|  |  |
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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): |
|  |  |