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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SCN #** |  | | | | | | | | |
| **SECTION 1 – SUPPLIER INFORMATION**  **To be completed by Supplier and sent to: SupplierQuality@rtix.com** | | | | | | | | | | |
| Name of Organization: | | | | | | | Supplier SAP #:  (Filled by RTI Surgical, Inc.) | | | |
| Facility Location (Address): | | | | | | | | | | |
| Contact Name/Ph. #: | | | | | | | | Date: | | |
| **Description of Change** | | | | | | | | | | |
| **Change Type (check all that apply)** | | | | | | | | | | |
| **Type of Change**: | | | Material/Part Change  Location Change  Design Change | | | Mfg. Process Change  QMS Change  Labeling Change | | | Tooling Change  Pkg. Process Change | |
|  | | | Other – Describe: | | | Discontinuation – Describe: | | | | |
| Sterilization method?  EO  Radiation  Reusable  Other:        N/A | | | | | | | | | | |
| **Change Details (describe details of change)** | | | | | | | | | | |
|  | | | | | | | | | | |
| Attachments (check all that apply):  Material Spec(s)  SDS  Drawing(s)  Other: | | | | | | | | | | |
| **List of Parts/Services Affected** | | | | | | | | | | |
| **RTI Surgical SKU** | | **RTI Surgical Rev.** | | **Mfg. SKU** | **Description of Parts/Services Affected** | | | | | |
|  | |  | |  | Add/Remove lines as needed | | | | | |
|  | |  | |  | Add/Remove lines as needed | | | | | |
|  | |  | |  | Add/Remove lines as needed | | | | | |
|  | | | | | | | | | | |
| **Justification for Change** | | | | | | | | | | |
|  | | | | | | | | | | |
| **Plan for Implementation of the Change (Validation, Testing, Evaluation, etc.)** | | | | | | | | | | |
|  | | | | | | | | | | |
| **Cost/Lead Time/Inventory Impact** | | | | | | | | | | |
| Will this change impact unit cost and/or product lead time?  Yes  No, Explain: | | | | | | | | | | |
| **Preliminary Implementation Information** | | | | | | | | | | |
| Requested Implementation Date: | | | | | | Will Change be Phased In?  Yes  No | | | | |

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| **SCN #** | |  | | | | | |
| SECTION 2 – RTI Surgical, Inc. Response **To be completed by RTI Surgical, Inc. Supplier Quality and Cross Functional Team** | | | | | | | | |
| **Evaluation (Impact Assessment)** | | | | | | | | |
| Highest risk level associated with an affected part/service:  (Reference Document 8400 for guidance) | | | | | | | | |
| Does the change impact current RTI Surgical, Inc. specifications? | | | | Yes, Document #:  No | | | | |
| Is the change a Significant Change per Document 10840? | | | | Yes (New Part Number required)  No | | | | |
| Explain impact of change (Documentation, QMS, Process, Products, etc.) | | | | | | | | |
| SCN Classification:  Major  Minor  Negligible  (Reference Document 10748 and Document 11565 for guidance) | | | | | | | | |
| Preliminary Decision | | | | | | | | |
| Conditionally Approved (see rationale below)  Rejected (see rationale below) | | | | | | | | |
|  | | | | | | | | |
| Implementation Plan | | | | | | | | |
| Below, list all additional action items necessary to ensure this change does not produce any unintended affects. Examples to consider: | | | | | | | | |
| First Article Inspection (FAI) | | | Update Material Specification | | Product Testing (Validation) | | | |
| OEM Approval | | | Geographical Notifications | | Lab Testing (Biocompatibility, Sterility, Bioburden) | | | |
|  | | | | | | | | |
| # | Action Description | | | Owner(RTI Surgical / Supplier) | | Responsible Person | Proposed Date of Implementation | |
| 1 | Add/Remove lines as needed | | |  | |  |  | |
| 2 | Add/Remove lines as needed | | |  | |  |  | |
| 3 | Add/Remove lines as needed | | |  | |  |  | |
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| **SCN #** |  | | | | | | |
| SECTION 3 – RTI Surgical, Inc. Approval of Evaluation and Implementation Plan **To be completed by RTI Surgical, Inc. Supplier Quality and Cross Functional Team**  **[minimum of three (3) signatures needed for approval]** | | | | | | | | |
| Required | | | Department | Title | Name (Print) | Signature | Date | |
|  | | | Commercial |  |  |  |  | |
|  | | | Donor Services |  |  |  |  | |
|  | | | Donor Information |  |  |  |  | |
|  | | | Manufacturing Engineering |  |  |  |  | |
|  | | | Operations |  |  |  |  | |
|  | | | Purchasing |  |  |  |  | |
|  | | | Quality Engineering |  |  |  |  | |
|  | | | Quality Systems |  |  |  |  | |
|  | | | R&D |  |  |  |  | |
|  | | | Regulatory Affairs |  |  |  |  | |
|  | |  | | | | | | |
| SECTION 4 – Change Control Board Review and Evaluation **To be completed by RTI Surgical, Inc. Supplier Quality** | | | | | | | | | |
| Decision on further action | | | | No further action required. Further action required, but not subject to change control process.  Change control process necessary. | | | | | |
| Additional Actions Required | | | |  | | | | | |

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| SECTION 5 – Verification and Supplier Change Notification Closure **To be completed by RTI Surgical, Inc. Supplier Quality** | | |
| Executed Implementation Plan Verified | | |
| Supplier Change Notification Approved | | |
| Comments: | | |
| Completed by (sign and date): | | |
|  |  |