Class 2 Device Recall Stryker AccuLIF PL Cages

Recall Date: September 12, 2016
Recall Status: Open
Recall Number: Z-2786-2016
Recall Event ID: 74931
510(K) Number: K132505, K143616, K141217
Product Classification: Intervertebral fusion device with bone graft, lumbar
Product: AccuLIF PL 6-9 mm x 11 mm x 27 mm x 8 Cage. Rx only. Stryker 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, 06251506, 06251507, 06291506, 06291507, 06291508, 06291509, 06291510, 06291511, 06291512, 06291513, 06291514, 06291515, 06291516, 07081301, 07081302, 07081303, 07081304, 07081503, 07081505, 08191309, 08251402, 08251403, 08251404, 09251502, 09251503, 09251504, 10071307, 10071308, 10141504, 10141505, 10251507, 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 Inquiries (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 (> 1 mm) of AccuLIF PL Expandable Cages is approximately 0.47% and has demonstrated a slight upward trend since September 2015.

FDA Determined Cause: 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-operative evaluation. Should the patient report any change in or develop...
Recall Date: September 12, 2016
Recall Status: Open
Recall Number: Z-2787-2016
Recall Event ID: 74931
510(K) Number: K132505, K143616, K141217
Product Classification: Intervertebral fusion device with bone graft, lumbar - Product Code MAX

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 cortico cancellous 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 an 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 cortico cancellous 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, 04161509, 05161503, 05161505, 05161506, 05161507, 05161508, 05161509, 05161510, 05161511, 05161512, 05161513, 05161514, 05161515, 06031401, 06031402, 06031403, 06031404, 06201305, 07291404, 07291405, 08191310, 08215011, 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 Inquiries (Pls) 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 (>1 mm) of AccuLIF PL Expandable Cages is approximately 0.47% and has demonstrated a slight upward trend since September 2015.

FDA Determined Cause: 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

Recall Date
September 12, 2016

Recall Status
Open

Recall Number
Z-2788-2016

Recall Event ID
7493123

510(K) Number
K13250654 K14361625 K14121726

Product Classification
Intervertebral fusion device with bone graft, lumbar27 - Product Code MAX28

Product
AccuLIF PL 10-16mm x 11mm x 27mm x 6 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 Inquiries (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
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-operative evaluation. Should the patient report any change in or develop near-onset symptoms, more urgent clinical and radiographic evaluation should be