Class 2 Device Recall Cartiva

See Related Information[22]

Date Initiated by Firm	October 31, 2024
Date Posted	December 04, 2024
Recall Status[1]	Open[3], Classified
Recall Number	Z-0598-2025
Recall Event ID	95661[23]
PMA Number	P150017[24]
Product Classification	Prosthesis, metatarsophalangeal joint cartilage replacement implant[25] - **Product Code** PNW[26]
Product	Cartiva Synthetic Cartilage Implant (SCI) Catalog: CAR-06-US (6mm), CAR-08-US (8mm), CAR-10-US (10mm), CAR-12-US (12mm)
Code Information	Catalog/UDI-DI: CAR-06-US/00852897002328, CAR-08-US/00852897002021, CAR-10-US/ 00852897002038, CAR-12-US/00852897002335. All lots Distributed from July 2016 to October 2024.
Recalling Firm/ Manufacturer	Cartiva, Inc 6120 Windward Pkwy Ste 220 Alpharetta GA 30005-4185
For Additional Information Contact	Meghan Wells 901-201-9298
Manufacturer Reason for Recall	Patients implanted with synthetic cartilage implant, may experience a higher-than expected occurrence rate of the following hazards: revision, removal, implant subsidence, displacement, pain, nerve damage or fragmentation.
FDA Determined Cause [2]	Device Design
Action	On 10/31/24 recall notices were mailed or emailed to customers asking them to do the following: 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 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 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 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, isolate/quarantine the

unit(s), and return.
4) Share and maintain awareness of this communication in your practice with until all required actions have been completed within your facility.
5) If you have further distributed the affected product, please notify the applicable parties about this notice. You may copy and distribute this notification letter.
6) 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.
7) If you are a distributor, note that you are responsible for notifying your affected customers.
8) Complete and return the response form via email to fieldaction@stryker.com

For questions or concerns, contact fieldaction@stryker.com.

Distribution	Worldwide - US Nationwide distribution in the states of CO, CT, FL, IL, MI, MS, NY, OH, RI, UT, VA, AL, AR, AZ, CA, IA, ID, IN, KS, KY, MA, MN, MO, MT, NC, NE, NM, NV, OK, OR, PA, TN, TX, WA, WI and the countries of Australia, Austria, Brazil, Canada, Chile, Cyprus, Finland, France, Germany, Hong Kong, Ireland, Israel, Italy, Kuwait, Latvia, Lebanon, Netherlands, New Zealand, Panama, Poland, Saudi Arabia, Singapore, Slovenia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

PMA Database	PMAs with Product Code = PNW[29]

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22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=95661
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28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
29. /scripts/cdrh/cfdocs/cfPMA/pma.cfm?start_search=1&productcode=PNW&applicant=Cartiva%2C%20Inc

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=95661
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