Class 2 Device Recall HARVEST TERUMOBCT, GCP10 Graft Delivery Pack

Date Initiated by Firm: October 20, 2017
Create Date: November 08, 2017
Recall Status: Open, Classified
Recall Number: Z-0075-2018
Recall Event ID: 78309
510(K) Number: K043264
Product Classification: Syringe, piston - Product Code FMF

Product: HARVEST TERUMOBCT, GCP-10 Graft Delivery Pack, REF 51449, Rx Only, STERILE EO
Harvest Graph Delivery System is a disposable pack that takes the cell concentrate created while using the BMAC Procedure Packs and allows for hydration of bone graft material for application to the sites doctors deem necessary

Code Information: UDI Case 35020583514493, Each 05020583514492, Batch/Number: 04A9925, Exp. 01MAR2018, 05A9928, Exp. 01MAY2019, 06A9948, Exp. 01JUN2019, 06A9978, Exp. 01JUN2019, 08A9950, Exp. 01AUG2019

Recalling Firm/Manufacturer: Terumo BCT, Inc.
1081 1 W Collins Ave
Lakewood CO 80215-4440

Manufacturer Reason for Recall: Certain lots of the Harvest Graft Delivery System GDP-10 Procedure Packs may have a lack of a seal on the inner pouch.

FDA Determined Cause: Packaging

Action: Harvest Terumo sent a Voluntary Medical Device Product Recall letter dated October 20, 2017, to all affected customers. The letter stated the following: "ACTIONS REQUIRED FOR HEALTHCARE PROVIDERS AND DISTRIBUTORS 1. For product shelved in the original case (white box), or kit components, examine the outer label for catalog/lot numbers as shown in Figure A above. 2. Please return any unused affected product in your inventory. Please contact your local Terumo BCT Customer Support Center at 1.877.3.FYI.BCT (U.S. toll-free 1.877.339.4228) or +1.303.231.HELP (+1.303.231.4357), Terumo BCT Europe N.V. at +32.2.715.0590 or your local Terumo BCT representative, and Terumo BCT will issue a return goods authorization for product return. 3. Continue to use unaffected Harvest Graft Delivery System GDP-10 Procedure Packs in accordance with the instructions for use. 4. Distribute this notification to all Harvest Graft Delivery System GDP-10 Procedure Pack users within your organization. 5. IMPORTANT: Complete the attached acknowledgement form and return it by fax or email to Harvest Terumo BCT by 15 November 2017. Your return of the acknowledgement form is critical so we can confirm that you have received the recall notice. 6. As a reminder, please comply with the recommended practices for maintaining a sterile field as recommended by the Association of periOperative Registered Nurses (AORN) and refer to the instructions for use." Customers with questions, please contact your Terumo BCT representative or your regional Customer Support Center. U.S. Toll-Free: 1.877.3.FYI.BCT (394 228) U.S.: +1.303.231.HELP (4357) Canada Toll-Free: 1.877.722.8411 Europe: