

The purpose of this form is to collect information to evaluate the scientific merit of the proposed study. Submissions will be reviewed by the Aesculap Investigator-Initiated Study Review Committee. To save the changes made to this form, please first download by saving it to your desktop. Questions should be directed to Medical Scientific Affairs at 1-800-258-1946.

Complete forms and supporting documentation should be submitted to Aesculap Medical Scientific Affairs utilizing one of the following submission methods:

E-Mail to: research.us@aesculap.com

Fax to: (484) 821-9018

Mail to: Aesculap, Inc.

ATTN: Medical Scientific Affairs
3773 Corporate Parkway
Center Valley, PA 18034

1. CONTACT INFORMATION

Investigator Name:	
Institution or Practice Name:	
Address:	
Phone:	
Email:	
Study Coordinator Name:	
Phone:	
Email:	
Sub-Investigator(s):	<input type="checkbox"/> N/A

2. STUDY PROPOSAL

Complete protocol is attached to submission. (Skip Section 2)

Proposed Study Title:				
Study Device(s):				
Control Device(s):	<input type="checkbox"/> N/A – Uncontrolled			
Indication:				
Study Design (select all that apply):	<input type="checkbox"/> Prospective <input type="checkbox"/> Retrospective <input type="checkbox"/> Bench and/or pre-clinical <input type="checkbox"/> Other: _____	<input type="checkbox"/> Randomized <input type="checkbox"/> Controlled <input type="checkbox"/> Observational	<input type="checkbox"/> Single Center <input type="checkbox"/> Multi-Center: # of sites: ____ List Countries: _____ _____ _____	<input type="checkbox"/> Cohort <input type="checkbox"/> Case Series

<p>Research Objective/Rationale:</p> <p>Provide a detailed description of the aims and objectives of the study, including scientific rationale.</p>		
<p>Key Inclusion/Exclusion Criteria:</p> <p>Associated with the target patient population</p>		
<p>Study Endpoint(s):</p> <p>Provide Primary and Secondary (if applicable) Endpoints</p>		
<p>Subject Follow-up Visit Schedule:</p> <p>Provide the anticipated follow-up schedule including purpose, number, and frequency of study visits.</p>		
<p>Statistical Analysis:</p>	<p><input type="checkbox"/> N/A <input type="checkbox"/> Superiority <input type="checkbox"/> Non-inferiority <input type="checkbox"/> Descriptive Comparison</p> <p>Additional Study Design Details:</p>	
<p>Key Study Metrics:</p>	<p>Anticipated Start Date:</p>	<p>Anticipated End Date:</p>
	<p>Anticipated Sample Size:</p>	<p>Anticipated Enrollment Duration:</p>

3. INSTITUTION PROFILE

Where is the research taking place?	<input type="checkbox"/> Hospital <input type="checkbox"/> Private Practice <input type="checkbox"/> Other, specify: _____
Research Institution Name:	_____
Address:	_____
Phone:	_____
Institutional Review Board (IRB):	<input type="checkbox"/> Central IRB/Name: _____ <input type="checkbox"/> Local IRB/Name: _____
Additional Facility Approvals Necessary:	List all that apply: _____
Are the necessary resources available to oversee and support the study at institution?	<input type="checkbox"/> Yes <input type="checkbox"/> No

4. REQUESTED SUPPORT AND ANTICIPATED OUTPUT

Support: 1) A breakdown of all costs will be requested for study approval. 2) All costs are subject to Fair Market Value assessment.	<input type="checkbox"/> Financial Support Anticipated Budget: \$ _____
Anticipated Output:	<input type="checkbox"/> Manuscript <input type="checkbox"/> White Paper <input type="checkbox"/> Abstract <input type="checkbox"/> Poster Presentation <input type="checkbox"/> Other, please specify: _____ Target: _____ Timeframe: _____

4. DOCUMENT SUBMISSION CHECKLIST

Signed/Dated Curriculum Vitae (CV) Attached? (required)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Full Protocol Attached? (optional)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Itemized Study Budget Attached? (optional)	<input type="checkbox"/> Yes <input type="checkbox"/> No

By typing my name in the field below, I hereby certify that the information provided above and/or attached is complete and accurate to the best of my knowledge; that approval of this request for funding by Aesculap is not guaranteed and; that any amount awarded be tied to contractual obligations in written agreement.

Principal Investigator Signature