Class 2 Recall NaturalKnee System Patella Bushings

See Related Information[22]

Date Posted	September 04, 2014
Recall Status[1]	Open
Recall Number	Z-2582-2014
Recall Event ID	68655[23]
Premarket Notification 510(K) Number	K073286[24]
Product Classification	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer[25] - **Product Code** JWH[26]
Product	Natural-Knee System Patella Bushings. Orthopedic surgical instrument. Part Number 6290-00-690. Per the Natural-Knee II Primary System Surgical Technique, the patellar bushing is placed on the cut surface of the patella and used as a guide for the matching size patella cutter.
Code Information	Part Number 6290-00-690. Lots Manufactured by Zimmer: 1327524, 1339783, 1344879, 1346702, 1361955, 1368604, 1382204, 1386058, 1388164, 1429297, 1437553, 1441291, 1441897, 1451867, 1465171, 1470848, 1470849, 1472371, 1516851, 1530342, 1538118, 1547978, 1555574, 1560246, 1565076, 1583036, 1593277, 1594775, 1595926, 1598696, 1601040, 1606098, 1606511, 170454, 171324, 173342-09, 173342-10, 173342-2, 173342-3, 173342-9, 601863, 60319687, 60339959, 60415511, 60457440, 60539669, 60621386, 60732865, 60929928, 60946367, 60951770, 60961665, 60970630, 60994794, 61028392, 61080335, 61099775, 61171949, 61171950, 61208215, 61247557, 61444751, 61580595, 61732750, 61905939, 61924234, 61999723, 62156016, 62190266, 62220910, 62281030, 62298031, 62400882, 62597910, 640601, 669401, 691488, 741824, 783833, 784261, 789465, 789470, 791158, 796231, 796408, 802258, 803823, 810082, 825931-1, 825931-2, 831825-2, 863224-1, & 869009. Lots Manufactured by Centerpulse: 93302, 95066, 95067, 95068, 95069, 97240, 97538, 97539, 99928, 1142822, 1147427, 1148798, 1151284, 1151286, 1151287, 1151288, 1153331, 1155442, 1155443, 1156670, 1156671, 1156672, 1157975, 1163692, 1163693, 1163694, 1163695, 1179240, 1179241, 1179242, 1179243, 1179244, 1190722, 1190723, 1190724, 1190725, 1190726, 1204516, 1204517, 1204518, 1204519, 1204537, 1204538, 1204539, 1204540, 1204541, 1204542, 1226013, 1238476, 1238477, 1238478, 1238479, 1238480, 1268798, 1268799, 1276896, 1276897, 1276898, 1276899, 1276900, 1307948, 1307949, 1312646, 1321254, 1324202, 1327524, 1332586, 1339783, 1340512, 1344879, 1346702, 1351210, 1361955, 1368604, 1373550, 1382204, 1386058, 1388164, 1429297, 1437553, 1441291, 1441897, 1451867, 1465171, 1470848, 1470849, 1472371, 1516851, 1530342, 1534065, 1538118, 1547978, 1555574, 1560246, 1565076, 1583036, 1583719, 1583720, 1593277, 1594775, 1595926, 1598696, 1601040, 1606098, & 1606511.
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
Manufacturer Reason for Recall	Zimmer received a trend of complaints indicating corrosion of product.
FDA Determined Cause [2]	DESIGN: Device Design

Class 2 Recall NaturalKnee System Patella Bushings

See Related Information[22]

Date Posted	September 04, 2014
Recall Status[1]	Open
Recall Number	Z-2585-2014
Recall Event ID	68655[23]
Premarket Notification 510(K) Number	K073286[24]
Product Classification	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer[25] - **Product Code** JWH[26]
Product	Natural-Knee System Patella Bushings Orthopedic surgical instrument. Part Number 6290-00-704. Per the Natural-Knee II Primary System Surgical Technique, the patellar bushing is placed on the cut surface of the patella and used as a guide for the matching size patella cutter
Code Information	Part Number 6290-00-704. Lots Manufactured by Zimmer: 1137602, 1324205, 1331331, 1346218, 1351208, 1368598, 1373552, 1376006, 1382199, 1386059, 1422626, 1426895, 1438006, 1441899, 1475757, 1475758, 1478938, 1493445, 1517176, 1525953, 1525954, 1549263, 1551990, 1554289, 1556787, 1560245, 1596097, 1601264, 1601980, 1606097, 1606956, 170675, 172228, 173342-3, 173342-8, 173342-9, 593336, 597424, 60259011, 60293370, 60305590, 60380932, 60398259, 60607433, 60671091, 60704501, 60744843, 60924671, 60931675, 60946362, 60949827, 60956490, 60961653, 60973615, 60983070, 60987243, 61010771, 61092652, 61099690, 611105, 61132248, 61240154, 61240155, 61513545, 61750140, 62028651, 62130964, 62238170, 62477497, 625041, 689492, 747883, 783836, 784561, 789471, 791165, 796410, 802259, 803825, 825355-1, 825355-2, 831825-1, 863226-1, 863226-2,& 9907272. Lots Manufactured by Centerpulse: 9827, 10406, 95319, 95659, 95660, 95661, 96666, 97909, 97910, 97911, 97918, 97919, 97920, 97921, 97922, 1137602, 1141806, 1142826, 1142827, 1146540, 1147430, 1148802, 1155438, 1155439, 1164234, 1164235, 1164236, 1164237, 1180626, 1180627, 1180628, 1180629, 1180630, 1190942, 1190943, 1190944, 1200830, 1200831, 1200832, 1200833, 1200834, 1200835, 1200836, 1200837, 1200838, 1200839, 1200840, 1232870, 1232871, 1232872, 1232873, 1232874, 1265021, 1265022, 1265023, 1265024, 1265025, 1265026, 1299412, 1299413, 1307097, 1307745, 1307746, 1313080, 1321261, 1324205, 1331331, 1331516, 1340515, 1346218, 1351208, 1353797, 1361953, 1368598, 1373552, 1376006, 1382199, 1386059, 1388166, 1422626, 1426895, 1438006, 1441899, 1475757, 1475758, 1478938, 1493445, 1517176, 1525953, 1525954, 1549263, 1551990, 1554289, 1556787, 1560245, 1583307, 1583622, 1583623, 1594529, 1596097, 1601264, 1601980, 1606097, 1606956, & 1346218-B.
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
Manufacturer Reason for Recall	Zimmer received a trend of complaints indicating corrosion of product.
FDA Determined Cause [2]	DESIGN: Device Design
Action	Zimmer issued an Urgent Medical Device Recall-Lot Specific notification via e-mail/letter

Class 2 Recall NaturalKnee System Patella Bushings

See Related Information[22]

Date Posted	September 04, 2014
Recall Status[1]	Open
Recall Number	Z-2584-2014
Recall Event ID	68655[23]
Premarket Notification 510(K) Number	K073286[24]
Product Classification	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer[25] - **Product Code** JWH[26]
Product	Natural-Knee System Patella Bushings Orthopedic surgical instrument. Part Number: 6290-00-703. Per the Natural-Knee II Primary System Surgical Technique, the patellar bushing is placed on the cut surface of the patella and used as a guide for the matching size patella cutter.
Code Information	Part Number: 6290-00-703. Lots Manufactured by Zimmer: 1324204, 1346689, 1361954, 1371127, 1374460, 1382191, 1386076, 1388163, 1421648, 1440890, 1441119, 1476227, 1476229, 1493832, 1493841, 1516853, 1530324, 1549264, 1549388, 1554288, 1554290, 1560754, 1563440, 1598691, 1598692, 1598693, 1598695, 1601605, 1606099, 1606510, 170675, 172016, 173342-09, 173342-10 , 173342-3 , 173342-5, 173342-9 , 601804, 60278820, 60310873, 60426582, 60541727, 60621363, 60641020, 60728521, 60763272, 60933532, 60936986, 60946365, 60947926, 60954309, 60961655, 60964904, 60970610, 60978734, 60998043, 61004755, 61019426, 61025143, 61037534, 61092670, 61092673, 61092674, 61099693, 61188779, 61208208, 61244656, 61444749, 61588176, 61626531, 61815323, 618303, 61910780, 62007198, 62159771, 62238171, 62298008, 62495684, 672559, 691440, 739625, 751350, 784259, 784516, 786652, 791148, 795930, 802251, 803806, 825358-2, 831816-1, 863218-1, 865553, 866726, & 869004. Lots Manufactured by Centerpulse: 9878, 11486, 95318, 95657, 97415, 98273, 98697, 98698, 98699, 98700, 1142825, 1146539, 1147429, 1155440, 1155441, 1163886, 1163887, 1163888, 1163889, 1180631, 1180632, 1180633, 1180634, 1180635, 1190945, 1190946, 1190947, 1190948, 1190949, 1190950, 1204513, 1204514, 1204515, 1204529, 1204530, 1204531, 1204532, 1204533, 1204534, 1204535, 1204536, 1216592, 1238464, 1238465, 1238466, 1238467, 1238468, 1267379, 1267380, 1267381, 1267383, 1267384, 1267385, 1299603, 1299604, 1306224, 1306225, 1307950, 1307951, 1312647, 1324204, 1331517, 1332138, 1339782, 1340514, 1346689, 1353798, 1361954, 1371127, 1373553, 1374460, 1382191, 1386076, 1388163, 1421648, 1439178, 1440890, 1441119, 1476227, 1476228, 1476229, 1493832, 1493833, 1493841, 1498789, 1503345, 1516853, 1530324, 1533357, 1549264, 1549388, 1554288, 1554290, 1560754, 1563440, 1583518, 1583721, 1583722, 1593708, 1595927, 1598691, 1598692, 1598693, 1598695, 1601605, 1606099, 1606510, & 95658-A.
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
Manufacturer Reason for Recall	Zimmer received a trend of complaints indicating corrosion of product.
FDA Determined Cause [2]	DESIGN: Device Design

Class 2 Recall NaturalKnee System Patella Bushings

See Related Information[22]

Date Posted	September 04, 2014
Recall Status[1]	Open
Recall Number	Z-2583-2014
Recall Event ID	68655[23]
Premarket Notification 510(K) Number	K073286[24]
Product Classification	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer[25] - **Product Code** JWH[26]
Product	Natural-Knee System Patella Bushings. Orthopedic surgical instrument. Part Number: 6290-00-702. Per the Natural-Knee II Primary System Surgical Technique, the patellar bushing is placed on the cut surface of the patella and used as a guide for the matching size patella cutter.
Code Information	Part Number: 6290-00-702. Lots Manufactured by Zimmer: 1324203, 1339203, 1346701, 1363348, 1373979, 1382208, 1385813, 1391253, 1421647, 1437118, 1440906, 1440943, 1451869, 1464915, 1469681, 1470531, 1472373, 1474483, 1538141, 1549267, 1552408, 1554291, 1554292, 1567743, 1598694, 1601263, 1601606, 1606096, 1606957, 170454, 172361, 173342-10, 173342-3, 173342-8, 173342-9, 596146, 597424, 60278535, 60305599, 60319668, 60426581, 60557544, 60712149, 60767845, 60931683, 60946366, 60947929, 60968638, 60970621, 60986924, 60986941, 61025150, 61037537, 61080336, 61080337, 61088939, 61099737, 61099765, 61105152, 61149082, 61240132, 61444750, 61588175, 61799358, 62007189, 62043610, 62123986, 62156012, 62192074, 62216444, 62253081, 62298037, 62304814, 62353344, 625039, 62575710, 640562, 731461, 752886, 783833, 784261, 784530, 789465, 789470, 791153, 791158, 796231, 802256, 803819, 810082, 825360-1, 825360-2, 833061-1, 863221-1, & 869007. Lots Manufactured by Centerpulse: 10249, 95077, 95316, 95317, 95655, 95656, 96228, 97923, 97923, 97924, 97925, 97926, 97927, 97928, 1141805, 1142824, 1146537, 1146538, 1146673, 1154080, 1155982, 1160641, 1164199, 1164200, 1164232, 1164233, 1179234, 1179235, 1179236, 1179237, 1179238, 1190951, 1190952, 1190953, 1190954, 1190955, 1202697, 1202698, 1202699, 1202700, 1202701, 1202702, 1202703, 1202704, 1202705, 1202706, 1204532, 1238469, 1238470, 1238471, 1238472, 1238473, 1238474, 1238475, 1267914, 1268394, 1268395, 1268396, 1268397, 1299414, 1299415, 1299416, 1306226, 1306227, 1308485, 1308486, 1313079, 1324203, 1332585, 1332695, 1339203, 1340513, 1346701, 1351209, 1353798, 1363348, 1371128, 1373979, 1382208, 1382209, 1385813, 1391253, 1421647, 1437118, 1440906, 1440943, 1451869, 1464915, 1469681, 1470531, 1472373, 1474483, 1538141, 1549267, 1552408, 1554291, 1554292, 1567743, 1583624, 1583727, 1594531, 1594583, 1595925, 1598694, 1601263, 1601606, 1606096, 1606957, 1299414-A, 1299419-A, & 95315-A.
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
Manufacturer Reason for Recall	Zimmer received a trend of complaints indicating corrosion of product.
FDA Determined Cause [2]	DESIGN: Device Design