| Event Report. No.  ***{eventReportNumber}*** | Return Authorization No. if applicable: |
| --- | --- |

| **Information about the Hospital where the event occurred** | |
| --- | --- |
| Hospital name:     {hospitalName} | Clinician name:      {clinicianName} |
| Address:   {address} | |
| Country:   {country} | Had the staff completed training? ☐ Yes ☐ No ☐ N/A |

| **Information about the Event** | | | |
| --- | --- | --- | --- |
| Healthcare professional reporting event: | Name: | | Title: |
| Detailed information regarding the circumstances of the event:  \*Attach copies of all supplemental documentation to this report in English\* | | | |
| Date the event occurred: | | Does Physician allege event was caused by device? ☐ Yes ☐ No ☐ Unknown | |
| Was a governing body informed of event? ☐ Yes ☐ No ☐ Unknown | | | |

| **Patient Information\* *(****This information is confidential and protected will not be reported unless required for MDR or vigilance reporting by regulatory agencies)* | | | |
| --- | --- | --- | --- |
| **☐** 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: | Age: | Sex: | Weight: |
| Condition after event: | | | |
| Did the patient experience any adverse consequences due to this event? ☐ Yes ☐ No ☐ Unknown  \*Please describe: | | | |

| **Disposable Information** | | | (skip to next section if not applicable) | | |
| --- | --- | --- | --- | --- | --- |
| Did the event involve a sterile disposable item or kit? ☐ Yes ☐ No ☐ Unknown | | | | | |
| Product name/number: | | Lot number: | | Expiration date: | |
| Was a replacement disposable used? ☐ Yes ☐ No ☐ Unknown  If “Yes”: Include disposable name, product number & lot number: | | | | | |
| **Device Information** | | | (skip to next section if not applicable) | | |
| Did the event involve a ThermoChem Device? ☐ Yes ☐ No ☐ Unknown | | | | | |
| Device model number: | | Serial number: | | | |
| Device: *☐* Temporary Malfunction *☐* Other? | Device to be returned? ☐ Yes ☐ No. | | | | Reused? ☐ Yes ☐ No |
| Was a replacement device used?☐ Yes ☐ No ☐ Unknown  Replacement Device Information: Model number & serial number: | | | | | |
| **Component Information** | | | (skip if not applicable) | | |
| Did the event involve a reusable component? (Ex: temperature extension cable, water line…) ☐ Yes ☐ No ☐ Unknown | | | | | |
| Component name: | | Product number (if known): | | | |

| **Representative Reporting the Event Information** | |
| --- | --- |
| Rep’s Name: | Company Name: |
| Contact Information: | Was representative present during event? ☐ Yes ☐ No ☐ N/A |
| Event was communicated to representative via: ☐ telephone/text ☐ email/letter ☐ in person ☐ other: | |
| Date the event was reported to representative, if different than the date the event occurred: | |
| Date the event was reported to ThermaSolutions, if different than the date the event occurred: | |
| **Email to service@thermasolutions.com within 3 (three) business days to the ThermaSolutions** | |