

Technical Publications Release

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1.0 **PURPOSE**

This work instruction defines the steps required to release IFUs and other documents maintained by the Technical Publications group to draft, pre-production released/production or obsolete.

Advertising and promotional materials, manufacturing and distribution center procedures, and site-specific regulatory labeling (Japan, China, etc.) are not included in the scope of this document.

2.0 **REFERENCES**

2.1 **Applicable Documents**

Number	Title
N/A	N/A

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2.2 External References

Number	Title
N/A	N/A

3.0 RESPONSIBILITIES

Function or Title	Responsibility
Technical Publications	Creates COs/CAs Completes proof inspection, if applicable Delivers files for printing, if applicable Uploads eIFU to Informatica, if applicable Uploads IFU PDF files to POD, if applicable

4.0 DEFINITIONS

Term	Definition
CA	Change Activity
CAT	Cardiovascular and Ablation Technologies
CCB	Change Control Board
CIF	Change Impact Form
CIB	Change Implementation Board
CIF	Change Implementation Form
CO	Change Order
CoC	Certificate of Conformance
CRM	Cardiac Rhythm Management
ECO	Engineering Change Order
ECR	Enterprise Change Request
EDC	European Distribution Center
IFU	Instructions for use
NM	Neuromodulation
PLM	Product Lifecycle Management
POD	Print on Demand
Proof	A hardcopy or digital sample of finished labeling
RIP	Receiving Inspection Procedure
TcE	Teamcenter Engineering
WC	WindChill

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5.0 FLOW CHART

N/A

6.0 INSTRUCTIONS

6.1 Change Management

Complete training in and obtain the required access to the applicable PLM system.

Release the IFU in the PLM system of record for the product according to the processes established for that system.

6.1.1 WindChill

6.1.1.1 Change Order

Step	Action
1	Create an ECR/CO per the change management process requirements.
2	Add CA(s) for Resulting Objects (include Affected Objects if needed as required by CO instructions) and add peer reviewers.
3	<p>Ensure the appropriate Resulting Objects are included in the CA(s). Objects typically include:</p> <ul style="list-style-type: none"> • IFU PDF file identified with document subtype “instructions for use” or “supplementary IFU.” <p>NOTE: If the IFU content was substantially derived from a predicate, a redline document comparison of new vs. predicate file must be included with the change.</p> <p>NOTE: When changes are being made to translated IFU because of an update to the English IFU (source for translated IFUs), a redline document comparison of the English IFU changes along with the CoC must be included with the change.</p> <p>NOTE: When changes are being made to a translated IFU that is being updated independently from its source IFU (for example when correcting a typo or formatting error in a translated manual), then redlines comparing the predicate translated IFU to the revised translated IFU must be included with the change.</p> <p>NOTE: IFU PDF redlines may be attached to the CA, or they may be placed in the document iteration history.</p> <p>All comparisons must be initiated using an automated tool (eg, Word compare, FrameMaker compare, PDF compare). The tool-based output may be modified, if needed, for readability. Manually generated redline comparisons may be necessary for files authored in InDesign or other legacy tools with limited compare functionality. In this instance, another Technical Writer must review the redline to ensure completeness prior to WindChill upload.</p> <p>NOTE: Include source files as an attachment to the IFU PDF Resulting Object. For translations, also include CoC as an attachment to the Resulting Object.</p> <ul style="list-style-type: none"> • Artwork Specification identified with document subtype “artwork specification” or “supplementary IFU artwork.”

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Step	Action
	<ul style="list-style-type: none"> • SAP part • RIP, if generic procedure is not used. <p>NOTE: If releasing a legacy CAT supplementary IFU, populate language/country attributes, include quality/prevention manager on the CIB, and ensure that the appropriate distribution facility appears in the list of affected sites.</p>
4	<p>Ensure the appropriate documents are structured in the Related Objects tab.</p> <p>SAP part (parent)</p> <ul style="list-style-type: none"> • IFU PDF file (child) • Artwork specification document (child) • RIP, if applicable (child)
5	Add CO/CA attachments per PLM system requirements.
6	When populating members of the CIB for localized multilingual IFUs, include a writer and a localization coordinator to the Technical Publications roles.
7	<p>After CO is approved, set up pre-release tasks.</p> <p>NOTE: For supplementary IFUs, assign EDC a print proof task.</p>

6.1.2 TeamCenter

6.1.2.1 Change Request

Step	Action
1	Create an ECO per the change request process requirements.
2	Add the Affected Objects and list of reviewers.
3	<p>Ensure the appropriate affected objects are included in the ECO. Objects typically include:</p> <ul style="list-style-type: none"> • Part and Artwork Numbers <p>NOTE: If the IFU part and artwork numbers are new, place them in the New Items folder. If the IFU is a revision (eg, A to B), place the new revision in the Revised Items folder and place the old revision in the Items to be Changed folder.</p> <ul style="list-style-type: none"> • Drafts and redlines of the manuals to be released are required for pre-production and production changes. For an IFU initial release to revision 01 or A, place the redlines in the Reference Items folder of the ECO. For an IFU revision release (eg, A to B), redlines are placed at the same level as the IFU draft, CIF, etc. <p>NOTE: If the IFU content was substantially derived from a predicate, a redline document comparison of new vs. predicate file must be attached to the ECO.</p> <p>NOTE: When changes are being made to a translated IFU because of an update to the English IFU (source for translated IFUs), a redline document comparison of the English IFU changes along with the CoC are required to be included with the change.</p> <p>NOTE: When changes are being made to a translated IFU that is being updated independently from its source IFU (for example when correcting a typo or formatting error in a translated manual), then redlines comparing the predicate translated IFU to the</p>

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Step	Action
	<p>revised translated IFU must be included with the change.</p> <p>All comparisons must be initiated using an automated tool (eg, Word compare, FrameMaker compare, PDF compare). The tool-based output may be modified, if needed, for readability. Manually generated redline comparisons may be necessary for files authored in InDesign or other legacy tools with limited compare functionality. In this instance, another Technical Writer must review the redline to ensure completeness prior to TeamCenter upload.</p> <ul style="list-style-type: none"> • Forms (CIF and Detail Form) NOTE: CIF forms are required for production ECOs only. • ECO Reviewer List NOTE: Place the ECO Review List in the Reference Items folder.
4	<ul style="list-style-type: none"> • After CCB has approved the ECO you will receive an email for your final approval. Structure the final objects as follows: <ul style="list-style-type: none"> ○ Attach the Detail Form under the Part Number item revision located in the “New Items” folder or the “Revised Items” folder, as appropriate. ○ Attach the final PDF file and the source files (as a Zipped file) under the Artwork Number item revision located in the “New Items” folder or the “Revised Items” folder, as appropriate.
5	<p>Structure the Affected Objects under the child portion of the ECO (three triangles).</p> <ul style="list-style-type: none"> • IFU PDF file • Redline PDF file (unless it is a new Part and Artwork number then place the redline in the Reference Items folder) • CIF (production ECO only) • Detail Form • List of CCB Reviewers (place in the Reference Items folder)

6.1.3 Omnify

6.1.3.1 Change Order

Step	Action
1	Create a CO per the change order process requirements.
2	Add Affected Items. Make any necessary changes to Affected Items.
3	<p>Attach redlines (compare file) of document (IFU, alarm guides, addendums, etc.)</p> <p>Attach necessary reference documents (First Article Instructions, Change Impact Assessment, New Purchase Part form, etc.) to the Documents tab.</p> <p>NOTE: If the IFU content was substantially derived from a predicate, a redline document comparison of new vs. predicate file must be attached to the CO.</p> <p>NOTE: When changes are being made to a translated IFU because of an update to the English IFU (source for translated IFUs), a redline document comparison of the English IFU changes along with the CoC are required to be included with the change.</p>

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Step	Action
	<p>NOTE: When changes are being made to a translated IFU that is being updated independently from its source IFU (for example when correcting a typo or formatting error in a translated manual), then redlines comparing the predicate translated IFU to the revised translated IFU must be included with the change.</p> <p>All comparisons must be initiated using an automated tool (eg, Word compare, FrameMaker compare, PDF compare). The tool-based output may be modified, if needed, for readability. Manually generated redline comparisons may be necessary for files authored in InDesign or other legacy tools with limited compare functionality. In this instance, another Technical Writer must review the redline to ensure completeness prior to Change Order upload.</p> <p>NOTE: For translations, also include CoC as an attachment.</p> <p>Redlines of Print Specifications.</p>
4	Add Pre-CCB signatures and send pre-CCB notification for review.
5	Submit Change Order to CCB.
6	Once complete approval has been received, CO moves to Implementation. Final documents are added to the Change Order, including source files.
7	If the affected item is a buy part, Quality Assurance must approve the print proof.
8	Document Control performs implementation activities. Change Order is "Released." Final files that are released into Omnify (clean PDFs, native files, print specs) are added to the Item Changes tab/Documents Changes.

6.2 Hardcopy IFUs

6.2.1 CAT and NM: Order and Review of Proofs

NM: Review print proofs for all hardcopy IFUs.

CAT: Review print proofs as the project timeline allows.

Role	Technical Publications
Step	Action
1	Obtain a print proof.
2	Verify that the proofs are acceptable. For legacy CAT print proofs, use the IFU printer proof form. If rejecting the proof(s), provide feedback to the supplier and request a second proof.
3	Notify purchasing and the supplier when the proofs are approved.

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6.2.2 CRM: Delivery to Print on Demand (POD) Folder

Role	Technical Publications
Step	Action
1	Deliver files per the POD file delivery process. Not required for CRM IFUs released in WC.

6.3 Electronic IFUs

6.3.1 CAT, NM, and CRM: Upload of Electronic Instructions for Use

Role	Technical Publications
Step	Action
1	If required, upload electronic instructions for use per the established process.

7.0 APPENDICES

N/A