

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

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

PRETRIAL ORDER NO. 9

The parties having stipulated thereto, the Court orders that:

1. All documents and things that are produced by the FDA responsive to the MDL Plaintiffs' subpoena shall have a legible, unique document identifier (Bates #) placed onto the document at a location that does not obliterate any information. The document identifier shall be 8 digits in length, the first 3 being a unique alpha character that denotes the FDA as the producing party (e.g., FDA00001). The documents shall be sequentially numbered as they are produced by the FDA.

2. The FDA shall provide the MDL plaintiffs and St. Jude Medical the following information at the time any documents are produced:

- a) the date the documents are produced;
- b) the unique document identifier numbers of the documents produced;

- c) a general description of the documents produced or alternatively an indication of what the documents are responsive to, as relates to the subpoena;

3. The original produced documents shall be produced by the FDA to counsel for St. Jude Medical (Crosby, Heafey, Roach & May, Attention: David E. Stanley, 355 S. Grand Avenue, Suite 2900, Los Angeles, CA 90071). Counsel for St. Jude Medical will subsequently produce all documents to the MDL plaintiffs in accordance with this order.

4. St. Jude Medical shall have the opportunity to review all documents and redact the documents as set forth in numbers 5 and 6 below.

5. St. Jude Medical shall maintain a full and complete copy (without such redactions) for review by the court or magistrate should the MDL Plaintiffs elect to challenge such redactions.

6. St. Jude Medical shall provide a clear and specific log of all documents containing any redactions or redacted in full. The log shall identify the Bates number, the type of document, and the specific reason and basis for redaction (e.g., information St. Jude Medical deems highly sensitive because it constitutes trade secrets, information pertaining to products not at issue in the litigation or information which St. Jude Medical is prohibited by statute or regulation from disclosing. However, St. Jude Medical shall not redact information relevant or relating to "Silzone®" even if it references other products nor shall St. Jude redact information concerning products that were predecessors or successors of any

Silzone product). Notwithstanding the foregoing, the MDL Plaintiffs shall have all rights to challenge any redactions. If an entire document is redacted, then in addition to the information above, the log shall also identify the author of the document, recipient of the document, anyone who got copies of the document, the date of the document, and whether the document is an attachment to another document. The log shall be produced to the plaintiffs within ten (10) business days of the documents being forwarded to the MDL Plaintiffs as set forth in number 9 below.

7. Any redactions made shall constitute a representation by counsel for St. Jude Medical that the document has been reviewed by counsel of record or an attorney designated by counsel of record and counsel of records believes there is a good faith basis for such redaction.

8. St. Jude Medical shall produce all of the documents produced by the FDA according to the time parameters set forth in paragraph 9. At the time such documents are to be produced, St. Jude Medical may designate any or all such documents as Confidential Discovery Material pursuant to Pre-Trial Order No. 4. The MDL Plaintiffs shall have the right to challenge any redactions or designation of Confidential Discovery Material in accordance with the procedures set forth in Pre-Trial Order No. 4, which are deemed to apply to both challenges to redactions as well as "CONFIDENTIAL" designations.

9. St. Jude Medical shall not delay the review of documents provided by the FDA in response to the subpoenas. St. Jude Medical shall produce, following

their review for redaction and confidentiality, all documents which the FDA has determined are responsive to the subpoena. St. Jude Medical shall have ten (10) business days from the date of receipt of the documents from the FDA to review and forward to the MDL Plaintiffs the first 12,000 pages of materials produced by the FDA and ten (10) business days to review and forward to the MDL Plaintiffs each subsequent 12,000 pages of materials produced by the FDA following the initial production.

10. All of the documents produced by the FDA, whether or not redacted under the terms of this order, shall initially be produced by St. Jude Medical in hard copy. St. Jude Medical shall not be required to image documents that are duplicative of documents previously imaged and produced to the MDL Plaintiffs. St. Jude Medical, however should advise the MDL Plaintiffs of the FDA numbers that are not being imaged and their corresponding "SJM" Bates number. Documents not previously imaged and produced to the MDL Plaintiffs shall be imaged by St. Jude Medical at St. Jude Medical's expense and produced to the MDL Plaintiffs in multi-page TIFF CD-ROM format.

11. Each document produced by the FDA, whether or not redacted hereunder, shall be deemed authentic under Federal Rule of Evidence 901.

IT IS SO ORDERED:

Honorable Judge John R. Tunheim

ENTERED: February 19, 2002