## 1. CUSTOMER INFORMATION

| | |
|---|---|
| Name | |
| Address | |
| Contact | |
| Email | |

## 2. HEALTHCARE FACILITY INFORMATION

| | |
|---|---|
| Name | |
| Address | |
| Contact | |
| Email | |

## 3. COMPLAINT INFORMATION

| | | | |
|---|---|---|---|
| a. Date of event | | b. Date of awareness | |
| c. Description | | | |
| d. Initial reporter | ☐ Healthcare professional<br>☐ Patient<br>☐ Authority | ☐ Representative<br>☐ Attorney<br>☐ Other, please specify | |
| e. If a representative of the customer attended | Name | | |
| | Email | | |
| f. User | Name | | |
| | Email | | |
| g. Consequences of the event (mandatory to check all that apply) | ☐ No patient involvement<br>☐ No health consequences or impact<br>☐ Explantation / revision<br>☐ Prolonged surgery: Time of extension (min)<br>☐ Additional surgery planned / required<br>☐ Modified surgical procedure due to the event<br>☐ Parts / fragments remain in the body<br>☐ Additional X-rays / CT scans needed<br>☐ Other, please specify | | |

## 4. PRODUCT INFORMATION

| | | | | | |
|---|---|---|---|---|---|
| Ref | | Description | | | |
| Lot | | SN | | Quantity | |

☐ Implant ☐ Instrument ☐ Custom made device

| | | | | |
|---|---|---|---|---|
| a. Product combined with, if applicable | Ref | | Ref | |
| | Lot | | Lot | |
| | SN | | SN | |
| | Ref | | Ref | |
| | Lot | | Lot | |
| | SN | | SN | |

| | |
|---|---|
| b. Usage of the product | ☐ Problem noted prior use<br>☐ Initial use<br>☐ Reuse, please specify: in use since number of cycles<br>☐ Refurbished prod<br>☐ Unknown |
| c. Current location of the product | ☐ In transit to Lincotek<br>☐ In transit to distributor<br>☐ Distributor<br>☐ Healthcare facility<br>☐ Patient (explanted components)<br>☐ Remains implanted<br>☐ Discarded<br>☐ Other, please specify |
| d. Accompanying information | ☐ Copy of implant card / product labels<br>☐ Surgery report of revision<br>☐ Surgery report of implantation<br>☐ X-rays / CT scans pre-revision<br>☐ X-rays / CT scans post-implantation<br>☐ Images (e.g. intraoperative)<br>☐ Other, please specify |

## 5. PATIENT INFORMATION

| | | | | | |
|---|---|---|---|---|---|
| Age | | Weight (kgs) | | Height (cm) | |

☐ Male ☐ Female ☐ Unknown

Activity level: ☐ Low ☐ Normal ☐ High ☐ Unknown

| | |
|---|---|
| Other relevant condition | |
| Implantation date | |
| Healthcare facility name | |

Send this form to qualityassurance.it.bo@lincotek.com