FDA

Class 2 Device Recall Lactosorb RapidFlap

See Related Information[22]

Date Initiated by Firm	April 05, 2018
Create Date	May 07, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-1705-2018
Recall Event ID	79987[23]
510(K)Number	K003281[24]
Product Classification	Plate, bone[25] - **Product Code** JEY[26]
Product	Lactosorb RapidFlap, bone plate, Model No. 915-0020 The RapidFlap LS Cranial Fixation System is indicated for use in pediatric craniotomy flap fixation.
Code Information	Lots 013040 013050 013060 013070 013080 013090 013100 013120 013130 013140 013150 025720 038090 038100 038 110 038120 038130 038160 038170 038200 038210 038220 038230 054050 054070 054080 054090 054110 075970 089200 089210 108270 108280 110830 110840 110860 110870 110900 110910 110920 110930 110940 110950 11 0980 110990 111000 111010 111020 111030 111070 144270 144280 147300 147350 165500 165510 173190 17321 0 173220 173230 173260 173270 173280 173290 173300 173320 173340 218330 218340 255340 255370 264730 2 64750 264760 264770 264780 291390 291400 293380 293390 293400 293410 293470 293480 315430 315450 3154 60 315470 315500 315520 315530 315540 315560 331750 331800 331820 331840 331850 331880 335580 335590 335600 335610 348850 348860 348870 379760 379800 379810 379870 379920 389450 389460 389470 404640 404 650 404660 443260 443270 443280 444360 444380 444390 444400 444420 456140 456340 456350 456370 467210 467220 469270 469280 469300 469310 471700 471720 471760 479790 479810 479820 479840 480560 480620 48 0660 508530 508540 525820 525830 525850 525860 543340 543370 543380 543390 543400 550440 550450 55046 0 550470 559890 559900 559910 559920 559930 559950 559960 559980 559990 562220 562230 562240 562260 5 63380 563390 563400 581190 581200 669150 669160 669180 669190 669200 675730 676640 676650 676720 6767 30 676740 676750 676760 676780 676790 676800 676820 676830 676840 676850 691060 691100 691110 691230 691240 691250 691290 691300 691320 701210 701220 701230 701240 701250 701270 701280 715290 715300 715 310 715320 715330 715340 788400 788410 788420 788430 788440 792970 792990 793000 793010 793050 793080 793090 793100 810070 810100 810110 835080 835090 835100 835110 835120 835140 875960 876060 876070 87 6090 876100 876110 876120 876130 876150 898160 898170 898200 898240 898260 898320 898360 914430 91445 0 914460 930760 930780 930810 930840 930850 930860 930870 946980 947030 947070 991710 991740 991760 9 91770 991780 997070 997110 997120 997130 997150 997160 997170 997190 997260 997300 997320 997340 9973 60 997390 997400 997410
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	411 Technical Services 574-371-3071
Manufacturer Reason for Recall	The recalling firm has confirmed that the Outer Plate component exhibits an excessive chamfer on the threading after deburring operations. This excessive chamfer results in non-conforming product where the threads of the outer plate component have limited to no engagement with the post component.
FDA Determined Cause [2]	Process control
Action	Zimmer Biomet sent an Urgent Medical Device Recall letter dated April 5, 2018, to Distributors, Sales Representatives, and Distribution Managers. A separate recall letter was sent to Risk Managers on the same date. Consignees were informed of the product issue and risk of non-functioning device and delays in surgery. All parties were instructed to review the notice, locate and quarantine affected product in inventory, return all affected product with a completed return form and mark "RECALL" on the outside of returned cartons, and return the completed customer response form. If you have further questions or concerns regarding this recall, please call (904)741-4400 extension 9133 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of operating hours will receive a voicemail prompt. For further questions, please call (574) 371-3071.
Quantity in Commerce	13175
Distribution	worldwide Distribution - US Distribution to the states of : CA, FL, MO, NC, SC, TX, and WI., and to the countries of :