| **SECTION 1. CONTACT INFORMATION** | |
|---|---|
| **A. Role of preparator**<br>☐ **Distributor**<br>☐ **Other,** *Please specify*:_____ | |
| Company name (if applicable) | |
| Address (if applicable) | |
| Contact person | Name:_____<br>Email:_____ |
| **B. Healthcare facility involved** | |
| Hospital name | |
| Address | |
| Contact person | Name:_____<br>Email:_____ |
| C. **Reporting** | |
| Initial reporter | ☐ Healthcare professional: _____<br>☐ Patient:_____<br>☐ Competent Authority:_____<br>☐ Distributor:_____<br>☐ Attorney:_____<br>☐ Other:_____ |

| **SECTION 2. MEDICAL DEVICE INVOLVED** | |
|---|---|
| Legal manufacturer | |
| Type of device: | ☐ Implant<br>☐ Instrument<br>☐ Custom-made device |
| Product code (REF) | |
| Medical device description | |
| ☐ Lot<br>☐ Serial number | *Please specify lot or serial number:*_____ |
| UDI-DI | |
| Medical device used in clinical investigations: | ☐ Yes<br>☐ No |
| Is the medical device used in combination with other medical devices? *If yes, please fill out the boxes below.* | |
| Ref:<br>SN:<br>LOT: | |

| | |
|---|---|
| Ref:<br>SN:<br>LOT: | |
| Product use | ☐ Issue detected<br>☐ Before use<br>☐ During the use<br>☐ After use<br><br><u>Only for resusable medical devices:</u><br>☐ First use<br>☐ Reused. Please specify, since:_____. Number of cycles (if known):_____<br><br>☐ Unknown |
| Current location of the medical device | ☐ In transit to Lincotek Bologna Srl<br>☐ In transit to distributor *(please specify:_____)*<br>☐ Distributor *(please specify:_____)*<br>☐ Healthcare facility<br>☐ Remains implanted<br>☐ Discarded<br>☐ Other, *please specify:* _____ |

| **SECTION 3. COMPLAINT INFORMATION** | | |
|---|---|---|
| Date of event | | |
| Event description | | |
| Intended user | Name | |
| | Email | |
| Consequences of the event<br>(mandatory to check all that apply) | ☐ No patient involvement<br>☐ No health consequences or impact<br><br>☐ Life-threatening illness or injury<br>☐ Temporary or permanent impairment of a body structure or a body function<br>☐ Hospitalisation or prolongation of existing hospitalisation<br>☐ A clinically relevant increase in the duration of a surgical procedure.<br>Time of extension (min): _____<br>☐ Professional medical care or additional unplanned medical treatment<br>☐ Chronic disease<br>☐ Death of the patient, user or other person<br>☐ Other, *please specify:*_____ | |

*Fill out section 4 only in case of patient involvement.*

| SECTION 4. PATIENT INFORMATION | |
|---|---|
| Age | |
| Weight (kgs) | |
| Height (cm) | |
| Gender | ☐ Male<br>☐ Female<br>☐ Unknown |
| Activity level | ☐ Low<br>☐ Normal<br>☐ High<br>☐ Unknown |
| Implantation date | |
| Other relevant condition (i.e. trauma, medical history etc.) | |

| SECTION 5. ATTACHED DOCUMENTS |
|---|
| ☐ 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:_____ |

| | |
|---|---|
| **Date** | |
| **Signature (full name)** | |

Send this form to regulatory@recon-i.com

**THIS APPLIES ONLY TO LINCOTEK BOLOGNA SRL**

| **1. REGISTRATION** | |
|---|---|
| **Complaint ID (yymmdd_cliente)** | |
| Communication | ☐ Oral<br>☐ Phone<br>☐ Videocall<br>☐ Email (please archive the email in the dedicated folder) |
| Additional information requested/received (if any) | |

| **2. COMPLAINT ASSESSMENT** | |
|---|---|
| A. Complaint is an incident according to the article 2(64) MDR? | ☐ Yes<br>*If yes, please fill in F-226 Incident Assessment Form to define if the incident is serious or non-serious and then answer the question B.*<br><br>☐ No<br>*Please directly go the box 3. COMPLAINT RESOLUTION* |
| B. In case of incident, according to the related F-226, the incident is: | ☐ Serious incident<br>*In this case, please proceed according to the internal WI-159.*<br><br>☐ Non-serious incident<br>☐ Unwanted side effect / adverse event. Please specify:_____<br>_____<br><br>☐ Other<br><br>Please refer to **CAPA ID** _____ |

| **3. COMPLAINT RESOLUTION** | |
|---|---|
| | |
| Responsible for final resolution | Name:<br>Signature: |
| Approver | Name:<br>Signature: |
| Date | |