Investigator Initiated Study Program (IISP)

Study Proposal Form

The purpose of this form is to collect information in order to assess scientific attributes of your proposed study.

- **Submissions considered complete and qualified will be reviewed by the Coloplast IISP Review Committee.**
- **For human subject studies, Coloplast device use must align with current approved labeling for the geographical location in which the study will be conducted, to be eligible for consideration.**
- **Ethics approval (e.g., Ethics Committee, Institutional Review Board, Institutional Animal Care and Use Committee), where relevant, will be required.**
- **Financial and product/materials/services support granted are subject to Fair Market Value assessment.**
- **In compliance with applicable state and federal laws, Coloplast will report under the Federal Physician Payments Sunshine Act the Fair Market Value of all grants, products, materials and services provided.**

Instructions:

- **Complete all sections relevant to your request. Mark as N/A anything that is not applicable to your study.**
- **Return the completed form to IISP@coloplast.com, with any required attachments (items in red, as relevant).**

Section I. SITE INFORMATION

Investigator Name	
Institution or Practice Name	
Institution Profile	☐ Private Practice ☐ Academic Center ☐ Hospital System ☐ Other (specify): _____
Address	
Phone	
Email	

Section II. STUDY DESCRIPTION

Please include a study protocol or protocol synopsis with this submission.

Include, as applicable, at a minimum:

- **Primary research objective**
- **Patient population, inclusion/exclusion criteria**
- **Primary/secondary study endpoints**
- **Comparison or control group**
- **Subject follow-up visit schedule (for human subject studies)**

Coloplast Product(s) (Check all that apply)

☐ Genesis	☐ Altis	☐ Restorelle DirectFix
☐ Titan/Titan Touch	☐ Aris	☐ Restorelle M/L/XL
☐ Torosa	☐ Axis	☐ Restorelle Y/Restorelle Y-Contour
☐ Tutoplast	☐ Supris	☐ Suspend
☐ Other: _____	☐ Other: _____	☐ Other: _____

Type of Study (Check all that apply)

☐ Prospective	☐ Multicenter	☐ Experimental Model
☐ Retrospective	☐ Cohort	☐ Record-based analysis
☐ Randomized	☐ Observational	☐ Other: _____
☐ Controlled	☐ Case Series	☐ Other: _____

Statistical Analysis (Indicate the test that will be applied for comparator group, if applicable)

☐ Superiority ☐ Non-inferiority ☐ Descriptive ☐ Other (specify):_____

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SECTION III. PUBLICATION/PRESENTATION PLANS		
	Targeted Meeting(s)	**Submission Deadline(s)**
☐ Abstract(s) to be submitted to scientific meeting(s)		
	Targeted Journal(s)	**Anticipated Time Frame**
☐ Manuscript(s) to be submitted to peer-reviewed journal(s)		

SECTION IV. KEY STUDY METRICS (Provide your best estimte for study milestones and metrics)			
Anticipated Study Start Date		Anticipated Enrollment Duration	
Anticipated Study End Date		Anticipated Sample Size	

SECTION V. INVESTIGATOR PROFILE

Please include a current copy of your Curriculum Vitae with this submission.

SECTION VI. FINANCIAL AND TECHNICAL SUPPORT

Please check all that apply:

☐ Funding to pay for expenses that are directly related to study activities **(include your anticipated budget)**

☐ Technical support that is directly related to study activities (e.g. statistician) **(include estimated amount of time technical support will require)**

☐ Free product or other clinical trial materials to support study activities **(include enough detail to allow calculation of Fair Market Value, e.g., device or other materials, size(s), quantity needed)**

☐ None

SECTION VII. IISP RESEARCH AGREEMENT INFORMATION

Investigator Initiated Research Agreements are typically milestone-based, and structured as follows:

- Study start-up costs (e.g., IRB fees, database/supplies/equipment)
- Interim milestones (e.g., patient enrollment/data collection/analysis)
- Study completion (e.g. abstract/manuscript submission)

List all parties who, pending approval of this proposal, would be named to the research agreement:

☐ Investigator Name_____ Title_____
Name_____ Title_____
Name_____ Title_____

☐ Institution Name_____ Title_____

☐ Other Name_____ Title_____

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SECTION VIII. SIGNATURE
Investigator Name (print or type)
Signature Date