

**URGENT:
MEDICAL DEVICE RECALL****Dual Mobility Insert Neck**

Attn: Health Care Professionals, Operators of Medical Devices, Distributors

Recall Number: 2758599

08 25, 2021/ 25 08 2021

Product affected

Catalog number	Product description	Lot number(s)
9303131	Dual Mobility Insert Neck M, CoCr, Polyethylene	86898
9303131	Dual Mobility Insert Neck M, CoCr, Polyethylene	86896
9303141	Dual Mobility Insert Neck L, CoCr, Polyethylene	86899

Dear Customer,

The purpose of this notification is to advise you that Stryker GmbH (Trauma & Extremities Division) is conducting a voluntary recall regarding three specific lots of Dual Mobility Insert Neck. Please refer to the table above for catalogue and lot numbers that were identified as shipped to distributors and end users.

Reason for Voluntary Recall

Stryker has identified a mismatch between the packaging label (size M) and the actual device packed inside (size L). The internal investigation reveals that the packaging Dual Mobility Insert Neck Size M can contain a Dual Mobility Insert Neck Size L, and vice versa.. One related complaint for the concerned products has been received from the market.

Risk to Health

This issue is highly detectable for the user; therefore, the risk for the patient's health is generally low. A check can be performed intraoperatively on whether the optimal sized device is present in the operating room, which should then be used, resulting in a prolongation of surgery.

The patient is at a higher risk when a change in surgery method is considered when the correct sized implant is not available, which can also lead to a prolongation of surgery.

If the correct size is not available and a proper alternative is not at hand, it can be considered to use the incorrect size in the patient. Using an incorrect size may lead to bone/ joint damage for the patient and functional loss over time, which could lead to revision surgery.



Mitigating Factors

Other products with the appropriate size might be available intraoperatively.
The wrong size of the product is easily recognizable for the user.

Recommendations for patients already treated with an affected device

With regards to cases where a device of a different size was implanted, we suggest that physicians continue the monitoring of those patients per their standard clinical protocols.

Potential Alternative Products

The removal of the products is lot specific, and devices not impacted by this issue can be ordered and are available.

Actions to be taken by the Customer/User:

Our records indicate that you may have received one or more of the subject devices. 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. Inform individuals within your organization who need to be aware of this device recall.
2. Immediately check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility. **Response is required, even you may not have any physical inventory on site anymore.**
3. Quarantine and discontinue use of the recalled devices.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility
5. 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.
6. Complete the attached customer response form (acknowledgement 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 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 Action.

We request that you **respond to this notice within 7 calendar days** from the date of receipt. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions. We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

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:

Email

Telephone

Fax

Yours Sincerely,

Signature

Business Reply Form

Account number:
Account name:
Account Address:

Dual Mobility Insert Neck

Recall Number: 2758599

08 25, 2021/ 25 08 2021

Please complete and sign this form. Email the completed form to <xxx@stryker.com> by <MMM DD YYYY>.

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product	Lot number(s)	Quantity on hand*
9303131	Dual Mobility Insert Neck M, CoCr, Polyethylene	86898	
9303131	Dual Mobility Insert Neck M, CoCr, Polyethylene	86896	
9303141	Dual Mobility Insert Neck L, CoCr, Polyethylene	86899	

*If all devices have been used and no affected devices are available for return please enter 0 (zero).

Form completed by:

Printed Name		Title	
Signature		Phone	
Date		Email	

If you have further distributed any affected product, please indicate to whom:

Product(s) Distributed		Quantity Distributed	
Facility Name		Contact Person	
Full Address			