #3', the following potential hazards have been identified:

- Loss or deterioration of robotic system function.
- Delay in surgery to:
  - Exit and reenter the application page;
  - Restart the Mako Arm software;
  - Obtain a replacement Mako Robotic System, or
  - Convert to manual surgery.

Potential Harms

Complications associated with extended surgery.

Risk Mitigation

- **System Restart**: Once an application has been launched a Mako System shutdown or a Mako System restart prior to launching another application eliminates occurrence of the issue.

- **Restart Arm Software**: Restarting the Mako Arm software prior to the start of a case or after the occurrence of Software Error 3 (SE3) eliminates occurrence of the issue. The "Restart Arm Software" option is accessible through the "Robot Arm Utilities".

Recommendations for patient

Patients should continue to be followed per the normal protocol established by his or her surgeon(s). There are no recommended changes to the frequency of the standard follow-up care protocol. Additional or more frequent patient monitoring or follow up may be required in accordance with clinical judgment.

Actions needed

Our records indicate that you may have received the affected product(s). It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions:

1. Please inform users of this Urgent Medical Device Correction and forward this notice to all individuals who need to be made aware.
2. Maintain awareness of this notice internally until all required actions have been completed within your facility.
3. Utilize the above risk mitigation steps to prevent the occurrence of software error #3 or to clear software error #3 if it is generated by the Mako Robotic System.
4. Inform Stryker if any of the subject devices have been distributed to other organizations.
    a. Please provide contact details so that Stryker can inform the recipients appropriately.
    b. If you are a Distributor, note that you are responsible for notifying your affected customers.
5. Please inform Stryker of any serious incidents concerning the use of the subject devices.
    a. Please comply with any local laws or regulations concerning the notification of serious incidents to your National Competent Authority.
6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete it even if you no longer have any of the subject devices in your physical inventory.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA.

We request that you respond to this notice within 7 calendar days from the date of receipt.

Please respond even if you do not have a record of receiving affected inventory. This will enable us to update our records and negate the need to send unnecessary reminder letters.
Your timely response will enable us to update our records and negate the need to send reminder notices.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:
Position:
e-mail: xxxxxxx@stryker.com

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,

RA2024-3598242
Business Reply Form - response required

Urgent Field Safety Notice: RA2024-3598242

May xx, 2024

Product Name:	**Total Knee Arthroplasty (TKA) 2, Total Knee Arthroplasty (TKA) 1, Partial Knee Arthroplasty (PKA) 3, Total Hip Arthroplasty (THA) 4.0, 4.1 on Mako 3.0, 3.1.**
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700002190743-05	TKA 2.0.es.1 + PKA 3.0.2.es.1 + THA 4.0.	07613327599633

I have received the **Urgent Medical Device Correction** letter from Stryker dated May XX, 2024, stating that the company has initiated a voluntary correction on the above referenced affected products and I acknowledge receipt of the risk mitigation steps required if software error #3 is generated by the Mako Robotic System.

Please complete the form even if you do not have inventory. This will preclude us from following up.

Customer information

Customer name: _____

Name of person completing this form: _____ Title: _____

Direct phone number: _____ Email _____

Address: _____ City: _____

Postal code: _____ Country:_____

If you have further distributed subject devices, please provide the information below:

Facility Name	Facility Address	Contact person	Product code	Lot number	Qty

I have read and understand the instructions provided and acknowledge receipt of the subject Field Safety Notice. I also agree to further distribute and communicate this important information from this letter to those to whom I distributed any of the subject devices noted in this letter.

Name (print): _____ Signature: _____ Date: _____

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL XXXXXX@stryker.com