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| **The purpose of this form is to collect information in order to assess scientific validity and relevance for Coloplast of your proposed study.**  **This form must be completed for studies, investigating performance and/or safety parameters (e.g. extent of leakage, change of skin characteristics, registration of skin reactions, change in quality of life, extent of bladder emptying, registration of urethral bleeding and pain, change in wound size and/or local wound pain, wear time).**  **Forms considered complete and qualified will be reviewed by the Study & Publication Board.** |

**Please submit to Study and Publication Board** [Study\_Publ\_Board@coloplast.com](mailto:Study_Publ_Board@coloplast.com)

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| **Requestor must submit the following documents or supporting information.**  **Requests submitted without these documents will not be reviewed and will be returned to the requestor:**   * **Signed and dated Study Proposal Form with all sections completed** * **Study protocol or synopsis, where relevant (see Section 2)** * **Investigator CV, signed and dated** * **Information about funding (see Section 5 for requirements)**   **Complete all sections relevant to your request.**  **Mark as N/A anything that is not applicable to your request.**  **Return the completed form and supporting documentation to the Study and Publication Board.** |

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| **Section 1. SITE INFORMATION** | |
| Investigator (Clinician) Name(s) |  |
| Institution or Practice Name |  |
| Institution Profile | Private Practice  Academic Center  Hospital System  Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| Section 2. STUDY DESCRIPTION  **Please include a study protocol or protocol synopsis with this submission.**  **Include, as applicable, but as a minimum:**   * **Study name** * **Hypothesis** * **Primary research objective** * **Patient population, inclusion/exclusion criteria** * **Number of patients with rationale for choice** * **Statistical considerations (eg. descriptive, superiority, non-inferiority etc.)** * **Primary/secondary study endpoints (include information on how endpoints will be defined and measured)** * **Comparison or control group** * **Study follow-up schedule** * **Enough detail to support/explain budget (see also Section 5)** |
| Coloplast product(s) concerned:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Type of Study (Check all that apply)   |  |  | | --- | --- | | Interventional |  | | Observational |  | | Multicenter | Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Case Series | Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **SECTION 3. PUBLICATION/PRESENTATION PLANS** | | |
|  | **Targeted Scientific Meeting(s)** | **Submission Deadline(s)** |
| Abstract(s) |  |  |
|  |  |
|  |  |
|  | **Targeted Journal(s)** | **Anticipated Time Frame** |
| Manuscript(s) |  |  |
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| Do you plan to register your study?    Yes      No  If Yes, please specify all that apply:     ClinicalTrials.gov           EU register           Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

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| **SECTION 4. KEY STUDY METRICS (Provide your best estimate)** | |
| Time of final protocol |  |
| Time of submission to Ethics committee/Institutional Review Board (IRB) |  |
| Study Start Date (first patient in) |  |
| Study End Date (last patient out) |  |

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| **SECTION 5. FINANCIAL OR OTHER SUPPORT REQUESTED** |
| Please check all that apply and specify activities and associated costs:  Suggested funding: Please provide proposed budget in a separate document.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Free product or other clinical trial materials funded by HQ to support study activities  E.g., devices, other materials, size(s), quantities requested.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **SECTION 6. Local Coloplast contact person** |
| |  |  | | --- | --- | | Name |  | | Title/function |  | | Email address |  | | Phone number |  | |