stryker

URGENT:

MEDICAL DEVICE Recall

Cartiva Synthetic Cartilage Implant

Attn: Surgeons and Hospital Risk Managers

Advisory Notice Number: PFAA 3775099/PFAE 3794726

31-October-2024

Product affected

Catalog number	Primary Device Identifier	Product description	Lot number(s)	Distribution Dates
CAR-06-US CAR-08-US CAR-10-US CAR-12-US	00852897002328 00852897002021 00852897002038 00852897002335	Cartiva Synthetic Cartilage Implant (SCI) 6mm, 8mm, 10mm, 12mm, respectively	All lots	July 2016 to October 2024

Stryker, on behalf of Cartiva Inc.,[1] is conducting a safety notification regarding the Cartiva Synthetic Cartilage Implant (SCI) device. The purpose of this notification is to provide updated postmarket 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 in the first metatarsophalangeal (MTP) joint.

The Cartiva SCI, a molded cylindrical implant, is placed into the metatarsal head in the first metatarsophalangeal joint via press-fit implantation.

Cartiva SCI is manufactured in multiple sizes for treatment of first metatarsophalangeal joint osteoarthritis - 6mm, 8mm, 10mm, and 12mm. 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

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

observed in some cases to be revised/removed at higher rates than previously observed in the initial Cartiva SCI premarket and post-approval studies.

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 postmarket risks. We therefore request that you read this notice carefully and complete the following actions.

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 big toe 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 for first metatarsophalangeal joint osteoarthritis with your patients.
3. 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).
4. 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 it even if you no longer have any of the subject devices in your physical inventory.
5. Return all affected devices available at your location to the following address
    Product Field Action Product Return
    ATTN: Return PFAA 3775099/PFAE 3794726
    Memphis-Arlington Rd
    Arlington, TN 38002
    a. When you return any physical items on hand, please include a copy of this field action letter, if possible, and write "ATTN: Return PFAA 3775099/ PFAE 3794726" on the box to help identify the return.
    b. If possible, provide tracking once the return is initiated.
6. 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.
7. 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.
8. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations. For questions or concerns, please contact fieldaction@stryker.com.

If adverse reactions or quality issues are experienced with the use of this product, please report the matter to:

- Stryker's Trauma & Extremities division complaint dept. [traumaextremitiescomplaints@stryker.com]; or
- the FDA MedWatch Serious Injury Reporting Program:
    - Online: By completing and submitting the report online at: www.fda.gov/medwatch/report.htm

- Regular mail or fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

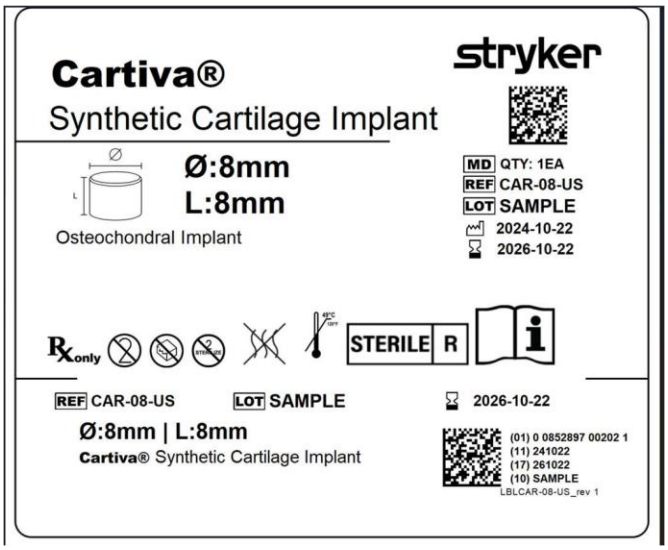
On behalf of Stryker, we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that post market surveillance will continue to monitor the device performance and will update the instructions if the data supports further risk mitigation. Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

Sincerely,

Meghan Wells
Product Field Action Manager
Stryker
Trauma & Extremities
meghan.wells@stryker.com

Once again, please email fieldaction@stryker.com the enclosed acknowledgement of this notification.

Appendix A: Sample Copy of Labels



Business Reply Form

Account name:
Account Address:

Attn: Surgeons and Hospital Risk Managers
Advisory Notice Number: PFAA 3775099/PFAE 3794726

31-October-2024

Please complete and sign this form. Email the completed form to fieldaction@stryker.comby **07-November-2024**.

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, To be returned
CAR-06-US	Cartiva Synthetic Cartilage Implant (SCI) 6mm		
CAR-08-US	Cartiva Synthetic Cartilage Implant (SCI) 8mm		
CAR-10-US	Cartiva Synthetic Cartilage Implant (SCI) 10mm		
CAR-12-US	Cartiva Synthetic Cartilage Implant (SCI) 12mm		

*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			