

Investigator Brochure (IB) For Medical Device Study

1. General

- a) Introduction
- b) Identification of the IB
 - 1. Name of the investigation device.
 - 2. Document reference number, if any.
 - 3. Version or date of the IB.
 - 4. Confidentiality statement, if appropriate.
 - 5. Summary of the revision history in the case of amendments, if appropriate.
 - 6. A version/issue number reference number, if any, with the page number and the total number of pages on each page of the IB.
- c) Sponsor/Manufacturer

2. Investigational device information

- a) Summary of the literature and evaluation supporting the rationale for the design and intended use of the investigational device.
- b) Statement concerning the regulatory classification of the investigational device, if relevant.
- c) General description of the investigational device and its components including materials used.
- d) Summary of relevant manufacturing processes and related validation processes.
- e) Description of the mechanism of action of the investigational device, along with supporting scientific literature.
- f) Manufacturer's instructions for installation and use of the investigational device, including any necessary storage and handling requirements, preparation of use and any intended re-use (e.g. sterilization), any pre-use safety or performance checks and any precautions to be taken after use (e.g. disposal), if relevant.
- g) Description of the intended clinical performance.

3. Pre-clinical testing

Summary of the preclinical testing that has been performed on the investigational device, together with an evaluation of the results of such testing justifying its use in human subjects.

The summary shall include or, where applicable, refer to the results of

- a) design calculations,
- b) in vitro tests,
- c) mechanical and electrical tests,
- d) reliability tests,
- e) validation of software related to the function of the device,
- f) any performance tests,
- g) ex vivo tests,
- h) an evaluation of biological safety

Note: Guideline on the biological evaluation of medical device is given in ISO 10993-1

4. Existing clinical data



- a) Summary of relevant previous experience with the investigational device and with medical devices that have similar characteristics, including such characteristics relate to other indications for use of the investigational device.
- b) Analyze of adverse device effects and any history of modification or recall.

5. Risk management

- 5.a.1. Summary of the risk analysis, including identification of residual risks.
- 5.a.2. Result of risk assessment.
- 5.a.3. Anticipated risks, contra-indications, warnings, etc. for the investigational device.

6. Regulatory and other references

- 6.a.1. List of International Standards, if any, complied with in full or in part.
- 6.a.2. Statement of conformity with national regulations, where appropriated.
- 6.a.3. List of references, if relevant.