Class 2 Device Recall Stryker AccuLIF PL Cages

Recall Date	September 12, 2016
Recall Status[1]	Open
Recall Number	Z-2786-2016
Recall Event ID	74931[23]
510(K)Number	K132505[24] K143616[25] K141217[26]
Product Classification	Intervertebral fusion device with bone graft, lumbar[27] - **Product Code** MAX[28]
Product	AccuLIF PL 6-9mm x 11mm x 27mm x 8 Cage, Rx only, Sterile R, Legal The AccuLIF PL Cages are indicated for intervertebral body fusion with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, the AccuLIF PL Cages can be used as in adjunct to fusion in patients diagnosed with degenerative scoliosis. The AccuLIF Pl Cages are always to be used with supplemental internal spinal fixation. Additionally, the AccuLIF PL Cages are to be used with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion.
Code Information	Catalog #400006 Lot #'s 01141604, 01141609, 01141614, 01231506, 01231507, 01271513, 01271514, 02021508, 02021509, 02021510, 02021511, 03271306, 04291403, 04291404, 04301513, 04301514, 04301515, 04301516, 06251504, 06291506, 06291507, 06291508, 06291509, 06291510, 06291511, 07081301, 07201503, 07201504, 07201505, 07201506, 08191309, 08251402, 08251403, 09231504, 09251502, 09281510, 10071307, 10071308, 10141504, 10141505, 10261507, 10261508, 11061405, 11061406, 11061407, 11061408, 11121513, 11121517, 11121520, 11121524, 12151512, 12151518, 12151522 and 12301314
Recalling Firm/ Manufacturer	Howmedica Osteonics Corp. 2 Pearl Ct Allendale NJ 07401-1611
For Additional Information Contact	Mr. Tim Huntington 201-749-8346
Manufacturer Reason for Recall	Since Stryker acquired the AccuLIF product in March of 2014, there have been Product Inquires (PIs) related to the PL implant confirming to have a reduction of height > 1 mm. The current occurrence rate for reported post-operative reduction of cage height (> 1mm) of AccuLIF PL Expandable Cages is approximately 0.47% and has demonstrated a slight upward trend since September 2015.
FDA Determined Cause [2]	Unknown/Undetermined by firm
Action	Stryker Spine sent an "Urgent Recall Letter and Product Accountability Form" dated July 26, 2016 to all affected customers. For patients who have had an AccuLIF Posterior Lumbar (PL) Expandable Interbody implant, Stryker Spine is recommending routine clinical and radiographic post-operated evaluation. Should the patient report any change in or develop

Class 2 Device Recall Stryker AccuLIF PL Cages

See Related Information[22]

Recall Date	September 12, 2016
Recall Status[1]	Open
Recall Number	Z-2787-2016
Recall Event ID	74931[23]
510(K)Number	K132505[24] K143616[25] K141217[26]
Product Classification	Intervertebral fusion device with bone graft, lumbar[27] - **Product Code** MAX[28]
Product	AccuLIF PL 8-12mm x 11mm x 27mm x 8 Cage, Rx only, Sterile R, Legal The AccuLIF PL Cages are indicated for intervertebral body fusion with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, the AccuLIF PL Cages can be used as in adjunct to fusion in patients diagnosed with degenerative scoliosis. The AccuLIF Pl Cages are always to be used with supplemental internal spinal fixation. Additionally, the AccuLIF PL Cages are to be used with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion
Code Information	Catalog #400008 Lot #'s 01141602, 01141607, 01141610, 01141612, 01141617, 02021601, 02021603, 02021605, 02161503. 02161504, 02161506, 02161507, 02161508, 02161509, 02161510, 02161511, 02161512, 02161513, 02161514, 02161515, 03061309, 04161501, 04161502, 04161503, 04161504, 04161505, 04161506, 04161507, 04161508, 05171305, 05181505, 05181506, 05181507, 05181508, 05181509, 05181510, 05181511, 05181512, 05181513, 05181514, 05181515, 06031401, 06031402, 06031403, 06031404, 06201309, 07291404, 07291405, 08191310, 08191311, 08261506, 08261507, 08261508, 10111302, 10111303, 10111304, 10111305, 10291405, 10291406, 11101406, 11101407, 11101408, 11101409, 11101410, 11101411, 11121525, 12151510, 12151515, 12151516, 12151523, 12151526 and 12301315
Recalling Firm/ Manufacturer	Howmedica Osteonics Corp. 2 Pearl Ct Allendale NJ 07401-1611
For Additional Information Contact	Mr. Tim Huntington 201-749-8346
Manufacturer Reason for Recall	Since Stryker acquired the AccuLIF product in March of 2014, there have been Product Inquires (PIs) related to the PL implant confirming to have a reduction of height > 1 mm. The current occurrence rate for reported post-operative reduction of cage height (> 1mm) of AccuLIF PL Expandable Cages is approximately 0.47% and has demonstrated a slight upward trend since September 2015.
FDA Determined Cause [2]	Unknown/Undetermined by firm
Action	Stryker Spine sent an "Urgent Recall Letter and Product Accountability Form" dated July 26,

Class 2 Device Recall Stryker AccuLIF PL Cages

See Related Information 22

Recall Date	September 12, 2016
Recall Status[1]	Open
Recall Number	Z-2788-2016
Recall Event ID	74931[23]
510(K)Number	K132505[24] K143616[25] K141217[26]
Product Classification	Intervertebral fusion device with bone graft, lumbar[27] - **Product Code** MAX[28]
Product	AccuLIF PL 10-16mm x 11mm x 27mm x 8 Cage, Rx only, Sterile R, Legal The AccuLIF PL Cages are indicated for intervertebral body fusion with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, the AccuLIF PL Cages can be used as in adjunct to fusion in patients diagnosed with degenerative scoliosis. The AccuLIF Pl Cages are always to be used with supplemental internal spinal fixation. Additionally, the AccuLIF PL Cages are to be used with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion
Code Information	Catalog #400010 Lot #'s 01021403, 01121508, 01121509, 01271515, 01271516, 02021512, 02021513, 02021514, 02021515, 02021602, 03221310, 04141508, 04141509, 04141510, 04141511, 04141512, 04251312, 06101405, 06101406, 06101407, 06251311, 07011406, 07201510, 07201511, 07201512, 08141303, 08141313, 09251504, 09281512, 10081301, 10081302, 10201502, 10201503, 10301504, 11121514, 11121518, 11121521, 12151511 and 12151517
Recalling Firm/ Manufacturer	Howmedica Osteonics Corp. 2 Pearl Ct Allendale NJ 07401-1611
For Additional Information Contact	Mr. Tim Huntington 201-749-8346
Manufacturer Reason for Recall	Since Stryker acquired the AccuLIF product in March of 2014, there have been Product Inquires (PIs) related to the PL implant confirming to have a reduction of height > 1 mm. The current occurrence rate for reported post-operative reduction of cage height (> 1mm) of AccuLIF PL Expandable Cages is approximately 0.47% and has demonstrated a slight upward trend since September 2015.
FDA Determined Cause [2]	Unknown/Undetermined by firm
Action	Stryker Spine sent an "Urgent Recall Letter and Product Accountability Form" dated July 26, 2016 to all affected customers. For patients who have had an AccuLIF Posterior Lumbar (PL) Expandable Interbody implant, Stryker Spine is recommending routine clinical and radiographic post-operated evaluation. Should the patient report any change in or develop near-onset symptoms, more urgent clinical and radiographic evaluation should be