| Event Report. No. | Return Authorization No. if applicable: |
| --- | --- |

| **Information about the Hospital where the event occurred** | |
| --- | --- |
| Hospital name: {hospitalName} | Clinician name: {hospitalClinicianName} |
| Address: {hospitalAddress} | |
| Country: {hospitalCountry} | Had the staff completed training? {hospitalTraining} |

| **Information about the Event** | | | |
| --- | --- | --- | --- |
| Healthcare professional reporting event: | Name: {eventReporterName} | | Title: {eventTitle} |
| Detailed information regarding the circumstances of the event:  {eventDetails}  \*Attach copies of all supplemental documentation to this report in English\* | | | |
| Date the event occurred: {eventDate} | | Does Physician allege event was caused by device? {eventAllegeCaused} | |
| Was a governing body informed of event? {eventBodyInformed} | | | |

| **Patient Information\* *(****This information is confidential and protected will not be reported unless required for MDR or vigilance reporting by regulatory agencies)* | | | |
| --- | --- | --- | --- |
| **{patientImpacted}** Check here if there was no patient impact (if this is checked, the patient information section and the worksheet to determine if reportable are not required). | | | |
| *If patient information is required to complete product inquiry process, please fill in below.* | | | |
| Patient Identifier: {patientIdentifier} | Age: {patientAge} | Sex: {patientSex} | Weight: {patientWeight} |
| Condition after event: **{**patientCondition} | | | |
| Did the patient experience any adverse consequences due to this event? {patientAdverseConsequences}  \*Please describe: {patientDescribe} | | | |

| **Disposable Information** | | | (skip to next section if not applicable) | | |
| --- | --- | --- | --- | --- | --- |
| Did the event involve a sterile disposable item or kit? {disposableSterileKitInvolved} | | | | | |
| Product name/number: {disposableProductName1}  {disposableProductNumber1} | | Lot number: {disposableLotNumber1} | | Expiration date: {disposableExpirationDate1} | |
| Was a replacement disposable used? {disposableReplacementUsed}  If “Yes”: Include disposable name, product number & lot number:  {disposableProductName2} {disposableProductNumber2} {disposableLotNumber2} {disposableExpirationDate2} | | | | | |
| **Device Information** | | | (skip to next section if not applicable) | | |
| Did the event involve a ThermoChem Device? {deviceThermoChemInvolved} | | | | | |
| Device model number: {deviceModelNumber1} | | Serial number: {deviceSerialNumber1} | | | |
| Device: {deviceTempMalfunctionBool} | Device to be returned? {deviceToBeReturnedBool} | | | | Reused? {deviceReusedBool} |
| Was a replacement device used?{deviceReplacementUsed}  Replacement Device Information: Model number & serial number: {deviceModelNumber2} {deviceSerialNumber2} | | | | | |
| **Component Information** | | | (skip if not applicable) | | |
| Did the event involve a reusable component? (Ex: temperature extension cable, water line…) {componentReusableInvolved} | | | | | |
| Component name: {componentName} | | Product number (if known): {componentProductNumber} | | | |

| **Representative Reporting the Event Information** | |
| --- | --- |
| Rep’s Name: {repName} | Company Name: {repCompanyName} |
| Contact Information: {repContactInfo} | Was representative present during event? {repPresent} |
| Event was communicated to representative via: {repCommunicatedMethod} : {repOtherDescription} | |
| Date the event was reported to representative, if different than the date the event occurred: {repDateReportedBy} | |
| Date the event was reported to ThermaSolutions, if different than the date the event occurred: {repDateReportedToTherma} | |
| **Email to service@thermasolutions.com within 3 (three) business days to the ThermaSolutions** | |

**INVESTIGATION WORKSHEET**

*The following worksheet is to be completed by a ThermaSolutions, Inc. personnel assigned to complete the investigation requirements for the complaint.*

| **Investigation** | | | |
| --- | --- | --- | --- |
| Investigator Name: {investigationName} | | Start date of investigation: {investigationStartDate} | |
| Investigation comments:  {investigationComments} | | | |
| Root Cause:  {investigationRootCause} | | | |
| **This event can be classified into the following category:** (more than one can be selected) | | | |
| {invDurability}Durability/Reliability | {invFunctionality}Functionality | | {invSafety}Safety |
| {invEffectiveness}Effectiveness | {invPerformance}Performance | | {invIdentification}Identification |
| {invOther} Other category, explain: {invOtherDescription} | | | |
| **Complete and return to Product Management or Quality Representative** | | | |

**To be completed by the Product Management or Quality Representative:**

| **Risk Analysis** | **Severity of outcome to patient, user and/or environment** | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Probability of reoccurrence** |  | **1** | **3** | **5** | **8** | **10** |
| **1** | **Acceptable/Insignificant or negligible risk** | **Acceptable/Insignificant or negligible risk** | **Investigate further to control risk** | **Investigate further to control risk** | **Investigate further to control risk** |
| **3** | **Acceptable/Insignificant or negligible risk** | **Investigate further to control risk** | **Investigate further to control risk** | **Unacceptable** | **Unacceptable** |
| **5** | **Investigate further to control risk** | **Investigate further to control risk** | **Unacceptable** | **Unacceptable** | **Unacceptable** |
| **8** | **Investigate further to control risk** | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** |
| **10** | **Investigate further to control risk** | **Unacceptable** | **Unacceptable** | **Unacceptable** | **Unacceptable** |

| Risk Analysis | {riskAnalysisLevel} (not acceptable risk results in CAPA) |
| --- | --- |
| Justification for Risk Level: {riskJustification} | |

| **Actions Taken** | |
| --- | --- |
| Was a correction required? {actionCorrectionRequired} Details: {actionCorrectionDetails}  (**Note:** a correction utilizes the current disposable, device or component) | |
| Did correction mitigate complaint? {actionMitigatedBool} | |
| Is service required? {actionServiceRequiredBool} PSO# \_\_\_\_\_\_\_\_\_\_\_\_\_\_{actionPSONum} | Did service mitigate complaint? {actionServiceMitigatedBool} |
| Is Corrective & Preventative Action required? {actionCAPARequired}: CAPA#:{actionCAPANum}, {actionCAPAStatus}  {actionCAPAExplanation} | |

**COMPLAINT WORKSHEET TO DETERMINE IF REPORTABLE**

*The following worksheet is to be completed by a ThermaSolutions, Inc. Regulatory Affairs or designee for all customer complaints regarding product potential reporting requirements for the complaint. If there is no patient impact, this is not required to be completed. Upon completion, this worksheet is attached to the corresponding Complaint Report/ Form.*

**General Information about Complaint**

| 1. Is the device manufactured by or the responsibility of ThermaSolutions and does the information provided in the complaint “reasonably suggest” a device related event occurred?   *Where “responsibility of ThermaSolutions” includes distribution agreements.* | Yes, go to 2.  No, go to 5. |
| --- | --- |
| 1. Does the information reasonably suggest that the device may have caused or contributed to a death or “serious injury”?   *Where “serious injury” is an injury or illness that is life threatening, even if temporary in nature: results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure?* | Yes, go to 6, 13, 19.  No, go to 3 |
| 1. Does the information reasonably suggest that a malfunction of the device has occurred?   *A “malfunction” is a failure of the device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device* | Yes, go to 4.  No, go to 5. |
| 1. Does the information reasonably suggest that the device or any other device marketed by ThermaSolutions or its subsidiaries would be likely to cause or contribute to a death or “serious injury” if the malfunction were to recur? | Yes, go to 6, 13, 19.  No, go to 5. |
| 1. No action required by ThermaSolutions. | **END** |

**Relevance to FDA (21 CFR Part 803 subpart A, E and 820.198)**

| 1. Is the device available in the United States?   *If yes, also refer to Medical Device Reporting Regulation 21 CFR Part 803* | Yes, go to 7.  No, go to 10. |
| --- | --- |
| 1. Is there written medical justification by a qualified individual supporting not filing the event, written documentation from FDA stating event is not filable, or does event fall under FDA Exception/ Variance (i.e., Exemption from Medical Device Reporting)? | Yes, go to 9. Attach justification  No, go to 8. |
| 1. Does event result in reportable death, serious injury or malfunction?   *(Note: malfunctions not reportable if they are not likely to result in death, serious injury, or other serious adverse event)* | Yes, go to 9.  No, go to 10. |
| 1. Does the event require remedial action to prevent an unreasonable risk of substantial harm to the public health?   *(Note: MDR reportable adverse events would no longer be required for deaths, serious injuries and malfunctions involving a product undergoing remedial action.)* | Yes, go to 11.  No, but event resulted in reportable death or serious injury, go to 12.  No, go to 10. |
| 1. MDR report to the FDA is not required. | No FDA action required.  Go to 13. |
| 1. FDA action required, refer to SOP 1011. A 5-day MDR to the FDA is required (FDA MEDWATCH FORM 3500A)   {reportable5Applicable}Not applicable  5-Day Due Date: {reportable5DueDate} MDR #:{reportable5MDR} Person to file report: {reportable5Person} | |
| 1. FDA action required, refer to SOP 1011. A 30-day MDR to the FDA is required (FDA MEDWATCH FORM 3500A)   {reportable30Applicable}Not applicable  30-Day Due Date: {reportable30DueDate} MDR #:{reportable30MDR} Person to file report: {reportable30Person} | |

**Relevance to FDA (21 CFR Part 806.10)**

| If Reports of Corrections and Removals – 21 CFR 806.10, reportable to FDA (Yes or No) | {reportableFDA1} |
| --- | --- |
| Corrections and Removals required to be maintained but not required to be reported to FDA - 21 CFR 806.20 (Yes or No) | {reportableFDA2} |

**Relevance to European Community (EU MEDDEV 2.12-1 “GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM”: *note, ensure that latest revision is referred to*)**

| 1. Is the device available in the European Community?   *If yes, also refer to MEDDEV 2.12-1 Guidelines on a medical devices vigilance system”* | Yes, go to 14.  No, go to 16. |
| --- | --- |
| 1. Is the device considered an “Incident” defined as the potential for a death or serious deterioration in health should the incident recur? | Yes, go to 17.  No, go to 15. |
| 1. Is the event an Incident? Where “incident” is defined as any event related to any malfunction or deterioration in the characteristics and/ or performance of the device, as well as any inadequacy in the labeling or use which leads to a death or serious deterioration in health. | Yes, go to 17.  No, go to 16. |
| 1. An Incident Report to the Competent Authority is not required | No EU action required. Go to 18. |
| 1. EU action required. In general, the report should be made available to the National Competent Authority in the country of occurrence of the INCIDENT unless otherwise directed by the MEDDEV guidance 2.12-1. In addition, the authorized representative and certain notified bodies (i.e., their terms and conditions). In terms of timescales, the following must be considered:  * **Serious public health threat**: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by the MANUFACTURER of this threat. * **Death or UNANTICIPATED serious deterioration in state of health**: IMMEDIATELY (without any delay that could not be justified) after the MANUFACTURER established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event. * **Others**: IMMEDIATELY (without any delay that could not be justified) after the MANUFACTURER established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event. If after becoming aware of a potentially reportable INCIDENT there is still uncertainty about whether the event is reportable, the MANUFACTURER must submit a report within the timeframe required for that type of INCIDENT. All report times refer to when the National Competent Authority must first be notified. The relevant contact points are available from the Commission’s web site located in SOP 1011. | |

**COMPLAINT DETERMINATION IF REPORTABLE (Other geographies)**



Prepared By: {preparedByName} Position: {preparedByPosition} Date: {preparedByDate}