Investigator-Initiated Study (IIS) Proposal

General Information	
Cordis Product Line:	☐ Cardiology ☐ Endovascular
Application Type:	☐ New ☐ Amendment
Study Title:	
Principal Investigator / Sponsor	
Principal Investigator (PI):	PI Name:
PI Contact Information: (phone, address, institution, email)	Name: Institution: Address: Country: Phone: E-mail: @ .
Primary Site Contact (if different from PI above)	Name: Address: Country: Phone: E-mail: @ .
Institution/ Organization type:	☐ Academic ☐ Government ☐ Other (please specify):
Additional Personnel	
Additional Personnel (sub-Investigators, study coordinator, etc.)	Name: Role: Name: Role: Name: Role:

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	Name: Role:
Are additional Institutions involved?	☐ Yes ☐ No If Yes, Number of sites: If Yes, Indicate Site Name and Location (city, state, country):
<u>Study Design</u>	
Study Type/ Design:	☐ Retrospective ☐ Prospective ☐ Registry ☐ Randomized study ☐ Non-Randomized study ☐ In vitro study ☐ Pre-clinical
Procedure/ Indication	
Total Number of Subjects	
<u>Study Timeline</u>	
Estimated Study Duration/ Timelines:	Contract Execution to First Subject In: months Enrollment Period (first subject in to last subject in): months Follow-up Period (last subject in to last subject out): months Last subject out to Final Study Report: months Total Study Duration: Target Start Date: Target Completion Date: Target Date for Analysis Completion: Is an Interim Analysis Planned? ☐ Yes ☐ No If Yes, target date of Analysis Completion:
<u>Study Synopsis</u>	
Background / Rationale	

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Study Objectives:	Aim(s) of the study _____ Primary Endpoint(s) _____ Secondary Endpoint(s) _____ _____ _____ Patient Safety _____
Study Design	
Inclusion Criteria	
Exclusion Criteria	
Treatment/ Experiment Groups:	
Sample Size per Group:	
Procedure / Intervention Description	
Statistical Method, Assumptions and Rationale	
Support Request	
Support Request Type	☐ Funding ☐ Product ☐ Funding & Product
Budget Outline (provide line item detail):	Total Support Requested: $ Budget Outline:
Requested Product:	Product Type: Quantity :
Which type of devices relevant to the procedure detailed in this study proposal do you currently use?	

Do you have a financial or proprietary interest in these products?	
Number of procedures relevant to this proposal that have been performed at your Institution	In the past 12 months During an average month
<u>Preliminary Publication Plan</u>	
Target Publication Type (publication, presentation, other):	
Target Journal / Meeting	
<u>Institutional Review Board / Ethics Committee</u>	
Does your Institution have a local IRB / EC?	☐ Yes ☐ No If yes, please provide IRB/EC Name: Chairperson: Address: Phone Number:
How frequently does the IRB/EC meet?	
Any anticipated problems with the IRB/EC?	☐ Yes ☐ No If Yes, explain:
<u>Research Experience</u>	
Have you conducted clinical research?	☐ Yes ☐ No
Have you been a Principal Investigator in a trial?	☐ Yes ☐ No
Have you published on a trial for which you were the Principal Investigator?	☐ Yes ☐ No
Are you currently participating in, or due to commence participation in a competing trial?	☐ Yes ☐ No
Have you participated in similar studies before?	☐ Yes ☐ No

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Study Management	
Is a study coordinator available at your Institution/ office?	☐ Yes ☐ No If Yes, does the coordinator speak English: ☐ Yes ☐ No
Who negotiates your study budgets?	
Please list any business affiliations, potential collaborators, and/or sources of funding for this study.	
Attachments	
Please provide Curriculum Vitae	Please provide as an attachment
Please provide a copy of your Medical License	Please provide as an attachment

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I understand and agree that this Investigator-Initiated Study Proposal will be considered by Cordis only under the terms and conditions set forth below and further agree that these terms and conditions shall also apply to any previous or future disclosures made by me which relate to the Investigator-Initiated Study Proposal described herein.

As used below, the words “the company” refer to Cordis US Corp.

1. The company does not solicit suggestions, and all submissions or disclosures of ideas are voluntary on the part of the submitter. No confidential relationship is established or implied by the company’s acceptance or consideration of the submitted material.

2. All suggestions will be submitted in writing and the company shall have the right to retain any material submitted to it in connection with the suggestion.

3. Ideas which are not covered by a patent should be considered by the company only with the understanding that the use to be made of such ideas and the compensation, if any, are matters resting solely in the discretion of the company.

4. Patented ideas shall be considered only with the understanding that the submitter agrees to rely for his/ her protection wholly on such rights as he/ she may have under the patent laws. Pending applications for a patent are to be treated in the same manner as ideas not covered by a patent, as described in paragraph 3, above, unless and until a patent issues.

5. The company shall not be obligated to give reasons for its decision or to reveal its past or present activities relating to the submitted idea. Negotiating or offering to purchase an idea will not prejudice the company nor be deemed an admission of the novelty, priority or originality of the idea.

I represent and warrant to you that, except as noted herein, the material disclosed is wholly original with me; that no interest has been granted to or acquired by others; and that I have full authority to make the disclosure and to execute this release.

Name:

Signature: _____

Date: _____