Class 2 Device Recall HARVEST TERUMOBCT, GCP10 Graft Delivery Pack

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Date Initiated by Firm	October 20, 2017
Create Date	November 08, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0075-2018
Recall Event ID	78309[23]
510(K)Number	K043261[24]
Product Classification	Syringe, piston[25] - **Product Code** FMF[26]
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. 10811 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 [2]	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: