stryker

URGENT:
MEDICAL DEVICE Field Safety Notice

InSpace Implant - CE Mark missing from a label

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

Field Action Number: RA2023-3471621

December 2023

Product affected

Catalog number	GTIN	Product description	Lot numbers
0128	17290013396027	InSpace Implant – Medium	From June 13, 2023 until June 19, 2023 **Please see Attachment B for affected lots**

The purpose of this notification by Stryker Endoscopy, on behalf of Ortho-Space Ltd., is to advise you that an advisory notice of the products listed above is being conducted.
Please refer to the table above and to Attachment B for the catalog and lot numbers that have been identified as shipped to distributors and end users.

Product description

The InSpace™ Implant is a biodegradable device intended for implantation into the subacromial space of patients diagnosed with Rotator Cuff Syndrome. The device is provided sterile and is intended for single use only. The InSpace™ Implant biodegrades naturally (within 12 months of implantation). The implantation procedure is performed under general, regional, or local anesthesia as outpatient day surgery, or in a hospital Operating Room environment. An arthroscopic, mini-open or open technique is used by an orthopedic surgeon specifically trained in use of the device.

Product issue

Product that has been manufactured and packaged from June 13, 2023 until June 19, 2023 does not fully meet the CE Marking requirement. The CE mark is missing from the device sterile pack label. Please note, the outer packaging contains the CE Mark.
The impacted devices may continue to be used.

Potential risks

The devices themselves are conforming and the requirements for the product to have the CE mark & clearance have been completed. The CE mark is still present on the outer box and shipping box. There is not a potential for harm as there is no change in the intended device use or surgical technique.

Actions needed by Customers and Distributors

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. Immediately check your internal inventory to locate the product listed on the attached business reply form.
2. Review the product issue and risks as communicated in this Safety Notice & communicate the issue and risks as appropriate in your organization. We remind you that **the impacted devices may continue to be used.**
3. Return the enclosed business reply form by email to confirm receipt of this notification.
    a. **Response is required, even if you may not have any physical inventory on site anymore.** 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.
4. Maintain awareness of this communication internally until all applicable inventory is consumed.
5. If you have further distributed the affected product, please notify the applicable parties at once about this field action. You may copy and distribute this notification letter.
    a. If possible, inform us if any of the subject devices have been distributed to other organizations. Including contact details so that we can inform the recipients appropriately.
    b. If you are a distributor, note that you are responsible for notifying your affected customers.
6. Please inform us of any adverse event and/or report them to the Health/Competent Authorities in accordance with current regulations.

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: Jamie Harvey
Position: Senior specialist, Post-Market Surveillance
email: Jamie.harvey@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 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 and your expectations, remain on the market.

Sincerely,

Nina Goddard
Regulatory Affairs and Quality Assurance

Business Reply Form

InSpace Implant - CE Mark missing from a label

Field Action Number: RA2023-3471621

December-2023

Please complete and sign this form. Email the completed form to **nby_qara@stryker.com**

Note: Your signature indicates that you have received and understand the enclosed notification.
No product return is necessary.

Catalog number	Product description	Lot numbers	Quantity on Hand
0128	InSpace Implant – Medium	Please see Attachment B for affected lots	

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Hospital name		**Address**	
Date		**Email**	

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

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

☐ **I have read and understand the instructions provided and acknowledge receipt of the FSN**

☐ **I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.**

Name (print)_____**Signature**_____**Date** _____

Attachment B – Affected Lots

MEDICAL DEVICE ADVISORY NOTICE

120623-02	140623-05	180623-03
120623-03	140623-07	180623-04
120623-04	140623-08	180623-05
120623-06	140623-09	180623-06
120623-07	140623-10	180623-07
130623-02	150623-02	180623-08
130623-03	150623-03	180623-09
130623-04	150623-04	180623-11
130623-05	150623-05	180623-12
130623-06	150623-07	180623-13
130623-07	150623-08	180623-14
130623-08	150623-09	190623-02
130623-10	150623-14	190623-03
130623-11	150623-15	190623-04
130623-12	150623-16	190623-05
130623-13	150623-18	190623-06
130623-14	150623-19	190623-08
140623-02	150623-20	190623-09
140623-03	150623-21	
140623-04	180623-02	