UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

TIMOTHY CRAYTON Plaintiff, v. ROCHESTER MEDICAL CORPORATION, a Minnesota corporation and JOHN DOE DISTRIBUTOR, Defendants.	1:07-CV-1318 OWW GSA ORDER RE: PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND DEFENDANT'S CROSS MOTION FOR SUMMARY JUDGMENT (Docs. 92, 154, 165, 172)

I. Introduction[1]

Pending before the Court is Plaintiff, Timothy Crayton's ("Plaintiff") Motion for Summary Judgment filed on December 30, 2009. Also pending before the Court is Defendant, Rochester Medical Corporation's ("ROCM" or "Defendant") Cross Motion for Summary Judgment filed on April 21, 2010. Upon a review of all of the pleadings, Plaintiff's Motion for

[1] Throughout these proceedings Plaintiff has alleged that he has been prejudiced because he is disabled and has not had access to an ADA typewriter or that he has not had access to legal materials while in prison. Several extensions of time have been given to Plaintiff in an effort to accommodate these situations. (Doc. 64, 91, 174, and 188).

Summary Judgment is DENIED. Defendant's Cross Motion for Summary Judgment is GRANTED.

II. Relevant Background [2]

Plaintiff initially filed this action in the Superior Court of Kern County, California, on June 14, 2007 (Case No. S-1500-cv-261075). (Doc.1). The action was removed to this Court on September 7, 2007. (Doc. 1). Plaintiff is a wheelchair paralytic who is an inmate at Kern Valley State Prison ("prison" of "KVSP"). The matter arises from Plaintiff's allegations that he was injured when he used an Ultraflex Silicone Self-Adhering Male External Catheter ("Ultraflex catheter" or "catheter") manufactured by Defendant.

In an Amended Complaint filed on September 10, 2008, Plaintiff asserts that the catheter is inherently defective and dangerous because the glue of the condom is invisible, excessively strong, not water soluble, and unevenly distributed. (Doc. 34). Specifically, Plaintiff alleges that when he attempted to remove the catheter in March 2006, the glue tore the skin on his penis resulting in abrasions and the removal of patches of "pubic hair by the roots." (Doc. 34 at pg. 5).

Based on the above, Plaintiff alleges causes of action under California law for strict products liability, negligent products liability, fraudulent misrepresentations, and breach of implied warranty of fitness. Moreover, Plaintiff contends he has incurred hospital and medical expenses, a loss of earning capacity, and a loss of consortium including his "mating ability." Plaintiff is seeking $500,000.00 in compensatory damages, $1,000,000.00 in exemplary damages, punitive damages, and loss of earning capacity.

Pending before the Court is Plaintiff's Motion for Summary Judgment filed on December 30, 2009.[3] (Doc. 92, 93, 151). On January 26, 2010, Defendant filed an Opposition. (Docs. 111, 113-121). On May 3, 2010, Plaintiff filed a Motion to Strike Defendant's Opposition (Doc. 165),

---

[2] This case has an extensive procedural history that involved several discovery disputes, however, only the procedural history related to the instant motions is relevant and is outlined in this order.

[3] On March 26, 2010, Plaintiff filed a Notice of Correction regarding Exhibit 2 of his undisputed facts. (Doc. 151). The Court has considered this correction.

a Reply, and Requests for Judicial Notice. (Doc. 141, 167-170). On May 5, 2010, Defendant filed an Opposition to Plaintiff's Motion to Strike Defendant's Opposition. (Docs. 175-176).

Also pending before the Court is Defendant's Cross-Motion for Summary Judgment filed on April 21, 2010. (Docs. 154-161). On July 9, 2010, Plaintiff filed an opposition to the motion. (Docs. 190-195). Defendant filed a Reply on July 19, 2010. (Doc. 196). The Court has reviewed all of the documents listed above in rendering its decision.[4]

III. Legal Standard

Summary judgment is appropriate when it is demonstrated that there exists no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Under summary judgment practice, the moving party

> [a]lways bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," which it believes demonstrate the absence of a genuine issue of material fact.

Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

With regard to a plaintiff's motion for summary judgment, as the party with the burden of persuasion at trial, Plaintiff must establish "beyond controversy every essential element of its" his affirmative claims. *S. Cal. Gas Co. v. City of Santa Ana*, 336 F.3d 885, 888 (9th Cir. 2003) (quoting W. Schwarzer, California Practice Guide: Federal Civil Procedure Before Trial § 14:124-127 (2001)). The moving party's evidence is judged by the same standard of proof applicable at trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986).

If the moving party meets its initial responsibility, the burden then shifts to the opposing party to establish that a genuine issue as to any material fact actually does exist. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). In attempting to establish the existence of this factual dispute, the opposing party may not rely upon the denials of its pleadings, but is required to tender evidence of specific facts in the form of affidavits, and/or

---

[4] The Court carefully reviewed and considered all of the pleadings, including arguments, points and authorities, declarations, and exhibits. Any omission of a reference to an argument or pleading is not to be construed that this Court did not consider the argument or pleading.

admissible discovery material, in support of its contention that the dispute exists. Rule 56(e); *Matsushita*, 475 U.S. at 586 n.11. The opposing party must demonstrate that the fact in contention is material, i.e., a fact that might affect the outcome of the suit under the governing law, *Anderson*, 477 U.S. at 248; *Nidds v. Schindler Elevator Corp.*, 113 F.3d 912, 916 (9th Cir. 1996), and that the dispute is genuine, i.e., the evidence is such that a reasonable jury could return a verdict for the nonmoving party, *Matsushita*, 475 U.S. at 588; *County of Tuolumne v. Sonora Community Hosp.*, 263 F.3d 1148, 1154 (9th Cir. 2001).

In the endeavor to establish the existence of a factual dispute, the opposing party need not establish a material issue of fact conclusively in its favor. It is sufficient that "the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Giles v. Gen. Motors Acceptance Corp*., 494 F.3d 865, 872 (9th Cir. 2007). Thus, the "purpose of summary judgment is to 'pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial.'" *Matsushita*, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e) advisory committee's note on 1963 amendments).

In resolving the summary judgment motion, the court examines the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any. Rule 56(c). The evidence of the opposing party is to be believed, *Anderson*, 477 U.S. at 255, and all reasonable inferences that may be drawn from the facts placed before the court must be drawn in favor of the opposing party, *Matsushita*, 475 U.S. at 587 (citing *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962) (per curiam)). Nevertheless, inferences are not drawn out of the air, and it is the opposing party's obligation to produce a factual predicate from which the inference may be drawn. *Richards v. Nielsen Freight Lines,* 602 F. Supp. 1224, 1244-45 (E.D. Cal. 1985), aff'd, 810 F.2d 898, 902 (9th Cir. 1987).

Finally, to demonstrate a genuine issue, the opposing party "must do more than simply show that there is some metaphysical doubt as to the material facts. Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" *Matsushita*, 475 U.S. at 587 (citation omitted).

IV. Summary of Undisputed Material Facts [5]

1. Prior to the invention and development of self-adhering male external catheters, external male urinary catheters or condom catheters were generally retained on a penis of an incontinent male with adhesive tape. Declaration of Anthony J. Conway dated April 14, 2010 ("Conway Dec'l) at ¶ 8. (Doc. 157).[6]

2. If an incontinent male lacked sensation in his penis and put the tape on too tight, circulatory problems could occur. *Id.*

3. The self-adhering condom catheter eliminates the tape. *Id.*

---

[5] As a basis to establish his medical condition and his design defect claims, Plaintiff relies on his verified complaint, his own declaration, as well as the declarations of several inmates at the prison. A verified complaint may constitute an opposing affidavit for purposes of the summary judgment rule, where the complaint is based on an inmate's personal knowledge of admissible evidence, *and not merely on the belief*. *McElyea v. Babbitt*, 833 F.2d 196, 197-98 (9th Cir. 1987) (per curium); *Lew v. Kona Hospital*, 754 F.2d 1420, 1423 (9th Cir. 1985). Moreover, an affidavit must be made on personal knowledge setting out facts that would be admissible in evidence and show *that the affiant is competent to testify on the matters stated*. Fed. R. Civ. P. 56(e). In this case, Plaintiff has submitted his own declarations or declarations of other inmates regarding the causes of his injuries, experiments he has performed in prison regarding the strength of the adhesive, or proposals for a better design of the catheter. (Doc. 93, pgs. 54-67). Neither Plaintiff nor the other inmates are medical experts, nor are they experts in the field of catheter development. Therefore, they are not competent or qualified to render an expert opinion regarding Plaintiff's medical condition, the causes of any injuries, or the design of the catheter in question. Accordingly, these facts will remain undisputed. *See also*, Federal Rules of Evidence 702. *See also*, Section VI, 2 *infra*.

Additionally, throughout these proceedings, Plaintiff has made numerous allegations about defense counsel's alleged unethical conduct including accusations that counsel has altered evidence and failed to provide Plaintiff with copies of filings. Moreover, Plaintiff has alleged that prison officials have confiscated his personal property and prevented him from filing evidence. Plaintiff has requested that this Court take judicial notice of several of these facts. However, a motion for summary judgment may not be turned into a contested evidentiary hearing through the guise of having the court take judicial notice of affidavits, declarations, and depositions. Federal Rule of Evidence 201 requires that a judicially noticed fact must be one not subject to reasonable dispute that is either generally known within the territorial jurisdiction or capable of accurate determination whose accuracy cannot reasonably be questioned. Fed. R. Evid. 201. Plaintiff has not met this standard and therefore his requests for judicial notice filed on May 3, 2010 are denied. (Doc. 166). Conclusory allegations of collusion, without factual support, are insufficient to defeat summary judgment. *National Steel Corp. v. Golden Eagle Ins. Co.*, 121 F.3d 496, 502 (9th Cir. 1997).

Finally, to dispute several facts, Plaintiff merely offers argumentative responses or conclusory statements. This is not appropriate rebuttal evidence and the facts are deemed undisputed because Plaintiff failed to produce admissible evidence to refute Defendant's facts.

[6] In a Motion to Strike filed on May 3, 2010, Plaintiff makes several arguments that Mr. Conway's declaration should be stricken. (Doc. 165). The Court has reviewed Plaintiff's motion and finds that it lacks merit as Defendant has submitted a signed declaration made under penalty of perjury. Mr. Conway's declaration is admissible evidence. Moreover, Plaintiff argues that Mr. Anglin's declaration should be stricken because none of the referenced exhibits are attached to the declaration. (Doc. 165 at pg. 2). However, there are copies of the exhibits in the docket. Plaintiff has repeatedly asserted that he has not received materials related to this litigation, however, Defendants have indicated that Plaintiff was provided with complete copies of all filings and the Court has found that Plaintiff was re-served with documents he allegedly has not received. (Docs. 139 at pg. 4 and Doc. 175, pg. 3).

4. Instead of using tape, the self-adhering condom catheters use a band of adhesive on the interior of the device. *Id*. at ¶ 9.

5. A band adhesive holds the device in place and, at the same time, seals it so as to avoid leaking. *Id.*

6. In order to function properly, there has to be sufficient amount of adhesive to hold the device in place and it must be sufficient to avoid leaking. *Id.* ¶ 17.

7. Mr. Conway is the primary inventor of the Ultraflex. *Id*. at ¶ 2.

8. The Ultraflex is used in the United States and in other countries where large numbers of users are uncircumcised men. *Id*. at ¶ 26.

9. ROCM manufactures the Ultraflex self-adhering male external catheter. ROCM manufactures three categories of self-adhesive catheters for distribution in the United States. They are the : (1) WideBand; (2) PopOn; and (3) Standard. Declaration of Robert Anglin ("Anglin Dec'l") dated April 8, 2010 at ¶ 6 (Doc. 158); (Doc. 34).

10. Ultraflex is a brand name for one of the "Standard" category of catheters. Anglin Dec'l at ¶ 6.

11. Since 1993, there have been over one hundred fifty-six million ROCM Standard male external condom catheters sold worldwide. Conway Dec'l at ¶ 26 (Doc. 157); Anglin Dec'l at ¶ 29 (Doc. 158).

12. Plaintiff is a wheelchair paralytic state prison inmate who is incontinent. His medical condition requires the use of condom catheters, due to his inability to control his urine flow. Plaintiff is not circumcised. Declaration of Timothy Crayton in support of Motion for Summary Judgment dated December 18, 2009. (Doc. 93 at Exhibit 1).

13. On March 20, 2006, Plaintiff was examined by a medical professional at the prison and was diagnosed with active bleeding, pain, an injury to the skin flap, and swollen area in his pubic region. Plaintiff was medically cleared and released back to custody. Medical document dated March 20, 2006, entitled "Medical Report of Injury or Unusual Occurrence." (Doc. 93 at Exhibit 7 at pg. 47; Doc. 118 at Exhibit 4, pgs. 1-2; Doc. 160 at Exhibit 4, pgs. 1-2).

14. On March 20, 2006, Plaintiff submitted a Medical Care Service Request Form to

refill his medication, Tolnaftate, for "fungus" and "jock rash." [7] (Doc. 118-1 at Exhibit 3, pgs. 1-2; Doc. 160-3 at Exhibit 3 at pgs. 1-2).

15. Plaintiff claims adhesive on an Ultraflex catheter he used on March 20, 2006 caused the injuries to his penis. Amended Complaint. (Doc. 34 at pgs. 4-5).

16. On March 21, 2006, Plaintiff submitted a Health Services Request Form and stated, he "need[ed] to see doctor for stronger pain pills and no-glue condoms. I followed your instructions put the ointment on my penis skin rips and on the 4 x 4 pads before taping it to the rips [sic] area - hurts like hell when the wrapping comes off with still a little bleeding." Health Care Services Request Form dated March 21, 2006. (Doc. 93 at Exhibit 6, pg. 43; Doc. 118 at Exhibit 5, pg. 2).

17. Mr. Crayton's medical records for March 20, 2006 and March 21, 2006 do not indicate the injuries to his pubic area were the result of the use of a condom catheter.[8]

18. Mr. Crayton's medical records make no mention of use of the Ultraflex or any type of catheter on March 20, 2006.

19. On February 27, 2007, Plaintiff received a first level response to his appeal filed with the Department of Corrections and Rehabilitation. The appeal issue presented was that Plaintiff filed several written requests that he be provided with non-glue condoms in the correct size. Plaintiff indicated that he had found a way to remove the glue from the condoms but that the size of the condoms were incorrect. On February 27, 2007, Plaintiff was provided with correct sizes of the glue-on condom. Memorandum from the Department of Corrections and Rehabilitation dated February 27, 2007 (Appeal Log, KVSP-0-0602127). (Doc. 93 at Exhibit 9, pg. 51).[9]

---

[7] Plaintiff has disputed this fact on the basis that when he filled out the form he wrote "jock rash" but was actually requesting medicine for toe nail fungus because this is how inmates refer to toe nail fungus. (Doc. 191 at pg. 5.). Although Plaintiff has disputed the meaning behind the words on the form, he has not contested that the form was filled out in the manner as alleged by Defendant. Therefore, the fact the form was created is not disputed.

[8] Although Plaintiff attempts to dispute this fact by explaining reasons for the omission, he presents no admissible evidence to support his position. Furthermore, contrary to Plaintiff's assertions, he has not submitted any medical recordings indicating the catheter *caused* his injuries. Accordingly, this fact is undisputed.

[9] Plaintiff has not provided a copy of the appeal itself so the contents of the appeal, as well as the date it was filed, cannot be ascertained.

20. On April 19, 2007, Plaintiff received a second level response to his appeal filed with the Department of Corrections and Rehabilitation. Plaintiff had requested non-glue condoms to avoid further injuries. Plaintiff's appeal was granted and the appeal was withdrawn. Memorandum from the Department of Corrections and Rehabilitation dated April 19, 2007. (Appeal Log, KVSP-0-06-3488).[10] (Doc. 93 at Exhibit 10, pg. 53).

21. On December, 5, 2005, prior to the injury in question, Plaintiff filled out a Health Care Services Request Form. On the form Plaintiff indicated that he "[Did] not require glue-on condoms. Please change to regular condoms ... The Ultraflex condoms have changed to super glue and extremely [sic] painful to remove from my 'Johnson.' Soaking the condoms in soapy water to remove the glue no longer works. No glue-on condoms." Health Care Services Request Form dated December 5, 2005. (Doc. 160-1, Defendant's Exhibit 1 at pg. 1-2).

22. Dr. DiLeo, M.D. is a doctor at KVSP. Plaintiff listed Dr. DiLeo as his "post-injury physician" in his Initial Disclosures. Plaintiff's Initial Disclosures at pg. 3 (Doc. 161-1, Defendant's Exhibit no. 9).[11]

23. Dr. DiLeo indicated that he had no independent recollection of ever treating Plaintiff for complaints with regard to a catheter. After reviewing the medical records, it was Dr. DiLeo's opinion that Mr. Crayton had not suffered a serious injury as a result of a self-adhering condom catheter. Deposition Testimony of Dr. DiLeo on November 10, 2009. (Doc. 160-7, Defendant's Exhibit pgs. 6-7).[12]

---

[10] The Court notes that these two responses to Plaintiff's appeal reflect there was more than one appeal filed by Plaintiff. *See*, UMF numbers 19 and 20. Moreover, although Plaintiff argues that these decisions prove the catheter is defective and caused his injuries, these documents are not evidence of that fact as alleged by Plaintiff. (Doc. 190 at pg. 15). Although it appears that one of the appeals was granted and Plaintiff was permitted to have non-glue on catheters, there is no opinion in the appeal decision that the catheter in question was defective or that it caused any injuries to Plaintiff. (Doc. 93 at pg. 53 Ex. 10). The Court also notes that Plaintiff has not submitted complete copies of the appeal. Instead, only the final decision was submitted which omits pertinent information regarding the basis of the appeal.

[11] In his opposition to Defendant's Motion for Summary Judgment, Plaintiff has indicated that Dr. DiLeo did not treat his penis injury, nor perform any hands-on examination of the Plaintiff. (Doc. 190, pgs. 20 and 22). However, this is inapposite to Plaintiff's initial disclosures identifying Dr. DiLeo as his post injury doctor.

[12] Defendant also submitted the deposition of Dr. Jonathan Akanno, M.D. taken on November 10, 2009 in support of its proposition that Plaintiff suffered no injuries because of his use of the catheter. Dr. Akanno testified that he was Plaintiff's primary care physician. Based on a review of the medical record and his examinations of Plaintiff, Dr. Akanno concluded Plaintiff did not experience serious injury as a result of using the catheter. (Doc.

24. Crayton failed to produce the catheter for inspection despite Defendant's informal and formal requests that he do so.

25. Crayton's Rule 26 Disclosure states, "the actual defective glue-on condom catheter product that caused Plaintiff's injury ... has been retained and is in the Plaintiff's custody." Plaintiff's F.R.C.P. Rule 26(a)(1) Initial Disclosures (Doc. 161-1, Defendant's Exhibit 9, at pg. 3).

26. ROCM requested that Crayton produce the Ultraflex for inspection. ROCM's First Set of Request for Production of Documents and Tangible Things No. 1, Set One (Doc. 161-2, Defendant's Exhibit 10, pg. 2).

27. Crayton did not produce the Ultraflex to ROCM. Plaintiff's Response to ROCM's Request for Production No. 1. (Doc. 161-3, Defendant's Exhibit 11 at pg. 2)

28. ROCM made a second request that Crayton produce the Ultraflex. Stacy Spodick declaration dated April 20, 2010 ("Spodick Dec'l") at pg. 2 ¶ 6. (Doc. 163 at pg. 2, ¶6).

29. Crayton again did not produce the Ultraflex for inspection or testing. Spodick Dec'l at pg. 2, ¶7. (Doc. 163 at pg. 2, ¶ 7).

30. ROCM issued a subpoena to compel the warden at the prison to produce among other things, "any and all male external condom catheters, including but not limited to Ultraflex silicone male external condom catheters, confiscated and/or being held for inmate Timothy Crayton by Kern Valley State Prison from 2005-2010." Subpoena dated February 25, 2010, (Doc. 161-16, Defendant's Exhibit 24 at pg. 1)

31. In support of a Plaintiff's Motion to Quash ROCM's subpoena, Crayton offered his declaration which stated as follows :

> Regarding the actual defective Ultraflex glue-on condom catheter that caused me injury on March 20, 2006, I have no information that would lead me to believe that it remains part of my aforesaid boxes of unlawfully confiscated

---

160-6, Defendant's Exhibit 6 at pgs. 5-8). However, Plaintiff has disputed that Dr. Akanno was his doctor. Moreover, a review of the transcript indicates that the medical records Dr. Akanno reviewed indicated that Plaintiff transferred to Kern Valley State Prison in 2007 which is after this incident. (Doc. 200 at pg. 6-7). While arguably there is some evidence that Dr. Akanno reviewed all of the medical records since Plaintiff's incarceration, the deposition testimony is unclear. *Id*. at pg. 6. Therefore, the Court will view the evidence in the light most favorable to Plaintiff. Because of these inconsistencies in the doctor's testimony and Plaintiff's contentions, the Court finds Dr. Akanno's testimony is disputed.

> property or that it still exists.
>
> On August 21, 2009, during the evidentiary hearing of Kern County Superior Court Case No. HC0096778A, as the pro per attorney of record I was allowed to make an in-court inspection of the aforesaid boxes of unlawfully confiscated record. I did not see the March 20, 2006 injury causing Ultraflex glue-on condom catheter inside any of the boxes of records.
>
> Prison property officers who inventory confiscated inmate property do not admit to destroying the Ultraflex catheter, but did inform me that if they saw the used condom catheter in my property boxes they would dispose of it for sanitation and health reasons.
>
> I believe that the actual defective Ultraflex glue-on condom catheter that caused me injury on Marcy 20, 2006 has been destroyed by prison officers.

Declaration of Timothy Crayton in Support of Plaintiff's Motion to Quash Defendant's Subpoena directed to the Warden of Kern Valley State Prison. (Doc. 161-16, Exhibit 24, at pg. 1 and Doc. 145 pgs. 11-12).

32. A design feature of the Ultraflex is that it is clear, in other words, it is completely see through. This allows for visual inspection of the skin and the penis while an Ultraflex is being worn. If, for example, there were any discoloration or marks on the penis, these could be observed through the clear Ultraflex. Conway Dec'l at¶ 23. (Doc. 157 at pg. 5).

33. Adding a color tint to the adhesive would eliminate the design advantage of a colorless see through device that allows easy detection of any change in appearance, including the skin coloration, of the user's penis. Conway Dec'l at ¶ 24 (Doc. 157 at pg. 5).

34. Each Ultraflex contains less than one-thirteenth of one ounce of pressure sensitive adhesive. Conway Dec'l at ¶ 18. (Doc. 157 at pg. 4).

35. This design allows for a peel that raises from the baseline within the first half-inch of peel and starts near baseline with a force of less than 0.2 pounds. Conway Dec'l at ¶ 18. (Doc. 157 at pg. 4).

36. For the Ultraflex to function properly, there has to be a sufficient amount of adhesive to hold the device in place and it must be sufficient to avoid leaking. The amount of adhesive necessary to hold the Ultraflex in place and avoid leaking was determined by testing and is controlled during the production process. Conway Dec'l at ¶ 17. (Doc. 157 at pg. 4).

37. Approximately once per hour, a representative sample of ROCM catheters, including but not limited to the Ultraflex, are removed from the production line. From the batch,

the adhesive band is removed so that the weight of the band can be verified to match manufacture specifications. Additionally, the weight and the peel strength of the adhesive is tested on a Q-Test Tensile Tester, in terms of peel force. Declaration of Robert Anglin (Anglin Dec'l) dated September 15, 2009 at ¶ 1(b)(ii). (Doc. 116 at pgs. 2-3).

38. The Ultraflex has been tested to meet medical devices biocompatibility requirements, including the Elution 14-day repeated intravenous test, Systemic Injection Study, and a Sensitization Study (Kligman maximization study). Anglin Dec'l dated September 15, 2009 at ¶ 1(a)(ii). (Doc. 116 at pg. 1 and Doc. 161 at Defendant's Exhibits 15-18).

39. Since 2000, ROCM has received approximately seventy complaints that the adhesive was too strong or too sticky in the Ultraflex. Anglin Dec'l dated September 15, 2009 at ¶ 1(a)(v). (Doc. 116 at pg. 2).

40. The reason there is no lip is that the existence of a raised lip requires an increased thickness of silicone. The increased thickness that would be required to form a lip ridge is undesirable because it could potentially restrict blood flow to a user's penis. Conway Dec'l at ¶ 21. (Doc. 157 at pg. 4).

41. By design, the Ultraflex has an area of sheath at the open end of the catheter that contains no adhesive. This allows the user to grasp and roll or gently peel the catheter off the skin during removal. Conway Dec'l at ¶ 17 (Doc. 157 at pg. 4).

42. The Ultraflex catheters are sold in boxes of thirty or one hundred separately packaged catheters. Dec'l of Anthony Anglin dated April 8, 2010 ("Anglin Dec'l") at ¶ 23. (Doc. 158 at pg. 5).

43. Each box of Ultraflex catheters contains an "Instructions for Use Sheet." Anglin Dec'l at ¶ 23. (Doc. 158 at pg. 5).

44. At the time of Plaintiff's alleged injury, the "Instructions for Use Sheet" contained in Ultraflex catheters included instructions for the proper preparation for use, the proper manner in which the catheter should be placed on the penis, as well as instructions for removal of the catheter. Ultraflex Instruction Sheet (Doc. 160 at Exhibit 2).

45. The Ultraflex package at issue at a minimum contained illustrations of how to

apply and how to remove the catheter. Plaintiff's Response to The Defendant's Request for Production of Documents, No. 4. (Doc. 161-3 at Exhibit 11 at pg. 2).

46. Plaintiff produced a copy of a document that he labeled as "[ORIGINAL] packaging of Ultraflex catheter," and which Plaintiff's describes as "Attached is the same exact manufacturer's packaging that the injury causing Ultraflex product came in. The packaging lacks lot information and expiration date information." Plaintiff's Response to The Defendant's Request for Production of Documents, No. 4. (Doc. 161-3 at Defendant's Exhibit 11 at pgs. 14-15; Doc. 191 pg. 115 and 117).

47. The packaging Plaintiff alleges he received with the catheter includes three illustrations with the word descriptions "Unroll catheter," "Squeeze Catheter" or "Roll off to remove." Plaintiff's Response to The Defendant's Request for Production of Documents, No. 4. (Doc. 161-3, Defendant's Exhibit 11 at pgs. 14-15).

48. Crayton received the condom catheter from the prison. Plaintiff's Response to ROCM's Interrogatory No. 7 (Doc. 161- 15, Defendant's Exhibit 23 at pg. 3).

49. Crayton's Interrogatory No. 10 claims, " No information was ever provided to plaintiff regarding proper use and removal of ROCM products, including the Ultraflex product." Crayton's response to Interrogatory No. 10. (Doc. 161- 15, Defendant's Exhibit 23 at pg. 3).

V. Discussion

A. Plaintiff's Motion for Summary Judgment

In Plaintiff's Motion for Summary Judgment and in his opposition to Defendant's Cross-Motion for Summary Judgment, Plaintiff argues that the design of the catheter is defective. In particular, Plaintiff contends that rather than having distinct areas or rings of glue, the glue is coated along the entire interior sleeve of the condom which extends from the pubic hair down the entire shaft of the penis. Plaintiff argues this is problematic because the glue becomes bonded to the skin of the penis. Because the condom does not have a prominent lip ridge on the end of the condom sleeve, the user's fingers are unable to get sufficient "traction" which prevents the condom from rolling off the penis shaft smoothly resulting in serious injuries to the pubic area when the catheter is removed. Plaintiff contends he has developed a more effective design that

incorporates a ridge at the base of the catheter, colored adhesive, and rings of glue rather than glue along the entire interior of the condom so that the condom can be removed more easily.

Plaintiff also alleges that the catheter is not only defectively designed but the packaging of the product fails to inform the user of the risks of the glue. Specifically, Plaintiff argues that the packaging falsely deceives the user to believe that after unrolling the glue-on condom onto the penis, the condom can be removed without difficulty. Moreover, he contends that the condom should offer users multiple choice of glue strength. Plaintiff argues he has presented uncontroverted evidence to support all of his causes of action and requests that summary judgment be entered against Defendant.

B. Defendant's Cross-Motion for Summary Judgment

In opposition to Plaintiff's Motion for Summary Judgment and in support of its Cross-Motion for Summary Judgment, Defendant argues that Plaintiff has failed to produce the catheter and has not established that the catheter in question caused him injuries. Furthermore, Defendants contend that the design of the catheter is not defective and the packaging is adequate.

Moreover, Defendant argues Plaintiff is a sophisticated user who was familiar with self-adhering catheters. In fact, evidence exists that he had difficulty with the adhesive in this catheter previously. Plaintiff was therefore on notice of *any alleged* defect which undercuts his failure to warn cause of action. Finally, because Plaintiff received the catheter from the prison officials, Plaintiff cannot establish the catheter was in Defendant's control at the time of its use, nor can he establish privity to the Defendants which is a prerequisite to his breach of implied warranty of fitness claim. Accordingly, Defendant requests summary judgment be awarded against Plaintiff on all causes of action.

///

C. Preliminary Matters

All of the causes of action alleged by Plaintiff require that he establish he suffered injury and that the injury was caused by the catheter. For the reasons outlined below, because Plaintiff is unable to establish injury and causation, he has failed to meet his burden on all of his claims. Accordingly, summary judgment will be awarded to Defendant.

1. The Medical Evidence

Crayton's medical evidence fails to confirm his allegations that he suffered any injury caused by the use of the catheter on March 20, 2006. While the medical records indicate that Plaintiff sought medical attention on March 20, 2006 for treatment to his pubic area, there is no indication that this alleged injury was caused by the Ultraflex catheter. UMF 13. The records indicate that Plaintiff sought a prescription refill and he complained of jock rash. UMF 14. None of the medical documents Plaintiff submitted indicate that the injury to his penis was as serious as Plaintiff alleges, or that any injuries that he suffered were the result of Plaintiff's use of the condom catheter in question. In fact, Dr. DiLeo, the doctor Plaintiff identified in his Initial Disclosures as his post-injury doctor, testified that based on his examinations of Plaintiff and a review of Plaintiff's medical records, Plaintiff had not suffered a serious injury as a result of using a catheter manufactured by Defendant. [13] UMF 22, 23. Indeed, other than Plaintiff's own declaration, Plaintiff has not submitted any *admissible* evidence that he was using the condom catheter at the time in question. UMF 15. Although Plaintiff's verified declaration could be admissible evidence, he is not a doctor or expert qualified to render an opinion regarding the causes of his injuries or the design of the catheter. *See*, Footnote 5, *infra*. Therefore, his own declaration, or the declarations of other prisoners regarding his injuries and the effectiveness of the design of the catheter are not sufficient evidence to establish his claims.

2. Failure to Produce the Catheter

Furthermore, to date, Plaintiff has failed to produce the catheter he claims caused his injuries so that it could be inspected or tested. UMF 24. As such, Plaintiff has failed to establish that the catheter was in any way defective and he presented no evidence that if there had been a

---

[13] Plaintiff has objected to Dr. DiLeo's deposition because Plaintiff was not present when it was taken. However, Defendant has presented evidence that Plaintiff was notified of the deposition but was unable to attend due to security issues at the prison. The Court has considered the deposition as evidence because Plaintiff never filed a motion during discovery to address this alleged violation which was the appropriate time to do so, nor has he cited any authority under Federal law that his presence was required at the deposition of a third party witness. Plaintiff could also have deposed Dr. DiLeo yet he failed to do so.

Finally, even in the absence of Dr. DiLeo's testimony, Plaintiff has failed to submit sufficient medical evidence to establish injury and causation. Although Plaintiff has challenged the accuracy of the deposition transcript submitted by Defendant, the Court has reviewed the entire transcript and finds that the transcript was not altered. (Doc. 201).

defect, the defect was within Defendant's control.

The Court notes that Plaintiff has given inconsistent information regarding the location and existence of the catheter and its packaging since the beginning of this case. Indeed, Plaintiff represented numerous times to the Court that the catheter at issue was in his personal property allegedly confiscated by prison officials. UMF 25, 31; (Doc. 94, pg. 5, ¶ 5 and Doc. 125 pg. 2, ¶ 3). This Court spent a significant amount of its resources responding to discovery disputes and allowing Plaintiff several opportunities to locate and produce the catheter. At the Defendant's request, the Court issued a subpoena so that catheter could be obtained from prison officials. However, Plaintiff moved to quash the subpoena on the basis that during an inspection of his boxes (which occurred before he made the representations to the Court that he possessed the catheter), he did not see the catheter and was informed that the catheter would have been destroyed by prison officials for sanitation and safety reasons. (Doc. 145, pg. 12 at ¶¶ 5-7). The Court expressed its concern that Plaintiff had not be forthright with the information he submitted to the Court regarding this issue. Given the inconsistent information provided, the Court did not quash the subpoena. A search of Plaintiff's personal property was completed but the catheter could not be located. (Doc. 165 at pg. 6, and Doc. 184).

Plaintiff's inability to produce the catheter for inspection is not only prejudicial to Defendant, but it is also fatal to Plaintiff's case; without the ability to establish causation and injury, Plaintiff cannot demonstrate the product was being used, or that the product's design caused his injuries. Plaintiff has argued that he has submitted the packaging of the catheter in question. Nonetheless, he has only supplied copies of the alleged packaging. (Doc. 139 at pg. 6, lines 8-16). These copies lack information regarding the lot and expiration date which was vital to establishing when and where the catheter would have been manufactured. UMF 43.

Plaintiff contends that he does not need to present the catheter in question but instead can base his case on circumstantial evidence such as similar product defects. In support of this proposition Plaintiff has cited several cases. *See*, *Aetna Ca. & Sur Co. v. Farmers Bros. Co.*, 65 Cal. App. 4th 574 (1998); *Elsworth v. Beech Aircraft Corp*. 37 Cal. 3d 540, 555 (1984); *Ault v. International Harvester Co.,* 13 Cal. 3d 113, 117 (1974). However, in all of these cases, whether

the plaintiff was using the product in question at the time of injury was not an issue. Here, Plaintiff has not established that he was even using a condom catheter manufactured by Defendant during the relevant time period. Simply providing circumstantial evidence consisting of an altered product package from which Defendant is unable to determine the time and place of manufacturing is not sufficient. As such, Plaintiff has not met his burden.

VI. Claims

A. Strict Products Liability

In a products liability case under California law, a plaintiff may seek recovery "on the theory of strict liability in tort or on the theory of negligence." *Merrill v. Navegar, Inc.*, 26 Cal.4th 465, 478 (2001) (citation and quotation marks omitted). California law provides that a manufacturer may be held strictly liable for injuries caused by its product "(1) if the product is defectively manufactured; (2) if it is defectively designed; or (3) if it is distributed without sufficient warnings or instructions about its potential for harm." *Karlsson v. Ford Motor Co.*, 140 Cal.App.4th 1202, 1208 (Ct.App.2006); *see also Merrill v. Navegar*, 26 Cal.4th at 479.

In this instance, Plaintiff has pursued two theories of strict products liability: 1) defective manufacture, and 2) defective design. The California Court of Appeal has stated that "[t]he elements of a strict products liability cause of action are a defect in the manufacture or design of the product or a failure to warn, causation, and injury." *Nelson v. Superior Court*, 144 Cal.App.4th 689, 695 (Ct.App.2006). It has further stated that in a strict products liability action, the "plaintiff must ordinarily show: (1) the product is placed on the market; (2) there is knowledge that it will be used without inspection for defect; (3) the product proves to be defective; and (4) *the defect causes injury*." *Id.* (citations and quotation marks omitted).

1. Manufacturing Defect

"A manufacturing defect occurs when a product does not conform to the manufacturer's intended design." *Carlin v. Superior Court*, 13 Cal.4th 1104, 1121 (1996); *see also McCabe v. Am. Honda Motor Co.*, 100 Cal.App.4th 1111, 1120 (Ct.App.2002) ("A manufacturing defect exists when an item is produced in a substandard condition"). In general, a manufacturing or production defect is readily identifiable because a defective product is one that differs from the

manufacturer's intended result or from other ostensibly identical units of the same product line." *Barker v. Lull Eng'g Co.*, 20 Cal.3d 413, 429 (1978). The inquiry as to whether a manufacturing defect exists "focuses on whether the particular product involved in the accident was manufactured in conformity with the manufacturer's design." *In re Coordinated Latex Glove Litig.*, 99 Cal.App.4th 594 (Ct.App.2002) (citation and quotation marks omitted). Plaintiff must demonstrate four elements to establish a manufacturing defect. These four elements are that: 1) the Defendant manufactured the product, 2) the product contained a manufacturing defect when it left Defendant's possession, 3) Plaintiff was harmed while using the product in a foreseeable manner, and 4) the product's defect was a substantial factor in causing Plaintiff's harm. *See*, Cal. Civ. Jury Inst. ("CACI") § 1201.

In his Motion for Summary Judgment, Plaintiff contends that after Defendant obtained the patents for the glue on condom catheter, "it failed to perform the mandatory pre-market impact studies on uncircumcised consumers to determine if the glue on condom product is safe for use... ." (Doc. 92 at pg. 10-11). Although Plaintiff argues Defendant failed to establish it conducted tests specific to paralytic uncircumcised males, he has offered no authority that ROCM was required to do so.

Defendant has provided evidence for the bases for the catheter's design, as well as the quality control procedures it employs to ensure the product is manufactured according to its specifications. These tests include random testing of the catheters and the strength of the adhesive. UMF 34, 35, 36, 37, and 38. Furthermore, because Plaintiff has failed to produce the catheter, he is unable to establish that the product contained a manufacturing defect when it left Defendant's control, or that the defect was a substantial factor in causing Plaintiff's harm. This is especially true because Plaintiff received this product from prison officials and has not demonstrated that ROCM was in any way responsible for the condition of the catheter or its packaging at the time of the alleged incident. UMF 48, 49.

2. Design Defect

There are "two species of design defects" under California law. *Johnson v. Honeywell Int'l Inc.*, 179 Cal.App. 4th 549, 558 (Ct. App. 2009). A design defect may be proven under: 1)

the consumer expectation test (that the product failed to perform as safely as an ordinary consumer would expect) and/or, 2) the risk benefit test. *Barker v. Lull Eng'g Co.*, 20 Cal.3d 413, 418 (1978). Under the consumer expectation test, it must be proven that : 1) the defendant manufactured the product; 2) the product did not perform as safely as an ordinary consumer would have expected at the time of use; 3) that Plaintiff was harmed while using the product in a reasonably foreseeable way; and 4) that the product's failure to perform safely was a substantial factor in causing harm to the Plaintiff. CACI § 1203. To establish a design defect based on the risk benefit test, Plaintiff must prove that: 1) the defendant manufactured the product; 2) that plaintiff was harmed while using the product in a reasonably foreseeable way; and 3) that the product's design was a substantial factor in causing harm to Plaintiff. CACI § 1204.

"The consumer expectations test focuses on the safety expectations of an ordinary consumer rather than those of an expert." *Bell v. Bayerische Motoren Werke Aktiengesellschaft*, 181 Cal.App.4th 1108, 1129 (Ct.App.2010). Plaintiff correctly notes after that a prima facie showing that the injury was legally caused by the product's design, the burden shifts to the defendant to prove that the product was not defectively designed. *See*, *Cambell v. General Motors Corp* 32 C 3d 112, 118 (1982). However, the key is that *Plaintiff must first prove that his injury was caused by the product's design* prior to the burden shifting to the Defendant.

Although Plaintiff has argued that expert opinion to establish a design defect is not required because the condom catheter is within the knowledge of ordinary consumers, the Court disagrees. (Doc. 190 at pg. 5). Crayton's unsupported opinions of a design defect are insufficient to defeat a summary judgment motion. *See*, *Visueta v. General Motors*, 234 Cal. App. 3d 1609, 1616 (1991) (a nonexpert witness cannot express an opinion as to the cause of a particular accident where expert or special knowledge is essential to the formulation of an intelligent opinion which would be of aid to a jury.) While it is true that expert testimony may be limited in cases involving the consumer expectation test, "this test is reserved for cases in which the everyday experience of the product's users permits a conclusion that the product's design violated minimum safety assumptions." *Pruitt v. General Motors Corp.*, 72 Cal. App. 4th 1480, 1483 (1999). The development of a medical device such as the condom catheter is not part of the

"everyday experience" of the consuming public. Simply put, Plaintiff's experiments which include using his two fingers to simulate a penis or rolling a newspaper into the size of a penis and attempting to pull off the catheter to demonstrate the strength of the adhesive inside the catheter is not admissible evidence. (Doc. 93 at pg.65- 66).

Because Plaintiff never produced the condom or any admissible evidence that the catheter caused his injuries or was defectively designed, Plaintiff has not established the essential elements under the consumer expectation test. Similarly, Plaintiff's lack of evidence fails to establish a design defect under the risk benefit test.

Moreover, Plaintiff attempts to rely on other prisoners who allegedly have experienced difficulty with the catheter, as well as other consumer complaints regarding the strength of the adhesive to establish a design defect. (Doc. 93 at pgs. 54-63 and pgs. 74-106). Indeed, ROCM acknowledges that it has received approximately seventy complaints out of the 156,000,000 catheters it manufactured and distributed regarding the adhesive strength. UMF 11, 39. Notwithstanding the minuscule

l number of complaints ROCM received when compared to the number of catheters it manufactures, these other complaints do not create a disputed material fact because of Plaintiff's failure to establish causation. [14]

Additionally, even though the burden had not shifted to Defendant, ROCM submitted evidence regarding the bases for the catheter's design, including but not limited to, the fact that: 1) the clear adhesive allows for an inspection of the penis while it is being worn to prevent the risk of injury; 2) the adhesive must be strong enough to avoid leakage; 3) the creation of a lip at the base of the penis as proposed by Plaintiff would create a ridge resulting in a restriction of

[14] The Court notes that Defendant has objected to these reports as hearsay. However, the Court has considered the complaints in this instance because Plaintiff filed a motion to contact these consumers and witnesses to complete discovery and identify potential witnesses in support of his claim. The Court had not yet ruled on his motion. (Doc. 172). As such, this evidence will be viewed in the light most favorable to Plaintiff. Moreover, a close review of the list of complaints submitted by Plaintiff reveals that several pages of the list were submitted repeatedly and are duplicative. (Doc. 93 at pgs. 74-106).

blood flow; and 4) there is no adhesive at the base of the penis to avoid the condom getting stuck in pubic hair. UMF 32, 33, 36, 38, 40, and 41. For these reasons, Plaintiff has not established that a material disputed fact exists with regard to this cause of action.

3. Failure to Warn

Plaintiff's Motion for Summary Judgment alleges that the Ultraflex labeling is improper because: 1) there are no instructions to inform an uncircumcised consumer how to safely use and remove the condom; 2) there is no warning of "invisible glue" that actually bonds the condom to the skin of an uncircumcised penis; and 3) the label does not inform an uncircumcised consumer as to what he should do when the glue becomes bonded and stuck to the skin of an uncircumcised penis. (Doc. 92 at pgs. 15-16).

To establish this claim of strict liability for a failure to warn, Plaintiff must prove *all* of the following : 1) that ROCM manufactured the product; 2) that the product had potential risks that were known at the time of the sale; 3) that the potential risks presented a substantial danger to the users of the product; 4) that ordinary consumers would not have recognized the potential risks; 5) that ROCM failed to adequately warn of the potential risks; 6) that plaintiff was harmed by using the product in a reasonably foreseeable way; and 7) the lack of sufficient instructions or warnings was a substantial factor in causing Plaintiff harm. CACI § 1205.

In addition to Plaintiff's inability to establish that he was harmed by using the product, Plaintiff's claim for this cause of action is problematic because he cannot establish the lack of instructions or warnings was a substantial factor in causing him harm. On December 5, 2005, approximately three and a half months prior to the alleged incident, Plaintiff filled out a Health Care Services Request Form indicating that he was aware that the Ultraflex condoms had changed to "super glue" and that he had difficulty removing these from his penis. UMF 21. This complaint evidences that Plaintiff was aware there was adhesive in the catheter that could be painful for him to use the product, but he continued to use the catheter.

Plaintiff's experience with this catheter allows Defendant to assert "the sophisticated user defense." This defense exempts a manufacturer from its typical obligation to provide users with a warning about a product's potential hazards when the users are "sophisticated users" who

are already aware or should be aware of the dangers of the product. *Johnson v. American Standard, Inc.*, 43 Cal. 4th 56, 64-67 (2008). According to his own words, Plaintiff was on notice that the catheter contained glue and had given him difficulty in the past. Although Plaintiff attempts to explain this form away by arguing that the Health Care Services Request Form occurred at Salinas State Valley Prison and relates only to a medical supply error, his reasoning does not negate the fact that he was on notice that the glue caused him problems in the past. (Doc. 190 at pg.10). [15] Plaintiff's argument that ROCM changed the design of its packaging between 2005 and the date of the incident resulting in his inability to discern the catheter contained glue is similarly unpersuasive. Plaintiff submitted no evidence that the packing was in fact redesigned to the extent that would cause this confusion.

Finally, it is undisputed that at the time of the alleged incident ROCM's "Instructions for Use Sheet" which included instructions for the catheter's proper preparation and use was placed in all catheters it manufactured. UMF 44 and 45. It is also undisputed that Plaintiff obtained the catheter from prison officials and no information was ever provided to Plaintiff regarding the proper use and removal of the Ultraflex product. UMF 48 and 49. Plaintiff opines that for security reasons, distributor shipping boxes are delivered to a warehouse where the products are removed and searched for contraband and the boxes are discarded. (Doc. 190 at pg. 7). Accordingly, Plaintiff failed to establish that the product and the instructions were not altered after the catheter left Defendant's control. No matter what the "Instruction for Use Sheet" would have said, based on Plaintiff's representations, he would never have seen it, further undercutting his claim.

B. Negligent Products Liability

Plaintiff's Motion for Summary Judgment also alleges claims against ROCM for: 1) negligent manufacturing defects; 2) negligent design defects; and 3) negligent product label defect. (Doc. 92, at pgs. 17- 22). To establish his claims for negligent manufacturing defects and

[15] Defendants have also argued that Plaintiff's claims are barred by the Learned Intermediary Doctrine. (Doc. 111 at pgs 23-24 and Doc. 154 at pg. 17). However, this Court makes no finding regarding this issue because Plaintiff has failed to establish that he was using the catheter in question in a foreseeable way and that his injuries were caused by the product in question.

negligent design defects in the Ultraflex, Plaintiff must establish that: 1) ROCM designed and/or manufactured the product; 2) ROCM was negligent in designing and/or manufacturing the catheter; 3) Plaintiff was harmed; and 4) ROCM's negligence was a substantial factor in causing Plaintiff's harm. CACI § 1220. For the reasons already stated above in the strict liability analysis, namely that Plaintiff has failed to establish causation, Plaintiff has not met his burden of his negligent manufacturing defect and negligent design defect claims.

Similarly, Plaintiff has failed to establish a negligent product label defect. To prove this cause of action, Plaintiff must establish all of the following: 1) that ROCM manufactured, distributed and/or sold the product; 2) that ROCM knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner; 3) that ROCM knew or reasonably should have known that users would not realize the danger; 4) that ROCM failed to adequately warn of the danger [or instruct on the safe use of the product]; 5) that a reasonable manufacturer under the same or similar circumstances would have warned of the danger [or instructed on the safe use of the product]; 6) that Plaintiff was harmed; and 7) that ROCM's failure to warn [or instruct] was a substantial factor in causing Plaintiff harm. CACI 1222. The warning must be given to the prescribing physician and must include the potential risks or side effects that may follow the foreseeable use of the product. CACI 1222.

Plaintiff failed to meet his burden as he has not presented any *admissible* evidence that ROCM was negligent in the design or manufacture of the Ultraflex. Furthermore, Plaintiff has submitted no evidence that he was harmed by using the product or that ROCM's failure to warn caused him harm. Therefore, summary judgment shall be granted on behalf to Defendant.

///

C. Fraudulent Misrepresentations

California law provides for a cause of action for fraud when a product manufacturer knowingly misrepresents a product's safety information, or conceals material product information from potential users. *See Nodine v. Shiley Inc.*, 240 F.3d 1149, 1152-53 (9th Cir. 2001); *Khan v. Shiley Inc.*, 217 Cal.App.3d 848, 858, 266 Cal.Rptr. 106, 112 (Ct.App.1990). Under California law, "[t]he elements of fraud are: (1) a misrepresentation (false representation,

concealment, or nondisclosure); (2) knowledge of falsity (or scienter); (3) intent to defraud, i.e., to induce reliance; (4) justifiable reliance; and (5) resulting damage." *Robinson Helicopter Co. v. Dana Corp.,* 34 Cal.4th 979, 990 (2004) (citing *Lazar v. Superior Court,* 12 Cal.4th 631, 638 (1996)); *see also Conroy v. Regents of Univ. of Cal.,* 45 Cal.4th 1244, 1255 (2009).

Plaintiff's false misrepresentation claim is based on allegations that ROCM "made public misrepresentations of material facts about the character, quality and fit safe use [sic] of their glue-on catheter to the plaintiff." Plaintiff's Amended Complaint, (Doc. 34 ¶ 40). However, later Plaintiff indicates that "No information was ever provided to [him] regarding the proper use and removal of ROCM product." UMF 48 and 49. Plaintiff has not submitted evidence that he received any representations by ROCM. In fact, the only information Plaintiff contends he received regarding the catheter was the product packaging that contains three instructions : 1) "Unroll the catheter," 2) "Squeeze catheter," and 3) "Roll off to Remove." There is no evidence of a false representation here or that ROCM made this representation with an intent to deceive. Similarly, Plaintiff has failed to establish that the alleged misrepresentation was the cause of any resulting damage.

D. Breach of Implied Warranty of Fitness

Plaintiff's implied warranty claim alleges that Defendant "manufactured and furnished its glue-on condom catheter product to the Plaintiff for his foreseeable usage [sic] in the reasonable manner for which the product was intended to be used ... ." (Doc. 34 at ¶ 53). Furthermore, Plaintiff contends Defendant placed the product in its California market and supply area, and he relied on Defendant's experience and product expertise to supply and furnish the appropriate, safe product that would perform as the product information depicted. (Doc. 34 at ¶ 54.)

To establish a claim for beach of implied warranty of fitness, Plaintiff must prove: 1) that he bought the product from ROCM; 2) at the time of the purchase, ROCM knew or had reason to know that Plaintiff intended to use the product for a particular purpose; 3) that at the time of the purchase, ROCM knew or had reason to know that Plaintiff was relying on its skill and judgment to select or furnish a product that was suitable for a particular purpose; 4) that Plaintiff justifiably

relied on ROCM's skill and judgment; 5) that the product was not suitable for a particular purpose; 6) that Plaintiff took reasonable steps to notify ROCM within a reasonable time that the product did not have the expected quality; 7) that Plaintiff was harmed; and 8) that the failure of the product to be suitable was a substantial factor in causing Plaintiff's harm. CACI § 1232.

In addition to the elements of this cause of action, California has implemented the Uniform Commercial Code's implied warranty provision. Cal. Com.Code § 2315; Cal. Com.Code § 2314. "The implied warranty of fitness requires that a buyer of goods rely upon the seller's skill or judgment to select or furnish a suitable product." *Evreats v. Intermedics Intraocular, Inc.*, 29 Cal.App. 4th 788 (1994). "A warranty that the goods shall be merchantable is implied in a contract for their sale." Cal. Com.Code § 2314.

Under California law, privity between parties is required for either claim of implied warranty. "Privity of contract is a pre-requisite in California for recovery on a theory of breach of implied warranties of fitness and merchantability." *Blanco v. Baxter Healthcare Corp.*, 158 Cal.App.4th 1039, 1058 (2008). "There is no privity between the original seller and a subsequent purchaser who is in no way a party to the original sale." *Burr v. Sherwin Williams Co.*, 42 Cal.2d 682, 695-96,(1954).

Courts have held that a medical device sold by a hospital to a patient does not create an implied warranty between outside sellers or representatives. In *Evreats v. Intermedics*, a patient received a defective intraocular lens that was implanted in the patient's eye. *Evreats*, 29 Cal.App.4th at 788. The patient claimed a cause of action against the manufacturer. Id. The *Evreats* court held that the patient could not sue the manufacturer or distributor of the prosthetic, because there was no privity between the patient and manufacturer. *Id.* "[Plaintiff] relied upon his physician's skill or judgment to select or furnish a suitable product." *Id.*

Plaintiff's case is similar to *Evreats*. As in *Evreats*, Plaintiff's catheter was chosen by prison medical professionals. UMF 48. ROCM did not sell the product directly to Plaintiff. Like the plaintiff in *Evreats*, Crayton relied on the advice of his doctors. Plaintiff's amended complaint makes no mention of privity, nor is there any suggestion that privity exists between Plaintiff and ROCM.

Additionally, this cause of action requires that Plaintiff notify Defendant prior to bringing this suit that the product did not have the expected quality. However, Plaintiff has offered no evidence that he properly notified Defendant. Plaintiff submits no evidence to support his explanation that he did not notify Defendant because Defendant hid its address, making notification impossible. As such, the Court is unpersuaded by Plaintiff's arguments. Accordingly, Plaintiff has not met his burden of proof for this cause of action.

VII. Conclusion

Although a verified complaint in a pro se civil rights action may constitute an opposing affidavit for purposes of the summary judgment rule, the complaint must be based on the inmate's personal knowledge of admissible evidence, and not merely on the inmate's belief. McElyea v. Babbitt, 833 F.2d at 197-98 (per curium) (emphasis added); Lew v. Kona Hospital, 754 F.2d at 1423; Fed. R. Civ. Pro. 56(e). Plaintiff has tendered no evidence in support of his contention that a dispute exists. Plaintiff's mere belief that the defective design of the catheter in question caused injuries to his pubic region does not establish the existence of a genuine issue of material fact. In other words, Plaintiff must have presented admissible evidence that the catheter in question caused his injuries and that it was defectively designed.

The Court finds that Defendant met its initial burden of informing the Court of the basis for its Cross Motion for Summary Judgment, and identifying those portions of the record which it believed demonstrate the absence of a genuine issue of material fact. The burden therefore shifted to Plaintiff to establish that a genuine issue as to any material fact actually does exist. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. at 586. Simly stated, Plaintiff has not met his burden. Accordingly, the Court finds that Defendant ROCM is entitled to judgment as a matter of law on all of Plaintiff's claims.

Based on the foregoing, IT IS HEREBY ORDERED that :

1) Plaintiff's Motion for Summary Judgment (Doc. 154) is DENIED;

2) Plaintiff's Request for Judicial Notice (Doc. 166) is DENIED;

3) Plaintiff's Motion to Strike Portions of Defendant's Opposition to Plaintiff's Motion

for Summary Judgment (Doc. 165) is DENIED;

4) Defendant's Cross-Motion for Summary Judgment (Doc. 154) is GRANTED; and

5) Plaintiff's Motion for the Court to Devise a Means for Plaintiff to Contact Witnesses (Doc. 172) is DENIED.

The Court **DIRECTS** the Clerk to enter judgment in favor of Defendant Rochester Medical Corporation and against Plaintiff Timothy Crayton, and to close this case.

IT IS SO ORDERED.

Dated: February 4, 2011

/s/ Oliver W. Wanger
UNITED STATES DISTRICT JUDGE