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| **To:** | **Occlutech GmbH****Complaint Management**Winzerlaer Str. 207745 Jena – Germany | **Contact person:****(For correspondence and Customer Letter)** |  |
| Email: | complaints@occlutech.com | Email: |  |

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| **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** |  |

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| **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*
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| **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 |

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| **Additional comments relevant to the event:**  [ ]  N/A |
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| **Date** |  | **Completed by:**  |  |