FDA

Class 2 Device Recall Collagen Meniscus Implant

See Related Information[22]

Date Initiated by Firm	January 25, 2018
Create Date	March 12, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0974-2018
Recall Event ID	79030[23]
Product Classification	Scaffold, partial medial meniscal defects extending into the red/white zone, resorbable bovine collagen[24] - **Product Code** OLC[25]
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	Serial/Lot Number(s) Affected:, 4600: 15J456;, 4601: 16A463, 16G470, 17F510;, 4607: 16A461, 16D465, 16E467, 16F468, 17E506, 17E507;, 4612: 16A458, 16A459, 17D489, 17E503, 17E504
***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 [2]	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 4612) 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*[26]