IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

JAMES BOSTICK and	)	
BOBBY H. THRASHER,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**No. 03-2636 BV**
	)	
ST. JUDE MEDICAL, INC., and	)	
ST. JUDE MEDICAL S.C., INC.,	)	
	)	
Defendants.	)	

REPORT AND RECOMMENDATION ON PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

This action involves a product liability claim against defendants St. Jude Medical, Inc., and St. Jude Medical S.C., Inc. (collectively "St. Jude"). Before the court is the March 31, 2004 motion of the plaintiffs, James Bostick and Bobby Thrasher, seeking a determination, pursuant to Rule 23(c)(1) of the Federal Rules of Civil Procedure, that this action may be maintained as a class action on behalf of the following class:

> **All persons in the United States and its territories who have had a coronary artery bypass graft procedure utilizing the St. Jude Medical Symmetry Bypass System Aortic Connector Device, designed, manufactured and marketed by Defendant, St. Jude Medical, Inc. and/or St. Jude Medical S.C., Inc.**

Or, in the alternative:

> **All persons who have had a coronary artery bypass graft procedure utilizing the St. Jude Symmetry Bypass System Aortic Connector Device, designed, manufactured and marketed by Defendant, St. Jude Medical, Inc. and/or St.**

Jude Medical S.C., in the state of Tennessee.

The plaintiffs also seek an order confirming that James Bostick and Bobby Thrasher may serve as the representative plaintiffs and may be represented by the law firm of Deal, Cooper & Holton, PLLC, 296 Washington Avenue, Memphis, TN 38103. The motion was referred to the United States Magistrate Judge for report and recommendation. The magistrate judge held oral argument on August 3, 2004. Present at the hearing were Carroll Johnson for plaintiffs and DeWitt Shy and James Martin for St. Jude. Based on the briefs submitted by the parties, argument of counsel, and the record as a whole, it is recommended that the plaintiffs' motion for class certification be denied.

I. PROPOSED FINDINGS OF FACT

St. Jude Medical is a cardiac device manufacturer based in St. Paul, Minnesota. (Defs.' Mem. of Law in Opp'n to Class Certification at 4.) St. Jude manufactures pacemakers, prosthetic heart valves, and cardiac repair devices. One of their cardiac products is the St. Jude Medical Symmetry Aortic Connector ("aortic connector"). (*Id.* at 5.) St. Jude began developing, designing, manufacturing, marketing, and selling the aortic connector in 2001. (Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 1.)

The aortic connector is a small, star-shaped mechanical anastomosis device made of Nitinol that was designed for use by cardiac surgeons during surgery. (*Id.*) Coronary artery bypass graft surgery ("CABG") is designed to improve blood flow through coronary arteries to the heart muscle. (Def.'s Mem. of Law in Opp'n to Pl.'s Mot. for Class Certification at 2.) During bypass

surgery, the surgeon removes a portion of a blood vessel from the patient's leg, arm, or chest and uses the vessel as a conduit to bypass or detour an obstructed coronary artery. (*Id.* at 3.) Most often, surgeons use the saphenous vein from the leg as the bypass vessel. (*Id.*) The aortic connector is used to attach the saphenous vein graft to the aortic surface without sutures or the need for cross clamping or side biting of the aorta during CABG. (Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 1.)

Prior to the aortic connector's placement on the market, St. Jude submitted to the Food and Drug Administration ("FDA") a "pre-market notification" for the aortic connector claiming the device was a "substantially equivalent device" as contemplated in the Medical Device Amendment at 21 U.S.C. § 301 et seq.[1] The aortic connector received §510(k) approval by the FDA on May 21, 2001. (*Id.* at 7.)

The plaintiffs allege that St. Jude received adverse event reports from the medical community regarding complications associated with the aortic connector as early as August 2001. (*Id.*) The adverse reports describe a significantly higher incidence of complications in the form of restenosis and occlusion at the connector sites resulting in the need for re-operation using traditional hand-sewn techniques or other devices. (*Id.* at 2.) The first reported death associated with the aortic connector was

---

[1] Pursuant to the Medical Device Act of 1976, amended in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-95, a medical device covered under the statute may be marketed pursuant to a pre-market approval, or pursuant to a section 501(k) finding of "substantial equivalence." 21 U.S.C.A. § 360c(i).

on August 14, 2001. (*Id.*) The plaintiffs assert that since that date, multiple deaths associated with the aortic connector have been reported on the FDA's adverse events database. (*Id.*)

In addition to adverse reports, the plaintiffs also assert that a study conducted by Dr. G. Phillip Schoettle, a thoracic and cardiovascular surgeon in Memphis, on patients who had undergone bypass surgery using the aortic connector "revealed an 80 percent rate of occlusion or stenosis, uniformly occurring at the connector site" on patients having a repeat cardiac catheterization after the bypass surgery. (*Id.* at 8; *id.,* Ex. 1.) Dr. Schoettle's research indicated that in traditional bypass surgery using hand-sewn grafts, there were roughly the same number of repeat cardiac catheterizations performed but with only a 15 to 20 percent rate of occlusion and stenosis. (*Id.*)

The plaintiffs also rely on minutes obtained from a FDA Circulatory System Devices Advisory panel meeting during which Ulwe Klima, a professor of cardiac surgery at Hanover Medical School for Cardiac Surgery, stated that follow-up angiography six months after bypass surgery on ten patients revealed six patients with occlusions and one with highly significant stenosis. (*Id.* at 9.) Klima further stated "angiographic follow-up at six months after surgery 'was sufficient to detect a real, real problem at the site of the anastomosis, even though these patients were asymptomatic. This is a very clear message as I say that even though you have an asymptomatic patient, you might have a significant problem at the site of the anastomosis.'" (*Id.*)

In addition to the independent studies presented to the court,

the plaintiffs also submitted the affidavit of Dr. H. Frank Martin, Jr., a cardiologist who is board certified in cardiovascular disease and internal medicine.[2] Dr. Martin is not a cardiac surgeon, but asserts that he is familiar with techniques used during CABG and performs follow up care to CABG patients. (Martin Supp. Aff. at 1.) Dr. Martin opines, based upon his own personal knowledge and a review of Thrasher's and Bostick's medical records, that the implantation of St. Jude's aortic connector results in a "significantly increased risk of developing re-stenosis or occlusion of the bypass graft . . . as opposed to traditional bypass surgery using sutures." (Martin Aff. at 2.) Dr. Martin states in his opinion that the "re-stenosis and occlusion associated with use of this device is uniformly located at the connector site and is causally related to use of the connector." (*Id.*)

Dr. Martin indicates that the increased risk associated with the aortic connector can be attributed to the material from which the device is made and the procedure in which the bypass graft must be installed. (*Id.*) He suggests that all persons who have undergone a bypass surgery in which the aortic connector was used are in "need of immediate testing and medical monitoring to determine the extent of any compromise of the bypass graft because

---

[2] St. Jude has filed motions to strike both Dr. Martin's initial affidavit and his supplemental affidavit. At the time of the hearing, the plaintiffs had not responded to St. Jude's motion to strike Dr. Martin's supplemental affidavit and the time for response had not lapsed. Therefore, for the purposes of this report, the court will assume Dr. Martin's affidavit is admissible without deciding it is so, and the motions to strike will be addressed by separate order.

of the significantly increased risk of developing re-stenosis or occlusion associated with this device." (*Id.*) According to Dr. Martin, a cardiac catheterization is the "preferred procedure to determine the extent of bypass graft compromise." (*Id.*)

The plaintiffs contend that St. Jude's device has led to "severe and disabling medical conditions resulting from collapse and scarring of the graft as a result of the implanted aortic connector." (Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 2.) The plaintiffs assert that it is undisputed that over 40,000[3] aortic connectors have been implanted in persons worldwide, including at least 300 implantations in Tennessee. (*Id.* at 3, 18.) They contend that those patients receiving the implanted device "suffer a significantly increased risk of developing severe and life threatening compromise of the aortic/venous bypass graft" and is at "risk of occlusion and/or stenosis." (*Id.* at 10.) The plaintiffs assert that the condition has "necessitated removal of the aortic connector in numerous patients, and severe harm to others who must now be monitored for further signs and symptoms of potentially fatal arterial bypass graft compromise." (*Id.* at 2.)

The amended complaint alleges negligence, strict product liability failure to warn, strict product liability, negligence, breach of implied and express warranties, and unjust enrichment.

---

[3] In the class action complaint, the plaintiffs aver that over 50,000 aortic connectors have been implanted in persons worldwide. (Compl. at 6.) The discrepancy between 40,000 and 50,000 has little impact on the court's analysis of Rule 23(a)'s numerosity requirement.

On March 31, 2004, the plaintiffs filed a motion for class certification with this court. The plaintiffs assert that their nationwide class, or in the alternative, Tennessee class is comprised of two sub-classes:

> **Class I consists of all people in the United States and its territories who have had a coronary artery bypass graft procedure utilizing the St. Jude Medical Symmetry Bypass System Aortic Connector Device, or in the alternative all such people who received the device in the State of Tennessee, *except* those whose injuries have resulted in their death or serious injury resulting in the removal of the device.**
>
> **. . .**
>
> **Class II consists of all people in the U.S. or the State of Tennessee who received the aortic connector, or in the alternative all such people who received the device in the State of Tennessee, and who have sustained presently compensable physical injuries due to the aortic connector, including, without limitation, injuries requiring the removal of the aortic connector and injuries resulting in serious damages and/or death.**

(Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 4-5.) As a remedy for Class I ("medical monitoring class"), the plaintiffs seek access to a "coordinated program of medical monitoring services" to include diagnostic testing and preventative screening care along with an approved epidemiological study and review of the results of the monitoring. (*Id.* at 4.) The plaintiffs suggest that medical monitoring could take place in the form of a cardiac catheterization, MRI, CT scan, stress test, and/or echocardiogram. They contend that the court should create and control a trust fund to provide for necessary medical

monitoring and research.[4] (*Id.*) For Class II ("personal injury class"), the plaintiffs seek damages for personal injury, and if applicable, wrongful death and survival damages. (*Id.* at 5.)

Plaintiff James Bostick is a seventy-seven year old resident of Shelby County, Tennessee who seeks to represent Class I and II. Bostick underwent triple bypass surgery performed by Dr. Phillip Schoettle on August 27, 2002 in which the St. Jude aortic connectors were implanted. (*Id.* at 12; Defs.' Mem. of Law in Opp'n to Pls.' Mot. for Class Certification at 8.) In November 2002, Bostick experienced a sudden onset of intense chest pain. (Opp'n at 8.) He subsequently underwent a heart catheterization, stress tests, and an angioplasty performed on November 15, 2002. (*Id.* at 9.) Bostick contends that he has experienced medical problems due

---

[4] The plaintiffs assert that a medical monitoring program must include:

> locating and notifying the class members of the defects and the potential medical harm; the creation of a registry and a baseline database of Class members; the funding for periodic monitoring and assessment of the Class members; the researching, gathering and forwarding of epidemiological and treatment/diagnostic modality information to Class members' treating physicians and other health care providers; the researching and assessment of the injuries or complications which are or may result from the subject products' defects, including the recognition and assessment of risks of explant versus no-explant alternatives; providing medical treatment to remove the aortic connectors in those individuals who exhibit bypass graft compromise as a result of implantation of the device; the research and development and implementation of appropriate psychological and emotion support and treatment programs for Class members and their spouses.

(Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 11.)

to his initial bypass surgery and describes feeling tension, a nagging pain in his chest and a general lack of comfort in doing many of the things he previously did. (Pls.' at 12; Opp'n at 9.)) Nevertheless, Bostick has not had the aortic connectors removed and is purported to represent the class of presently asymptomatic bypass patients. Bostick seeks compensatory and other damages for medical expenses and pain and suffering. He does not, however, seek lost wages or loss of consortium damages.

Plaintiff Bobby Thrasher is a sixty-one year old resident of Alcorn County, Mississippi who seeks to represent Class II. Thrasher underwent bypass surgery performed by Dr. Schoettle on May 2, 2002 during which an aortic connector was implanted. Thrasher alleges that he began experiencing problems in October, 2002. (*Id.*) He continued to experience burning and pressure in his chest into November and December of 2002. (*Id.* at 13.) A cardiac catheterization revealed blockage, and on January 16, 2003, Thrasher underwent another bypass surgery to remove the aortic connector as a result of occlusion at the connector sites. (*Id.* at 13, 29.) Thrasher seeks compensatory and other damages for medical expenses, pain and suffering, wage loss, reduced earning capacity and loss of consortium type injuries.

At the August 3, 2004 evidentiary hearing, plaintiffs' counsel presented his argument for class certification first. During his opening remarks, counsel acknowledged that the variations in state law for the claims asserted in the complaint would make the certification of a nationwide class difficult but indicated nevertheless that plaintiffs were not abandoning that request. He

then proceeded to address the certification of a Tennessee class almost exclusively and presented no information on how a nationwide class action for either Class I or Class II could be maintained. Furthermore, plaintiffs' counsel failed to outline how variations in state law could be managed on a nationwide basis and did not address choice-of-law considerations.

II. PROPOSED CONCLUSIONS OF LAW

The defendants argue that courts in every circuit and the Supreme Court have denied certification of personal injury, product liability actions like this one because the requirements of Rule 23 could not be met. Essentially, the defendant's primary argument against certification is that there are too many individualized legal and factual circumstances in this case, which would make class treatment futile.

A. Framework of Federal Rule of Civil Procedure 23

Within the framework of Federal Rule of Civil Procedure 23, the district court has broad discretion in determining whether an action should be certified as a class action. *Craft v. Vanderbilt Univ.*, 174 F.R.D. 396, 401 (M.D. Tenn. 1996) (citing *Sterling v. Velsicol Chemical Corp.*, 855 F.2d 1188, 1197 (6th Cir. 1988)). That being said, district courts are required to conduct a "rigorous analysis" into whether the federal rule's prerequisites for a class action are met before certifying a class, "*especially*" in products liability cases involving drug or medical products that require FDA approval. *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1078-79, 1089 (6th Cir. 1996) (emphasis in original).

Rule 23 provides a two-part test for class certification and

the burden of proof is on the plaintiff to establish that the lawsuit is maintainable as a class action. *Id.* at 1079. First, a plaintiff seeking class certification must meet the threshold requirements of Rule 23(a) of the Federal Rules of Civil Procedure. The plaintiff must show that

> **(1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.**

FED. R. CIV. P. 23(a). After establishing those requirements, the plaintiff must satisfy one of the three subsections of Rule 23(b) that determine whether a class action is maintainable.

1. Rule 23(a)

a. Impracticable Joinder of All Members

Rule 23(a)(1) requires that a proposed class be "so numerous that joinder of all members is impracticable." FED. R. CIV. P. 23(a)(1). The impracticability of joinder for class action purposes is not determined by employing a strict numerical test. *In re Am. Med. Sys., Inc.*, 75 F.3d at 1079. "When class size reaches substantial proportions, however, the impracticability requirement is usually satisfied by the numbers alone." *Id.* (citations omitted).

Here, the plaintiffs contend that the class members are so numerous and geographically diverse that joinder of all members is impracticable. St. Jude does not dispute that both proposed classes meet the numerosity requirement of Rule 23(a)(1).

Accordingly, the requirement for numerosity as to both classes is satisfied by the fact over 40,000 aortic connectors have been implanted worldwide and approximately 300 in Tennessee.

b. Questions of Law and Fact Common to the Class

This requirement is ordinarily referred to as the commonality test. The commonality test "is qualitative rather than quantitative, that is, there need be only a single issue common to all members of the class." *In re Am. Med. Sys., Inc.*, 75 F.3d at 1080 (quoting Newberg & Alba Conte, *Newberg on Class Actions*, § 3.10, at 3-50 (3d ed. 1992)). Nevertheless, "the prerequisites of commonality and typicality will normally be hard to satisfy" in a products liability case. *In re Temple*, 851 F.2d 1269, 1273 n.7 (11th Cir. 1988) (cited in *In re Am. Med. Sys*. Inc., 75 F.3d at 1089).

The plaintiffs contend that in this case, all class members seek to resolve the legal issue of whether a product was defective and caused plaintiffs harm.[5] In turn, St. Jude argues that there

---

[5] **The plaintiffs assert that the questions of law and fact common to Class I and II include:**

> **(a) whether the subject aortic connector designed, developed, manufactured, distributed, fabricated, supplied, advertised, promoted and/or sold by St. Jude has a defect or defects;**
> **(b) the nature of said defect(s);**
> **(c) whether the aortic connector causes an increased risk of occlusion at the connector sites;**
> **(d) whether St. Jude conducted testing on the aortic connectors to the extent reasonably necessary to determine its safety prior to selling and/or distributing it;**
> **(e) whether said testing was adequate and responsible;**

(f) whether St. Jude accurately reported its test results;

(g) whether St. Jude failed to disclose to the FDA information known to it and relevant to the aortic connector's safety and efficacy;

(h) whether the warnings, if any, given by St. Jude were reasonable in light of what it knew or should have known;

(i) whether St. Jude's failure to give adequate and timely warnings of the dangers of the aortic connector constitutes negligence per se;

(j) whether consumers who were implanted with the aortic connector are at an increased risk of developing serious adverse health effects including respiratory failure, heart attacks, and death;

(k) whether monitoring and testing procedures which make early detection and treatment of the serious adverse health effects caused by occlusion at the connector sites are possible and beneficial;

(l) whether medical monitoring and an epidemiological program is appropriate and necessary;

(m) whether St. Jude designed and manufactured aortic connectors that were dangerously defective because they had a tendency to cause occlusion at the connector sites which could lead to serious adverse health effects including respiratory failure, heart attacks and death;

(n) whether St. Jude concealed adverse information regarding the testing and safety of the aortic connectors used during their bypass surgeries;

(o) what steps, if any, St. Jude took to cure or mitigate the defects in the aortic connectors after it knew of the defects and of the injuries and risks associated with their use;

(p) whether St. Jude is strictly liable to those injured by their defective aortic connectors;

(q) whether St. Jude acted negligently towards Plaintiffs and members of the classes;

(r) whether Plaintiffs and others similarly situated need and would benefit from a notice and registry program, a medical surveillance program, and/or medical research program designed to address the substantially increased risk of harm that St. Jude's defective products have put them in;

are no common legal issues and no common factual issues from which the commonality requirement can be satisfied. As for common legal questions, St. Jude contends that the court must undertake a choice-of-law analysis to determine which state law applies to the claims of each class member. With state law differences on issues such as strict product, negligence, and medical monitoring, St. Jude asserts that there will not be any legal issues common to the class as a whole.

As for common factual issues, St. Jude contends that any claim of commonality is overshadowed by individual variations in the factual circumstances of each class member. St. Jude points to differences in class members' individual case histories and the fact that complications with the device could be due to surgical error. St. Jude notes that in a failure-to-warn case, each plaintiff's surgeon would be required to testify to determine what oral and written statements were made by St. Jude to the physician, and what he in turn told the patient. *See In re Am. Med. Sys., Inc.*, 27 F.3d at 1081.

c. Typicality of Claims and Defenses of the Representative Parties as Compared to the Class

Rule 23(a)(3)'s typicality requirement requires that "claims or defenses of the representative parties [be] typical of the claims or defenses of the class." FED. R. CIV. P. 23(a)(3).

> **(s) whether Class II Plaintiffs have suffered injury and/or death as a result of the implanted St. Jude aortic connector.**

(Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 20-22.)

> **Typicality determines whether a sufficient relationship exists between the injury to the named plaintiff and the conduct affecting the class, so that the court may properly attribute a collective nature to the challenged conduct. In other words, when such a relationship is shown, a plaintiff's injury arises from or is directly related to a wrong to a class, and that wrong includes the wrong to the plaintiff. Thus, a plaintiff's claim is typical if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory.**

In re Am. Med. Sys., Inc., **75 F.3d at 1082 (6th Cir. 1996) (quoting 1 *Newberg*, *supra*, § 3.13, at 3-76). "A necessary consequence of the typicality requirement is that the representative's interests will be aligned with those of the represented group, and in pursuing his own claims, the named plaintiff will also advance the interests of the class members." *Id.* The plaintiff "whose claim is typical will ordinarily establish the defendants' liability to the entire class by proving his or her individual claim." ALBA CONTE & HERBERT B. NEWBERG, 6 NEWBERG ON CLASS ACTIONS § 18:8, at 29 (4th ed. 2002).**

The named plaintiffs contend that their claims are typical because each representative plaintiff's claim arises from the same course of events as other members of each class, apparently referring to, without explicitly stating, bypass surgery and implantation of the aortic connector. The plaintiffs argue that their claims "involve specific actions taken by St. Jude which affect each class member, including the marketing of thousands of aortic connectors each of which had the same dangerous defect." (Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 24.) Bostick and Thrasher assert that the relief they seek is exactly

the same as the relief sought by absent class members and that each individual claim will rely on the same evidence proving St. Jude's wrongful conduct. (*Id.*) Moreover, the plaintiffs argue that St. Jude's defenses will be the same. (*Id.* at 26.)

St. Jude contends that are "numerous aspects" of the representative class members' claims that establish the absence of typicality. (Opp'n at 24.) In support of its argument, St. Jude directs the court's attention to the case of *In re Baycol Products Litig.*, 218 F.R.D. 197, 205 (D. Minn. 2003), where a district court in Minnesota rejected plaintiff's argument that their claims were typical merely because they involved a single product and the same purported conduct. *Cf. In re Paxil Litigation*, 212 F.R.D. 539, 550 (C.D. Cal. 2003) ("In focusing its typicality argument almost exclusively on the fact that there is a single defendant [], a single drug [], and a single set of alleged misleading statements nationwide, Plaintiffs misconstrue the typicality requirement.") The court went on to recognize the existence of issues such as "injury, causation, the learned intermediary defense, and comparative fault" would require the presentation of individualized evidence. *Id.* Furthermore, the court noted that "[b]ecause the theories asserted by this putative class are based on what Defendants' knew at the time Baycol was prescribed, and whether Defendants acted reasonably based on such knowledge, the claims of the named representatives are not typical of the class." *Id.* at 205-06; *see also* .

Applying the rationale of *In re Baycol Products Litigation* to the facts at hand, St. Jude argues that the plaintiffs claims are

not typical of the classes they seek to represent. First, St. Jude contends that the plaintiffs allege breach of warranty, which may require in some states that plaintiffs present proof that they relied on statements made regarding the product. However, Thrasher and Bostick cannot recall whether they were informed Dr. Schoettle would be using St. Jude's aortic connector during bypass surgery or not. Thus, St. Jude argues that the plaintiffs are not typical of class members who were informed of the use of aortic connectors. (Opp'n at 24.)

Furthermore, St. Jude asserts that plaintiff Bostick's claims are not typical of the thousands of other patients who received an aortic connector and have experienced no trouble with the device. It contends that other aspects of Thrasher's and Bostick's medical and family histories are unique, which present substantial proof problems that may not be shared by all class members. St. Jude also argues that the plaintiffs' damage claims are not typical of the class and notes that Class II includes aortic connector recipients with claims for wrongful death and survival while the plaintiffs themselves are alive and well. *But see Alpern v. UtiliCorp. United Inc.*, 84 F.3d 1525, 1540 (8th Cir. 1996) ("The fact that damage calculations might differ slightly for [different plaintiffs] is a minor matter in comparison with the fundamental similarities.") *See also In re Telectronics Pacing Sys., Inc.*, 172 F.R.D. 271, 288-89 (S.D. Ohio 1997) ("No matter how individualized the issue of damages may be, these issues may be reserved for individual treatment with the question of liability tried as a class action.").

d. Adequacy of Representation

The final requirement of Rule 23(a) is that "the representative parties will fairly and adequately protect the interests of the class." FED. R. CIV. P. 23(a)(4). This rule has two requirements. First, "the representative must have common interests with unnamed members of the class." *In re Am. Med. Sys., Inc.*, 75 F.3d at 1083. Second, "it must appear that the representatives will vigorously prosecute the interests of the class through qualified counsel." *Id.* The adequate representation requirement "overlaps with the typicality requirement because in the absence of typical claims, the class representative has no incentives to pursue the claims of the other class members." *Id.*

In addition to their arguments for typicality, the plaintiffs contend that Thrasher and Bostick possess all of the qualities of adequate class representatives. They assert that each named plaintiff meets the definition of his respective class and is willing to represent others similarly situated. Thrasher and Bostick have responded to St. Jude's discovery requests and the disclosure requirements of the federal rules. Moreover, both plaintiffs have attended and participated in a class representative deposition. The plaintiffs argue that no facts suggest that Bostick and Thrasher have any conflict or other interest antagonistic to the vigorous pursuit of class claims against St. Jude on behalf of the entire class. Finally, Bostick and Thrasher propose that they have retained experienced and qualified counsel to vigorously represent the interests of the proposed classes.

St. Jude does not challenge the adequacy and qualifications of

plaintiffs' counsel; however, St. Jude does challenge Bostick's and Thrasher's suitability as class representatives on the same grounds upon which it opposed the representative plaintiffs' satisfaction of the typicality requirement.

2. Rule 23(b)

Even if the prerequisites of Rule 23(a) are met, the plaintiff also has the burden of meeting one of the three criteria listed in 23(b). A class action will be maintained only if one of the criteria of Rule 23(b) is satisfied. In this case, the plaintiffs seek certification under all three provisions of Rule 23(b). They first seek to certify both classes under Rule 23(b)(3), which permits certification where plaintiffs can show that common questions predominate and that a class action is the superior method to adjudicate the controversy. Plaintiffs also seek to certify Class I, the medical monitoring class, under Rule 23(b)2), which permits injunctive relief, if plaintiffs can show that St. Jude acted or refused to act on grounds generally applicable to the class. Finally, plaintiffs seek certification of Class I under Rule 23(b)(1)(A), which provides for class certification when separate actions would create a risk of inconsistent or varying adjudications that would establish incompatible standards of conduct for the party opposing the class.[6]

a. Certification of Medical Monitoring Class under Rule

[6] The plaintiffs did not seek class certification under Rule 23(b)(1) in their complaint. They raise this argument only in their motion for class certification, and plaintiffs' counsel indicated at the hearing that the plaintiffs primarily sought certification of the medical monitoring class under the second and third subsections of Rule 23(b).

23(b)(1) and (b)(2)

St. Jude challenges certification of Class I under Rules 23(b)(1) and (b)(2) on four grounds. First, St. Jude contends that plaintiffs in Class I do not have constitutional standing to bring a medical monitoring claim. Second, St. Jude argues that medical monitoring is not an injunctive remedy and is therefore unavailable under Rule 23(b)(2). Third, St. Jude asserts that the medical monitoring class is not sufficiently cohesive. Finally, St. Jude claims that certification under Rule 23(b)(1) is inappropriate because there is no risk of inconsistent judgments.

Rule 23(b)(1)(A) provides for class certification when separate actions would create a risk of inconsistent or varying adjudications that would establish incompatible standards of conduct for the party opposing the class. The plaintiffs contend that medical monitoring relief must be uniform to be effective. In response, St. Jude argues that any risk of divergent results from multiple cases exists only because the individual issues surrounding each class members claims will dictate each class member's prospective entitlement to medical monitoring. Therefore, St. Jude contends that class certification is inappropriate as a altogether.

Rule 23(b)(2) provides that plaintiffs may be eligible for relief when the party opposing certification has acted or refused to act on grounds generally applicable to the class. FED. R. CIV. P. 23(b)(2). The rule permits class actions in which the plaintiffs seek damages, but only in those cases where the *primary* relief sought is injunctive or declaratory. *Alexander v. Aero*

Lodge No. 735, 565 F.2d 1364, 1372 (6th Cir. 1977) (emphasis in original). Unlike Rule 23(b)(3), Rule 23(b)(2) has no requirement of superiority or predominance. ***In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.***, MDL No. 01-1396, 2004 U.S. Dist. LEXIS 149, at 14 n.7 (D. Minn. Jan. 5, 2004). However, the rule does include "an implicit 'cohesiveness' requirement, which precludes certification when individual issues abound." ***Thompson v. Am. Tobacco Co.***, 189 F.R.D. 544, 577 (D. Minn. 1999) (citing ***Barnes v. Am. Tobacco Co.***, 161 F.3d 127, 143 (3d. Cir. 1998) (relying on the cohesiveness requirement enunciated by the Supreme Court in ***Amchem Prods., Inc. v. Windsor***, 521 U.S. 591 (1997)).

Here, Bostick and Thrasher seek medical monitoring relief consisting of a "supervised trust, funded by St. Jude, that would provide to the class the medical procedures and diagnostic tests recommended to uncover the likely conditions resulting from the implantation of an aortic connector." (Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 37.) The plaintiff's assert that the monitoring program they seek would not provide compensation for any personal injuries that patients have suffered or might suffer. (***Id.*** at 37-38.) Furthermore, the plaintiffs contend that the tests and procedures they propose are "not routinely performed as part of a routine follow-up of a patient who has received a bypass surgery." (***Id.*** at 38.)

St. Jude contends that Class I may not be certified under this subsection of Rule 23(b) because plaintiffs do not seek equitable relief. St. Jude claims that because the proposed medical monitoring trust fund would be paid for by St. Jude, the medical

monitoring claim is equivalent to one for money damages. There is a Tennessee case holding otherwise. In *Craft v. Vanderbilt Univ.*, 174 F.R.D. 396, 406-07 (M.D. Tenn. 1996), the court held that an action for court-supervised medical monitoring could qualify as injunctive relief under Rule 23(b)(2). *See also In re St. Jude Med., Inc. Heart Valves*, 2003 WL 1589527 (D. Minn., March 27, 2003); *Day v. NLO, Inc.*, 144 F.R.D. 330, 336 (S.D. Ohio 1992) (holding that a medical monitoring program could constitute injunctive relief as required by Rule 23(b)(2)). *But see Zinser v. Accufix Research Inst., Inc.*, 253 F/3d 1180, 1195-96 (9th Cir. 2001) (addressing *Craft* decision and citing other cases where the equitable nature of medical monitoring was at issue). The key query is whether the plaintiffs can demonstrate that the "primary relief they are seeking is injunctive or declaratory" as opposed to a request for what is essentially monetary relief. *Kurczi*, 160 F.R.D. at 672.

b. <u>Predominance of Common Issues Versus Individual Issues under Rule 23(b)(3) for Classes I and II</u>

The plaintiffs argue that both classes can be certified under Rule 23(b)(3). This rule has two requirements: (1) that common questions of law or fact predominate over any questions affecting only individual class members and (2) that a class action is superior to other available methods of adjudicating the controversy. FED. R. CIV. P. 23(b)(3). This rule parallels Rule 23(a)(2) in that both subdivisions require that common issues exist, but 23(b)(3)'s predominance test goes further by insuring that the common issues predominate over individual issues. *In re Am. Med. Sys., Inc.* 75 F.R.D. at 1084.

St. Jude argues that certification under Rule 23(b)(3) is not appropriate because there are too many factual and legal differences among the class members, thereby destroying predominance. Furthermore, St. Jude contends that a class action would not be a superior method of adjudicating either class's allegations because of the inherent difficulties in dealing with the laws of many states.

"[A] claim will meet the predominance requirement when there exists generalized evidence which proves or disproves an element on a simultaneous, class-wide basis, since such proof obviates the need to examine each class member's individual issues." ***Weinberg v. Insituform Tech.*****, No. 93-2742, 1995 WL 368002, at *7 (W.D. Tenn. April 7, 1995) (Gibbons, C.J.). "Predominance is usually decided on the question of liability, so that if the liability issue is common to the class, common questions are held to predominate over individual ones."** ***Id.***

The plaintiffs contend that the controlling issues of whether aortic connectors are defective, and whether St. Jude was negligent in failing to adequately test the product before placing in the stream of commerce "plainly predominate over any individual issues in this case." (Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 33.) The plaintiffs also argue that as to Class I, there are no legally relevant individual issues at all because Dr. Frank Martin contends that anyone with an aortic connector is injured by the aortic connector's presence in them alone and thus requires monitoring. (Pls.' at 33.) The plaintiffs do not address the fact that all class members claims will not be governed under

the law of a single jurisdiction. Various jurisdictions have rejected class certification where the applicable states' laws vary and preclude a finding that common issues predominate. *In re Am. Med. Sys., Inc.*, 75 F.3d at 1085.

"[T]he purpose of the superiority requirement is to assure that the class action is the most efficient and effective means of settling the controversy . . . ." Wright, 7 *Federal Practice & Procedure*, § 1780 at 562. Rule 23(b)(3) identifies four factors which should be examined by the court to determine whether class treatment would be fair and efficient:

> **(A) the interest of members of the class in individually controlling the prosecution or defense of separate actions;**
> **(B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class;**
> **(C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum;**
> **(D) the difficulties likely to be encountered in the management of a class action.**

FED. R. CIV. P. 23(b)(3)(A)-(D). In analyzing superiority, the court primarily considers "the difficulties likely to be encountered in the management of a class action." FED. R. CIV. P. 23(b)(3). Here, the main factor affecting superiority involves application of state law to plaintiff's claims. Even if common questions of law exist, the application of multiple state laws may render the case unmanageable as a class action. *See Telectronics*, 172 F.R.D. at 290-91.

Bostick and Thrasher claim that variations in state law should not bar this class action and assert that "[i]f the elements of the cause of action are the same and legal standards on significant

issues are substantially similar the state laws can be grouped for purposes of class certification." (Pls.' Mem. of Law in Supp. of Mot. for Class Certification at 34 (citing *Telectronics*, 172 F.R.D. at 292).)

B. Certification of a Nationwide Class

After a careful review of the record, argument presented at the hearing, and the briefs submitted to the court, it is clear that the plaintiffs have not carried their burden of establishing that this medical product liability action is maintainable or manageable as a nationwide class under either prong of Rule 23. Turning first to the threshold requirements of Rule 23(a), the plaintiffs have not presented any argument or evidence to the court as to how choice of law considerations and variations in state law can be reconciled with the requirements of commonality, typicality, and adequate representation of a nationwide medical monitoring or personal injury class.

Before the court can determine, for instance, whether the commonality requirement of Rule 23(a)(2) is satisfied, the court must undertake a choice of law analysis to determine which state's law applies to the claims of each class member. *See In re Am. Med. Sys., Inc.* 75 F.3d 1069, 1085 (6th Cir.). In diversity cases, a federal court must apply the choice of law rules of the forum state. *Klaxon Co. v. Stentor Elec. Mfg.*, 313 U. S. 487 (1941). Thus, Tennessee's choice of law rules will apply to this case. Tennessee follows the approach of the *Restatement (Second) of Conflicts of Laws* and "provides that the law of the state where the injury occurred will be applied unless some other state has a more

significant relationship to the litigation." *Hattaway v. McKinley*, 830 S.W.2d 53, 59 (Tenn. 1992). The plaintiffs have averred that approximately 40,000 patients in all fifty states have received the aortic connector in bypass surgeries. Therefore, the possibility exists that the laws of all fifty states could apply to the rights and liabilities of the parties.

With state law differences on issues such as strict product liability, negligence, medical monitoring, and the availability of affirmative defenses, such as comparative fault and the learned intermediary doctrine, this court finds it difficult to see a common legal standard applicable to all class members, and the plaintiffs have not provided the court with any analysis on the issue. At most, the plaintiffs have listed generic "common questions" that can be characterized as "common" at the most superficial level. For instance, the plaintiffs include within their list of common questions issues such as whether St. Jude is strictly liable, whether St. Jude is negligent, and whether a medical monitoring program is appropriate and necessary. Because a choice of law analysis will be required to determine the law to be applied to the claims of each class member, the law that applies to these questions necessarily will differ as to each class member. Even the basic question of whether St. Jude's aortic connectors are defective will depend on the application of the laws of all fifty states and perhaps upon facts particular to each individual plaintiff.

The plaintiffs, both in their briefs and during oral argument, merely gloss over the choice of law issues. They give the court

general assurances that any issues arising out of state law variations will be overcome. They have not submitted to the court a plan as to how the differences in state law could be managed. Without more, the plaintiffs have failed to meet their burden of proof under Rule 23 and have not illustrated that a common question of law exists, much less predominates as required under Rule 23(b)(3). *See Chin v. Chrysler Corp.*, 182 F.R.D. 448, 453 (D.N.J. 1998) (finding that the plaintiff failed to meet its burden to "credibly demonstrate, through an 'extensive analysis' of state law variances, 'that class certification does not present insuperable obstacles'"); *In re Am. Med. Sys., Inc.*, 75 F.3d at 1079, 1085. For this reason and for others that will be discussed below in the court's analysis of the certification of a Tennessee class, this court does not recommend the certification of Class I or II on a nationwide basis.

C. Certification of a Tennessee Class Action

In the alternative to a nationwide class, the plaintiffs seek certification of a Tennesseee class action with two subclasses limited to patients who received the aortic connector in Tennessee. St. Jude asserts, however, that limiting the classes to Tennessee will not solve the problem plaintiffs face with state law variations because patients receiving the bypass in Tennessee may reside elsewhere, which would necessitate a choice of law analysis for the claims of each Tennessee class member. As this court stated above in the court's choice of law analysis for a nationwide class, there is a presumption in Tennessee that the law of the location of the injury controls. Under the plaintiffs' theory of

this case, the location of the alleged injury is the place where the patients were implanted with the aortic connector and that place would be Tennessee under the plaintiffs' alternative class definition. In light of the place-of-injury presumption, this court submits that narrowing the medical monitoring class and personal injury class to Tennessee would in fact remove the overwhelming choice-of-law issues facing a nationwide class. The plaintiffs have asserted, without challenge by St. Jude, that at least 300 aortic connectors have been implanted in the state of Tennessee. That figure, as opposed to the 40,000 possible nationwide class members, would be manageable even if the court had to determine if another state had a more significant relationship to the plaintiffs' claims. Thus, there are common issues of law in a Tennessee class, and there is no dispute as to the numerosity requirement. Accordingly, the court must analyze the two Tennessee classes in more detail to determine whether the other requirements of Rule 23 are satisfied.

1. Class I - The Medical Monitoring Class

At the outset, the court must address whether Class I has standing to bring an action for medical monitoring because standing is a requirement of Article III. *Sutton v. St. Jude Med., Inc.*, 292 F. Supp. 2d 1005, 1007 (W.D. Tenn. 2003) (citations omitted) ("Standing must be determined at the outset of litigation, as failure of a plaintiff to show standing deprives the federal courts of jurisdiction to hear the case."); *see also Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 612-13 (1997) ("Rule 23's requirements must be interpreted in keeping with Article III constraints . . .

.”).

The burden is on the plaintiff to prove standing. Standing consists of three elements: (1) the plaintiff must have suffered an injury in fact; (2) there must be a causal connection between the injury and the defendant’s conduct of which the plaintiff complains; and (3) it must be likely that the injury will be redressed by a favorable decision. *Id.* (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). The “injury in fact must be actual or imminent, not conjectural or hypothetical.” *Id.* Furthermore, in a class action, “the named plaintiff must allege an individual personal injury in order to seek relief on behalf of himself, or herself, or any other member of a class.” *Id.* (citing *O’Shea v. Littleton*, 414 U.S. 488, 494 (1974)). When analyzing standing at the class certification stage, the court assumes the truth of facts alleged by the plaintiff. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

The plaintiffs have stated in support of their motion for class certification that “[t]here can be no confusion as to who belongs to Class I. Quite simply, Class I includes every U.S. or Tennessee patient who still has an aortic connector.” (Pls.’ Mem. of Law in Supp. of Mot. for Class Certification at 12.) At the hearing, plaintiffs’ counsel repeatedly referred to Class I as the class encompassing those patients who have been implanted with the aortic connector but are asymptomatic or without injury. After the hearing, however, the plaintiffs filed a Supplemental Statement Regarding Oral Argument on Motion for Class Certification that indicated that Class I also includes patients like Bostick who have

allegedly suffered injury related to the aortic connector. (*See* Pls.' Supplemental Statement Regarding Oral Argument at 1.) Thus, proposed Class I includes not only those people who have allegedly been injured but also patients who have experienced no trouble whatsoever with the implantation of the connector.

In addition to proposed class members who allege injury in fact, the plaintiffs argue that all members of Class I have been injured merely by the aortic connector's presence in their bodies. The plaintiffs cite the opinion of Dr. Martin, the study conducted by Dr. Schoettle, and statements made by Dr. Klima as support for their assertion. (*See* Pls.' Mem. of Law in Supp. of Motion for Class Certification at 33.) The argument plaintiffs make here is basically the same argument made by the plaintiff in *Sutton v. St. Jude Medical, Inc.*, 292 F. Supp. 2d 1005, 1007 (W.D. Tenn. 2003).

In *Sutton*, the plaintiff represented a class of individuals who had had an aortic connector implanted in their bodies. *Id.* While some patients included in the class had actually incurred physical injuries, the plaintiff had not suffered any physical injury or medical consequences from implantation of the aortic connector. *Id.* Nevertheless, the plaintiff argued that he and similarly situated class members suffered an increased risk of physical complications by merely having the device. *Id.* The issue confronted by the District Court of Western Tennessee in *Sutton* was "whether [plaintiff's] increased risk of complications constitutes an 'injury in fact' sufficient to confer standing." *Id.* The court noted that the issue was one of first impression in Tennessee. *Id.* After analyzing cases outside the Sixth Circuit, including a case

specifically relied upon by Bostick and Thrasher in the present case,[7] the *Sutton* court held that the plaintiff's increased risk of harm did not meet the "constitutional requirement that an injury be neither 'conjectural' nor 'hypothetical'" because the plaintiff had not presented any evidence of increased risks or complications among aortic connector recipients or any specific incidents of harm. *Id.* at 1008. Consequently, the court found that the plaintiff was unable to demonstrate standing and the court was without jurisdiction to hear the case. *Id.*

Here, Bostick and Thrasher are essentially making the same "increased risk of harm" argument. Unlike the plaintiff in *Sutton*, however, Bostick and Thrasher have presented what they contend is evidence of an increased risk of harm associated with the aortic connector by way of a study performed by Dr. Schoettle, comments

---

[7] The plaintiffs rely on an unreported medical device products liability case currently pending in the District of Minnesota in support of their increased risk of harm argument. In *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396 JRTFLN, 2003 WL 1589527 at *11-12 (D. Minn. March 27, 2003), a district court found that a class of patients who had heart valve implants, but who had not suffered any injurious side effects as a result, had an increased risk of harm constituting injury in fact. That medical monitoring class, however, was later limited to patients from fifteen states in which medical monitoring is recognized as a stand-alone cause of action, without proof of injury. In *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396 JRTFLN, 2004 U.S. Dist. LEXIS 149 at *17 (D. Minn. Jan. 5, 2004). Tennessee was originally included as a state recognizing such a claim but was withdrawn from the class in a later order. *See* In *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396 JRTFLN, 2004 U.S. Dist. LEXIS 13965 at *15-16 (D. Minn. July 15, 2004). Accordingly, this case no longer supports Bostick's and Thrasher's increased risk of harm argument because Tennessee was specifically excluded from the medical monitoring class.

made by Dr. Klima, and an affidavit filed by Dr. Martin. The evidence presented, however, does not demonstrate to a reasonable medical certainty that the aortic connector, in and of itself, increases the risk of physical complications. *See Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1204-05 (6th Cir. 1988).

In light of the court's ruling in *Sutton*, this court finds that the asymptomatic members of Class I lack standing to bring an action for medical monitoring under the laws of Tennessee. Moreover, not only have the plaintiffs failed to demonstrate that asymptomatic Class I members have standing, they have not presented to the court any case law from Tennessee supporting their assertion that Tennessee recognizes an action for medical monitoring in the absence of a present injury. In fact, a review of the applicable case law reveals that Tennessee does require a present injury. *See In re St. Jude Med., Inc., Silzone Heart Valves Prods. Liab. Litig.*, MDL No. 01-1396(JRT/FLN), 2004 U.S. Dist. LEXIS 13965 at *12 n.3 (July 15, 2004) (noting that Tennessee requires present injury for medical monitoring claims); *Jones v. Brush Wellman, Inc.*, No. 1:00 CV 0777, 2000 WL 33727733 at *8 (N.D. Ohio, Sept. 13, 2000) ("No Tennessee cases support a cause of action for medical monitoring in the absence of a present injury."); *Potts v. Celotex Corp.*, 796 S.W.2d 678, 681 (Tenn 1990). Because there can be no showing that each class member has been injured, this court recommends that a medical monitoring class not be certified because the class is overly broad and lacks standing.

The court also recommends that Class I not be certified on the grounds that plaintiff Bostick is not an adequate class

representative as required by Rule 23(a)(4). Bostick is said to represent Class I and Class II because he still has an aortic connector and has been injured, although not injured enough to require the removal of the device. However, Bostick does not represent those members of Class I that are asymptomatic because he alleges he has been injured. An adequate class representative "must be part of the class and possess the same interest and suffer the same injury as the class members." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 594-95 (1997); *see In re Baycol Prods. Litig.*, 218 F.R.D. 197, 210-11 (D. Minn. 2003) ("Given the nature of a medical monitoring claim, the Court is not convinced that the named representatives will adequately represent the interests of those class members who have not suffered any injury as a result of taking Baycol . . . ."). As a patient who allegedly has been injured by the implantation of the aortic connector, Bostick cannot adequately represent the portion of Class I that has experienced no problem whatsoever with the device.

The fact that Bostick has been injured also affects his satisfaction of the typicality requirement of Rule 23(a)(3). *See Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1234 (9th Cir. 1996) (no typicality where class representative alleges different injuries from those suffered by other class members).

As the definition for Class I stands, an undetermined portion of the class has not established standing to bring an action for medical monitoring because they lack an injury-in-fact as required under Tennessee law, and they are not adequately represented by plaintiff Bostick who has allegedly sustained an injury. In

addition, Bostick claims are not typical of the other members of the medical monitoring class. While the court has the discretion to redefine the class, it is recommended that the court decline to exercise that discretion. Accordingly, it is recommended that the plaintiffs' motion to certify a Tennessee medical monitoring class be denied.

2. Class II - The Personal Injury Class

In addition to its argument that the plaintiffs cannot satisfy the requirements of Rule 23 for a personal injury Tennessee class, St. Jude contends that the definition of Class II, which is limited to patients who have "sustained presently compensable physical injuries due to the aortic connecter," is an improper definition because "it purports to identify the class member by reference to the ultimate question in this case – whether either plaintiff or any individual they purport to represent has a 'presently compensable injury due to the aortic connector.'" (Opp'n at 26.) The court need not conduct a detailed evaluation of the requirements of Rule 23(a) and 23(b) and an analysis of whether those requirements are met in this instance, because the court agrees with St. Jude's argument that the definition of Class II is an improper definition.

"Although not specifically mentioned in Rule 23(a), a class must be sufficiently definite in order to warrant certification." *Hagen v. Winnemuca*, 108 F.R.D. 61, 63 (D. Nev. 1985). An inquiry into the merits of the case should not be required of the court in its determination of whether a person is a member of a class. *Id.* at 63-64; *accord Forman v. Data Transfer, Inc.*, 164 F.R.D. 400, 403

(E.D. Pa. 1995) (rejecting class defined to include all those who "received unsolicited facsimile advertisements" because determination of class membership wold require a "mini-hearing on the merits" as to the central issue of liability); *Dunn v. Midwest Buslines, Inc.*, 94 F.R.D. 170, 172 (E.D. Ark. 1982) (finding class definition "vague[] and ambigu[ous]" where class definition depended on an initial determination by the court that the each potential class member experienced discrimination); *see also Telectronics Pacing Sys., Inc.*, 172 F.R.D. at 282 ("While the Court must probe behind the pleadings in order to determine if class certification is proper, it is inappropriate for the Court to examine the merits of the claim in doing so."). The ascertainability of class member is important so a court can decide "who will receive notice, who will share in any recovery, and who will be bound by the judgment." *Van Nest v. Midland Nat'l Life Ins. Co.*, 199 F.R.D. 448, 451 (D.R.I. 2001). The requirement of ascertainability "is not satisfied when the class is defined simply as consisting of all persons who may have been injured by some generically described wrongful conduct allegedly engaged in by a defendant." *Id.*

This appears to be exactly what the plaintiffs have done in this case in their definition of Class II. To establish who belongs in the personal injury class, the court would have to conduct "mini-trials on the merits" to determine the patients who have "sustained presently compensable physical injuries due to the aortic connector." The fact that the aortic connector caused injury to each bypass patient would have to be established before

class notice could be issued. Furthermore, the court would have the daunting task of determining whether the injury caused by the aortic connector is "presently compensable" for over 300 patients receiving the device in Tennessee. As St. Jude has indicated to the court, such a determination "would involve all the diverse issues of liability, causation, etc. that these claims present" and would essentially require the adjudication of every potential class member's individual claim. (Defs.' Mem. of Law in Opp'n to Pls.' Mot. for Class Certification at 27.) Because the members of Class II are not presently ascertainable without an adjudication of the merits of their claim, it is recommended that the court decline class certification of a Tennessee personal injury class as Class II is presently defined. Therefore, this court finds it unnecessary to complete further analysis of class certification pursuant to Federal Rule of Procedure 23.

CONCLUSION

Accordingly, for the reasons stated herein, it is recommended that the plaintiffs' motion for certification of a nationwide class, a Tennessee medical monitoring class, and a Tennessee personal injury class be denied.

Respectfully submitted this 17th day of August, 2004.

_____
DIANE K. VESCOVO
UNITED STATES MAGISTRATE JUDGE

NOTICE

ANY OBJECTIONS OR EXCEPTIONS TO THIS REPORT MUST BE FILED

WITHIN TEN (10) DAYS AFTER BEING SERVED WITH A COPY OF THE REPORT. 28 U.S.C. § 636(b)(1)(C). FAILURE TO FILE THEM WITHIN TEN (10) DAYS MAY CONSTITUTE A WAIVER OF OBJECTIONS, EXCEPTIONS, AND FURTHER APPEAL.