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| **Study Proposal Form** | | | | |
| Instructions: The purpose of this form is collect information in order to assess the scientific merit of the proposed study. Submissions that are considered complete and qualified will be reviewed by the Coloplast Investigator Initiated Study Committee. Please complete all sections that are relevant to your request, and return this form to **usdibe@coloplast.com**. | | | | |
| Investigator Name: | |  | | |
| Institution or Practice Name: | |  | | |
| Address: | |  | | |
| Phone: | |  | | |
| Email: | |  | | |
| STUDY DESCRIPTION  This section may be omitted if protocol or protocol synopsis is attached to submission | | | | |
| Coloplast Product Name(s) | | | | |
| Type of Study (Check all that apply) | | | | |
|  | Prospective | |  | Multicenter |
|  | Retrospective | |  | Cohort |
|  | Randomized | |  | Observational |
|  | Controlled | |  | Case Series |
| Primary Research Objective (What questions do you plan to answer through your study; what do you plan to explore or demonstrate) | | | | |
| Patient Population (List the key inclusion/exclusion criteria associated with the target patient population) | | | | |
| **Study Endpoint(s)** (Provide primary and secondary study endpoints) | | | | |
| **Comparison or Control Group** (If applicable) | | | | |
| **Subject Follow-up Visit Schedule** (For prospective studies, what is your anticipated follow-up timeline to assess outcomes/endpoints) | | | | |

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| **Statistical Analysis** (Indicate the test that will be applied for comparator group, if applicable) | | | | | | | |
|  | Not applicable | | | | | | |
|  | Superiority | | | | | | |
|  | Non-inferiority | | | | | | |
|  | Descriptive Comparison Only | | | | | | |
| **Comments/Additional Study Design Details** | | | | | | | |
| **KEY STUDY METRICS** | | | | | | | |
| Anticipated Study Start Date | |  | Anticipated Enrollment Duration | | |  | |
| Anticipated Study End Date | |  | Anticipated Sample Size | | |  | |
| Investigator PROFILE (Attach current copy of Curriculum Vitae with submission) | | | | | | | |
| Have you been trained on the use of the product(s) under study? | | | |  | Yes |  | No |
| Have you completed formal Good Clinical Practice (GCP) training? | | | |  | Yes |  | No |
| Have you been inspected by FDA (as a Principal Investigator) within the past 2 years? | | | |  | Yes |  | No |
| If yes, indicate the inspection results: | | | | | | | |
|  | No Findings | | | | | | |
|  | 483 Issued | | | | | | |
|  | Warning Letter Issued | | | | | | |

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| Financial and TechnicalSupport  (Requests for financial support are subject to Fair Market Value assessment)  \*If requesting full, partial or technical support funding, include anticipated budget with submission | | | | | | | | |
| Are you seeking financial and/or technical support from Coloplast for the proposed study? | | | |  | Yes |  | | No |
| If yes, please check all that apply:  *I plan to request…* | | | | | | | | |
|  | Full funding to pay for expenses that are directly related to study activities\* | | | | | | | |
|  | Partial funding to pay for expenses that are directly related to study activities\* | | | | | | | |
|  | Free product or other clinical trial materials to support study activities | | | | | | | |
|  | Technical support that is directly related to study activities (e.g. statistician)\* | | | | | | | |
|  | Data | | | | | | | |
| INSTITUTIONAL PROFILE | | | | | | | | |
| What type of Institutional Review Board (IRB) will be used for the study? | | | | | | | | |
|  | Local IRB/Name: | | | | | | | |
|  | Central IRB/Name: | | | | | | | |
| (IRB approval of your protocol will be required, if funding is approved) | | | | | | | | |
| Does your facility or institution maintain Standard Operation Procedures for the conduct of clinical research (i.e. procedures for obtaining informed consent)? | | | |  | Yes |  | No | |
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|  | | Print Investigator Name | Date | | | | | |
|  | | Investigator Signature | Date | | | | | |