



CUSTOMER COMPLAINT (CPT) & FIELD EVENT

INFORMATION ABOUT THE HOSPITAL / DISTRIBUTOR INFORMATION SUR L'ETABLISSEMENT / DISTRIBUTEUR

Reporter name /Nom de l'émetteur :

Phone number /N° de téléphone :

Email address /Adresse email:

Name and address of the hospital or distributor /Nom et adresse de l'établissement ou du distributeur :

Name of surgeon or healthcare professional (if applicable) /Nom du chirurgien ou du professionnel de santé (si applicable) :

INFORMATION ABOUT THE FIELD EVENT INFORMATION SUR L'ÉVÈNEMENT

Please, provide us all information to help us to investigate / Merci de nous faire parvenir toute information nécessaire pour mener l'investigation liée à l'évènement :

Event date /Date de l'évènement :

Quantity/Quantité :

Lot n° /N° de lot :

Reference /Référence :

Device/Dispositif : Returned to Spineart **after Decontamination/ Envoyé à Spineart après Décontamination**

Scrapped/Mis au rebut Other /Autre :

Accidentally broken instrument - no investigation required (ex : the instrument fell down) – Do not fill the following information / *Instrument cassé accidentellement – pas d'investigation requise (ex : instrument tombé) – Ne pas remplir les informations ci-dessous*

Investigate details /Complément d'infos : Pictures/ Images X-Rays Surgery report/Rapport de chirurgie

Patient features /Caractéristiques: Man/Homme Woman/Femme Age :

Patient's diseases /Maladies : Smoker/Fumeur Obese /Obèse Alcoholic /Alcoolique

Bone quality /Qualité de l'os : Hard bone /Os particulièrement dur Other :

Event description /Description de l'évènement : Pre-operative Per-operative Post-operative Improvement

Patient output /Impact sur le patient : No impact/Pas d'impact Serious injury/Blessure grave Death/Mort

Procedure completed successfully /Procédure terminée avec succès :

Surgical delay /Retard de la chirurgie :

Potential cause / Cause potentielle :

Product related/ Lié au dispositif Use error/Erreur d'utilisation Patient related/ Lié au patient

Spineart ONLY/A remplir par Spineart

Spineart Assessment for registration /Evaluation de Spineart pour l'enregistrement :

Is this information assessed as a complaint according to the definition as per WI-05-02? /L'information fournie répond-elle à la définition d'une réclamation (WI-05-02) ?

Yes /Oui :

No /Non : Rationale/Justification :

Information to transfer to the people concerned / Information à transférer aux personnes concernées

How to reach us ?

SPINEART SA, Quality Department
Chemin du Pré-Fleuri 3,
1228 Plan-les-Ouates (Switzerland)
@ complaint@spineart.com



DOCUMENT CONTROL FORM

DCF

1. Document initiation

Originator

Document reference: Form 1 of WI-05-02
WI-05-02

New rev: 3
6

Originator: LVX

SOP WI/AX Form QM P22/P16 Training support

Description of the changes:

Spineart assessment for the registration of the complaints

Replace and obsolete:

Reasons for changes:

- Original issue Improvement Obsolescence
- NC: ____ CAPA: ____ Change control : ____

N/A

Applicable Immediately Date: _____ Concurrently with: _____

2. Training or Information

Trainer

- Yes Name of the trainer: N/A
- No Reason: _____ Minor change

3. Document approval

Approvers

Author	Date & signature	Process leader (if different from author or reviewer)	Date & signature
	LVX 18.OCT.2022	RDO 24oct2022	
Reviewer	Date & signature	Quality system	Date & signature
	XDE 18Oct2022	LDN 24-OCT-2022	

4. Training or Information

Evidences of training or information are in page 2

5. QMS Update

QS

Folder "Validated" Folder "History" Document master file

System Risk Management

Is there a new system risk generated? No Yes

Is there a modification of the occurrence of an existing risk? No Yes

If yes, Update risk analysis evidence: N/A

Controlled paper copies

Location	Alpes CN Archamps	SLI	Alpes CN Fillinges	Subs: US	Subs: SPAIN	Subs: UK	Subs: BELGIUM	Subs: ITALY
Qty	1							
New version transmitted to	CDL					N/A		
Previous version destroyed by	CDL							

5. Document Control Form Closure

QS

QS Approval: LDN Date: 24-OCT-2022



DOCUMENT CONTROL FORM

DCF

Trainer

4. Training or Information

Document reference:

Rev:

Training

Information

Comments: N/A

First Training date: _____

Trainer : _____

Attendees or persons informed

attest to be trained or informed for the properly use of the document

Attendees

Name

Signature

Date

_____	_____	_____
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N/A

Additional trainings on the document

Name

Signature

Date

Trainer Signature

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Attach additional sheet if needed