

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE ST. JUDE MEDICAL, INC. :
SILZONE HEART VALVES PRODUCTS :
LIABILITY LITIGATION : MDL DOCKET NO. 1396

PRE-TRIAL ORDER NO. 4/5

The Court finds that good cause exists for discovery in MDL 1396 to be conducted under a Protective Order pursuant to Rule 26(C)(7) of the Federal Rules of Civil Procedure. Accordingly, it is hereby ordered and adjudged:

1. This Protective Order governs the production and handling of confidential information contained in or derived from documents or testimony ("discovery material") disclosed by anybody ("disclosing party") during MDL 1396 and any related action ("Action") in which this Order has been adopted and stipulated to in writing by counsel of record for Plaintiffs or St. Jude Medical. The word "document" is defined as letters, words, numbers, pictures, sounds or symbols set down by handwriting, typewriting, printing, photostatting, photographing, magnetic impulse, mechanical or electronic recording, or any other form of data compilation.

2. A disclosing party may designate as "CONFIDENTIAL" any discovery material that the disclosing party believes contains or discloses a trade secret or other confidential research, development or commercial information, including but

not limited to sensitive financial data, technical information, proprietary or nonpublic commercial information, information involving privacy interests, and other commercially and/or competitively sensitive information of a nonpublic nature, or received on a confidential basis. Discovery material may be so designated by stamping "CONFIDENTIAL" on each page of each document or by using such other procedures upon which the parties agree.

3. Discovery material and information Plaintiff or St. Jude Medical designates as CONFIDENTIAL shall be revealed only to the following persons:

a. Counsel of record for each Plaintiff in this litigation and St. Jude Medical, and employees of such counsel, including secretaries, and legal assistants:

b. The parties to the Action and any employees or officers of a party;

c. Experts or consultants retained to assist counsel of record for Plaintiff or St. Jude Medical in the Action provided:

(1) each expert or consultant has read this Stipulated Protective Order in advance of disclosure and has agreed in writing to be bound by its terms by executing an affidavit in the form of Exhibit A, a copy of which counsel for the party who retained the expert or consultant will keep and produce to the disclosing party at such party's request at the conclusion of the litigation, and;

(2) each such expert or consultant is not currently working as a salaried or hourly employee of a direct competitor of the Heart Valve division of St. Jude Medical;

(3) Notwithstanding the provisions of paragraph 3(c)(2), if counsel of record for a Plaintiff in MDL 1396 or an Action wants to retain a salaried or hourly employee of a direct competitor of the Heart Valve division of St. Jude Medical to consult in this litigation, they must first initiate a "meet and confer" by sending a facsimile correspondence to designated liaison counsel identifying the proposed consultant. If within fourteen (14) days of the initiation of the "meet and confer" the parties are unable to agree as to whether the consultant can be retained, St. Jude Medical shall, within twenty-one days (21) of the termination of the meet and confer period, file a motion for an order precluding plaintiff from retaining the consultant. Pending a ruling from the Court, plaintiff may not disclose CONFIDENTIAL documents to or share CONFIDENTIAL information with the proposed consultant. If St. Jude Medical fails to file a motion for an order precluding plaintiffs from retaining the consultant within the time set forth above, then plaintiffs may proceed to retain the consultant.

d. The Court or any other court having jurisdiction over discovery procedures in the Action provided the party seeking review by a court follows the procedures in Paragraph 15;

e. Any court reporter or typist recording or transcribing testimony in the Action;

f. Any employee of an outside independent reproduction firm who has read this Stipulated Protective Order and has agreed in writing to be bound by its terms by executing an affidavit in the form of Exhibit A; and

g. Any person whose deposition is taken by any party to this stipulated protective order, so long as such disclosure is made during the course of the deposition and the deponent (other than a present or former employee, consultant, expert, or other person under the control of St. Jude Medical) signs an affidavit in the form of Exhibit A.

h. A jury empanelled in a case subject to MDL 1396.

i. Counsel of record for any party with a pending Silzone heart valve lawsuit against St. Jude Medical, provided that in advance of disclosure, each such attorney and party has read this Stipulated Protective Order, agreed in writing to be bound by it and the jurisdiction of the Court in MDL 1396, only as to the enforcement of this Order, and has provided St. Jude Medical with an executed affidavit in the form of Exhibit A.

4. CONFIDENTIAL discovery material shall be maintained in confidence by the party or parties to whom it is produced and shall not be disclosed by such party except to persons entitled to access pursuant to Paragraph 3.

5. Nothing contained in this Order shall restrict use or disclosure of discovery material designated CONFIDENTIAL by the disclosing party.

6. All oral deposition testimony, regardless of whether designated as CONFIDENTIAL on the record, shall be treated as CONFIDENTIAL and subject to this Protective Order for thirty (30) days after counsel of record for Plaintiffs and St. Jude Medical receive the transcript of the deposition.

7. Any party may, on the record at a deposition or by written notice to counsel for all parties no later than thirty (30) days after receipt of the deposition transcript, designate portions of oral testimony, or the testimony in its entirety, as CONFIDENTIAL. A separately bound transcript of those portions of the testimony that contain CONFIDENTIAL discovery material shall be made. If any portion of any transcript so marked is required to be lodged with the Court, it shall be lodged under seal.

8. When CONFIDENTIAL discovery material is offered as an exhibit or quoted or referenced in any deposition, hearing, trial or other proceeding, only persons entitled to such information pursuant to Paragraph 3 may be present during such an offer, quotation or reference.

9. When CONFIDENTIAL information is introduced as an exhibit or through testimony in any deposition, hearing, trial or other proceeding, counsel introducing such information shall advise the court reporter that the testimony or exhibits are CONFIDENTIAL pursuant to this Stipulated Protective Order. The court reporter shall separately bind the transcript of the testimony or the exhibit and mark the cover of the bound transcript or exhibit with the applicable CONFIDENTIAL designation. If the transcript with the CONFIDENTIAL discovery material is required to be lodged with the Court, it shall be lodged under seal following the procedures in Paragraph 15.

10. For purposes of disclosing documents for inspection, the disclosing party may refrain from designating specific documents CONFIDENTIAL until after the inspecting party or parties have selected specific documents and/or materials for

copying. In this event, the disclosing party shall announce in writing prior to producing the documents or material for inspection that all such documents and material should be considered CONFIDENTIAL for the purposes of the inspection. After the inspecting party selects specified documents and material for copying but before the production of such copies, the disclosing party shall designate any CONFIDENTIAL discovery material.

11 . All written discovery requests and responses that contain CONFIDENTIAL discovery material shall be so designated.

12. Before producing discovery material, a disclosing party may redact CONFIDENTIAL information that is not relevant to the subject matter involved in MDL 1396. Any discovery material that is redacted shall have "REDACTED" stamped on each page from which CONFIDENTIAL information has been redacted. Upon the request of counsel of record for Plaintiffs or St. Jude Medical, the disclosing party shall produce a log describing the nature of the redacted information.

13. Information designated as CONFIDENTIAL shall be used only in these MDL proceedings or the Action for the preparation for trial, for trial, or for any appeal and shall not be used in any other proceeding.

14. The recipient of any CONFIDENTIAL discovery material disclosed pursuant to this Stipulated Protective Order shall maintain the discovery material in a secure area and shall exercise due and proper care to protect its confidentiality.

15. Unless otherwise ordered by the Court, or agreed to by the parties, CONFIDENTIAL discovery material that is filed with the Court shall be filed in a

sealed envelope or other suitable container with a cover label bearing the caption of the Action, the title of the document, and a statement substantially in the following form:

**TO BE FILED UNDER SEAL PURSUANT TO ORDER OF
THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF MINNESOTA - MDL 1396**

This envelope contains CONFIDENTIAL information that is protected by a STIPULATED PROTECTIVE ORDER. This envelope is not to be opened, and its contents may not be revealed without Order of this Court.

CONFIDENTIAL discovery material filed under seal shall be available to the Court and counsel of record for Plaintiffs or St. Jude Medical.

16. Counsel of record for Plaintiffs or St. Jude Medical may at any time request from the disclosing party in writing, the release of CONFIDENTIAL discovery material from the requirements of the terms and provisions of this Stipulated Protective Order. Upon making such a request, the party requesting the exemption shall initiate a "meet and confer" by sending a facsimile correspondence to designated liaison counsel identifying the disputed documents and designations. If within fourteen (14) days of the initiation of the "meet and confer" the parties are unable to agree as to whether the discovery material at issue is properly designated CONFIDENTIAL, the disclosing party shall, within twenty-one days (21) of the termination of the meet and confer period, file a motion for an order protecting the CONFIDENTIAL designation. Pending a ruling from the Court, the disclosing party's designation shall control. If the disclosing party fails to file a motion for an order

protecting the CONFIDENTIAL designation within the time set forth above, then the CONFIDENTIAL designation shall no longer be applicable.

17. Nothing in this Stipulated Protective Order shall preclude Plaintiffs or St. Jude Medical from responding to a validly issued subpoena that seeks disclosure of CONFIDENTIAL information, unless the issuing person is not entitled to access under Paragraph 3. The party responding to the subpoena must provide written notice of such a subpoena to the disclosing party at least five (5) business days before responding to the subpoena. The party issuing the subpoena must sign an affidavit in the form of Exhibit A before any CONFIDENTIAL discovery material can be disclosed. If the party issuing the subpoena is not entitled to access under Paragraph 3 then the disclosing party shall move this Court for enforcement of this Stipulated Protective Order.

18. Nothing in this Order, nor any failure by a party to challenge the designation of discovery material as CONFIDENTIAL, shall be construed as an admission concerning the confidential or proprietary nature of the discovery material, the relevance for discovery purposes of the discovery material, or the admissibility of the discovery material.

19. Upon final conclusion of MDL 1396, including all appeals, all CONFIDENTIAL discovery material and all copies shall, at the discretion of the disclosing party, either be returned to the disclosing party or its counsel, or destroyed. If the CONFIDENTIAL discovery material is destroyed, counsel for the receiving party shall certify that the CONFIDENTIAL discovery material has been

destroyed. Each party may retain one archival copy of all pleadings in MDL 1396, regardless of whether such pleadings contain or refer to CONFIDENTIAL discovery material.

20. A party's inadvertent or unintentional disclosure of CONFIDENTIAL discovery material without that designation shall not be deemed a waiver in whole or in part of its claim of confidentiality, either as to the specific discovery material or as to any other related discovery material. Any such inadvertently or unintentionally disclosed discovery material shall be designated as CONFIDENTIAL as soon as reasonably possible after the disclosing party becomes aware of the disclosure and shall be treated as CONFIDENTIAL by all to whom it has been disclosed in the Action.

21. Nothing in this Protective Order shall be construed as a limitation on the use of admissible evidence at trial, subject to such confidentiality provisions as may be ordered by the Court. Furthermore, Plaintiffs and St. Jude Medical shall have the right to request that any hearing or portions of any hearing be conducted in camera.

22. In rendering services or otherwise communicating with his or her client, counsel shall not disclose the specific content of any CONFIDENTIAL material, documents or information where such disclosure would not otherwise be permitted under the terms of this Order. Nothing shall bar or otherwise restrict counsel from rendering advice to his or her client with respect to an Action or in MDL 1396, and in the course of any such Action or MDL 1396, from relying upon CONFIDENTIAL discovery material or information.

23. The obligations of this Stipulated Protective Order shall survive the termination of MDL 1396 or an Action and shall continue to restrict the disclosure and use of discovery material designated CONFIDENTIAL by the parties, their counsel, and all who signed an Affidavit in the form of Exhibit A. Following termination of MDL 1396, the Court will retain jurisdiction to enforce the terms of this Stipulated Protective Order.

24. St. Jude Medical reserves the right to move the Court for additional restrictions on Plaintiffs' disclosure and/or dissemination of discovery material that St. Jude Medical believes contains or discloses a trade secret or other confidential research, development or commercial information, including but not limited to sensitive financial data, technical information, proprietary or nonpublic commercial information, information involving privacy interests, and other commercially and/or competitively sensitive information of a nonpublic nature, or received on a confidential basis, which is of such a nature that disclosure to persons other than those specified in Paragraph 4 might reasonably be expected to result in injury to St. Jude Medical.

IT IS SO ORDERED.

Dated: November 23, 2001

Honorable John R. Tunheim
UNITED STATES DISTRICT JUDGE

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

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SILZONE HEART VALVES PRODUCTS :
LIABILITY LITIGATION : MDL DOCKET NO. 1396

AFFIDAVIT

I, [NAME], acknowledge that I am to view information designated "CONFIDENTIAL" in the captioned litigation. I certify my understanding that such information has been provided to me pursuant to the terms and restrictions of a Protective Order dated _____, 2001, in the above-captioned litigation, and that I have been given a copy of and have read the Protective Order and agree to be bound by its terms.

I agree not to make use of the CONFIDENTIAL information I am viewing except for purposes of this action. I agree that I will not disseminate the CONFIDENTIAL information to any other person or entity nor will I discuss the CONFIDENTIAL information with anyone other than the counsel who discloses it to me and those persons counsel identifies who are actively assisting him or her in preparation for trial of this matter.

I further agree to and do submit myself to the jurisdiction of the captioned Court in all matters concerning enforcement of violation of the

EXHIBIT A

Protective Order. For this purpose, I accept service and may be served by registered mail, return receipt requested, at the following address:

Dated: _____

(Signature)