



## CUSTOMER COMPLAINT (CPT) & FIELD EVENT

### INFORMATION ABOUT THE HOSPITAL / DISTRIBUTOR INFORMACIÓN DEL ESTABLECIMIENTO / DISTRIBUIDOR

Reporter name / Nombre de quien reporta:

Phone number / Número de Teléfono :

Email address / Correo Electrónico/ email :

Name and address of the hospital or distributor / Nombre y dirección del Hospital o Distribuidor:

Name of surgeon or healthcare professional (if applicable) / Nombre del Cirujano o profesional de la Salud (si fuera aplicable)

### INFORMATION ABOUT THE ADVERSE or FIELD EVENT INFORMACIÓN DEL EVENTO

**Please, provide us all information to help us to investigate / Por favor, proporciónenos toda la información para ayudarnos a investigar**

Event date / Fecha del Evento :

Quantity/ Cantidad :

Lot n° / Número de Lote :

Reference / Referencia :

**Device/ Dispositivo :**  Returned to Spineart / Devuelto a Spineart  Scrapped/ Desechado  Other /Otros: .....

**Investigate details / Detalles de la investigación:**  Pictures/ Foto  X-Rays  Surgery report/ Reporte de la Cirugía

Patient features / Características del paciente:  Man/Hombre  Woman/ Mujer Age / Edad: .....

Patient's diseases / Enfermedades :  Smoker/Fumador  Obese / Obeso  Alcoholic / Alcoholico

Bone quality / Calidad osea:  Hard bone / Hueso duro  Other / Otros: .....

Event description / Descripción del Evento:  Pre-operatorio  Intra-operatorio  Post-operatorio  Mejora

Patient output/Impacto sobre el paciente:  No impact/sin impacto  Serious injury/Lesion grave  Death/Fallecimiento

Procedure completed successfully / Cirugía completada satisfactoriamente:  Yes/Si  No

Surgical delay / Retraso quirurgico:  Yes/Si > 30min  Yes/Si < 30min  No

Potential cause / Causa potencial:

Product related/Relacionada con el producto  Use error/Mala utilización  Patient related/ Relacionado con el paciente

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#### Como Localizarnos?

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



# DOCUMENT CONTROL FORM

DCF

## 1. Document initiation

Originator

Document reference: Training Support - CPT - Rev 1 (EN)  
Field event Quizz rev 0  
 Form 4 of WI-05-02 Rev 1 Spanish CPT form

New rev: Rev 0 / Rev 1      Originator: RBT

SOP       WI       Form       QM       P22/P16       Training support

### Description of the changes:

Training support has been updated to reflect the field event definition and include information and improvement request.  
Quizz has been created using Quicktapsurvey to assess the training efficiency  
Form 4 of WI-0502 has been updated to include imprvment request

Reasons for changes:       Original issue       Improvement       Obsolescence       NC: \_\_\_\_\_       CAPA: \_\_\_\_\_       Change control : \_\_\_\_\_

Replace and obsolete:

Applicable       Immediatly       Date: \_\_\_\_\_       Concurrently with: \_\_\_\_\_

## 2. Training or Information

Trainer

Yes      Name of the trainer: \_\_\_\_\_  
 No      Reason: Reviewers are users

## 3. Document approval

Approvers

Author	Date & signature	Process leader (If different from author or reviewer)	Date & signature
RBT	29 sep 2021	XDE	30sep2021
Reviewer	Date & signature	Quality system	Date & signature
Timothy BARNETT	29 SEP 2021	Aeu 30 SEP 2021	
Ramiro COUCEIRO	30 sep 2021		

## 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      If yes, Update risk analysis evidence: \_\_\_\_\_  
 Is there a modification of the occurrence of an existing risk?       No       Yes      N/A

### Controlled paper copies

Location	Alpes CN Archamps	SLI	Alpes CN Fillinges	Subs: US	Subs: SPAIN	Subs: UK	Subs: BELGIUM	Subs: ITALY
Qty				<u>u</u>				
New version transmitted to								
Previous version destroyed by				<u>A</u>				

## 5. Document Control Form Closure

QS

QS Approval: Aeu      Date: 30 SEP 2021