**Initial Report Local Report No. Initial Receipt Date:**

**Follow-Up Report Global Report No. T *(DD/MMM/YYYY)***

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| 1. **Reporter Information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of reporter | | | | | | | | | | | | | Function of reporter (Physician, pharmacist, technician, nurse, patient, authority etc.)       Pharmacist | | | | | | | | | | | | | |
| If reported by patient, consent to contact Health Care Professional obtained?  Yes, consent date:        No  HCP name:  HCP phone: | | | | | | | | | | | | | Institution name and department (If patient report, give HCP details) | | | | | | | | | | | | | |
| Phone number of reporter: | | | | | | | | | | | | | Institution address (If patient report, give HCP details) | | | | | | | | | | | | | |
| Email address of reporter: | | | | | | | | | | | | |
| 1. **Patient Information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Initials | | Date of Birth | | | Age | | | Weight (kg) | | | | | Height (cm) | | | | | Sex (M/F) | | | If female, is patient pregnant?  Yes  No  Unknown | | | | | |
| Medical history (Underlying diseases, allergies, further risk factors)    Previous reaction to the same product?  Yes  No | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Mallinckrodt Suspect Drug and Procedural Information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Drug Name & Formulation (If suspect drug is Optimark, complete Page 2)** | | | | | | | | | | | | | | **Indication** | | | | | | | | | | | | |
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| **Lot No.** | **Dose** | | **Strength** | | | | **Route** | **Start Date** | | | **Stop Date** | | | | | **Frequency** | | | **Expiration Date** | | | | | | **Accidental Exposure?** | |
|  |  | |  | | | |  |  | | |  | | | | |  | | |  | | | | | | Yes  No  Unk | |
| **If suspect product is an opiate or an opioid**  History of taking an opiate/opioid products | | | | | | | | | | | | | | No  Unknown  Yes, product name: | | | | | | | | | | | | |
| **If suspect product is Contrast Media**  Was an injector used? | | | | | | | | | | | | | | No  Unknown  If yes, name of injector and flow rate: | | | | | | | | | | | | |
| 1. **Concomitant Therapy *(Including pre-medications)***   *please fill one form for each event/**if more space needed, append separate page* | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Drug Name and Strength** | | | | | | **Indication** | | | | | | **Dose** | | | | | **Freq** | | | **Route** | | | **Start Date** | | | **End Date** |
|  | | | | | |  | | | | | |  | | | | |  | | |  | | |  | | |  |
| 1. **Case Event Information**  *(please fill one form for each event)* | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Adverse Event** | | | | **Outcome** | | | | | **Treatment** | | | | | | **Seriousness** | | | | | | | | | **HCP Opinion of Causality** | | |
| Event :    Onset Date:    Abated Date: | | | | Recovered  Improved  Ongoing  Fatal  Unknown | | | | |  | | | | | | Select only as applicable:  Death  Life-threatening  Hospitalization due to adverse event  Prolonged hospitalization due to adverse event  Persistent/significant disability  Congenital anomaly | | | | | | | | | Is there a reasonable probability for a plausible causal relationship?  Yes  No  Other possible causes?  Yes  No  If yes, please state: | | |
| Narrative (append separate pages as needed) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Submitted By** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name: | | | | | | | | | | Signature: | | | | | | | | | | | | Date: | | | | |

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| 1. **Reports in which a suspect product is Optimark:** | | | | | | | | | |
| **Additional Information to Evaluate and Quantify the Risk for Nephrogenic Systemic Fibrosis** | | | | | | | | | |
| Is the patient known to have renal dysfunction? | | | | | Yes  No | | | | |
| If yes, when was renal dysfunction first diagnosed in the patient? | | | | | | | | | |
| Is the patient on dialysis? | | | | | Yes, hemodialysis  Yes, peritoneal dialysis  No | | | | |
| What was the renal function of the patient prior to the current MR procedure? (Please specify method) | | | | | | | | | |
|  | | | | | | | | | |
| Is the patient on any of the following medications? | | | | | | | | | |
| ACE inhibitors | | Yes  No  Unknown | | | | If yes, Name:       Dose: | | | |
| Beta blockers | | Yes  No  Unknown | | | | If yes, Name:       Dose: | | | |
| Erythropoietin | | Yes  No  Unknown | | | | If yes, Name:       Dose: | | | |
|  | | | | | | | | | |
| How many contrast-enhanced MR procedures has the patient undergone prior to this one? (estimate if not exactly known)  0  1  2  3-4  5-6  7-9  10 or more  Unknown | | | | | | | | | |
| For what indication?  Same as for this one  Other  Several  Unknown  (If other or several indications, please specify in table below) | | | | | | | | | |
| Please give details about any previous contrast-enhanced MR procedure, most recent first (Put in brackets if estimated and not exactly known, write “?” if unknown) | | | | | | | | | |
| **Date** | **MRI or MRA** | | **Indication** | | | | **Contrast Trade Name** | | **Dose** |
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| **Submitted By** | | | | | | | | | |
| Name: | | | | Signature: | | | | Date: | |