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| **Complete Sections 1.0 – 12.0 to create the Protocol for Submission.** | | |
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| **Section 1.0: Protocol Background** | | |
| * 1. **Full Protocol Title** | Click here to enter text. | |
| * 1. **Version and Date** | Click here to enter text. | |
| * 1. **Principal Investigator** | Click here to enter text. | |
| * 1. **Institution and Address** | Click here to enter text. | |
| * 1. **Sub-Investigators (if applicable)** | Click here to enter text. | |
| * 1. **Multi-center Institutions and Address (if applicable)** | Click here to enter text. | |
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| **Section 2.0: Statement of Compliance** | | |
| * 1. **Include a statement that the study will be conducted in accordance with specific provisions of the associated IRB/IECs, and in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable national and regional regulatory requirement(s)** | Click here to enter text. | |
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| **Section 3.0: Background Information and Scientific Rationale** | | |
| * 1. **Identification and description of the study product and its intended purpose** | Click here to enter text. | |
| * 1. **Description of the intervention and/or procedures for which the study product is intended** | Click here to enter text. | |
| * 1. **Description of the populations and indications for which the study product is intended** | Click here to enter text. | |
| * 1. **A summary of relevant previous pre-clinical and clinical studies (as applicable)** | Click here to enter text. | |
| * 1. **A summary of potential risks and benefits (including steps that will be taken to control or mitigate risks)** | Click here to enter text. | |
| * 1. **References to literature and data that are relevant to the study and that provide background for the study** | Click here to enter text. | |
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| **Section 4.0: Study Objectives/Design** | | |
| * 1. **Describe the purpose of the study** | Click here to enter text. | |
| * 1. **Primary Objective** | Click here to enter text. | |
| * 1. **Secondary Objective** | Click here to enter text. | |
| * 1. **Exploratory Objective** | Click here to enter text. | |
| * 1. **Rationale for selection of endpoints** | Click here to enter text. | |
| * 1. **Describe the hypothesis (i.e. non-inferiority or superiority)** | Click here to enter text. | |
| * 1. **Describe the design of the control group used (i.e. type, prospective, historic), if any** | Click here to enter text. | |
| * 1. **Describe the expected duration of subject participation, targeted enrollment duration along with sequence and duration of all study periods, including follow up** | Click here to enter text. | |
| * 1. **Describe measures to be taken to minimize or avoid bias on the part of subjects, investigators, and analysts including randomization, if applicable. Include process of the randomization procedures** | Click here to enter text. | |
| * 1. **Describe “stopping rules” or “discontinuation criteria” for individual subjects, parts of study, and entire study** | Click here to enter text. | |
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| **Section 5.0: Study Population** | | |
| Describe the population to be studied | | |
| * 1. **As appropriate, include background discussion/details on prevalence, for example: sex/race specific prevalence considerations, diagnosis, treatment patterns, and patients currently undergoing procedure regardless of study participation** | Click here to enter text. | |
| * 1. **List inclusion and exclusion criteria. Include characteristics of subjects by age, sex, and condition.** | Click here to enter text. | |
| * 1. **Describe withdrawal criteria and procedure(s), and procedures for replacement of subjects** | Click here to enter text. | |
| * 1. **Describe the number of investigational sites and number of subjects. Include the minimum and maximum number of subjects to be included from each center in a multi-center study** | Click here to enter text. | |
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| **Section 6.0: Study Procedures and Methodology** | | |
| * 1. **List key materials/devices required to execute the study (i.e. device, fixation, grafting material, sutures, neuromonitoring)** | Click here to enter text. | |
| * 1. **Describe the study/surgical procedure and approach** | Click here to enter text. | |
| * 1. **Describe all clinical observations/evaluations, medical history assessments, radiographic assessments, patient reported outcomes as applicable** | Click here to enter text. | |
| * 1. **Attach Study Calendar to capture section timepoints/visits** | See example  IIS Study Calendar\* | Check box to indicate Study Calendar is attached: |
| * 1. **Document criteria for radiographic assessment (i.e. fusion criteria, subsidence) and who will conduct the assessment (i.e. radiologist, 2 independent surgeons)** | Click here to enter text. | |
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| **Section 7.0: Assessment of Safety** | | |
| Safety parameters should be clearly outlined in this section. As appropriate for the study, state applicable definitions. | | |
| * 1. **Describe the management and reporting of device and procedure related Adverse Events (AEs) and safety data** | Click here to enter text. | |
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| **Section 8.0: Methods of Quality Control** | | |
| * 1. **A general outline of the methods of quality control of data should be outlined here** | Click here to enter text. | |
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| **Section 9.0: Statistical Methodology** | | |
| Include a description of the analyses which will be performed including planned analyses when applicable (i.e. 12 months planned analysis), safety assessment, and the final analysis plan. | | |
| * 1. **Provide a description of how the sample size for the study was determined. If appropriate, show sample size derivations and/or statistical power estimates for each appropriate endpoint, and estimate the overall power for successfully meeting all endpoints. This section may include a statement about the number of sites and/or the number of subjects at each site** | Click here to enter text. | |
| * 1. **Expected drop-out rates** | Click here to enter text. | |
| * 1. **Provisions for planned analyses** | Click here to enter text. | |
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| **Section 10.0: Ethics/Protection of Human Subjects** | | |
| * 1. **State the requirement to obtain IRB/IEC approval prior to execution of the protocol and IRB documentation required or provided rationale** | Click here to enter text. | |
| * 1. **Describe the general requirements for obtaining informed consent, including providing subjects with new information as needed.** | Click here to enter text. | |
| * 1. **State that a copy of the protocol, informed consent forms, and other information to be completed by participants, such as survey instruments or questionnaires, and any proposed advertising or recruitment materials will be submitted to the IRB/IECs for written approval. Additionally, the investigator must submit and obtain approval from the IRB/IEC for all subsequent amendments to the protocol, informed consent documents, and other study documentation referenced above.** | Click here to enter text. | |
| * 1. **Describe methods used to protect subject confidentiality** | Click here to enter text. | |
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| **Section 11.0: Data Handling and Record Keeping** | | |
| General procedures for data management should be included within the protocol | | |
| * 1. **Describe data management procedures, where the data will be stored, from example, data collection (specify whether via electronic data capture or paper records), data handling, review, electronic data systems verification/validation, and data retention** |  | |
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| **Section 12.0: Scientific References** | | |
| **List references as applicable to the background and scientific principles of the study** | | |
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**APPENDIX**

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| **Please mark X below (as appropriate)** | **IIS Study Calendar – JMP** |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Procedure | Pre-op | Surgery | Discharge | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 |
| Informed Consent |  |  |  |  |  |  |  |  |
| Demographics |  |  |  |  |  |  |  |  |
| Medical History |  |  |  |  |  |  |  |  |
| Physical Exam |  |  |  |  |  |  |  |  |
| Device / Procedure Related Adverse Events |  |  |  |  |  |  |  |  |
| Surgical Details |  |  |  |  |  |  |  |  |
| Patient Reported Questionnaires |  |  |  |  |  |  |  |  |
| X-ray |  |  |  |  |  |  |  |  |
| MRI |  |  |  |  |  |  |  |  |
| CT |  |  |  |  |  |  |  |  |
| Add additional info below  (if applicable) |  |  |  |  |  |  |  |  |
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