

# Field Safety Corrective Action

Use this template to fSCA plan and notice for [device\_issue].

## Template Metadata

Field	Details
Category	Medical Devices
Owner	[Team or owner]
Version	[Version number]
Effective Date	[Date]
Review Cycle	[Monthly / Quarterly / Annual / Event-based]
Status	[Draft / In Review / Approved]

## Issue Summary

Describe the field issue, discovery source, potential hazard, and FSCA decision.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Affected Devices

Identify product names, models, UDI, serial or lot ranges, distribution dates, and markets.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

### Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Health Hazard Evaluation

Summarize probability of occurrence, severity, exposed population, and medical consequences.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

### Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Corrective Action

Describe removal, correction, software update, labeling change, inspection, or customer communication.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Customer Instructions

Provide clear actions for consignees, users, distributors, and return acknowledgements.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Regulatory Notifications

List authorities, report numbers, timelines, and field safety notice controls.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Effectiveness Tracking

Define response targets, reconciliation, follow-up attempts, and closure criteria. Use direct, controlled language suitable for QA and regulatory review.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Review and Signoff

Document review conclusions, approvals, unresolved items, and next review date.

Role	Name	Date	Notes
Preparer	[Name]	[Date]	[Notes]
Reviewer	[Name]	[Date]	[Notes]
Approver	[Name]	[Date]	[Notes]