Endotherapeutics

## MONTAVIT PRODUCT COMPLAINT FORM

| COMPLAINT STATUS | | |
|---|---|---|
| **Name of Sales Representative lodging complaint:** | **Status of Supplied Stock:** | **Case Origin:** |
| | ☐ Sales Representative Stock<br>☐ Hospital Owned Stock<br>☐ Demonstration or Trial | ☐ Email<br>☐ Phone<br>☐ Sales Rep attended case |
| **Date of Incident / Product Fault:** | | |
| | | |

| CUSTOMER AND PRODUCT DETAILS | |
|---|---|
| **Name of Hospital / Institution:** | |
| **Address (Incl. Department):** | |
| **Name of Contact / Job Title:** | |
| **Phone Number of Contact:** | |
| **Email Address of Contact:** | |
| **Product Code and Description:** | |
| **Product Batch / Lot / Serial No.** | |
| **Expiry Date of Product:** | |
| **Name of End User:** | |
| **Requested Course of Action** | |

**Office Use Only:**

RGA: _____ Date of Filing: _____ *(Page 1)*

Endotherapeutics

## MONTAVIT PRODUCT COMPLAINT FORM

| DETAILS OF THE COMPLAINT |
|---|
| **Please provide a detailed description of the product complaint.**<br>*This description must include details of the product setup, the fault scenario, what troubleshooting may have occurred, what the outcome of the fault was and how the fault impacted the patient or procedure.* |
| |

| Experience of end user: | Status of stock: | Current location of stock: |
|---|---|---|
| ☐ First Time User | ☐ Sterile | ☐ Sales Representative* |
| ☐ Limited User | ☐ Non-Sterile | ☐ Hospital* |
| ☐ Trained and Proficient | ☐ Other: | ☐ Disposed of |
| ☐ Extensive User | _____ | ☐ Returned to Head Office |

**If the stock is with a sales representative or the hospital, please return the stock to Head Office.*

**Office Use Only:**

RGA: _____ Date of Filing: _____ *(Page 2)*

Endotherapeutics

## MONTAVIT PRODUCT COMPLAINT FORM

| REPORTER INFORMATION | | | |
|---|---|---|---|
| Name of Reporter: | | Nationality: | |
| City/Region: | | | |
| Qualification of Reporter: | ☐ Physician ☐ Patient<br>☐ Pharmacist ☐ Other: | | |
| Contact Details (e.g. Email) | | | |

| INCIDENT | |
|---|---|
| Type of the event: | ☐ Side Effect<br>☐ Malfunction or Deterioration of the Device<br>☐ Inaccuracy in the Labelling / Instructions for Use<br>☐ Other (Describe): |

| MEDICAL DEVICE (SUSPECTED MEDICAL DEVICE INFORMATION) | | | | |
|---|---|---|---|---|
| Device Name: | | | | |
| Active Substance(s): | | | | |
| Administration Dates | Start Date: | | | |
| | End Date: | | | |
| Dosage: | | | | |
| Indication(s) for Use: | | | | |
| Application Performed by: | ☐ Patient<br>☐ Healthcare Professional | | | |
| Sample Available: | ☐ Yes<br>☐ No | Application According to Instructions for Use? | ☐ Yes<br>☐ No | |

**Office Use Only:**

RGA: _____ Date of Filing: _____ *(Page 3)*

Endotherapeutics

## MONTAVIT PRODUCT COMPLAINT FORM

| PATIENT [1] | | | |
|---|---|---|---|
| Age (years): | | Initials: | |
| Weight (kg): | | Height (cm): | |
| Sex: | ☐ Male ☐ Female | | |
| **Concomitant Diseases:** Previous and Continuing (if applicable) | | | |
| *Diagnostics* | *Start Date* | *End Date* | |
| | | | |
| Other Relevant Information (if applicable) | | | |

| SIDE EFFECT(S) [1] | | | |
|---|---|---|---|
| Description of the Suspected Side Effects(s) | | | |
| **Duration of side effects(s):** | | | |
| Side Effect: | Start Date | End Date | Duration (hour/days) |
| | | | |
| Patient Outcome: | ☐ Recovered ☐ Not Recovered ☐ Unknown | | |
| Classification of the Side Effect: | ☐ Death ☐ Other: ☐ Serious Public Health Threat ☐ None of the mentioned | | |
| Treatment of the Side Effect / Tests Performed | | | |

**Office Use Only:**

RGA: _____ Date of Filing: _____ *(Page 4)*

Endotherapeutics

## MONTAVIT PRODUCT COMPLAINT FORM

| SIDE EFFECT(S) [1] | | | | |
|---|---|---|---|---|
| **Action Taken with the Medical Device: (Tick all Appropriate)** | | | | |
| Was Treatment with the Suspected Device Discounted? | ☐ *Yes* | ☐ *No* | ☐ *Unknown* | ☐ *N/A* |
| Did Side Effect Abate After Stopping Use of the Device? | ☐ *Yes* | ☐ *No* | ☐ *Unknown* | ☐ *N/A* |
| Did Side Effect Reappear if Device was Reintroduced? | ☐ *Yes* | ☐ *No* | ☐ *Unknown* | ☐ *N/A* |
| Was the Device Used Previously Without any Complaints? | ☐ *Yes* | ☐ *No* | ☐ *Unknown* | ☐ *N/A* |
| Has the Reporter Informed the Authorities? | ☐ *Yes* | ☐ *No* | ☐ *Unknown* | ☐ *N/A* |
| Causal Relationship between the Medical Device and the Side Effect(s) | ☐ Related | ☐ *Unrelated* | ☐ *Unknown* | |
| ***Concomitant Medication(s)*** (if applicable): exclude those to treat side effect | | | | |
| *Name, Indication, dose, duration* | | | | |
| Causal Relationship between the Medication(s) and Side Effect(s) | ☐ Related | ☐ Unrelated | ☐ Unknown | |

| ***Comments: (if applicable)*** |
|---|
| |

*Once all fields are populated, please return an electronic copy of this form along with any relevant photographs, additional information or correspondence to hjacobs@endotherapeutics.com.au*

[1] Applicable if a Side Effect was Reported

**Office Use Only:**

RGA: _____ Date of Filing: _____ *(Page 5)*