stryker

URGENT:

MEDICAL DEVICE RECALL

Cartiva Synthetic Cartilage Implant

Attn: Surgeons and Hospital Risk Managers

Recall Number: RA2024-3794726

31-October-2024

Product affected

Catalog Number	GTIN	Product Description	Lot Numbers	Distribution Dates
CAR-06, CAR-06-AUS, CAR-06-BRZ, CAR-06-US	00852897002168 00852897002557 00852897002687 00852897002328	Cartiva Synthetic Cartilage Implant (SCI) 6mm, 8mm, 10mm, 12mm, and 15mm respectively	All lots	July 2016 to October 2024
CAR-08, CAR-08-AUS, CAR-08-BRZ, CAR-08-US	00852897002175 00852897002564 00852897002694 00852897002021			
CAR-10, CAR-10-AUS, CAR-10-BRZ, CAR-10-US	00852897002182 00852897002571 00852897002700 00852897002038			
CAR-12, CAR-12-AUS, CAR-12-BRZ, CAR-12-US	00852897002939 00852897002335			
WDG-10	00852897002489			
WDG-15	00852897002496			
CMC-08, CMC-08-BRZ	00852897002274 00850013558063			

Stryker, on behalf of Cartiva Inc.,[1] is conducting a field safety corrective action regarding the Cartiva Synthetic Cartilage Implant (SCI) device. The purpose of this notification is to provide updated post market safety data regarding Cartiva SCI and to provide instructions for the return of such devices. Please refer to the table above for catalog numbers within the scope of this notice.

Product description

The Cartiva SCI device is comprised of an organic hydrogel polymer made of polyvinyl alcohol and saline. Cartiva SCI has a high-water content, and its elastic and compressive mechanical properties are similar to articular cartilage. The device is intended to replace focal areas of painful damaged cartilage, thereby reducing pain and maintaining range of motion.

Cartiva SCI is manufactured in multiple sizes for treatment. This product is single use and provided sterile.

Potential risks

Stryker has become aware of recently published data and post market reports indicating that patients implanted with Cartiva SCI may experience a higher-than- expected occurrence rate when compared to data submitted in the 2016 PMA of the following documented hazards: revision, removal, implant subsidence, displacement, pain, nerve damage or fragmentation. Cartiva SCI devices have been observed in some cases to be revised/removed at higher rates than previously observed in the initial Cartiva SCI premarket and post-approval studies.

[1] Cartiva, Inc. was a wholly owned subsidiary of Wright Medical Group NV. Stryker acquired Wright Medical Group NV in 2020.

Patient recommendation

1. Continue to follow patients treated with an impacted product for new or worsening symptoms of pain, difficulty walking, skin reactions, stiffness, swelling, or weakness of the joint, consistent with your follow up protocols. Per the Cartiva Instructions for Use: the long-term effects of cartilage replacement are not known; and the clinical and medical status of each patient should be considered when treating Cartiva patients.
2. To help minimize complications, reference the information in the Instructions for Use and the information included in this notification. Per standard practice, continue to discuss all potential risks identified for Cartiva SCI and discuss the benefits and risks of all relevant treatment options with your patients.

Actions needed

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, which highlights identified post market risks. We therefore request that you read this notice carefully and complete the following actions.

1. Check your internal inventory to locate the products listed on the attached business reply form, remove them from their point of use, and isolate/quarantine the unit(s).
    a. Sign and return the enclosed Business Reply Form by email to Amandip.auluck@stryker.com to confirm receipt of this notification/documenting product segregation.
    b. **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 it even if you no longer have any of the subject devices in your physical inventory.
2. Upon receipt of the completed Business Reply Form, Stryker will contact you to arrange for the return of your product(s).
3. Share and maintain awareness of this communication in your practice with individuals that have or will use the Cartiva SCI until all required actions have been completed within your facility.

4. If you have further distributed the affected product, please notify the applicable parties about this notice. 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.
3. Please inform us of any adverse events 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: Amandip Auluck
Position: Associate Manager, PMS
email: Amandip.auluck@stryker.com

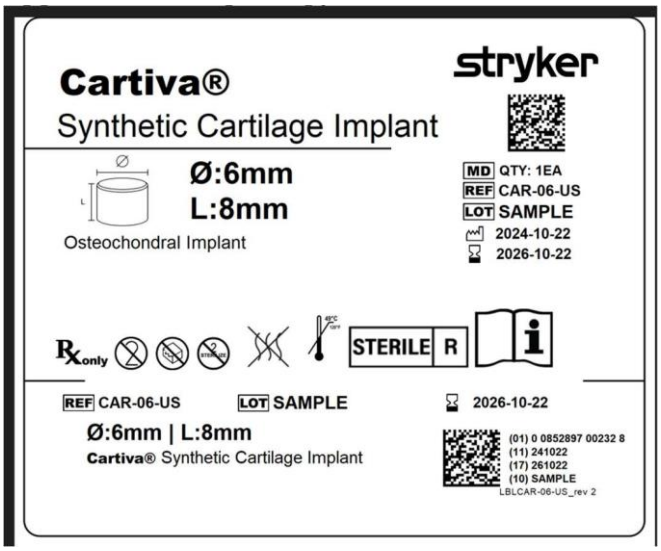
In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

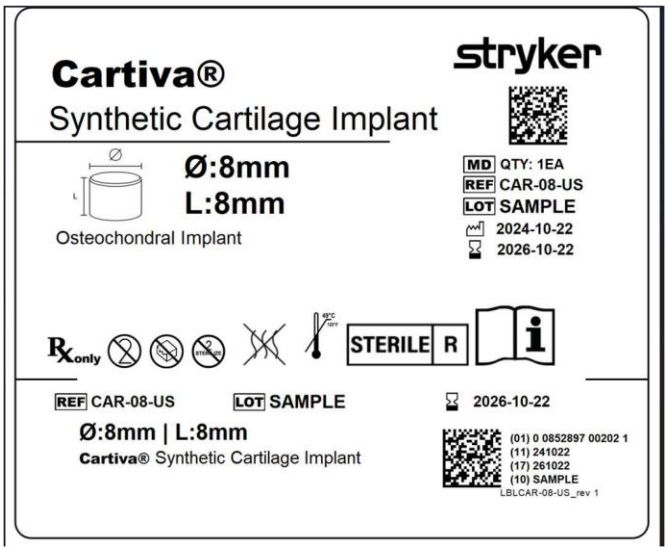
On behalf of Stryker, we thank you sincerely for your help and support in completing this action and regret any inconvenience caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain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

Sincerely,

Nina Goddard
Regulatory Affairs and Quality Assurance

Appendix A: Sample Copy of Labels





Business Reply Form

Cartiva Synthetic Cartilage Implant

Recall Number: RA2024-3794726

31-October-2024

Please complete and sign this form. Email the completed form to Amandip.auluck@stryker.com

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

Catalog number	Product Name	Lot Number(s)	Quantity on Hand, To be returned
CAR-06, CAR-06-AUS, CAR-06-BRZ, CAR-06-US	Cartiva Synthetic Cartilage Implant (SCI) 6mm		
CAR-08, CAR-08-AUS, CAR-08-BRZ, CAR-08-US	Cartiva Synthetic Cartilage Implant (SCI) 8mm		
CAR-10, CAR-10-AUS, CAR-10-BRZ, CAR-10-US	Cartiva Synthetic Cartilage Implant (SCI) 10mm		
CAR-12, CAR-12-AUS, CAR-12-BRZ, CAR-12-US	Cartiva Synthetic Cartilage Implant (SCI) 12mm		
WDG-10	Cartiva SL 15mm		
WDG-15	Cartiva SL 15mm		
CMC-08, CMC-08-BRZ	Cartiva Synthetic Cartilage Implant (SCI) 8mm		

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

Form completed by:

Hospital Name		**Address**	
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			