### Class 2 Device Recall Collagen Meniscus Implant

**Date Initiated by Firm**  
January 25, 2018

**Create Date**  
March 12, 2018

**Recall Status**  
Open, Classified

**Recall Number**  
Z-0974-2018

**Recall Event ID**  
790302

**Product Classification**  
Scaffold, partial medial meniscal defects extending into the red/white zone, resorbable bovine collagen

**Product**  
CMI (Collagen Meniscus Implant) device, Ivy Sports Medicine's collagen-based meniscus implant

**Product Usage**  
The CMI device, Ivy Sports Medicine's collagen-based meniscus implant, is comprised primarily of bovine type I collagen (nominally 99%) derived from tendon and small quantities of glycosaminoglycans (GAGs: chondroitin sulfate and sodium hyaluronate). The device functions as a resorbable scaffold that is replaced by the patient's own tissue. The CMI device is designed to function as an absorbable template to facilitate host meniscus tissue regeneration in patients who have an irreparable meniscus tear or loss of meniscus tissue. The CMI meniscus tissue through the implant's absorption and replacement by patient's native tissue.

**Code Information**  

**Recalling Firm/Manufacturer**  
Stryker Corporation  
5900 Optical Ct  
San Jose CA 95138-1400

**Manufacturer Reason for Recall**  
The recalled products were shipped without the required temperature control packaging, therefore could potentially have been exposed to elevated temperatures during transit.

**FDA Determined Cause**  
Packaging

**Action**  
The international Stryker site was notified by email on 1/25/2018. Customers are instructed to: 1. Inform individuals within your organization who need to be aware of this device removal. 2. Review Part Numbers (4600, 4601, 4607, and 4812) for affected lot numbers. Please determine if you have the affected product in stock. Response is required. 3. If no product is found, notify your local Stryker office. 4. If you do have product, segregate the product and call your local Stryker office to arrange for product return and issuance of credit.

**Quantity in Commerce**  
155 devices

**Distribution**  
Netherlands

**Total Product Life Cycle**  
TPLC Device Report

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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=161212  
3/19/2018