

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

IN RE:

MIRENA IUD PRODUCTS LIABILITY LITIGATION

This Document Relates to All Actions

13-MD-2434(CS)

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: <u>9-4-2013</u>

Siebel
Siebel, J.

PROTOCOL FOR DOCUMENT FORMAT PRODUCTION

I. GENERAL

This Order governs the format of Documents, Data, and/or Tangible things that will be produced in cases filed in, transferred to, or consolidated before this Court as components of In re: Mirena IUD Products Liability Litigation in the United States District Court, Southern District of New York, and to every action that is or will be filed, transferred or consolidated into this court (collectively the "Litigation"). This Order does not govern the scope of production of Documents, Data, and/or Tangible things in the Litigation. All parties reserve their rights with respect to the scope of the document production.

II. PRODUCTION FORMAT

A. Hard copy documents. Hard copy documents and their attachments will be produced as follows:

1. Single page Group IV TIFF format (black and white, 300 dpi). Each image should have a unique file name, which is the Bates number of the page. Where possible, original

document orientation should be maintained (i.e., portrait to portrait and landscape to landscape) and the Bates number shall be outside of the margins of the imaged pages.

2. **OCR Text Files.** Defendant will provide Plaintiffs with the name of the OCR software and the settings of that software used to create the OCR. OCR text files shall be provided as a single text file for each hard copy document, not one text file per page. The filename itself should match its respective TIFF filename, which is the Bates number. The text files will not contain the redacted portions of the documents. For foreign language “hard” copy documents being produced, in addition to the metadata fields required for English language documents, the Unicode values will be produced in a corresponding metadata field.

3. **Coding Fields.** The following information shall be produced with the OCR text files accompanying hard copy documents:

- a. Beginning Document Bates Number;
- b. Ending Document Bates Number;
- c. Attachment Beginning Bates Number;
- d. Attachment Ending Bates Number;
- e. Custodian or Source;
- f. Custodian ID;
- g. Document Type;
- h. Confidentiality (Y/N);
- i. Page Count;
- j. Redaction (Y/N);
- k. Replacement (Y/N); and
- l. OCR Text File Name.

4. **Database Load Files/Cross-Reference Files.** Documents will be provided with a Concordance delimited file with an IPRO delimited file and an Opticon delimited file, as detailed in Exhibit B. Each TIFF in a production must be referenced in the corresponding load file. The total number of documents referenced in a production's load file should match the total number of TIFF files in the production.

5. **Bates Numbering.** All images must be assigned a Bates/control number that must always: (1) be unique across the entire document production; (2) maintain a constant length (0-padded) across the entire production; (3) contain no special characters or embedded spaces; and (4) be sequential within a given document. If a Bates number or set of Bates numbers is skipped in a production, the producing party will note which Bates numbers are skipped and the reason why in a cover letter accompanying the production.

6. **Unitizing of Documents.** In scanning paper documents, documents are to be produced as they are kept in the normal course of business. For documents found in file folders and other containers that have labels or tabs or other identifying information, such labels and all sides of such file folders and tabs shall be scanned. In the case of an organized compilation of separate documents – for example, a binder containing several separate documents behind numbered tabs – the document behind each tab should be scanned separately, but the relationship among the documents in the binder should be reflected in proper coding of the beginning and ending document and attachment fields. Documents will be unitized at the lowest possible level and attachment information preserved. For example, if a folder contains two documents, the folder and each document will constitute a separate document, but they will have the same attachment start and end.

B. Electronically Stored Information (“ESI”)

1. Non-standard and Microsoft PowerPoint documents agreed on by the parties pursuant to Sections I.B.2.k and I.B.2.n, audio and video files as provided in section I.B.2.m, and Microsoft Excel Spreadsheets as provided in section I.B.2.j will be produced in native format with a link in the "NativeLink" field, along with all extracted text and applicable metadata fields set forth in Exhibit A.

2. All ESI documents other than those identified above in section I.B.1 will be produced in single page Group IV TIFF format (black and white, 300 dpi) with extracted text, along with the metadata and coding fields set forth in Exhibit A that exist for a particular item, to be provided in a standardized load file compatible with Concordance (default delimiter), with a Bates number field included in the load file so that text and metadata can be matched with TIFF images. Original document orientation should be maintained (i.e., portrait to portrait and landscape to landscape) when possible.

a. **Text Files.** For each document, the text of native files will be extracted directly from the native file and provided as a single text file for each document. The text filename itself should match its respective TIFF filename, which is the Bates number. However, if a document has been redacted, OCR of the redacted text will suffice.

b. **System Files.** Common system and program files as defined by Kröll's NIST library (a copy of which is attached as an Appendix to this Production Format) need not be processed, reviewed, or produced.

c. **De-Duplication.** A party is only required to produce a single copy of a responsive standalone document and a party may de-duplicate (based on MD5 or SHA-1 hash values at the document level) across custodians, except that any document which is part of a family group that includes a produced document cannot be withheld as a duplicate. The identity

of other custodians of de-duplicated documents must be listed in the "Other Custodians" field of any copies of the document that are produced. The load file will identify the de-duped custodian or source and provide the ProgBeg of the produced copy.

d. Unproduced Duplicates. A produced copy of an unproduced duplicate may be used, and shall be treated as if it were, the unproduced document for any purpose in this action.

e. Parent-Child Relationships. Parent-child relationships (the association between an attachment and its parent document or between embedded documents and their parent) should be preserved.

f. Family Groups. A document and all other documents in its attachment range constitute a family group. If any document which is part of a family group is produced, then all documents in that family group, except for documents which are withheld in their entirety for privilege will be produced. No document which is part of a family group that contains a document which is produced, can be withheld as a duplicate.

g. Database Load Files/Cross-Reference Files. Documents should be provided with a Concordance delimited file with an IPRO delimited file and an Opticon delimited file, as detailed in Exhibit B. Each TIFF in a production must be referenced in the corresponding load file. The total number of documents referenced in a production's load file should match the total number of TIFF files in the production.

h. Bates Numbering. All images must be assigned a Bates/control number that must always: (1) be unique across the entire document production; (2) maintain a constant length (0-padded) across the entire production; (3) contain no special characters or embedded spaces; and (4) be sequential within a given document. If a Bates number or set of

Bates numbers is skipped in a production, the producing party will note which Bates numbers are skipped and the reason why in a cover letter accompanying the production.

i. Embedded Documents shall be extracted and produced as standalone files along with corresponding attachment metadata to the parent document.

j. Microsoft Excel Spreadsheets shall be produced as native files with the source file path provided along with the extracted text and metadata identified in Exhibit A. If a spreadsheet requires redactions it can be produced as a TIFF image with all rows and columns expanded and capable of being viewed within the TIFF image.

k. Microsoft PowerPoint presentations or slide shows will be converted to TIFF images as follows: a conversion to black and white will be done utilizing PowerPoint's print feature; background will be turned off so all text is visible; hidden slides will be revealed; and if any slides in the presentation contain speaker notes, then all slides will be printed in Slide and Notes view (one slide per page) with the slide appearing at the top of the page and the notes appearing at the bottom of the page. For those presentations or slide shows in which the black and white TIFF affects the ability to interpret the document, the parties will meet and confer regarding a reasonable alternative form of production (i.e., a color copy or native format).

l. Microsoft Word documents will be converted to TIFF images with comments and track changes exposed. Embedded images or documents will be extracted and produced as TIFFs with the source file path provided along with the extracted text and metadata identified in Exhibit A.

m. Audio and Video Files in any form including but not limited to all VCR, DVD, Blu-ray or web/internet files shall be produced as native files with the source file path, extracted text and metadata, as applicable and as identified in Exhibit A.

n. Non-Standard Files. For documents and ESI that convert with errors to TIFF (e.g., oversized drawings, picture files, etc.), the producing party will either produce the document in native format or will ask the receiving party to meet and confer regarding a reasonable alternative form of production. A Bates-numbered placeholder will be inserted in production sets for documents produced in native form.

o. Color. For those color documents for which the black and white TIFF image affects the ability to interpret the document, the parties will meet and confer regarding the production of the document in color.

p. Replacement files. Any documents that are replaced in later productions shall be clearly designated as such, by appending a “- R” to the production prefix and by a letter communication accompanying the production clearly designating such documents as replacements.

q. Time Zone. GMT should be selected as the time zone.

r. Dynamic Fields. Documents with dynamic fields for file names, dates, and times will be processed to show the field code (e.g., “[FILENAME]” or “[AUTODATE]”), rather than the values for such fields existing at the time the file is processed.

s. The parties will meet and confer if needed regarding the production of potentially relevant structured data sources.

t. **Compressed files.** Compression file types (i.e., .CAB, .GZ, .TAR, .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual folders and/or files.

C. **MISCELLANEOUS PROVISIONS**

1. Documents and ESI that contain information that identifies patients or any other information protected by law will be redacted from any documents produced.

2. Any practice or procedure set forth herein may be varied by agreement of the parties, confirmed in writing, where such variance is deemed appropriate to facilitate the timely and economical exchange of documents or ESI.

3. The parties understand that this protocol contemplates the production of large volumes of documents and that productions will be made on a rolling basis.

4. The parties further acknowledge that nothing in this Order waives, restricts or eliminates the parties' "claw-back" rights pursuant to the Protective Order(s) in this case or governing law, rules, orders, or agreements regarding inadvertently produced documents.

5. The parties shall meet and confer and endeavor to resolve any disputes arising hereunder before submitting such disputes to the Court for determination.

SO ORDERED.

Dated: 9/4, 2013
White Plains, New York



CATHY SEIBEL, U.S.D.J.

EXHIBIT A

Field Name	Populated For (Email, Edoc, or Both)	Field Description
ProdBeg	Both	Control Numbers
ProdEnd	Both	Control Numbers
BegAttach	Both	Control Numbers (First production Bates number of the first document of the family)
EndAttach	Both	Control Numbers (Last production Bates number of the last document of the family)
PgCount	Both	Page Count
Source	Both	Name of party producing the document
Custodian	Both	Custodian name (ex. John Doe)
NativeFile	Both	Native File Link
EmailSubject	Email	Subject line of email
DateSent	Email	Date and time email was sent – Format: (mm/dd/yyyy hh:mm:ss AM)
DateMod	Edoc	Date and time the document was modified – Format: (mm/dd/yyyy hh:mm:ss AM)
To	Email	All recipients that were included on the “To” line of the email
From	Email	The name and email address of the sender of the email
CC	Email	All recipients that were included on the “CC” line of the email
BCC	Email	All recipients that were included on the “BCC” line of the email
Attach	Email	The file name(s) of the attached documents
DateCreated	Edoc	Date and time the document was created – Format: (mm/dd/yyyy hh:mm:ss AM)
FileName	Both	File name of the edoc or email (for email this is the subject line of the email with a .htm extension)
Title	Edoc	Any value populated in the Title field of the document properties
Subject	Edoc	Any value populated in the Subject field of the document properties
Author	Edoc	Any value populated in the Author field of the document properties
DocExt	Both	File extension of the document
Applic	Edoc	Commonly associated application for the specified file type.
Text	Both	Text extracted from the email or edoc

Field Name	Populated For (Email, Edoc, or Both)	Field Description
Confidentiality	Both	Y/N – Yes or No Indicates if document has been designated as “Confidential” or “Highly Confidential” under the Protective Order
FileSize	Both	File size
TextPath	Both	Filepath for OCR or extracted text files
AttachBates	Email	Bates numbers of the first pages of each attachment, separated by semicolons
AttachCount	Email	Number of email attachments
AttachNames	Email	Names of the attachments as listed in the email, separated by semicolons
DateReceived	Email	Date and time received - Format: (mm/dd/yyyy hh:mm:ss AM)
Importance	Email	Indicates Important of the e-mail message
HashValue	Both	MD5 or SHA1 hash value
LastModBy	Edoc	Last person who modified a document
DocumentType	Both	Descriptor for the type of document: "E-document" for electronic documents not attached to emails; "Emails" for all e-mails Physicals" for hard copy physical documents that have been scanned and converted to an electronic image.
Redacted	Both	“yes” if document was redacted
Replacement	Both	“Yes” if document was a Replacement
ProdVol	Both	Name of production media
OtherCustodians	Both	Names of any other custodians whose copy of the document was not produced as a duplicate in format last name, first names with each name delimited by semicolons
OtherCustodianID	Both	Each OtherCustodian will be assigned a unique numeric identifier that will be maintained throughout productions. Where data is collected from an archive, the archive will be listed as custodian; Multi-valued, separated by semicolons

Field Name	Populated For (Email, Edoc, or Both)	Field Description
CustodianID	Both	<p>Name of person or data source (non-human) from where documents/files are produced. Each Custodian will be assigned a unique numeric identifier that will be maintained throughout productions. Where data is collected from an archive, the archive will be listed as custodian. <i>*Where redundant names occur, individuals should be distinguished by an initial which is kept constant throughout productions (e.g., Smith, John A. and Smith, John B.)</i></p> <p><i>** Defendant will use reasonable means to determine if a custodian changed his/her name for work purposes during the relevant time period (e.g., Jane Doe got married, changed her name to Jane Smith and used her married/hyphenated name at work). Defendant will notify plaintiffs of any and all name changes in production cover letters.</i></p>
Relative FilePath Append	Email	File Path in which the attachments were stored
EmailDateSort	Email	Sent Date of the parent email (physically top email in a chain, i.e. immediate/direct parent email)
Read/Unread	Email	Whether the Outlook item was read or unread at the time of collection. Values provided will be "Yes" for read, "No" for unread, and a null value where the read/unread flag value is unavailable.

EXHIBIT B

File Formats

Image Load Files

- The name of the image load file should mirror the name of the delivery volume, and should have an .LFP or an OPT extension (i.e., ABC001.LFP; ABC000.OPT)
- The volume names should be consecutive (i.e., ABC001, ABC002, et. seq.)
- There should be one row in the load file per TIFF image.
- Every image in the delivery volume should be contained in the image load file.
- The image key should be named the same as bates number of the page.
- Load files should not span across media (e.g., CDs, DVDs, Hard Drives, Etc.), i.e., a separate volume should be created for each piece of media delivered.
- Files that are the first page of a logical document should include a "D" where appropriate. Files that are the first page of an attachment to an e-mail should include a "C" where appropriate. Subsequent pages of all documents (regular document, e-mail, or attachment) should include a blank in the appropriate position.

```
IM,VN00000001,D,0,@29502601;295026001\0000;VN00000001.TIF;2
IM,VN00000002, ,0,@29502601;295026001\0000;VN00000002.TIF;2
IM,VN00000003, ,0,@29502601;295026001\0000;VN00000003.TIF;2
IM,VN00000004, ,0,@29502601;295026001\0000;VN00000004.TIF;2
IM,VN00000005,D,0,@29502601;295026001\0000;VN00000005.TIF;2
IM,VN00000006, ,0,@29502601;295026001\0000;VN00000006.TIF;2
IM,VN00000007, ,0,@29502601;295026001\0000;VN00000007.TIF;2
IM,VN00000008, ,0,@29502601;295026001\0000;VN00000008.TIF;2
IM,VN00000009,D,0,@29502601;295026001\0000;VN00000009.TIF;2
IM,VN00000010, ,0,@29502601;295026001\0000;VN00000010.TIF;2
```

Opticon Delimited File:

```
MSC000001,MSC001,D:\IMAGES\001\MSC000001.TIF,Y,,,3
MSC000002,MSC001,D:\IMAGES\001\MSC000002.TIF,Y,,,,
MSC000003,MSC001,D:\IMAGES\001\MSC000003.TIF,Y,,,,
MSC000004,MSC001,D:\IMAGES\001\MSC000004.TIF,Y,,,2
MSC000005,MSC001,D:\IMAGES\001\MSC000005.TIF,Y,,,,
```

Concordance Delimited Files:

␣BegDoc␣␣EndDoc␣␣BegAttach␣␣EndAttach␣␣Custodian␣

- The data load file should use standard Concordance delimiters:
 - Comma – ¶ (ASCII 20)
 - Quote – ␣ (ASCII 254)
 - Newline – ® (ASCII174)
- The first record should contain the field names in the order of the data;
- All date fields should be produced in mm/dd/yyyy format;
- Use carriage-return line-feed to indicate the start of the next record;
- Load files should not span across media (e.g., CDs, DVDs, Hard Drives, Etc.); a separate volume should be created for each piece of media delivered;
- The name of the data load file should mirror the name of the delivery volume, and should have a .DAT extension (i.e., ABC001.DAT);
- The volume names should be consecutive (i.e., ABC001, ABC002, et. seq.)