UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

LINDA WOLICKI-GABLES,
and ROBERT GABLES, etc.,

Plaintiffs,

v. CASE NO. 8:08-CV-151-T-17TBM

ARROW INTERNATIONAL, INC.,
CODMAN & SHURTLEFF, INC.,
JOHNSON & JOHNSON, and
GREG NELSON,

Defendants.

_____/

ORDER

This cause is before the Court on:

Dkt.	66	Motion for Partial Summary Judgment Counts IV and VII
Dkts.	70-78	Depositions
Dkt.	90	Response
Dkt.	85	Motion for Summary Judgment
Dkt.	101	Response
Dkt.	80	Motion for Summary Judgment
Dkt.	82	Motion for Summary Judgment
Dkt.	89	Order - Joinder
Dkts.	95-100	Depositions
Dkt.	102	Deposition
Dkt.	103	Response
Dkt.	115	Supplemental Authority
Dkt.	81	Motion in Limine to Exclude Plaintiffs' Experts
Dkt.	104	Response
Dkt.	109	Notice

The Second Amended Complaint includes the following claims:

Count I	Strict Liability	Arrow
Count II	Negligence	Arrow
Count III	Consortium	Arrow
Count IV	Strict Liability	Codman
Count V	Negligence	Codman
Count VI	Consortium	Codman
Count VII	Strict Liability	J&J
Count VIII	Negligence	J&J
Count IX	Consortium	J&J
Count X	Negligence	Nelson
Count XI	Vicarious Liability	Arrow
Count XII	Vicarious Liability	Codman
Count XIII	Vicarious Liability	J&J
Count XIV	Consortium	Nelson
Count XV	Consortium	Arrow
Count XVI	Consortium	Codman
Count XVII	Consortium	J&J

The Court previously dismissed Count V and Count VIII, claims for negligence as to Defendants Codman & Shurtleff, Inc. and Johnson & Johnson (Dkt. 51).

A Stipulation of Dismissal with Prejudice was filed as to Count XI, Vicarious Liability - Arrow, and Count XV, Consortium - Arrow (Dkt. 69), which was granted (Dkt. 79).

Defendants Codman & Shurtleff, Inc., Johnson & Johnson, and Greg Nelson, have joined in the Motion for Summary Judgment of Defendant Arrow International, Inc., and the Motion in Limine to Exclude Plaintiffs' Experts (Dkt. 89).

I. Standard of Review

Summary judgment should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and

that the movant is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c).

> The plain language of Rule 56(c) mandates the entry of summary judgment after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."

Celotex Corp. v. Catrett, 477 U.S. 317 (1986).

The appropriate substantive law will guide the determination of which facts are material and which facts are...irrelevant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). All reasonable doubts about the facts and all justifiable inferences are resolved in favor of the non-movant. See Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1115 (11th Cir. 1993). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." See Anderson, 477 U.S. at 248. But, "[i]f the evidence is merely colorable...or is not significantly probative...summary judgment may be granted." Id. at 249-50.

II. Statement of Facts

1. On April 30, 2002, Dr. Brian James performed surgery on Plaintiff Linda Wolicki-Gables to implant a drug delivery pump and catheter for treatment of chronic pain. (Dkt. 103-3, Operative Note).

2. The components implanted in Plaintiff Linda Wolicki-Gables included a pump that released pain medication, an intrathecal catheter through which the medicine was delivered into the spinal canal, and a metal connector that linked the pump catheter to the intrathecal catheter.

3. The identifying information for the pump follows:

ARROW	Implant Model: Codman/Arrow
Model 3000	Cont. No. AP-07009
Serial No. 8035	Lot No.: 335918
MADE IN U.S.A.	Size: 105 cm, ID 0.5 mm
CE 0128"	Diopters: N/A
	Co.: N/A
	Exp. Date: 2006-03

4. The identifying information for the catheter kit follows:

Arrow Flextip Plus Intraspinal Kit
Catalog No. AP-07009
Lot No. 312737

The catheter kit includes a connector. (Dkt. 66-8, p. 80). The catheter connector also comes individually. (Dkt. 66-8, p. 85).

5. After implantation, over a period of time, Dr. James adjusted the dosage of the pain medication to be administered to Plaintiff Linda Wolicki-Gables through the pump. Dr. James testified that it was a common process to start with a low dosage and gradually find a balance of the amount of medicine with the level of pain relief. Dr. James testified that although his records state the diagnosis as "malfunctioning implanted device," the diagnosis should have stated "failed back surgery syndrome." Dr. James testified that there was no finding during those days

of any malfunction of the pump. (Dkt. 96, pp. 95-109.)

6. On August 15, 2002, at Plaintiff Linda Wolicki-Gables' request, Dr. James performed a dye injection test to assess whether the infusion pump was working properly. Dr. James observed no leaks in the system and saw appropriate intrathecal spread of the dye. (Dkt. 103-6, Procedure Note). After the test, Plaintiff Linda Wolicki-Gables complained of pain radiating to the pump. (Dkt. 103-7).

7. On July 10, 2003, Dr. James again tested the pump (Dkt. 103-9, Progress Note). In Dr. James' records, Dr. James states:

> "...When the dye was injected, it just came back out through the nipple and extravasated near the needle entry site, coming externally and dripping down the side of the patient on both sides. Clearly, the bolus function of the pump is malfunctioning. The rep for Arrow Medical, Greg Nelson, was contacted. We will schedule Linda for replacement of her malfunctioning pump.
>
> She is to continue on her present meds. We reviewed her pump refill notes. She is in fact receiving the medication through the regular functioning system of the pump. It is just the bolus function is malfunctioning..."

8. On July 15, 2003, Plaintiff Linda Wolicki-Gables executed an "Informed Consent to Treat and Disclose Information" at Doctors Same Day Surgery Center. In the Informed Consent Plaintiff signed, Plaintiff Linda Wolicki-Gables did not consent, inter alia, to the admittance of students and persons required for technical support to the room in which the procedure [was] performed, and did not consent to the disposal of any tissues or

body parts...removed in accordance with customary practice. Plaintiff initialed "We want old pump." on the form (Dkt. 103-11).

9. On July 15, 2003, Dr. James performed surgery at Doctors Same Day Surgery Center to replace the infusion pump. During the surgery, the pump was removed, a connector was replaced, and the same pump was reimplanted. (Dkt. 103-12).

10. Defendant Greg Nelson, sales representative for Defendant Arrow International, was present in the Operating Room during the revision procedure of July 15, 2003.

11. On July 17, 2003, Dr. James examined Plaintiff Linda Wolicki-Gables, refilled her pump, confirmed it was working properly, noted that Plaintiff's surgical incision site looked fine, and identified no clinical signs of any infection.

12. On July 29, 2003, Plaintiff Linda Wolicki-Gables was unable to move her lower extremities, and was admitted to Sarasota Memorial Hospital (Dkt. 103-15). Plaintiff Wolicki-Gables remained hospitalized until August 8, 2003, after which Plaintiff was transferred to another facility for rehabilitation. The discharge diagnosis was transverse myelitis of undetermined cause.

13. Plaintiff Wolicki-Gables was readmitted to Sarasota Memorial Hospital on August 11, 2003 for the removal of the pump (Dkt. 103-17). Dr. Raymond Priewe removed the pump. At that time Dr. Priewe found a superficial skin infection; Dr. Preiwe's note states: "No pus in pump pocket or dorsal spine, only

superficial skin." (Dkt. 77, p. 39).

14. After removal, the pump was cultured at Sarasota Memorial Hospital. The pump and catheter is now in the custody of Plaintiff's counsel.

15. Small parts, such as the connector, in the absence of a request to save or test the part, are discarded as waste in accordance with the policies of Doctors Same Day Surgery Center. Linda Burns testified that in 2003 the policy to discard medical waste is to place it in a "red bag situation" to be discarded under the universal biohazardous protocol. (Dkt. 102, p. 60). Linda Burns further testified that there was no policy that would have prohibited sales rep. Greg Nelson from taking the connector with him when he left. (Dkt. 102, p. 49.)

16. The following chronology of events shows the relationship of Defendant Greg Nelson to Defendants Codman & Shurtleff, Inc. and Johnson & Johnson:

December, 1998	Greg Nelson forms Venture Medical Devices, Inc., which served as a distributor of Arrow's implantable pump products in Florida pursuant to a contract;
Pre-March, 2002	Arrow designed, manufactured and distributed the pump and catheter kit like those implanted in Plaintiff;

March 1, 2002	Codman acquired Arrow's pump division. Codman assumed the distribution contract between Arrow and VMD; VMD continued as an independent contractor authorized to distribute Codman products;
April 30, 2002	Pump and catheter kit implanted in Plaintiff; Greg Nelson attended the implant procedure and delivered the pump;
July, 2003	Greg Nelson became a Codman employee.

17. The distribution contract between Arrow and Venture Medical Devices, Inc. provides that: "nothing in the Agreement is to be construed as creating a principal/agent relationship, an employer/employee relationship, or a joint venture or partnership." (Dkt. 66, Exh. E, Par. 17).

18. Defendant Arrow admits that Defendant Arrow designed, manufactured, tested and sold the subject pump and catheter kit. Plaintiffs admit Defendants Codman & Shurtleff, Inc. and Johnson & Johnson did not design, manufacture, test or sell the pump and catheter kit. Plaintiffs contest only the alleged distribution of the pump and catheter kit by Defendants Codman & Shurtleff, Inc. and Johnson & Johnson.

19. In Count X of the Second Amended Complaint (Dkt. 30), Plaintiffs allege a negligence claim as to Defendant Greg Nelson, based on the alleged breach of the duty to use reasonable care in the instruction and education of physicians as to the implantable drug delivery system so that it would be reasonably safe for its

intended use. Plaintiffs also allege a breach of the duty to ensure that the implantable drug delivery system was functioning properly before allowing it to be implanted. Plaintiffs further allege a duty to ensure that Plaintiffs consented to Defendant Nelson's presence in the operating room, and a duty to verify that Plaintiffs consented the destruction of the pump parts removed.

In the Second Amended Complaint, Plaintiffs include no allegations which refer to the liability of Defendant Nelson on the basis of Defendant Nelson's distribution of the subject products. The allegations of Paragraph 7 refer to the liability of Defendants Codman and Johnson & Johnson, based on the actions of Defendant Nelson while a representative or employee of Defendants.

20. Dr. Brian James was deposed on October 15, 2008, November 19, 2008, January 7, 2009 and February 4, 2009. Dr. James testified that he had only a vague recollection of Plaintiffs. (Dkt. 95, p. 12.) Dr. James testified that it was a common practice for sales representatives of device companies to attend surgical procedures. (Dkt. 95, p. 9.) Dr. James testified that sales representatives are not in the sterile field and do not participate in the surgical procedure. (Dkt. 95, pp. 9-11). Dr. James further testified:

> "A. The decisions regarding patient care that I'm immediately involved in are under my discretion and my decisions. What I don't see when I'm not around I obviously don't have any say-so in.
>
> I mean, there's periods where the product's

> brought in where it's handled. I don't participate in that. I'm not aware what's going on. My decisions are not involved. There's periods when the product is then given to the staff of the facility.
>
> I'm not involved in many of the decision-making that-any of those encounters, I would not be involved in that. I'm involved in the immediate surgical field and patient care issues regarding that."

Dkt. 95., p. 11, Lines 6-18).

Dr. James testified as to Plaintiff Linda Wolicki-Gables' revision surgery, relying upon the medical records of that surgery. Dr. James testified that the revision surgery was performed because the bolus function of the pump did not work when Dr. James tested it on July 10, 2003. During the revision procedure, after the catheter was cut, the bolus function of the pump did work. Dr. James testified:

> Q. When you went in intraoperatively and cut the catheter so there was no potential catheter blockage or crimp, the bolus function of the pump worked just fine.
>
> A. Apparently.
>
> Q. Now, you made the decision to put the original pump back in, correct?
>
> A. According to the operative note I have, a new connector was used to connect the intrathecal catheter, the catheter that was presently in the patient, to the pump catheter system. It was then bolused and rechecked with the dye and spread within the spinal canal where it's supposed to go was

> confirmed. No leaks were seen.
>
> Then I took out the old medication that was in the pump, because I did not think she had been receiving it; or I wasn't certain; and I wanted to drop the dosage down just to be-it's better to be safe than sorry in that aspect to avoid any respiratory depression or potential overdose. So that's what was done.
>
> Q. So I'm-all right. Strike that. The decision was made after you bolused the pump and saw that the bolus function was working fine to return the original pump into Ms Gables' pump pocket, correct.
>
> A. Apparently.
>
> Q. So the only-well, not only apparently. That's what happened based on the operative report, correct.
>
> A. Right.

(Dkt. 95, pp. 36-38).

21. In his deposition of February 4, 2009, Dr. James testified that he has a wealth and depth of experience in the implantation of intrathecal pain pumps. (Dkt. 72-2, p. 193). Dr. James further testified that intrathecal pain pumps come with instructions for use, and that Dr. James was aware of all information offered by the manufacturer before performing an implantation, including all of the known complications reported by the manufacturer associated with the intrathecal pain pump. (Dkt. 72-2, p. 199-200).

22. Defendant Nelson was deposed on September 20, 2008 and October 1, 2008. Defendant Nelson testified that he did not have an independent recollection of the surgery performed on July 15, 2003. Defendant Nelson testified that, in general, the reason

for his presence in the Operating Room was so products were on hand in the event they were needed. (Dkt. 66-7, p. 34). Defendant Nelson testified that his role was limited to handing a package containing the part to an operating room nurse, who would hand the part to a scrubbed-in nurse, who would hand it to the doctor (Dkt. 66-8, p. 89), and observation of the physician's examination of the pump and test. Defendant Nelson testified that, in a revision surgery, it was routine to remove the connector to visualize the free flow of CSF (cerebro-spinal fluid) (Dkt. 66-9, p. 149). Defendant Nelson testified that the connector is a one-time use device once it's been connected. (Dkt. 66-9, p. 149). Defendant Nelson testified that Defendant Nelson did not deem the replacement of a connector to be a modification of the device (Dkt. 66-9, p. 152).

21. Plaintiff Linda Wolicki-Gables was deposed on September 18, 2008, September 24, 2008, September 29, 2008 and October 30, 2008. Plaintiff Linda Wolicki-Gables testified:

> Q. Did Doctor-What do you recall Dr. James telling you about the potential complications of the procedure?
>
> A. You know, I trusted Dr. James with my life. He put the pump in and he was going to fix the pump. He was going to take it out and put a new one in.
>
> Q. Do you recall him telling you of any potential complications from the procedure?
>
> A. No.
>
> Q. You understood there was a risk of infection?

A. There is always a risk of infection.

(Dkt. 78-4, p. 325).

Plaintiff Wolicki-Gables testified in detail as to what she heard and saw before and after the surgery of July 15, 2003. (Dkt. 78-3, 78-4, pp. 312-341) Plaintiff Wolicki-Gables testified that Defendant Greg Nelson was present and spoke to her after the surgery. (Dkt. 78-4, p. 327.) Plaintiff Wolicki-Gables testified that she recalled Defendant Nelson telling her that Defendant Nelson cut the catheter, and did a connection in her back. (Dkt. 78-4, p. 331). Plaintiff Linda Wolicki-Gables later testified that Plaintiff's best recollection was that Defendant Nelson did not speak with Plaintiff in the recovery room after surgery of July 15, 2003. (Dkt. 78-4, pp. 356-357).

23. Dr. Michael Meriwether, Plaintiff's medical expert, testified that there was an obstruction at the connector catheter junction, but the obstruction resulted from something unrelated to the product's design or manufacture:

> Q. However, because of some idiosyncratic complication with the patient, whether it was scar tissue, whether it was a granuloma or, with regard to some technique by the surgeon, a tie-down on the suture, something impaired the ability of the properly designed and properly manufactured system to function as designed?
>
> A. I would say, yes.

(Dkt. 74, p. 72-73).

Dr. Meriwether testified that a properly designed and implanted device might "fail" as the term is used medically, but

that does not mean that the device was defective. (Dkt. 74, p. 64).

24. Edward Reese, Ph.D., Plaintiffs' regulatory expert, testified that the specific malfunction of the device was a clog in the catheter connector. Dr. Reese further testified that a connector can become clogged without being defective. Dr. Reese also testified that, if medicine is flowing out of the pump reservoir through its continuous infusion mechanism into the spinal cord, there would be no clog in the catheter connector. (Dkt. 75-5, p. 483-484). Dr. Reese did not render an expert opinion as to a design defect, only as to a manufacturing defect. (Dkt. 75-2, p. 173, 75-4, pp. 291-292).

25. Dr. Reese submitted his Initial Report on September 1, 2008. Dr. Reese submitted an Amended Report on December 8, 2008. Dr. Reese submitted a further Amended Report on January 11, 2009. Dr. Reese submitted a further Amended Report on February 16, 2009. Dr. Reese was deposed on January 13, 2009, and February 26, 2009.

26. In his deposition, Dr. Reese testified that Dr. Reese did not include any criticism of Greg Nelson in any report, "signed or scribble amended to this moment" (1/13/2009) of him (Greg Nelson) being present in an OR on April 30, 2002. (Dkt. 75-3, pp. 242-243.)

27. A "Class III" medical device under 21 U.S.C. 360c(a)(1)(C) is one :

> a) for which the Agency could not establish[] that a less stringent classification would provide reasonable assurance of safety and effectiveness;

b) which is purported or represented to be for a use in supporting or sustaining human life or for which is for a use of substantial importance in preventing impairment of human health; or

c) which represents a potential unreasonable risk of illness or injury.

27. The FDA-approved labeling (Instructions for Use ("IFU") for the Arrow Model 3000 30 mL Constant Flow Implantable Pump with Bolus Safety Valve states:

ADVERSE EFFECTS

Possible adverse effects of the Pump are those potential risks associated with any implanted drug delivery device and include: catheter thrombosis, bolus path occlusion, vessel thrombosis, pump dislodgement, seroma, or recurrent hematoma, infection, extravasation, catheter shear, dislodgment or leakage, and migration. Drug extravasation may result if the instructions for use are not followed correctly during a Pump refill (see page 13) or bolus procedure (see page 19)....

SUSPECTED PUMP CATHETER OCCLUSION

If difficulty is encountered in administering fluids via the Bolus route,..., consider the following possible causes before proceeding to Fibrinolytic Therapy:

The Arrow Special Bolus Needle may not be perpendicular to the Pump and fully inserted through the septum, making contact with the needle stop. Reinsert the needle until it is in contact with needle stop.

The needle may be occluded. Remove from the septum and flush to confirm patency.

The catheter may be kinked. Confirm radiologically.

> If the occlusion persists after taking the above steps, proceed to prepare appropriate Fibrinolytic agent (urokinase, streptokinase) according to hospital pharmacy guidelines....
>
> If occlusion continues to persist after steps 1 through 4, call for technical assistance....

(Dkt. 80-1, p. 3, p. 22).

28. The Medical Device Amendments' preemption clause provides "no State....may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from or in addition to, any requirement applicable under this chapter to the device and (2) which relates to safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. Sec. 360k(a).

III. Motions for Summary Judgment - Discussion

A. Count I - Strict Liability - Arrow
Count II - Negligence - Arrow

Defendant Arrow International, Inc. moves for entry of summary judgment in favor of Defendant Arrow. Defendant Arrow argues that Plaintiffs' claims are preempted by the Medical Device Amendments, 21 U.S.C. Sec. 360(c), et seq., ("MDA"), to the Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 301, et seq., and Plaintiffs cannot provide evidence sufficient to sustain Plaintiffs' strict liability claim as required under Florida law.

Plaintiffs respond that there is no preemption of Plaintiffs' claim based on the acts and/or omissions of Defendant Greg Nelson. Plaintiffs contend that Defendant Nelson should

have disallowed the replacement of the connector or suggested replacement of the pump system (the infusion pump and catheter kit). Plaintiffs argue that Defendant Arrow International Inc., through the presence of Defendant Greg Nelson at the surgery of Plaintiff Linda Wolicki-Gables on July 15, 2003, was directly involved in "off label" use of the subject product, having provided the replacement connector to Dr. James at that time. Plaintiffs argue Defendant's Motion for Summary Judgment should be denied.

1. Off Label Use

"Off label" use of a medical device occurs when the medical device is used in a manner that varies in some way from the instructions in the device's labeling, which are limited to FDA-approved uses. The Federal Food, Drug and Cosmetic Act regulates the manufacture and marketing of medical devices, not the practice of medicine. A physician may, as part of the practice of medicine, lawfully prescribe a different dosage of prescription medication, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining approval of the Food and Drug Administration. U.S. v. Evers, 453 F.Supp 1441, 1449-50 (M.D. Ala. 1978), aff'd, 643 F.2d 1043 (5th Cir. 1981). Further, a physician may modify a legally marketed medical device. The Food and Drug Administration recognizes no difference between the "off label" use of drugs and devices.

The Food and Drug Administration Modernization Act of 1997, 21 U.S.C. Sec. 396, provides:

> "Nothing in this Chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."

2. Express Preemption

The Arrow Model 3000 Implantable Pump with Bolus Safety Valve ("infusion pump") and Arrow Flextip Plus Intraspinal Kit ("catheter kit") are Class III medical devices which were approved by the Food and Drug Administration through the premarket approval process ("PMA")(Dkt. 80-13). The premarket approval process is a "rigorous" process in which manufacturers submit detailed information as to the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission. Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). Once a device receives premarket approval, the manufacturer may not change its design, specifications, manufacturing processes, labeling, or any other attribute which would affect the device's safety or efficacy without FDA approval. 21 U.S.C. Sec. 360e(D)(6)(A)(I). If a manufacturer wishes to make such changes, an application for a supplemental PMA must be submitted, which is evaluated under the same criteria as the initial application. Riegel v. Medtronic, Inc., 128 S.Ct. 999, 1007 (2008); 21 C.F.R. 814.39(c). Once a device receives PMA, a manufacturer must inform the FDA when it becomes aware of adverse events in patients using the device. 21 C.F.R. Secs. 803.50, 803.53.

In Riegel v. Medtronic, Inc., 128 S.Ct. 999 (2008) the United States Supreme Court held that the preemption clause of

the MDA barred common law claims challenging the safety and effectiveness of a medical device given premarket approval by the FDA. The Supreme Court explains that the MDA preemption clause establishes a two-pronged test for determining if state law claims are preempted. First, a court must determine whether the PMA process imposes device-specific requirements on manufacturers. If so, a court must then determine whether the state law claims at issue impose requirements "different from, or in addition to" the specific FDA requirements. If both conditions are met, preemption applies to bar a plaintiff's claims. Id., at 1006. The Supreme Court found that "[p]remarket approval imposes 'requirements' under the MDA" which are "specific to individual devices." Id., at 1007. The Supreme Court notes "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." Id. After premarket approval, devices are subject to reporting requirements, which include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of...and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred. The FDA has the power to withdraw premarket approval based on newly reported data or existing information, and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.

In Riegel, supra, the Supreme Court further notes that claims alleging a failure to comply with the federal standards which were established through the PMA process are not preempted. Such claims are "parallel" claims, which do not add to or differ from federal requirements. Id. at 1011.

The Court views Riegel v. Medtronic, supra, to abrogate the decision in Goodlin v. Medtronic, 167 F.3d 1367 (11th Cir. 1999); see Blunt v. Medtronic, 760 N.W.2d (Wis. Feb. 17, 2009). The Court also notes the decision in Wyeth v. Levine, 129 S.Ct. 1187 (2009), in which the United States Supreme Court held that federal law and FDA approval do not preempt state tort claims relating to prescription medication. Wyeth v. Levine, supra, is based on implied preemption. Since the MDA contains an express preemption provision for medical devices, Riegel v. Medtronic, supra, controls the preemption of individual and derivative claims involving medical devices approved through premarket approval.

Under Riegel v. Medtronic, supra, the PMA approval of the Model 3000 30 mL Constant Flow Implantable Pump with Bolus Safety Valve, and the PMA supplemental approval of the Flextip Plus Intraspinal Kit establish requirements specific to those devices. The Court therefore considers whether Plaintiffs' state law claims impose requirements different from, or in addition to, the FDA requirements for those medical devices.

3. Plaintiffs' Strict Liability Claim

In the Amended Complaint, Plaintiffs allege that Defendant Arrow defectively designed, manufactured, tested, and/or sold the

implantable drug delivery systems in a defective condition unreasonably dangerous to its ultimate user, Plaintiff Linda Wolicki-Gables, in the following respects:

> a) failing to reasonably design the implantable drug delivery system in a manner which would have prevented injury to those like Linda Wolicki-Gables;
>
> b) failing to reasonably manufacture the implantable drug delivery systems in a reasonable manner;
>
> c) failing to reasonably provide adequate warnings regarding the defective and unreasonably dangerous implantable drug delivery system, having actual or constructive knowledge of the hazards associated with the product.

In West v. Caterpillar Tractor, 336 So.2d 80, 84 (Fla. 1976), the Florida Supreme Court adopted the doctrine of strict liability as stated by the American Law Institute Restatement (Second) of Torts, Sec. 402A:

> "(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold,

> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller."

To prove a strict liability manufacturing defect claim, Plaintiffs must prove by a preponderance of the evidence: 1) that the Arrow pump system, consisting of the pump and catheter kit, implanted into Plaintiff Linda Wolicki-Gables was defective; 2) that the defect existed at the time the pump system left Defendant Arrow's control, and 3) that the defect in the pump system proximately caused Plaintiff Linda Wolicki-Gables' injuries. See Colville v. Pharmacia & Upjohn Co., LLC, 565 F.Supp.2d 1314, 1320 (N.D. Fla. 2008).

The FDA regulates manufacturing practices of Class III medical devices. See 21 U.S.C. Sec. 360e(c)(1); 21 C.F.R. 814, 820. Under Florida law, when the defect is a manufacturing defect, "a product is defective if it is in a condition unreasonably dangerous to the user, and the product is expected to and does reach the user without substantial change affecting that condition." See Florida Standard Jury Instruction PL 4 (Civil). A fact-finder considering a strict liability claim could find liability if a manufacturing defect rendered the subject medical devices unreasonably dangerous, even if the manufacturer followed the FDA's manufacturing practices. After consideration, the Court finds that the strict liability manufacturing defect claim is expressly preempted, and therefore

grants Defendant Arrow's Motion for Summary Judgment as to this issue.

To prove a claim for strict liability for defective design, a plaintiff must show that the defendant manufactured or distributed the product in question, that the product has a defect that renders it unreasonably dangerous and that the unreasonably dangerous condition is the proximate cause of the plaintiff's injury. See Marzullo v. Crosman Corp., 289 F.Supp.2d 1337, 1346 (M.D. Fla. 2003) (quoting Jennings v. Bic Corporation, 181 F.3d 1250, 1255 (11th Cir. 1999).

The FDA regulates the design of Class III medical devices. See 21 U.S.C. 360e(c)(1); 21 C.F.R. 814. Under Florida law, when the defect is a design defect, "if by reason of its design the product is in a condition unreasonably dangerous to the user, and the product is expected to and does reach the user without substantial change affecting that condition. A product is unreasonably dangerous because of its design if "the product fails to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the manufacturer, or the risk of danger in the design outweighs the benefits." See Florida Standard Jury Instruction PL 5 (Civil). A fact-finder considering a strict liability claim could find liability if a design defect rendered the subject medical devices unreasonably dangerous, even if the manufacturer complied with all FDA regulations addressed to design.

After consideration, the Court finds that this claim is expressly preempted, and **grants** Defendant Arrow's Motion for Summary Judgment as to this issue. The Court notes that, even if

this claim were not preempted, this claim fails because Plaintiff's expert witness, Dr. Reese, does not render an opinion as to defective design.

The FDA regulates content and appearance of prescription medical device labels. See 21 360e(c)(1); 21 C.F.R. 801.1, 801.15, 801.109, 814. The regulations exempt such devices from the requirement that there be directions to a layperson on how to use the product safely, if the package describes, inter alia "any relevant hazards, contraindications, side effects and precautions" for the prescribing physician. 21 C.F.R. 801.109.

To establish strict liability [for] failure to warn, a plaintiff must prove that the defendant is a manufacturer or distributor of the product at issue and that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. See Marzullo v. Crosman Corp., 289 F.Supp.2d 1337, 1347 (M.D. Fla. 2003)(quoting Ferayorni v. Hyundai Motor Co., 711 So.2d 1167, 1172 (Fla. 4th DCA 1998). A fact-finder considering a strict liability claim could find liability for failure to warn even if the product's labeling completely conformed to FDA regulations.

After consideration, the Court finds that this claim is expressly preempted, and therefore **grants** Defendant Arrow's Motion for Summary Judgment as to this issue. Even if this claim were not preempted, however, Plaintiffs' strict liability claim for failure to warn would fail. The subject medical devices at issue in this case are available only by prescription. The

physician acts as a learned intermediary between a manufacturer or seller and a patient. It is the physician's duty to inform himself of the qualities and characteristics of the products which he prescribes for his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. Buckner v. Allergan Pharmaceuticals, Inc., 400 So.2d 820 (Fla. 5th DCA 1981). The duty to warn is fulfilled by an adequate warning given to the members of the medical community lawfully authorized to prescribe, dispense and administer the medical devices such as those involved in this case. In determining the adequacy of the warning, the critical inquiry is whether it is adequate to warn the physician of the possibility that the [medical device] caused the injury alleged by the plaintiff. Upjohn v. MacMurdo, 562 So.2d 680, 683 (Fla. 1990). The adequacy of a warning is a question of law where the warning is accurate, clear and unambiguous. Felix v. Hoffman-LaRoche, Inc., 540 So.2d 102, 105 (Fla. 1989).

In this case, Plaintiffs' theory is that product implanted in Plaintiff Linda Wolicki-Gables contained a manufacturing defect, which caused Dr. James to perform a revision surgery, after which Plaintiff Linda Wolicki-Gables contracted an infection which caused Plaintiffs' injuries. Dr. James testified that Dr. James was aware of all the information offered by the manufacturer prior to performing the implantation, including all of the known complications, which are stated in the "package insert." Known adverse affects include the risk of infection. The duty to warn of Defendants is fulfilled by the adequate warning to Dr. James.

4. Plaintiffs' Negligence Claim

Plaintiffs assert the same claims Plaintiffs raise under the strict liability theory under a negligence theory. Under the strict liability theory, the focus in on the product itself; under the negligence theory, the focus is on the whether a duty of care was owed to the injured parties, and whether the defendants breached that duty of care.

In Count II, Plaintiffs allege that Defendant Arrow owed Plaintiff Linda Wolicki-Gables a duty to use reasonable care in the design, manufacture, assembly and sale of the implantable drug delivery system so that it would be reasonably safe for its intended use. Plaintiffs allege that Defendant Arrow breached its duty by negligently designing, manufacturing and assembling the implantable drug delivery system by:

> (a) failing to reasonably design the implantable drug delivery system in a manner which would have prevented injury to those like Plaintiff Linda Wolicki-Gables;
>
> (b) failing to reasonably manufacture the implantable drug delivery system in a reasonable manner; and
>
> (c) failing to reasonably provide adequate warnings regarding the defective and unreasonably dangerous implantable drug delivery system, having actual or constructive knowledge of the hazards associated with the product.

Plaintiffs allege that Plaintiff Linda Wolicki-Gables suffered damages as a direct and proximate result of the negligence of Defendant Arrow.

Proof of negligent design and negligent manufacturing requires "evidence of the existence of [a] defect in the product." Alvarez v. General Wire Spring Co., 2009 WL 248264 (M.D. Fla. Feb. 1, 2009)(citing Broderick v. Danek Medical, Inc., 1999 WL 1062135 (S.D. Fla. Apr. 9, 1999). Further, in order to establish a prima facie case in a negligence action, Florida law requires Plaintiffs to prove by a preponderance of the evidence, with "reasonable medical probability" that Defendant Arrow's alleged negligence was the proximate cause of Plaintiffs' injuries. Plaintiffs must show that it is "more likely than not" that Defendant Arrow's act(s) was/were a substantial factor in bringing about the injuries. "A mere possibility of such causation is not enough; and when the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant. Reaves v. Armstrong World Industries, 569 So.2d 1307, 1309 (Fla. 4th DCA 1990).

Under Florida law, negligence is the failure to use reasonable care. Reasonable care is that degree of care which a reasonably careful person would use under like circumstances. Negligence may consist either in doing something that a reasonably careful person would not do under like circumstances, or in failing to do something that a reasonably careful person would do under like circumstances. Negligence is a legal cause of loss, injury or damage if it directly and in a natural and continuous sequence produces or contributes substantially to producing such loss, injury or damage, so that it can reasonably be said that, but for the negligence, the loss, injury or damage would not have occurred. In order to be regarded as a legal cause of loss, injury or damage, negligence need not be the only

cause. Negligence may be a legal cause of loss, injury or damage even though it operates in combination with the act of another, if such other cause occurs at the same time as the negligence, and if the negligence contributes substantially to producing such loss, injury or damage. See Florida Civil Jury Instructions, Model Charge No. 8.

A fact-finder considering a negligent design claim could find liability for negligent design in spite of the FDA's pre-market approval of the design of the subject medical devices. the Court finds that this claim is expressly preempted, and therefore **grants** Defendant Arrow's Motion for Summary Judgment as to this issue.

If the claim based on negligent design were not expressly preempted, the claim would still fail because Dr. Reese does not render an opinion as to the presence of a design defect, and no evidence is offered to establish a causal link between negligent design and Plaintiffs' injuries. The Court recognizes that proximate causation will ordinarily be determined by the jury; the Court may make this determination as a matter of law only in plain and undisputed cases, considering all facts and reasonable inferences in favor of the non-moving party.

The FDA's "good manufacturing practices" regulations require manufacturers to develop and implement "appropriate," "adequate," or "sufficient" quality control, quality assurance, personnel training, environmental controls, equipment maintenance, testing, inspection and storage and distribution procedures, to assure that devices are safe and effective. A fact-finder considering claims of negligent manufacture and negligent assembly could find

liability for these claims, even though the there was complete compliance with FDA regulations controlling the manufacture and assembly of the subject medical devices, applying standards differing from or adding to FDA's.

As to negligent manufacture and negligent assembly, the Court finds that these claims are expressly preempted, and therefore **grants** Defendant Arrow's Motion for Summary Judgment as to this issue.

B. Count III - Consortium - Arrow

The Court has granted Defendant Arrow's Motion for Summary Judgment as to strict liability and negligence. Because the claim for consortium is derivative of the claims for strict liability and negligence, the Court finds that the claim for consortium is preempted. The Court **grants** Defendant Arrow's Motion for Summary Judgment as to this claim.

C. Count IV - Strict Liability - Codman

Defendant Codman joined in Defendant Arrow's Motion for Summary Judgment on the basis of express preemption, which was granted. The Court therefore **grants** Defendant Codman's Motion for Summary Judgment on the basis of express preemption.

Defendants Codman & Shurtleff, Inc. and Johnson & Johnson have moved for partial summary judgment on the basis that the undisputed record evidence establishes that Defendant Arrow designed, manufactured, tested and sold the subject medical devices.

Plaintiffs have moved for entry of partial summary judgment as to Defendants Codman & Shurtleff, Inc., Johnson & Johnson and Greg Nelson on the issue of distribution of the subject pump and catheter kit medical devices. Plaintiffs seek the Court's determination that Defendants Codman & Shurtleff, Inc., Johnson & Johnson and Greg Nelson are all distributors of the subject medical devices.

Plaintiffs argue that Plaintiffs alleged the vicarious liability of Defendants Codman and Johnson & Johnson, in paragraph 7 of the Second Amended Complaint, for the actions of Defendant Nelson. Plaintiffs request that, to the extent that the Court determines that only Defendant Nelson is a distributor, Defendants Codman and Johnson & Johnson authorized Defendant Nelson to act as a distributor of the subject products and are liable as distributors.

The undisputed record evidence in this case establishes that, at the time of the initial implantation of the pump and catheter medical devices on April 30, 2002, Venture Medical Devices, Inc., operated by Defendant Greg Nelson, was the distributor of the subject medical devices. Venture Medical Devices, Inc. is not a party to this case. Pursuant to the distribution contract between Defendant Arrow and Defendant Nelson, later assumed by Defendant Codman, Venture Medical Devices, Inc. was to act as an independent contractor in selling the medical devices. However, the Court notes that the use of descriptive labels in a contract is not determinative of the actual legal relationship of the parties. Villazon v. Prudential Health Care Plan, Inc., 843 So.2d 842, 854 (Fla. 2003). The status of the parties depends upon the language of the contract

and all the circumstances in their dealing with each other. Id at 854.

Generally, the existence of an agency relationship is a question of fact; however, when the moving party fails to produce any supportive evidence or when the evidence presented is so unequivocal that reasonable persons could reach but one conclusion, that question of fact becomes a question of law to be determined by the court. Rubin v. Gabay, 979 So.2d 988, 990 (Fla. 4th DCA 2008).

Actual agency requires: 1) acknowledgment by the principal that the agent will act for him; 2) the agent's acceptance of the undertaking; and 3) control by the principal over the actions of the agent. See Goldschmidt v. Holman, 571 So.2d 422, 424 n. 5 (Fla. 1990). The key element is establishing actual agency is the control by the principal over the actions of the agent. Dorse v. Armstrong World Industries, Inc., 513 So.2d 1265 n. 4 (Fla. 1987)(principal must control means to achieve the outcome, not just the outcome itself). The party who seeks to establish the existence of such a relationship carries the burden of proof. See Pinion v. International Harvester Co., 390 So.2d 154 (Fla. 3d DCA 1980).

There is no evidence in the record that Defendant Codman & Shurtleff, Inc. or Defendant Johnson & Johnson controlled the means Defendant Nelson used to sell medical devices.

Apparent agency requires: 1) a representation by the purported principal; 2) reliance on that representation by a third party; and 3) a change in position by the third party in

reliance upon such representation. See Ilgen v. Henderson Properties, Inc., 683 So.2d 513, 514 (Fla. 2nd DCA 1996). A principal's actions may also give rise to apparent authority. See Chase Manhattan Mortgage Corp. v. Scott, Royce, Harris, Bryan, Barra & Jorgensen, P.a., 694 So.2d 827, 832 (Fla. 4th DCA 1997)(existence of agency relationship may be established expressly, by estoppel, apparent authority, ratification).

The Court has looked for some evidence that Defendant Codman and Defendant Johnson & Johnson participated in directing or managing the acts of Defendant Nelson, and for evidence that such control was communicated to Plaintiffs at the relevant time, but has found none.

A partnership exists when two or more persons join together or agree to join together in a business or venture for their common benefit, each contributing money or property or services, and each having an interest in the profits. Each member of a partnership is responsible for the negligence of any partner if such negligence occurs while the partner is acting on behalf of the partnership and within the scope of the partnership's business. See Florida Civil Jury Instructions, Comment on 3.3c.

The Court has looked for evidence that Defendant Codman & Shurtleff, Inc., Defendant Johnson & Johnson and Defendant Nelson each had an interest in the profits of Defendant Nelson's sales of medical devices, and has found none.

The Court concludes that on April 30, 2002, the date of implantation, Defendant Greg Nelson operated Venture Medical Devices, Inc. as an independent contractor, and not as an agent,

employee or partner of Defendants Codman and Johnson and Johnson, relying on the parties' intent as expressed in the provisions of the distribution agreement.

The undisputed record evidence further establishes that Defendant Arrow International, Inc. designed, manufactured, tested and sold the pump and catheter kit medical devices.

The Court notes that Plaintiffs assert only a negligence claim against Defendant Greg Nelson in the Second Amended Complaint (Dkt. 30). The Court recognizes that, under Florida law, the doctrine of strict liability has been expanded to retailers, wholesalers and distributors. See Samuel Friedland Family Enterprises v. Amoroso, 630 So.2d 1067, 1068 (Fla. 1994). However, the Court cannot read into a complaint a claim which is not there. Defendants are entitled to notice of the claims asserted against Defendants, and the grounds on which the claims rest. Plaintiffs cannot amend their Complaint through a response to Defendants' Motion for Summary Judgment, or through Plaintiffs' Motion for Summary Judgment. After consideration, the Court **grants** the Motion for Partial Summary Judgment of Defendants Codman& Shurtleff, Inc. and Johnson & Johnson. The Court **denies** Plaintiffs' Motion for Partial Summary Judgment.

D. Count VI - Consortium - Codman

This claim is a derivative claim based on the claim of strict liability against Defendant Codman. The Court has granted Defendant Codman's Motion for Summary Judgment on the basis of express preemption, and therefore **grants** Defendant Codman's Motion for Summary Judgment as to this consortium claim.

E. Count VII - Strict Liability - Johnson & Johnson

Defendant Johnson & Johnson joined in the Motion for Summary Judgment of Defendant Arrow on the basis of express preemption, which the Court granted. The Court therefore **grants** Defendant Johnson & Johnson's Motion for Summary Judgment on the same basis.

F. Count IX - Consortium - Johnson & Johnson

This claim is derivative of the strict liability claim Plaintiffs assert as to Defendant Johnson & Johnson. The Court has granted Defendant Johnson § Johnson's Motion for Summary Judgment as to strict liability on the basis of express preemption, and therefore **grants** Defendant Johnson & Johnson's Motion for Summary Judgment as to this consortium claim.

G. Count X - Negligence - Nelson

In the Second Amended Complaint, Plaintiffs allege that Defendant Nelson, as a sales representative, owed a duty to Plaintiffs to instruct and educate Plaintiff Linda Wolicki-Gables' operating surgeon to ensure that the pain pump was functioning properly, to verify Plaintiff's consent to Defendant Nelson's presence in the operating room, and to not dispose of any devices removed from Plaintiff.

The Court notes that Defendant Nelson joined in Defendant Arrow's Motion for Summary Judgment based on express preemption. Because the Court granted Defendant Arrow's Motion for Summary Judgment, the Court **grants** Defendant Nelson's Motion for Summary

Judgment. If Plaintiffs' negligence claim is not preempted, the negligence claim still fails.

Defendant Greg Nelson, in his capacity as a sales representative, was present at the initial implantation procedure, according to the medical records of that procedure. The Court notes that Dr. Reese does not render an expert opinion which is critical of Defendant Nelson's presence at the implantation procedure of 4/30/2002. In addition, Dr. James testified that he relied on his own experience in performing such procedures. Dr. James tested the pump on 8/15/2002, and confirmed that the pump was functioning. After consideration, the Court **grants** Defendant Nelson's Motion for Summary Judgment as to this issue.

Defendant Nelson was present at the revision procedure of 7/15/2003. The undisputed facts show that Defendant Nelson did not participate in the decision-making during that procedure. Defendant Nelson's role was limited to carrying "back up" products in their sterile packages to have available for the surgeon's use, if necessary, and to observe preparation of the products. Defendant Nelson did not "scrub in" for the procedure on 7/15/2003, and did not enter the sterile field. Defendant Nelson did not come into contact with the pump on 7/15/2003, which never left the sterile field. Dr. James testified that the decisions made while he performed surgery were his own decisions. Dr. Reese admitted that Dr. Reese was aware of no information relayed to Dr. James by Defendant Nelson during the procedure. (Cite). The Court is not aware of any evidence that establishes any interaction between Dr. James and Defendant Nelson during the 7/15/2003 procedure. Even if the finder of fact infers that

Defendant Nelson did have some interaction with Dr. James during that surgery, the Court does not know of any evidence that establishes that Defendant Nelson had a duty to affirmatively tell Dr. James, while Dr. James was performing surgery, that Dr. James should not replace the connector alone. Dr. James testified that Dr. James exercised his own medical judgment, and Dr. Reese testified that Dr. James acted within Dr. James' discretion. After consideration, the Court **grants** Defendant Nelson's Motion for Summary Judgment as to Plaintiffs' negligence claim involving Defendant Nelson's alleged participation in the revision surgery.

As to Plaintiffs' claim based on the lack of informed consent to Defendant Nelson's presence in the OR on 7/15/2003, the undisputed facts show that neither Dr. James nor Defendant Nelson knew that Plaintiff Linda Wolicki-Gable did not consent to Defendant Nelson's presence in the OR. The Court further notes that liability under the Florida Medical Consent Law, 766.103, Fla. Stat., is limited to medical practitioners. Defendant Nelson is a sales representative, not a medical doctor.

Plaintiffs admit that Defendant Nelson never received or saw the consent form for the 7/15/2003 surgery. Defendant Nelson could not have looked at the consent form himself due to patient privacy and HIPAA regulations. Dr. Reese admits that no facts contradict that Defendant Nelson did not know of Plaintiff Linda Wolicki-Gables' lack of consent to Defendant Nelson's presence in the OR. In her deposition, Plaintiff Linda Wolicki-Gables was unable to explain how Defendant Nelson's presence in the OR on 7/15/2003 damaged Plaintiff. The Court **grants** Defendant Nelson's Motion for Summary Judgment as to this issue.

As to Plaintiffs' claim for negligence based on Plaintiffs' alleged injury from the revision procedure, there is a complete absence of evidence establishing a causal connection between Defendant Nelson's presence in the OR on 7/15/2003 and Plaintiff Linda Wolicki-Gables' injury. While it is undisputed that Defendant Nelson was present in the OR on 7/15/2003, the Court is not aware of any evidence which documents any interaction between Dr. James and Defendant Nelson during the procedure. The Court **grants** Defendant Nelson's Motion for Summary Judgment as to this issue.

As to Plaintiffs' claim based on an alleged "off label" use of the pain pump, Dr. Reese testified that Dr. James' decisions on 7/15/2003 resulted in an "off label" use of the pain pump and Defendant Nelson should have advised Dr. James as such during the procedure. Dr. Reese, who is not a medical doctor, testified that Dr. James should have removed and replaced everything originally implanted: pump, catheter connector, and intrathecal catheter. According to Dr. Reese, the exercise of medical judgment by Dr. James went beyond the product labeling and resulted in an off label use, although Dr. Reese acknowledges that the replacement catheter connector itself was used exactly as indicated in the FDA approved labeling to connect the pump to the catheter.

The Court has already recognized that "off label use," within the context of medical treatment is not prohibited, as the FDCA does not regulate the practice of medicine.

The Court notes that a claim for negligence based on "off label use" is not pleaded in the Second Amended Complaint as to Defendant Nelson, a sales representative. The Court also notes that Dr. Reese concedes that Dr. James' exercise of medical judgment was within Dr. James' discretion, and that Dr. James was free to do what Dr. James did in replacing only the connector. The Court recognizes that the FDCA and its regulations prohibit off-label promotion by manufacturers, but, even if such a claim were present in this case, there is no private right of action for violations of the FDCA. There is a complete absence of evidence as to any claim for negligence based on "off label" marketing and promotion by Defendant Nelson, as well as Plaintiffs' claim for negligence against Defendant Nelson for "off label use." The Court **grants** Defendant Nelson's Motion for Summary Judgment as to this issue.

In the Second Amended Complaint, Plaintiffs allege:

> 69. GREG NELSON had a duty to ensure that prior to being present in the operating room on July 15, 2003, and prior to destroying or discarding any part(s) of the subject pump removed from MRS. GABLES that he first very whether MRS. GABLES consented to his presence in the operating room and to said destruction or discarding of any part(s) or the pump itself.
>
> ....
>
> 71. As a direct and proximate result of Defendant, GREG NELSON's actions of intentionally and recklessly destroying the subject part(s) removed from the subject pump during the July 15, 2003 surgery, Defendant has precluded Plaintiffs from determining to what extent, if any, other defects within the subject pump existed and/or contributed to her current physical problems.

In his deposition, Plaintiff Robert Gables testified that

Defendant Nelson approached him after the 7/15/03 surgery, as follows:

> Q. What else did he tell you in the lobby or outside the lobby area?
>
> A. It was in the lobby area. Told me that he had-he was in the room. They had taken the connectors, connection-some kind of connections out of the pump where-after removing the pump from my wife's body and removing the catheter, they turned it over, took out the connections, replaced them, cut a piece of catheter away, and placed it back in, reattached it to the body, and then sewed her up.
>
> Q. Anything else that he told you during this initial conversation?
>
> A. Yeah. I asked him where the parts were.
>
> Q. And what did he say?
>
> A. He said he had to take them back to the manufacturer for them to test them, I could call him in ten business days.

(Dkt. 82, Exh. A, pp. 63,64, ll. 18-9.)

> ....
>
> Q. When did you-when was the next time you spoke to Greg Nelson?
>
> A. About two weeks later.
>
> ....
>
> Q. What prompted you-how did it come about that you talked to Greg Nelson two weeks later?
>
> A. I got the number of Arrow.

Q. I'm sorry?

A. Of--I believe it was Arrow. I think it was Arrow at the that time. I'm not sure. He gave ne a number that--it was a number for Greg Nelson and I don't remember who answered it because what happened was, Linda yelled for me as I was in the middle of the conversation. So I didn't actually look, you know, it being like, you know, Greg Nelson, blah, blah, blah, a subsidiary company of Johnson & Johnson or something like that. You know what I'm saying? I didn't look at any of that.

He gave me a number. I called Greg, who was not in. I left a message. He got back to me about a day and a half later. I asked him where the equipment was that we wanted from the pump. He told me that it was disposed of. I says, what are you talking about? At which time, I got very, very upset. And he didn't feel like taking any abuse from me and he hung up on me.

(Dkt. 82, Exh. A, pp. 67-68, ll. 16-17).

....

Q. With Mr. Nelson. So the substance of the conversation with Mr. Nelson is that you were calling to follow up on the status of the parts that had been removed?

A. No. I wanted to know how I could go--how I could go about getting the parts. He says, you can't. I says, why not? You told me I could call you in ten days, ten business days, and get them. Ten business days, I want them.

And he said, They were destroyed. I said, For what reason? He says, That's our policy. After we check them out we destroy them, and there was nothing wrong with them.

> Q. Anything else you can remember from that conversation on the phone with Mr. Nelson?
>
> A. Yeah, I didn't believe him because he--I said, you promised them to me. And I told him it was in writing that I was supposed to get the materials and he told me I was going to get the materials and then he discarded them. And he says, click, and that was it.
>
> Q. Have you ever spoken to him since?
>
> A. No.

(Dkt. 82, Exh. A., pp. 69-70, ll. 15-9).

Defendant Nelson has no recollection of speaking with Plaintiff Gables after the surgery of 7/15/2003, and testified that he did not remove or discard the catheter connector. For the purpose of this Motion for Summary Judgment, the Court accepts Plaintiff Robert Gables' version of the facts. Dr. Reese, Plaintiffs' expert witness, testified as follows:

> Q. If you assume, would you agree with me, sir, that on page 64, line 7, Mr. Gables testified that he was told by Greg Nelson that Greg Nelson had to take them, referring to the catheter connector or the components that had been removed, back to the manufacturer for them to test them?
>
> A. Yes, that's what it says in the depo.
>
> Q. If you assume that Mr. Gables is correct, that is exactly what Mr. Nelson should have done, returned the removed components to the manufacturer for testing. Correct?
>
> A. Absolutely.
>
> ....

> Q. So if you believe-according to what Mr. Gables' recollection of what the events were, it wasn't Greg Nelson that discarded the components. He shipped them back to the manufacturer, and after the manufacturer had examined them, they were discarded. Correct?
>
> A. Well, as I said, there's conflicting testimony here compared to Greg Nelson's deposition testimony.
>
> ....
>
> Q. If you believe what Mr. Gables said concerning his recollection of events, Greg Nelson did not discard the components that was removed on July 15, 2003. Correct?
>
> A. Correct.

(Objection omitted). (Dkt. 75-5, pp. 446-449, ll. 15-23).

Dr. Reese also testified that federal regulation 803.50,(21 C.F.R. 803.50), does not require a manufacturer to retain possession of a returned device after an evaluation is complete. (Dkt. 75-5, pp. 433-435, ll. 18-2). Dr. Reese retracted his opinion that Defendant Nelson discarded or disposed of any component removed from Plaintiff Linda Wolicki-Gables on 7/15/2003. (Dkt. 75-5, pp. 453-454, ll. 11-17).

The Court notes that the pump and catheter removed from Plaintiff Linda Wolicki-Gables is now in the custody of Plaintiff's counsel, and Plaintiffs' expert witness, Dr. Reese, has rendered an opinion as to the alleged manufacturing defect. In his deposition, Dr. Reese testified as follows:

> Q. Sir, am I not correct you've never seen, put your hands on the product?

A. That's correct.

Q. You've never examined the catheter, whether it be the pump catheter or the intrathecal catheter-

A. Correct.

Q. -for any evidence of crimping; is that correct?

A. There is no evidence of crimping.

Q. Is that correct? How would you know? You've never looked at it.

A. That's correct. But the doctors who are responsible and should know, who looked at it, including Dr. James and Dr. Preiwe, indicated no reference to any crimping.

Q. My question of you, sir, is you, in terms of your individual analysis, have never looked for such evidence?

A. Correct.

(Dkt. 75-4, pp. 313-314, 11. 23-17).

Dr. Reese further testified that Dr. Reese identified alternative causes to blockage in the connector, but did not exclude those alternative causes:

Q. Okay. And in your opinion, something was done improperly in the manufacturing process that resulted in a blockage at the point of the coupling, yes?

A. Yes.

Q. What alternative-

A. Um-hmm.

> Q. -causes of the blockage did you consider?
>
> A. Well, again, one possibility is-following with your analogy of a pipe, we've all had experience, at least most of us, with regards to a pipe, a drain pipe or a water pipe, being clogged up because you have a continual daily deposition of, if you will, for lack of a term, rust that ultimately closes the pipe, or within the artery system where you have continual build-up of plaque that ultimately leads to a heart attack or other type of cardiovascular, neurological failures.
>
> In this particular case, the other considerations would be, the body has a natural tendency of wanting to reject materials, so we could have an interaction or a crystallization, if you will, of meds going through that built up and eventually would have clogged up the connector. I could go on with that. Do you want me to go on with that?
>
> Q. Well, I would like to know whether you identified and excluded any alternative causes, and I'd like to know what they were.
>
> A. No, I did not exclude any alternative causes.

(Dkt. 75-4, pp. 311-312, ll. 12-17).

As to Plaintiffs' claim for negligence based on acts subsequent to the revision procedure of 7/15/2003, there is no evidence of improper disposal by Defendant Nelson. Further, there is no evidence of a causal connection between the loss of the catheter connector and any alleged injury. Plaintiffs' expert witness, Dr. Reese was able to render his opinion without actual inspection of the pump, catheter and catheter connector. The Court **grants** Defendant Nelson's Motion for Summary as to this issue.

H. Count XII - Vicarious Liability - Codman

The Court has granted Defendant Nelson's Motion for Summary Judgment as to Plaintiff Linda Wolicki-Gables' claim for negligence. At the time of 7/15/03 medical procedure, Defendant Nelson was employed by Defendant Codman. Since the Court has found that Defendant Nelson, agent for Defendant Codman, was not negligent, no negligence can be imputed to Defendant Codman. See Mobil Oil Corp. v. Bransford, 648 So.2d 119, 121 (Fla. 1995). The Court therefore **grants** Defendant Codman's Motion for Summary Judgment as to this issue.

I. Count XIII - Vicarious Liability - Johnson & Johnson

The Court granted Defendant Nelson's Motion for Summary Judgment as to Plaintiff Linda Wolicki-Gables' claim for negligence. Since Defendant Nelson was not negligent, no negligence can be imputed to Defendant Johnson & Johnson. The Court **grants** Defendant Johnson & Johnson's Motion for Summary Judgment as to this issue.

J. Count XIV - Consortium - Nelson

This claim is derivative of the Plaintiff Linda Wolicki-Gables' claims. The Court has granted Defendant Nelson's Motion for Summary Judgment as those claims, and therefore **grants** Defendant Nelson's Motion for Summary Judgment as to this issue.

K. Count XVI - Consortium - Codman

This claim is derivative of Plaintiff Linda Wolicki-Gables' claims. Since the Court has granted Defendant Codman's Motion for Summary Judgment as to Plaintiff Linda Wolicki-Gables' claims, the Court **grants** Defendant Codman's Motion for Summary Judgment as to this issue.

L. Count XVII - Consortium - Johnson & Johnson

This claim is derivative of Plaintiff Linda Wolicki-Gables' claims. Since the Court has granted Defendant Johnson & Johnson's Motion for Summary Judgment as to Plaintiff Linda Wolicki-Gables' claims, the Court **grants** Defendant Johnson & Johnson's Motion for Summary Judgment as to this issue.

IV. Motion in Limine

Given the Court's disposition of the issues in this case in the Motions for Summary Judgment, it is not necessary for the Court to resolve the issues raised in the Motion in Limine, in which all Defendants join. The Court therefore **denies** the Motion in Limine without prejudice. Accordingly, it is

ORDERED Defendant Arrow's Motion for Summary Judgment (Dkt. 80), in which Defendants Codman & Shurtleff, Inc., Johnson & Johnson and Gregory Nelson join, is **granted**; it is further

ORDERED that Motion for Summary Judgment of Defendants Codman & Shurtleff, Inc., Johnson & Johnson and Gregory Nelson

(Dkt. 82) is **granted**; it is further

ORDERED that the Motion for Partial Summary Judgment of Defendants Codman & Shurtleff, Inc. and Johnson & Johnson is **granted** (Dkt. 66); it is further

ORDERED that Plaintiffs' Motion for Partial Summary Judgment (Dkt. 85) is **denied**; it is further

ORDERED that the Motion in Limine (Dkt. 81) is **denied** without prejudice.

The Clerk of Court shall enter a final judgment in favor of Defendants Arrow International, Inc., Codman & Shurtleff, Inc., Johnson & Johnson, and Greg Nelson and against Plaintiffs, and close this case.

DONE and ORDERED in Chambers, in Tampa, Florida on this 22nd day of July, 2009.

ELIZABETH A. KOVACHEVICH
United States District Judge

Copies to:
All parties and counsel of record