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

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

|  |
| --- |
| 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** |
|  |  |
| **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 [ ]  NoOther possible causes?[ ]  Yes [ ]  NoIf 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:       |