

EXHIBIT B

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12
13 IN THE UNITED STATES DISTRICT COURT
14 FOR THE NORTHERN DISTRICT OF CALIFORNIA
15 SAN JOSE DIVISION
16

17 KATY WALKER, SHIRLEY)
18 LIGHTSEY, AUDRY GULLEY, MARY)
19 MEADOWS, ROBERT REEVES,)
20 LARRY REEVES, LINDA LEGER,)
21 PATRICIA McCARTY and MARGARET)
22 BENNET,)

21 Plaintiffs,

22 v.

23 GUIDANT CORPORATION, INC. et al.

24 Defendants.
25
26
27
28

) CASE NO. C 01-21108

)
) **DEFENDANTS' ANSWER TO**
) **COMPLAINT**

) Judge Presiding: Hon. Jeremy Fogel
) Date Action Filed: Nov. 30, 2001
) Trial Date: N/A

) **JURY TRIAL DEMANDED**
)
)

1 Of the Defendants named in the Complaint as Guidant Corporation Inc., Guidant Corp.,
2 Inc., Guidant Planning, Inc., Guidant Vascular Intervention Group, Inc., Guidant CNVS, Inc.,
3 Guidant Cardiovascular System, Inc., Guidant Cardiac & Vascular Surgery, Inc., Devices For
4 Vascular Intervention, Inc., Advanced Cardiovascular Systems, Inc., Origin Medsystems, Inc.,
5 and EndoVascular Technologies, Inc., only Guidant Corporation,¹ Advanced Cardiovascular
6 Systems, Inc., Origin Medsystems, Inc, and EndoVascular Technologies, Inc., are corporations
7 that were involved in the ANCURE® System. These four corporations are hereafter
8 collectively referred to as “EVT”, and answering the allegations and claims of Plaintiffs’
9 Complaint, they admit, deny, and allege as follows. By the use of the term “EVT”, EVT does
10 not admit that all four of these corporations were involved in the activities alleged in the
11 Complaint, as explained further below. Any allegation, averment, contention, or statement in
12 the Complaint not specifically and unequivocally admitted herein is denied.

13 1. EVT denies the allegations in paragraph 1 due to lack of information or
14 knowledge sufficient to form a belief as to the truth of the matter alleged.

15 2. EVT denies the allegations in paragraph 2 due to lack of information or
16 knowledge sufficient to form a belief as to the truth of the matter alleged.

17 3. EVT denies that any of the following named defendants are corporations.
18 Furthermore, as EVT makes clear below, the following purported entities named as defendants
19 in the Complaint are either unincorporated operating divisions of Guidant Corporation or non-
20 existent entities and accordingly are improperly named as Defendants: (1) Guidant Corporation,
21 Inc.; (2) Guidant Corp., Inc., (3) Guidant Planning, Inc.; (4) Guidant Vascular Intervention
22 Group, Inc.; (5) Guidant CNVS, Inc.; (6) Guidant Cardiovascular System, Inc.; (7) Guidant
23 Cardiac & Vascular Surgery, Inc.; (8) Devices for Vascular Surgery Inc. EVT therefore denies
24 the allegations of paragraph 3 of the Complaint as they relate to these named defendants. EVT
25 admits that Guidant Corporation is an Indiana Corporation and that it exists under the laws of
26 incorporation of states other than the states of Mississippi, Florida, Louisiana, and Alabama, and
27

28 _____ ¹ Guidant Corporation is improperly named as Guidant Corporation, Inc.

1 has its principal place of business in states other than Mississippi, Florida, Louisiana, and
2 Alabama. EVT admits that Advanced Cardiovascular Systems, Inc. is a California corporation
3 and subsidiary of Guidant, with its principal place of business in California. EVT admits that
4 Origin Medsystems, Inc. is a Delaware corporation and subsidiary of Guidant, with its principal
5 place of business in California. EVT denies that EndoVascular Technologies, Inc. is a
6 California corporation and admits that EndoVascular Technologies, Inc. is a Delaware
7 corporation and subsidiary of Guidant, with its principal place of business in California. EVT
8 denies any remaining allegations in Paragraph 3 of the Complaint.

9 4. EVT admits that venue is proper in this District, that it conducted business in this
10 District, and that EVT subsidiaries received revenue from the sales of the Ancure® System in
11 this District. EVT denies that it made any material omissions or misrepresentations, breached
12 any warranty relevant to this case, or engaged in any tortious conduct related to this case. EVT
13 denies all remaining allegations in paragraph 4 of the Complaint.

14 5. EVT denies the allegations in paragraph 5 of the Complaint.

15 6. EVT denies the allegations in paragraph 6 of the Complaint.

16 7. EVT denies the allegations in paragraph 7 of the Complaint.

17 8. EVT denies that there is any corporation named "Guidant Corporation, Inc."
18 EVT admits that Guidant Corporation is an Indiana corporation with its principal place of
19 business in Indiana and doing business in California. EVT admits that EVT designed,
20 manufactured and tested the Ancure System. EVT denies the remaining allegations in
21 paragraph 8 of the Complaint.

22 9. EVT denies that there is any corporation named "Guidant Corp., Inc.", and
23 further denies the remaining allegations in paragraph 9 of the Complaint.

24 10. EVT denies that there is any corporation named "Guidant Planning, Inc.", and
25 further denies the allegations in paragraph 10 of the Complaint.

26 11. EVT denies that there is any corporation named "Guidant Vascular Intervention
27 Group, Inc.", and further denies the allegations in paragraph 11 of the Complaint.

28 12. EVT denies that there is any corporation named "Guidant CNVS, Inc.", and

1 further denies the remaining allegations in paragraph 12 of the Complaint.

2 13. EVT denies that there is any corporation named "Guidant Cardiovascular
3 System, Inc.", and further denies the allegations in paragraph 13 of the Complaint.

4 14. EVT denies that there is any corporation named "Guidant Cardiac & Vascular
5 Surgery, Inc.," and further denies the allegations in paragraph 14 of the Complaint.

6 15. EVT denies that there is any corporation named "Devices for Vascular
7 Intervention, Inc." EVT admits that such a corporation used to exist but denies that Devices for
8 Vascular Intervention, Inc. had any role in designing, manufacturing, testing, analyzing,
9 distributing, supplying, or selling the Ancure System. EVT denies the remaining allegations in
10 paragraph 15 of the Complaint.

11 16. EVT admits that Advanced Cardiovascular Systems, Inc. is a California
12 corporation and subsidiary of EVT, with its principal place of business in California. EVT
13 admits that certain Advanced Cardiovascular Systems, Inc. employees had limited involvement
14 in the testing and analyzing the Ancure system. EVT denies any remaining allegations in
15 paragraph 16 of the Complaint.

16 17. EVT admits that Origin Medsystems, Inc. is a Delaware corporation and
17 subsidiary of Guidant, with its principal place of business in California. EVT admits that certain
18 Origin Medsystems, Inc. employees may have been involved in the design, manufacture, testing,
19 or analyzing of the Ancure system. EVT denies that Origin Medsystems is currently performing
20 any business function related to the Ancure System and further denies any remaining allegations
21 in paragraph 17 of the Complaint.

22 18. EVT admits that EndoVascular Technologies, Inc. is a Delaware corporation and
23 subsidiary of Guidant, with its principal place of business in California and that EndoVascular
24 Technologies employees have been involved in the design, testing, analyzing, manufacturing,
25 marketing, promoting, or analyzing of the Ancure system. EVT denies the remaining
26 allegations in paragraph 18 of the Complaint.

27 19. EVT states that the allegations in paragraph 19 of the Complaint are not
28 assertions of fact, and, therefore, no response to this paragraph is required.

1 20. EVT denies the allegations in paragraph 20 of the Complaint.

2 **FACTUAL ALLEGATIONS**

3 21. EVT admits that it manufactured a system known as the Ancure® Endograft®
4 Delivery System (“Ancure System”) that is a safer and less invasive treatment for abdominal
5 aortic aneurysm than the conventional “open” procedure. EVT further admits that the Ancure
6 System is safe and effective. EVT admits that it marketed and promoted the Ancure System and
7 that the Ancure System was promoted and marketed as a safer and less invasive treatment for
8 aortic aneurysm than the conventional “open” procedure. EVT denies any remaining allegations
9 in paragraph 21 of the Complaint.

10 22. EVT denies that the Ancure System is a stent graft. EVT admits the remaining
11 allegations in paragraph 22 of the Complaint.

12 23. EVT denies that the Ancure System is a stent graft, that it is inserted in patients
13 using a “non-surgical procedure,” and that it is inserted through an “one-inch” incision. EVT
14 admits the remaining allegations in paragraph 23 of the Complaint.

15 24. EVT denies the allegations in paragraph 24 of the Complaint.

16 25. EVT admits that EVT began to market the Ancure System in 1999. EVT denies
17 the remaining allegations in paragraph 25 of the Complaint.

18 26. EVT admits the allegations in paragraph 26 of the Complaint.

19 27. EVT admits that it suspended production of the Ancure System on March 16,
20 2001 and announced a voluntary recall of all existing inventory. EVT further admits that it
21 made certain changes to improve the Ancure System delivery system but did not submit those
22 changes to FDA for its approval prior to making the changes, and that it had not reported to
23 FDA field observations regarding deployment issues with the Ancure System at the time of the
24 recall, although these events were later reported to FDA. EVT denies the remaining allegations
25 of paragraph 27 of the Complaint.

26 28. EVT denies that the Ancure System is a stent graft. EVT denies the allegations
27 in the first two sentences of paragraph 28 of the Complaint due to lack of information or
28 knowledge sufficient to form a belief as to the truth of the matter alleged. EVT denies the

1 remaining allegations of paragraph 28 of the Complaint.

2 29. EVT denies the allegations in paragraph 29 of the Complaint.

3 30. EVT denies the allegations in paragraph 30 of the Complaint.

4 31. EVT denies the allegations in paragraph 31 of the Complaint.

5 32. EVT denies the existence of any defect in the Ancure System and denies that the
6 Ancure System was the cause of the death of Helen Beatrice Gregory. EVT denies the
7 remaining allegations in paragraph 32 of the Complaint due to lack of information or knowledge
8 sufficient to form a belief as to the truth of the matter alleged.

9 33. EVT denies the allegations in paragraph 33 of the Complaint.

10 34. EVT denies the allegations in paragraph 34 of the Complaint.

11 **FIRST CAUSE OF ACTION**

12 **[Strict Liability In Tort; Failure To Warn]**

13 35. EVT restates and incorporates by reference its responses to paragraphs 1-34
14 herein.

15 36. EVT denies the allegations in paragraph 36 of the Complaint.

16 37. EVT denies the allegations in paragraph 37 of the Complaint.

17 38. EVT denies the allegations in paragraph 38 of the Complaint.

18 39. EVT denies, due to lack of information or knowledge, the allegations regarding
19 what Helen Beatrice Gregory knew or had reason to know. EVT denies all remaining
20 allegations in paragraph 39 of the Complaint.

21 40. EVT denies the allegations in paragraph 40 of the Complaint.

22 41. EVT denies, due to lack of information or knowledge, the allegations regarding
23 what Helen Beatrice Gregory knew or had reason to know. EVT denies all remaining
24 allegations in paragraph 41 of the Complaint.

25 **SECOND CAUSE OF ACTION**

26 **[Strict Products Liability Pursuant to Restatement Second of Torts**

27 **§ 402A(1965)]**

28 42. EVT restates and incorporates by reference its responses to paragraphs 1-41
herein.

- 1 43. EVT denies the allegations in Paragraph 43 of the Complaint.
2 44. EVT denies the allegations in Paragraph 44 of the Complaint.
3 45. EVT denies the allegations in paragraph 45 of the Complaint.
4 46. EVT denies the allegations in paragraph 46 of the Complaint.
5 47. EVT denies the allegations in paragraph 47 of the Complaint.
6 48. EVT denies the allegations in paragraph 48 of the Complaint.

7 **THIRD CAUSE OF ACTION**

8 **[Negligence]**

9 49. EVT restates and incorporates by reference its responses to paragraphs 1-48
10 herein.

- 11 50. EVT denies the allegations in paragraph 50 of the Complaint.
12 51. EVT denies the allegations in paragraph 51 of the Complaint.
13 52. EVT denies the allegations in paragraph 52 of the Complaint.
14 53. EVT denies the allegations in paragraph 53 of the Complaint.
15 54. EVT denies the allegations in paragraph 54 of the Complaint.

16 **FOURTH CAUSE OF ACTION**

17 **[Breach of Implied Warranty]**

18 55. EVT restates and incorporates by reference its responses to paragraphs 1-54
19 herein.

20 56. EVT admits that EVT manufactured, packaged, distributed, recommended,
21 advertised, promoted, and supplied Ancure, but denies that it did so “[a]t all times mentioned
22 herein.” EVT denies the remaining allegations in paragraph 56 of the Complaint.

23 57. EVT denies the allegations in paragraph 57 of the Complaint due to lack of
24 information or knowledge sufficient to form a belief as to the truth of the matter alleged.

25 58. EVT denies the allegations in paragraph 58 of the Complaint.

26 59. EVT denies the allegations in paragraph 59 of the Complaint.
27
28

FIFTH CAUSE OF ACTION

[Breach of Express Warranty]

60. EVT restates and incorporates by reference its responses to paragraphs 1-59 herein.

61. EVT denies the allegations in paragraph 61 of the Complaint.

62. EVT admits that it had knowledge of the purpose for which the Ancure System was to be used and that the Ancure System was fit, reasonably safe and free from defects or unreasonable dangers, and effective for such purpose. EVT denies that the Ancure System was “unaccompanied by warnings of its dangerous propensities,” denies that the Ancure System bore any unreasonably dangerous “propensities,” and denies any remaining allegations in paragraph 62 of the Complaint.

63. EVT denies, due to lack of information or knowledge, the allegations in the first sentence of paragraph 63 of the Complaint. EVT denies all remaining allegations in paragraph 63 of the Complaint.

64. EVT denies the allegations in paragraph 64 of the Complaint.

SIXTH CAUSE OF ACTION

[Fraud]

65. EVT restates and incorporates by reference its responses to paragraphs 1-64 herein.

66. EVT denies the allegations in paragraph 66 of the Complaint.

67. EVT denies the allegations in paragraph 67 of the Complaint.

68. EVT denies the allegations in paragraph 68 of the Complaint.

69. EVT denies the allegations of the first sentence of paragraph 69 of the Complaint. EVT denies the remaining allegations in paragraph 69 due to lack of information or knowledge sufficient to form a belief as to the truth of the matter alleged.

70. EVT denies the allegations in paragraph 70 of the Complaint.

71. EVT denies the allegations in paragraph 71 of the Complaint.

SEVENTH CAUSE OF ACTION

[Negligent Misrepresentation]

72. EVT restates and incorporates by reference its responses to paragraphs 1-71 herein.

73. The allegations of the first sentence of paragraph 73 regarding EVT's "duty and obligation" are a legal conclusion to which no response is required. EVT denies the remaining allegations in paragraph 73 of the Complaint.

74. EVT denies the allegations in paragraph 74 of the Complaint.

75. EVT denies the allegations in paragraph 75 of the Complaint due to lack of information or knowledge.

76. EVT denies the allegations in paragraph 76 of the Complaint.

77. EVT denies the allegations in paragraph 77 of the Complaint.

78. EVT denies the allegations in paragraph 78 of the Complaint.

79. EVT denies the allegations in paragraph 79 of the Complaint.

80. EVT denies the allegations in paragraph 80 of the Complaint.

81. EVT denies the allegations in paragraph 81 of the Complaint.

EIGHTH CAUSE OF ACTION

[Fraud by Concealment]

82. EVT restates and incorporates by reference its responses to paragraphs 1-81 herein.

83. EVT denies the allegations in paragraph 83 of the Complaint.

84. The allegations of the first sentence of paragraph 84 regarding EVT's "duty and obligation" are a legal conclusion to which no response is required. EVT denies the remaining allegations in paragraph 84 of the Complaint.

85. EVT denies the allegations in paragraph 85 of the Complaint.

86. EVT denies the allegations in paragraph 86 of the Complaint.

87. EVT denies the allegations in paragraph 87 of the Complaint.

88. EVT denies the allegations in paragraph 88 of the Complaint.

1 89. EVT denies the allegations in paragraph 89 of the Complaint.

2 90. EVT denies the allegations in paragraph 90 of the Complaint.

3 91. EVT denies the allegations in paragraph 91 of the Complaint.

4 92. EVT denies the allegations in paragraph 92 of the Complaint.

5 **NINTH CAUSE OF ACTION**

6 **[Survivorship Claims]**

7 93. EVT restates and incorporates by reference its responses to paragraphs 1-92
8 herein.

9 94. EVT denies the allegations in paragraph 94 of the Complaint due to lack of
10 information or knowledge.

11 95. EVT denies the allegations in paragraph 95 of the Complaint.

12 96. EVT denies the allegations in paragraph 96 of the Complaint.

13 **AFFIRMATIVE DEFENSES**
14 **FIRST AFFIRMATIVE DEFENSE**

15 **(Failure to State a Claim)**

16 97. The Complaint fails to state facts sufficient to constitute any claim for relief
17 against EVT, or at all.

18 **SECOND AFFIRMATIVE DEFENSE**

19 **(Learned Intermediary)**

20 98. Plaintiffs' claims are barred, in whole or in part, by the "learned intermediary" or
21 "informed intermediary" doctrine.

THIRD AFFIRMATIVE DEFENSE

(Restatement (Second) Of Torts § 402a / Restatement (Third) Of Torts:

Products Liability § 6)

99. Plaintiffs' claims are barred, in whole or in part, by the doctrine(s) contained in Restatement (Second) of Torts § 402A, Comment k, Restatement (Third) of Torts: Products Liability § 6, or both.

FOURTH AFFIRMATIVE DEFENSE

(Utility Outweighs Risk)

100. Plaintiffs' claims are barred, in whole or in part, because the utility of Ancure as marketed and sold outweighs its risks.

FIFTH AFFIRMATIVE DEFENSE

(Comparative Fault / Contributory Negligence)

101. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' injuries, if any, were caused, in whole or in part, by the negligence, fault, or wrongful conduct of Plaintiffs or third parties, and Plaintiffs' claims are subject to the doctrines of comparative fault and contributory negligence as recognized by California Civil Code sections 1714 and 1714.45, the law of the State of Mississippi, and the law of any other potentially applicable jurisdiction.

SIXTH AFFIRMATIVE DEFENSE

(Superseding Cause)

102. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' injuries, if any, were caused, in whole or in part, by the superseding or intervening conduct of Plaintiffs, independent third parties, or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, or independent of or far removed from EVT's conduct or control.

1 **SEVENTH AFFIRMATIVE DEFENSE**

2 **(Preemption)**

3 103. Plaintiffs' claims are barred, in whole or in part, because material aspects and
4 characteristics of the Ancure System are regulated by the United States Food and Drug
5 Administration pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq.
6 ("FDCA"), the Medical Device Amendments thereto, and regulations promulgated thereunder,
7 and Plaintiff's claims expressly or impliedly conflict with provisions, regulations, means,
8 purposes, and goals of such federal regulation. Accordingly, Plaintiffs' claims are preempted by
9 the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws and
10 regulations of the United States.

11 **EIGHTH AFFIRMATIVE DEFENSE**

12 **(Agency Deference)**

13 104. Plaintiffs' claim are barred, in whole or in part, by the deference that the
14 common law gives to discretionary action by the Food and Drug Administration under the Food,
15 Drug and Cosmetic Act, and the Medical Device Amendments thereto.

16 **NINTH AFFIRMATIVE DEFENSE**

17 **(Informed Consent)**

18 105. Plaintiffs' claims are barred, in whole or in part, by the doctrine of informed
19 consent.

20 **TENTH AFFIRMATIVE DEFENSE**

21 **(Statute of Limitations)**

22 106. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of
23 limitations, including California Code of Civil Procedure section 340(3).
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1 **ELEVENTH AFFIRMATIVE DEFENSE**

2 **(Waiver, Laches, Estoppel)**

3 107. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver,
4 laches, or estoppel.

5 **TWELFTH AFFIRMATIVE DEFENSE**

6 **(No Double Recovery)**

7 108. Plaintiffs' damages, if any, are subject to an offset in the amount of any
8 reimbursement received by Plaintiffs as a result of any insurance or other health benefits plan,
9 or any amounts paid for by any insurance or other health benefits plan.

10 **THIRTEENTH AFFIRMATIVE DEFENSE**

11 **(Bifurcation of Punitive Damages Claim)**

12 109. Unless the trial of this matter is bifurcated, the claim of Plaintiffs for punitive
13 damages against EVT cannot be sustained, because any award of punitive damages under
14 California or other applicable law without bifurcating the trial and trying all punitive damages
15 issues only if and after liability on the merits has been found, would violate EVT's due process
16 rights guaranteed by the Fourteenth Amendment to the United States Constitution, Article 1,
17 Section 7 of the Constitution of the State of California, the Constitution of the State of
18 Mississippi, and the Constitution of any other applicable state, and would be improper under the
19 common law and public policies of the State of California and under Cal. Code Civ. Proc.
20 §§ 597 and 598, of the State of Mississippi, and of any other applicable state.

21 **FOURTEENTH AFFIRMATIVE DEFENSE**

22 **(Unconstitutionality of Unlimited Punitive Damages Claim)**

23 110. Plaintiffs' claim for punitive damages cannot be sustained, because an award of
24 punitive damages under California or other applicable law subject to no predetermined limit on
25 the amount of punitive damages that a jury may impose, such as a maximum multiple of
26 compensatory damages or a maximum amount, would violate the Excessive Fines Clause of the
27 Eighth Amendment to the U.S. Constitution, Article 1, Section 7 of the Constitution of the State
28 of California, the Constitution of the State of Mississippi, and the Constitution of any other

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1 applicable state, and would be improper under the common law and public policies of the State
2 of California or any other applicable state.

3 **FIFTEENTH AFFIRMATIVE DEFENSE**

4 **(Punitive Damages Claim Violates Due Process)**

5 111. Plaintiffs' claim for punitive damages cannot be sustained, because an award of
6 punitive damages under California, Mississippi, or other applicable law by a jury that (a) is not
7 provided standards of sufficient clarity for determining the appropriateness, and the appropriate
8 size, of a punitive damages award; (b) is not adequately instructed on the limits on punitive
9 damages imposed by the applicable principles of deterrence and punishment; (c) is not expressly
10 prohibited from awarding punitive damages, or determining the amount of an award of punitive
11 damages, in whole or in part, on the basis of invidiously discriminatory characteristics,
12 including the residence, wealth, and corporate status of EVT; (d) is permitted to award punitive
13 damages under a standard for determining liability for punitive damages that is vague and
14 arbitrary and does not define with sufficient clarity the conduct or mental state that makes
15 punitive damages permissible; and (e) is not subject to trial court and appellate judicial review
16 for reasonableness and furtherance of legitimate purposes on the basis of objective standards,
17 would violate EVT's due process and equal protection rights guaranteed by the Fourteenth
18 Amendment to the United States Constitution and by Article 1, Section 7 of the Constitution of
19 the State of California, by the Constitution of the State of Mississippi, and by the Constitution of
20 any other applicable state, and would be improper under the common law and public policies of
21 the State of California, the State of Mississippi, and any other applicable state. It further would
22 violate those provisions for punitive damages to be awarded for the omission of warnings not
23 approved by the United States Food and Drug Administration and for the use of warnings
24 approved and required by that agency.

25 **SIXTEENTH AFFIRMATIVE DEFENSE**

26 **(Multiple and Extra-Territorial Nature of Punitive Damages)**

27 112. Any award of punitive damages based on anything other than EVT's conduct in
28 connection with the sale of the specific Ancure device that is the subject of this lawsuit would

1 violate the due process clause of the Fourteenth Amendment to the United States Constitution
2 and Article 1, Section 7 of the Constitution of the State of California, the Constitution of the
3 State of Mississippi, and the Constitution of any other applicable state, and would be improper
4 under the common law and public policies of the State of California and any other applicable
5 state, because any other judgment for punitive damages in this case cannot protect EVT against
6 impermissible multiple punishment for the same wrong and punishment for extra-territorial
7 conduct in jurisdictions where the conduct is legally proper. In addition, any such award would
8 violate the Commerce Clause of the United States Constitution and principles of comity under
9 the laws of the State of California or the State of Wyoming.

10 **SEVENTEENTH AFFIRMATIVE DEFENSE**

11 **(Abatement)**

12 113. EVT is informed and believes and thereon alleges that there may be a nonjoinder
13 of one or more parties plaintiff who are subject to service of process in California, whose
14 joinder will not deprive this Court of jurisdiction of the subject matter of this action, and whose
15 absence may result in incomplete relief or subject those who are already parties subject to a risk
16 of incurring double, multiple, or otherwise inconsistent obligations and, for these reasons, the
17 action should be abated and/or dismissed.

18 **EIGHTEENTH AFFIRMATIVE DEFENSE**

19 **(State of the Art)**

20 114. Plaintiffs' claims are barred, in whole or in part, because any and all products to
21 which Plaintiffs refers in the Complaint conformed to the state-of-the-art for the design and
22 manufacture of such or similar products.

23 **NINETEENTH AFFIRMATIVE DEFENSE**

24 **(Failure to Mitigate)**

25 115. Plaintiffs' claims may be barred, or any right to recover limited, by their failure
26 to mitigate damages, if any.

1 **TWENTIETH AFFIRMATIVE DEFENSE**

2 **(Assumption of the Risk)**

3 116. Upon information and belief, Helen Beatrice Gregory was fully aware of and
4 informed about the nature of the medical devices and the risks and possible adverse effects
5 pertaining to the surgical procedure performed upon her and the placement of medical devices
6 into his person, and all injuries, damages or losses, if any, that she or Plaintiffs sustained arose
7 from and were caused by risks of which Ms. Gregory was aware and which she voluntarily
8 encountered. Helen Beatrice Gregory accepted and assumed all such risks.

9 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

10 **(Change of Venue)**

11 117. For the convenience of the parties and the witnesses and in the interests of
12 justice, venue is more appropriate in the district in which the surgery at issue in this case took
13 place.


14
15 WHEREFORE, EVT requests that Plaintiffs' Complaint be dismissed in its entirety with
16 prejudice, that judgment be entered in favor of EVT, that EVT be awarded costs and, to the
17 extent provided by law, attorneys' fees, and any such other relief as the Court may deem proper.

18 **JURY TRIAL DEMANDED**

19
20 EVT hereby demands a trial by jury.

21 June 9, 2003

22 GORDON & REES, LLP

23
24 By 
25 JACK B. McCOWAN, JR.
26 Attorneys for Defendants
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