IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

WILLIAM W. ENGLE, III, Individually and as *
Personal Representative of the Estate of
ROSEZETTA ENGLE, Deceased *
28 South Lake Way
Reisterstown, Maryland 21136 *

AND *

JAMES ENGLE *
28 South Lake Way
Reisterstown, Maryland 21136 *

AND * Civil Action No.

ERIC ENGLE *
3544 Bremen Street
Frederick, Maryland 21704 *

Plaintiffs *

v. *

HOWMEDICA OSTEONICS *
CORPORATION, doing business as STRYKER
ORTHOPAEDICS and STRYKER *
CORPORATION
325 Corporate Drive *
Mahwah, New Jersey 07430
Serve On: The Corporation Company *
1675 Broadway, Suite 1200
Denver, Colorado 80202 *

Defendants *

* * * * * * * * * * * * * *

CIVIL COMPLAINT

COMES NOW, Plaintiffs, WILLIAM W. ENGLE, III, Individually and as

Personal Representative of the Estate of ROSEZETTA ENGLE, deceased, JAMES ENGLE, and ERIC ENGLE, (hereinafter "Plaintiffs"), by and through the undersigned counsel, and brings this complaint against HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS and STRYKER CORPORATION (hereinafter collectively "Defendants" and "Stryker"), and allege the following:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing distribution, marketing, supplying, and/or selling the defective products sold under the name "The Accolade II Femoral Hip Stem" and "LFIT Anatomic V40 Femoral Head" (hereinafter "Accolade II" or "V40 Cobalt Chromium femoral head" or "Defective Device").

PARTIES

2. Plaintiffs, are citizens and residents of Baltimore County and Frederick County, Maryland. Plaintiff William Engle is the surviving husband of Rosezetta Engle, deceased, and is also Personal Representative of her Estate. The Plaintiffs James Engle and Eric Engle are the natural sons of Rosezetta Engle.

3. Defendant, Howmedica Osteonics Corporation (hereinafter "Howmedica"), d/b/a Stryker Orthopaedics, is a corporation organized and existing under the laws of New Jersey and having its place of business located at 325 Corporate Drive, Mahwah, New Jersey 07430. Defendant does business throughout the United States, including in the State of Maryland. Defendant Howmedica Osteonics Corporation d/b/a Stryker Orthopaedics is a wholly owned subsidiary of parent corporation Stryker Corporation.

4. Defendant Stryker Corporation is the parent corporation organized and existing under the laws of the State of Michigan with its principal place of business in Kalamazoo, Michigan. Defendant does business throughout the world and throughout the United States, including the State of Maryland. Stryker holds itself out as "one of the world's leading medical technology companies and is dedicated to helping healthcare professionals perform their jobs more efficiently while enhancing patient care. Stryker provides innovative orthopaedic implants as well as state-of-the-art medical and surgical equipment to help people lead more active and more satisfying lives." (Source: www.stryker.com.)

5. Upon information and belief, at all times herein mentioned, the employees of Defendants, their subsidiaries, affiliates, and other related entities, as well as employees of each of the individual Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and, at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such designations shall be deemed to mean that the principals, officers, employees, agents and/or representatives of the Defendants committed, knew of, performed, authorized, ratified and/or directed such transactions on behalf of Defendants while actively engaged in the scope of their duties.

JURISDICTION & VENUE

6. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a)

because complete diversity exists between the Plaintiffs, who are citizens of the State of Maryland, which is different from the states where the Defendants are incorporated and have their principal places of business, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

7. Venue is proper within this District pursuant to 28 U.S.C. § 1391 and it is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391(a) and (c) because Defendants did (and do) business within the state of Maryland and have had continuous and systematic contacts with the State of Maryland, and they have consented to jurisdiction in the State of Maryland.

THE PRODUCTS

8. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, suppled, and/or sold the defective product sold under the name "The Accolade II Femoral Hip Stem" and "V40™ Taper LFIT™ Anatomic CoCr Femoral Head" (hereinafter "Accolade II Stem" or "V40 Cobalt Chromium Femoral Head" or "Defective Device"), either directly or indirectly, to members of the general public.

9. Defendants' Defective Devices were placed into the stream of interstate commerce and were implanted in the right hip of Rosezetta Engle, deceased, in 2011 at Sinai Lifebridge Hospital in Baltimore, Maryland.

10. As a direct and proximate result of Defendants placing the Defective Device into the stream of commerce, the deceased suffered injuries and damages,

including but not limited to physical pain and suffering, and has incurred medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages. On March 11, 2015, as a direct and proximate result of a post-operative infection that developed after revision surgery for the Defective Device, the deceased died.

11. On March 10, 2011, Defendants received FDA clearance to sell its Accolade II prosthetic hip stem in the United States under the 510(k) process, claiming substantial similarity with the other Howmedica Osteonics hip stems.

12. The Accolade II stem is a hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative joint disease, rheumatoid arthritis, and correction of functional deformity. It is also indicated for use in revision procedures where other treatments or devices have failed.

13. The Accolade II Stem is a monoblock, single piece artificial hip replacement device that is designed to be implanted into the patient's femur. The Accolade II Stem is designed to be used with any number of bearing surface components comprised of the modular ball or artificial femoral head and an acetabular cup or socket.

14. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, aluminum, and vanadium. Howmedica's alloy was designed and patented by Defendants.

15. Defendants marketed the V40 Cobalt Chromium femoral head to be paired with the Accolade II Stem to help maximize a patient's hip movement, as well as

stability and dislocation resistance.

16. At all times material hereto, the Accolade II Stem and V40 Cobalt Chromium Femoral Head implanted in the deceased were designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

17. The deceased began to experience pain and was evaluated by her physicians.

18. The deceased had revision surgery on January 8, 2015 at Sinai Lifebridge Hospital in Baltimore, Maryland. During this procedure, Dr. Nace found significant necrosis and fluid within the hip and gluteus minimus. As he performed the procedure, he encountered additional necrosis within the abductors and soft tissue, and there was corrosion and black staining under the ball and surrounding taper.

THE STRYKER ACCOLADE II FEMORAL STEM & LFIT V40 COCR

19. In or around March 2011, Stryker released its Accolade II Femoral Hip Stem, the latest evolution in the Company's Accolade Femoral Stem, which was cleared for market around 2000.

20. The basic design of the Accolade II Femoral Hip Stem is similar to the Accolade TMZF Hip Stem, but the design of the Accolade II Femoral Hip Stem is designed to be used with V40 Femoral Heads, which are offered in both forged Vitallium alloy (CoCrMo) and zirconia ceramic. The Accolade II Stem is also designed with two neck angles, the standard 132 degrees and the extended 127 degrees offset, to assist with joint stability and proper restoration of joint kinematics without lengthening the leg. The

neck lengths are proportionally relative to the patient's body geometry to accommodate a wider patient population using a standard femoral head.

21. The stem is comprised of a femoral stem and neck component and offers a variety of femoral head options intraoperatively.

22. The Accolade II Stem combines the material characteristics of the Ti-6A1-4V alloy with a Circumferential Plasma Titanium plasma spray coating and Pure-Fix HA for the stem and neck.

23. In or around March 2001, Stryker received clearance from the FDA to market the LFIT Anatomic V40 Femoral Head. The basis of Stryker's application was that the predicate devices were made of cobalt chromium alloy femoral heads conforming to ASTM F1537 and cobalt chromium alloy of these femoral heads are fabricated from cobalt chromium alloy conforming to AST M F799.

24. LFIT stands for "Low Friction Ion Treatment" and this technology was marketed to "enhance the material properties of CoCr to reduce frictional forces against Ultra-high-molecular-weight polyethylene (UHMWPE) surfaces."

25. Stryker advertised that an LFIT treated head better simulates the joint by allowing increased lubrication between the components and "LFIT™ heads demonstrated a 28% reduction in linear wear over CoCr heads in 100 patients at a minimum 3-year follow up."

26. The femoral head that is commonly used with the Accolade II Stem is the LFIT Anatomic V40 Femoral Head, which is made from a cobalt-chromium alloy.

27. Despite Stryker's claims, this material combination has been reported to cause corrosion. For decades, scientists have reported the occurrence of significant fretting and corrosion issues when dissimilar metals are combined. In its marketing and sale of the device, Stryker represented and warranted that is proprietary materials alleviate this problem.

28. Furthermore, in 2012, Stryker recalled its Rejuvenate and ABG II modular hip systems. These two systems employed a titanium alloy in the femoral stem. The modular neck of both devices was manufactured from chromium/cobalt. These devices were recalled after reports surfaced indicating device failure due to fretting and corrosion at the taper junction where these dissimilar metals were joined.

29. Patients in whom Stryker Rejuvenate and ABG II hip stems had been implanted were experiencing device failure, symptoms and diagnostic findings similar to the deceased. Information disseminated by Stryker at or about the time of the recall cited this failure mechanism as the reason for the recall.

30. Since the recall, revision rates for Rejuvenate and ABG II have been reported to exceed 50% in a very short period of time.

31. Additionally, Stryker has now recalled a large number of LFIT Anatomic V40 chromium/cobalt heads. The recall cites gross trunnion failure, metal wear, adverse tissue reaction, and the need for revision surgery as causes for recalling the femoral heads. The deceased suffered each of the above and the combination resulted in the need to surgically remove her Accolade II Stem and LFIT Anatomic V40 Head. As the direct

result of the revision surgery, the deceased became infected, septic and died.

CAUSES OF ACTION
COUNT I
COMMON LAW NEGLIGENCE

32. Plaintiffs reallege and incorporate by reference the allegations set forth above.

33. Defendants designed, manufactured, marketed, detailed, and advertised both to physicians and consumers the Accolade II Stem and V40 Femoral Head.

34. As a result, Defendants had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom the devices would be implanted.

35. Defendants failed to use reasonable and due care for the safety and well-being of those in whom the device would be implanted and are therefore negligent in the following respects:

a. Defendants failed to adequately warn of the increased risks of fretting, corrosion, and heavy metal toxicity associated with the use of the Accolade II Stem and LFIT V40 Cobalt Chromium Femoral Head.

b. Defendants failed to adequately design and manufacture the Accolade II Stem and V40 Femoral Head to ensure that it would not fret, corrode, erode, deteriorate and induce severe metal toxicity in patients. The flaws include, but are not limited to:

i. The incompatibility of the titanium with chromium/cobalt heads;

ii. Use of the titanium alloy with a known corrosion/fretting profile;

iii. Poor design of the taper junction between femoral head and neck such that micro motion was predictable;

iv. Poor manufacturing practices such that the taper junction between the femoral head and neck do not "fit" as designed and intended;

v. Not restricting authorized or recommended use of the Accolade II Stem to ceramic heads only;

vi. Allowing and promoting the use of large metal heads on Stryker's small and insufficient V40 trunnion which would predictably lead to excessive motion, fretting, mechanically assisted crevice corrosion and ultimately device failure; and

vii. A combination of the above factors leads to rapid, severe heavy metal cast off causing soft tissue and bony necrosis, pain and premature failure of the device.

c. Defendants failed to adequately test the "Defective Devices" and their combination to insure they would not fret, corrode, erode,

deteriorate and induce severe metal toxicity in the patient;

d. Prior to marketing the "Defective Devices," Defendants failed to conduct anything other than simple basic bench testing. At the time Defendants designed the "Defective Devices," sufficient scientific art and knowledge existed to conduct testing that would have exposed the defects in the Accolade II Stem when implanted in patients with the chromium/cobalt head;

e. In fact, Stryker has likely conducted testing that reveals the incompatibility of these two materials when used in this design;

f. Defendants made affirmative representations that the "Defective Devices" would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer;

g. Defendants trained its sales force to detail the "Defective Devices" utilizing representations the Defendants knew or should have known to be false, creating in the minds of both surgeons and consumers the belief that the "Defective Devices" were safe for its intended use;

h. Defendants specifically marketed the "Defective Devices" as a safe alternative to metal-on-metal bearing surface "Defective Devices" that had been widely publicized as capable of causing premature

failure due to heavy metal toxicity;

i. Defendants failed to manufacture the products to Defendants' own internal specifications such that the taper junction between the neck and stem prematurely failed causing metal debris cast-off and severe metal toxicity in patients;

j. Defendants failed to adequately test the titanium alloy's compatibility with chromium/cobalt components in an effort to prevent corrosion and fretting at the bearing surface junction of this stem;

k. Defendants failed to promptly act upon reports of failure or warn surgeons such that the device continued to be implanted in combination with chromium/cobalt femoral heads well after it should have been recalled or redesigned; and

l. Defendants chose these materials to be used in combination as a system at a time when safer alternative designs and materials were available.

36. The above conduct exhibits Defendants' failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure as well as severe debilitating injury that is permanent.

37. As a direct and proximate result of the Defendants' negligence, Plaintiff suffered severe physical pain and suffering, emotional distress, mental anguish, loss of

the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages and loss of earning capacity. These damages have occurred in the past and will continue into the future.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT II
STRICT LIABILITY – FAILURE TO WARN

38. Plaintiffs reallege and incorporate by reference the allegations set forth above.

39. The Accolade II Stem and LFIT V40 Cobalt Chromium femoral head implanted into the deceased contained no warnings or, in the alternative, inadequate warnings as to the risk that the products could independently cause significant heavy metal toxicity or cause significant heavy metal toxicity when used together.

40. The Accolade II Stem and LFIT V40 Cobalt Chromium femoral head implanted into the deceased contained no warnings that these components posed significant increased risk of fretting, corrosion and heavy metal toxicity in patients.

41. The Accolade II Stem LFIT V40 Cobalt Chromium femoral head implanted into the deceased contained no warnings against the use of these devices together.

42. The warnings that accompanied the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head failed to provide that level of information that an ordinary consumer would expect when using the Accolade II implant with a LFIT V40

Cobalt Chromium femoral head in a manner reasonably foreseeable to the Defendants.

43. Had the deceased received a proper or adequate warning as to the risks associated with using the Accolade implant and a LFIT V40 Cobalt Chromium femoral head, the deceased would not have used the products.

44. Had the deceased's surgeon received a proper or adequate warning as to the risks associated with using the Accolade Stem and its combination with a LFIT V40 Cobalt Chromium femoral head, he/she would not have recommended the device; would have used an alternate device; or at a minimum, provided the deceased with adequate warning and obtain her informed consent. As stated above, had the deceased received an adequate warning, she would not have agreed to have the Accolade Stem and LFIT V40 Cobalt Chromium femoral head implanted in her.

45. The failure to warn of the risks of the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head caused serious damage to the deceased, including bodily injury, the need for revision surgery, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damage and losses will continue in the future.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT III
STRICT LIABILITY – DESIGN DEFECT

46. Plaintiffs reallege and incorporate by reference the allegations set forth above.

47. This is an action based upon design defect against Defendants.

48. Integral to the design of the Accolade II Stem and the LFIT V40 Cobalt Chromium femoral head were their compatibility with one another.

49. Defendants' Accolade II Stem and LFIT V40 Cobalt Chromium femoral head are designed in such a way that, when used as intended in combination, it causes serious, permanent and devastating damage to patients in whom the devices are implanted. The damage and mechanism of injury have been previously described herein.

50. When combined with an accolade II Stem, Defendants' LFIT V40 Cobalt Chromium femoral heads to not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

51. When combined with LFIT V40 Cobalt Chromium femoral heads, Defendants' Accolade II Stems do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

52. The risks of using Defendants' Accolade II Stems in combination with LFIT V40 Cobalt Chromium femoral heads outweigh the benefits of using them.

53. The risks of using Defendants' LFIT V40 Cobalt Chromium femoral heads in combination with Accolade II Stems outweigh the benefits of using them.

54. The Accolade II Stem and LFIT V40 Cobalt Chromium femoral head

installed in the deceased's hip were defectively designed and safer alternative designs exist.

55. The design defect in Defendants' Accolade II Stem and LFIT V40 Cobalt Chromium femoral head caused serious damage to the deceased, including bodily injury, the need for revision surgery, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of Medicare care and expenses, loss of earnings and loss of the ability to earn money, and ultimately death, as a result of post-operative infection from the revision surgery.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT IV
STRICT LIABILITY – MANUFACTURING DEFECT

56. Plaintiffs reallege and incorporate by reference the allegations set forth above.

57. This is an action based on a manufacturing defect against the Defendants.

58. The Accolade II Stem and LFIT V40 Cobalt Chromium femoral head were designed for implantation into the human body and to last long-term. They are also designed to be compatible with component parts and human tissue and bone.

59. The Accolade II Stem and LFIT V40 Cobalt Chromium femoral head installed in the deceased's hip failed as previously described.

60. The Accolade II titanium stem and V40 Cobalt Chromium femoral head

were manufactured in a substandard manner such that either:

a. The tapers were poorly fashioned so that they did not "fit;"

b. The titanium material was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment;

c. The titanium material was fashioned in such a manner that it did not maintain structural integrity when mated with a Cobalt Chromium femoral head;

d. The Cobalt Chromium femoral head was manufactured in such a manner that it did not "fit;"

e. The Cobalt Chromium femoral head was fashioned in such a manner that did not maintain structural integrity when implanted in the biologic environment;

f. The Cobalt Chromium femoral head was fashioned in such a manner that it did not maintain structural integrity when mated with an Accolade II Stem; and

g. The HA coating of the stem, the Hydroxyapatite, became loose and caused third body wear thus enhancing the metallosis process

61. This combination installed in the deceased's hip was not compatible with human tissue, muscle and bone. Through a process of fretting and corrosion, it released heavy metals into the deceased's body causing severe and permanent destruction of

essential muscle and tissue. Defendants failed to manufacture the product in a manner that prevented fretting and corrosion and, in fact, manufactured the product such that it caused fretting and corrosion.

62. The Accolade II Stem and LFIT V40 Cobalt Chromium femoral head installed in the deceased's hip contained a manufacturing defect.

63. The manufacturing defect in the Accolade II Stem and the LFIT V40 Cobalt Chromium femoral head caused serious damage to the deceased, including bodily injury, the need for revision surgery, permanent loss of significant amounts of essential tissue and abductor muscle resulting in pain, suffering, disability, physical impairment, impaired gait, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, and ultimately her death due to post-operative infection after revision surgery.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT V
BREACH OF EXPRESS WARRANTY & IMPLIED WARRANTIES

64. Plaintiffs reallege and incorporate by reference the allegations set forth above.

65. Through their public statements, their descriptions of the Accolade II Stem and their promises relating to the Accolade II Stem, Defendants expressly and impliedly warranted, among other things, that the Accolade II Stem was efficacious and safe for its

intended use and was designed and constructed of materials that would prevent fretting and corrosion and would provide superior component longevity to or over competing products.

66. Through their public statements, their descriptions of the LFIT V40 Cobalt Chromium femoral head and their promises relating to these heads, Defendants expressly and impliedly warranted, among other things, that the LFIT V40 Cobalt Chromium femoral heads were efficacious and safe for its intended use and was designed and constructed of materials that would prevent fretting and corrosion.

67. These warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head, but which contained material misrepresentations and failed to warn of the risks of the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head; (iii) verbal assurances made by Defendants' consumer relations personnel to the public about the safety of the Accolade Stem and LFIT V40 Cobalt Chromium femoral head and the downplaying of the risks of use associated with the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head ; and (iv) false and misleading written information supplied by Defendants.

68. Plaintiffs further allege that all of the aforementioned written materials are known to Defendants and in their possession, and it is Plaintiffs' reasonable belief that these materials shall be produced by Defendants and be made of record once Plaintiffs

are afforded the opportunity to conduct discovery.

69. When Defendants made these express warranties, Defendants knew the purpose for which the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head were to be used and warranted them to be in all respects safe and proper for such purpose, including their use in combination.

70. Defendants drafted the documents and/or made the statements upon which these warranty claims are based, and in so doing, defined the terms of those warranties.

71. The Accolade II Stem and LFIT V40 Cobalt Chromium femoral head do not conform to Defendants' representations in that these devices are not safe, and produce serious side effects, particularly when combined with one another.

72. Defendants knew of the use for which these devices were intended and impliedly warranted the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head to be of merchantable quality and fit for such use together.

73. The Accolade II Stem and LFIT V40 Cobalt Chromium femoral head manufactured and supplied by Defendants were not of merchantable quality and were not fit for the ordinary and/or particular purpose for which they were intended as, among other defects, the risks included fretting and corrosion and the likelihood of painful and debilitating revision surgery.

74. The deceased and/or her physician reasonably relied upon the skill and judgment of Defendants as to whether the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head were of merchantable quality and fit/safe for their intended

particular use and purpose, and upon Defendants' implied warranty as to such matters, including use together.

75. Defendants knew or had reason to know that deceased and/or her physician would reasonably rely upon the skill and judgment of Defendants as to whether the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head were of merchantable quality and fit/safe for their intended and particular use and purpose, and upon Defendants' implied warranty as to such matters, including use together.

76. Contrary to such warranties, the Accolade Stem and the LFIT V40 Cobalt Chromium femoral head did not conform to Defendants' promises, descriptions or affirmations of fact and were not of merchantable quality or adequately packaged, labeled, promoted or fit for the ordinary purposes for which such "Defective Devices" are used.

77. Defendants, therefore, breached their express and implied warranties to the deceased herein in violation of common and statutory law, including those set forth under Maryland law, by manufacturing, marketing, and selling the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head to the deceased herein and causing damages as will be established at trial.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT VI
VIOLATION OF MARYLAND'S CONSUMER PROTECTION ACT

78. Plaintiffs reallege and incorporate by reference the allegations set forth

above.

79. The Defendants are subject to and their activities are governed by the Maryland Consumer Protection Act.

80. The Defendants' conduct, as more particularly described above, constitutes multiple violations of the Act, for which t he Defendants are liable to the Plaintiffs.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT VII
WRONGFUL DEATH

81. Plaintiffs reallege and incorporate by reference the allegations set forth above.

82. The Plaintiff, William W. Engle, III, was the husband of the deceased and the Plaintiffs James Engle and Eric Engle are her natural sons.

83. As a direct and proximate result of the wrongs outlined above, the deceased died from a post-operative infection after revisions surgery.

84. The Plaintiffs lost and will lose the companionship, love, affection, care, guidance, affiliation, etc. the deceased would have provided during their joint life expectancy.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT VIII
SURVIVAL ACTION

85. Plaintiffs reallege and incorporate by reference the allegations set forth above.

86. William W. Engle, III, is the Personal Representative of the Estate of Rosezetta Engle, deceased. Prior to her death, the deceased suffered pain, disability, mental anguish and emotional damage as a result of the implanting of the device, up to and past the date of revision on January 8, 2015.

87. These injuries were as a direct and proximate result of the wrongs outlined above. In addition, the deceased incurred medical expenses to treat these injuries and her Estate was responsible for her funeral costs.

88. So that all of her injuries, losses and damages were as a result of the Defendant's wrongful conduct, outlined above.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants, as contained in the Prayer for Relief.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs pray for judgment against the Defendants as follows:

1. Awarding compensatory damages resulting from Defendants' negligence, breach of warranties and for strict liability.

2. Awarding actual damages to the Estate of Rosezetta Engle incidental to the deceased's purchase and use of the Accolade II Stem and LFIT V40 Cobalt Chromium femoral head in an amount to be determined at trial, including

medical bills, funeral bills, and conscious pain and suffering.

3. Awarding damages to the Plaintiffs for the wrongful death of the deceased (solatium).

4. Awarding pre-judgment and post-judgment interest to the Plaintiffs.

5. Awarding the costs and the expenses of their litigation to Plaintiffs.

6. Awarding reasonable attorneys' fees and costs to the Plaintiffs as provided by law.

7. Grating all such other relief as the Court deems necessary.

Dated: 03/09/2018

/s/ Dennis F. O'Brien

Dennis F. O'Brien, Esquire (#00771)
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Attorney for Plaintiffs

DEMAND FOR JURY TRIAL

The Plaintiffs demand a jury trial on all claims so triable IN THIS CIVIL ACTION, as provided by Rule 34(b) of the Federal Rules of Civil Procedure.

/s/ Dennis F. O'Brien

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obie26@aol.com
Attorney for Plaintiffs

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

William W. Engle, III
James Engle
Eric Engle

(b) County of Residence of First Listed Plaintiff Baltimore Co., MD
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Dennis F. O'Brien, P.A.
2012 S. Tollgate Road, Suite 209
Bel Air, MD 21015 (410) 420-7411

DEFENDANTS

Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics and Stryker Corporation

County of Residence of First Listed Defendant Bergen Co., NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
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- ☐ 160 Stockholders' Suits
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TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC 1332

Brief description of cause:
Pharmaceutical Device Liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
03/09/2018

SIGNATURE OF ATTORNEY OF RECORD
/s/ Dennis F. O'Brien

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked**.** (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

William W. Engle, Individually and as Personal Representative of the Estate of Rosezetta Engle, deceased, and James Engle and Eric Engle	)	
Plaintiff(s)	)	
v.	)	Civil Action No.
Howmedical Osteonics Corporation, doing business as Stryker Orthopaedics and Stryker Corporation	)	
Defendant(s)	)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Howmedical Osteonics Corporation, d/b/a Stryker Orthopaedics and Stryker Corporation
Serve On: The Corporation Company
1675 Broadway, Suite 1200
Denver, Colorado 80202

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Dennis F. O'Brien, Esquire
Dennis F. O'Brien, P.A.
2012 S. Tollgate Road, Suite 209
Bel Air, Maryland 21015

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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