|  |  |  |  |
| --- | --- | --- | --- |
| **To:** | **Occlutech GmbH**  **Complaint Management**  Winzerlaer Str. 2  07745 Jena – Germany | **Contact person:**  **(For correspondence and Customer Letter)** |  |
| Email: | complaints@occlutech.com | Email: |  |

|  |  |  |
| --- | --- | --- |
| **General Information** | | |
| **Reporting person** |  | **When did the event occurred?**  **[please select relevant]** |
| **Date of occurence** |  |
| During incoming inspection  Prior to patient contact (during device preparation but before device positioning)  During patient contact (during implantation process)  Directly after the procedure  During the follow-up period |
| **Date of information to distributor** |  |
| **Country of occurrence** |  |
| **Hospital, address** |  |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Complaint device(s) information [Please select relevant complaint device(s)]** | | | | | | | | | | | |
| **Device type** | **Device ref. no.** | | **Serial/Lot no.** | | | **Please list the concomitant devices:** | | | | | |
| Occluder |  | |  | | |  | | | | | |
| Delivery Set |  | |  | | |  | | | | | |
| Pusher |  | |  | | |  | | | | | |
| Sizing balloon |  | |  | | |  | | | | | |
| Guidewire |  | |  | | |  | | | | | |
| **Will device(s) be returned:**  Yes  Device remains in patient  Discarded by hospital  Other, please specify: | | | **Occlutech has the permission to use the device for root cause analysis, storage it for 3 years and discard it after this time frame:**  Yes  No | | | | | | | | |
| **Following further information available for evaluation:**  TEE measurements and/ or device positioning  Used devices (occluder, delivery sheath, loader, pusher)  Catheter data | | | | | | MRI data  Images to balloon sizing  Other, please specify: | | | | | |
| **Name of the indication:** | | | | | | |  |  | | | |
| **Known infectious disease (e.g., hepatis B; aids) of the patient:** | | | | | | | | Yes  No | | | |
| **Summary to event [please select applicable]:** | | | | | | | | | | | |
| Delivery Set failure  Pusher failure  Compatibility problem  Device dislocation  Device dislocation (Pusher-related) | | | | Failure in shape development of the Occluder  Visual failure of the Occluder  Damaged packaging  Foreign material in the packaging  Other, please specify: | | | | | | | |
|  | | | |  | | | | | | | |
| **Occurrence details [Please provide as much information as possible]** | | | | | | | | | | | |
| **Event description:**   * *used measuring method for Occluder size selection* * *details of incident* * *medication details (before, during, after procedure)* * *consequences, actions, etc* * *patient outcome* | |  | | | | | | | | | |
| **Device(s) involved in any patient, user or third-party injury?**  Yes\*  No  \*Please provide further information under consequences to event in section occurrence details | | | | | | | | | | | |
| **Consequences to event [please select applicable]** | | | | | | | | | | | |
| No effect/ No patient injury  Impact to the patient/user/other persons **[please select applicable below]**: | | | | | | | | | | | |
| Significant prolonged procedure (e.g.2x standard procedure duration)  Additional medication  Additional surgical intervention  Damages to cardiovascular tissue  Neurological event (e.g., TIA, stroke, hemiparesis)  Arrythmia/ Tachycardia/ Cardiac arrest  Residual shunt | | | | | | | | | Air entering into vascular system  Thrombus formation  Embolism  Hypovolemic shock  Endocarditis/ Pericarditis  Death  Other, please specify: | | |
| **Current patient condition:** | | | | |  | | | |  | | |
| **Patient information:** | | | | | Female  Male | | | | | Weight: | Age: |
| **Was procedure completed successfully?** | | | | | Yes  No | | | | | | |
| **Was another device used to complete the procedure?** | | | | | No  Yes, please specify (Ref/Lot): | | | | | | |
| **Pre-existing condition and/ or pre-diagnosis relevant to the event:** | | | | | No  Yes, please specify: | | | | | | |
| **Measured size of defect:** | | | | |  | | | | | | |
| **Method of defect measurement:** | | | | | TEE measurement  Sizing balloon  Other, please specify: | | | | | | |
| **Was the event notified to an Authority?** | | | | | Yes  No | | | | | | |

|  |
| --- |
| **Additional comments relevant to the event:**   N/A |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** |  | **Completed by:** |  |