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| --- | --- | --- | --- | --- | --- | --- |
| Feedback Information #: | |  | | | Date: |  |
|  | |  | | |  |  |
| Organisation / Distributor: | |  | | | Contact Name: |  |
| Telephone: | |  | | | email: |  |
|  | |  | | |  |  |
| Hospital / Facility: | |  | | | Surgeon / Contact: |  |
| Telephone: | |  | | | email: |  |
| Address: | |  | | | | |
|  | |  | | |  |  |
| Device Name: | |  | | | Device Size: |  |
| Device Lot #: | |  | | | Patient Ref: |  |
| Age: |  | Sex: | Male □ Female □ | | Build: | S □ M □ L □ XL □ |
| Patient Pathology: | |  | | | | |
| **description of event (include date of event and date of INITIAL surgery)** | | | | | | |
| Clinical □ Non Clinical □ | | | | | | |
| **other devices/substances used** | | | | | | |
|  | | | | | | |
| **further action taken** | | | | | | |
|  | | | | | | |
| Is the device available for return? | | | | Yes □ No □ | | |
| If yes, please ensure the device has been decontaminated for safe handling and that the decontamination documents showing decontamination status are returned with the device | | | | | | |

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| Feedback Information submitted by (Name): |  | Telephone: |  |
| Email: |  |
| **Return Form To:** | | | |
| **North / Central / South America:**  Compliance Department, Biocomposites Inc., 700 Military Cutoff Road, Suite 320, Wilmington, NC 28405, USA.  email: [complianceus@biocomposites.com](mailto:complianceus@biocomposites.com) Tel +1 (910) 350 8015 | | **Rest of World:**  Compliance Department, Biocomposites Ltd, Keele Science Park, Keele, Staffordshire, ST5 5NL, England.  email: [compliance@biocomposites.com](mailto:compliance@biocomposites.com) Tel +44 (0) 1782 338 580 | |

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| Feedback Information received by (Name): |  | Signature: |  |
| Date: |  |

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| **evaluation sources** | | | |
|  | | | |
| **recommendation (Select One – see QAP8.0 Appendix 1)** | | | |
| □ Adverse Incident / Quality Problem / Complaint (Complaint) – Add to Reliance **CC#** \_\_\_\_\_\_\_\_  □ User Experience (Feedback) – Add to Reliance **FB#** \_\_\_\_\_\_\_\_  □ No further actions | | | |
| **RATIONALE:** | | | |
|  | | | |
| Feedback Information evaluated by (Name): |  | Signature: |  |
| Date: |  |