Test Protocol for Medical Devices

Template Provided by Element Materials Technology

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Approvals	Name	Signature	Date
R&D Engineer			
Test Engineer			
Management			

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1. Scope

The scope of this study applies to [Company Name] [Device Name] [type of] testing.
Briefly describe what the study entails and which device the test protocol is for.

2. Purpose

The purpose of this study is to define the test methods used to demonstrate the [Property] of the finished [Device Name] product when [Specify Conditions].
Describe the objective of the test and the data that will be used, give background information, and describe the device.

Figure 1: Device Drawing

3. Reference Documents

Reference all applicable and relevant internal and external documents: standards (e.g., ASTM, ISO, etc.), regulatory guidance documents, journal articles, drawings, design specifications, test reports, and standard operating procedures. If testing will be performed per a specific standard, clearly state which standard should be followed. You may also attach that document to the test protocol for direct reference.

Table 1: Reference Documents

Reference Document Number	Source	Title
xx-xxxx-xxx	Company Name	Drawing
	Company Name	Design specification
	Company Name	Previous or referenced test report
	Company Name	Standard operating procedure
	ASTM	Standard
	ISO	Standard
	FDA	Guidance document
	JAMA	Journal article

4. Test Samples

This section should include the following subsections:

- *Sample Identification*
- *Sample Size and Rationale*
- *Sample Traceability or unique project specific identification*
- *Worst Case Analysis*

Identify the size range of all applicable devices and highlight why the selected size is the worst case. If FEA was used, a screenshot of the model and the corresponding rationale is helpful. Define confidence and reliability levels if necessary, controls, reference samples, predicate samples, etc.

Identify preparation requirements for the samples. For example: samples tested will be finished devices in accordance with standard manufacturing practices. All components will be manufactured, inspected, and sterilized and will be considered suitable for clinical use.

Table 2: Description of samples to be tested

Item	Quantity	Item Name	Lot #	Description
1				
2				
3				

5. Materials and Equipment

The following materials and equipment are required:

List all materials and equipment that will be used for testing (include data sheets that you would like filled out if internal documents exist). Describe where testing will be performed, internal lab or outsourced. For major testing equipment, fill out the table below. Show pictures of major test equipment, critical materials, or test fixtures. Any relevant drawings or the test schematic should be added here as well.

Table 3: Equipment Information

Equipment Description	Equipment Model No or Serial No	Calibration Due Date

Figure 2: Equipment & Fixtures

6. Methods

Describe in detail the test methods that will be used. Reference any previous studies or test reports to ensure repeatability. If using a test standard, review the procedure language and replicate to ensure compliance. If performing custom testing, try to replicate similar wording and adapt to your test. Specify the requirements and provide the rationale for any deviations from recommended testing.

Provide details on all applicable items:

- *Specimen preparation including preconditioning*
- *Test conditions – loading rates, frequency, etc.*
- *Test duration – time, cycle count, etc.*
- *Environmental conditions – ambient, 0.9% saline at 37°C, etc.*
- *Test setup (include figures/images/drawings)*
- *Testing procedure (see table)*
- *Inspections (see table)*
- *Data sampling frequencies*
- *Sample disposal plan*
- *Fatigue testing load selection parameters or flowchart*

Table 4: Example Pre-test Operations

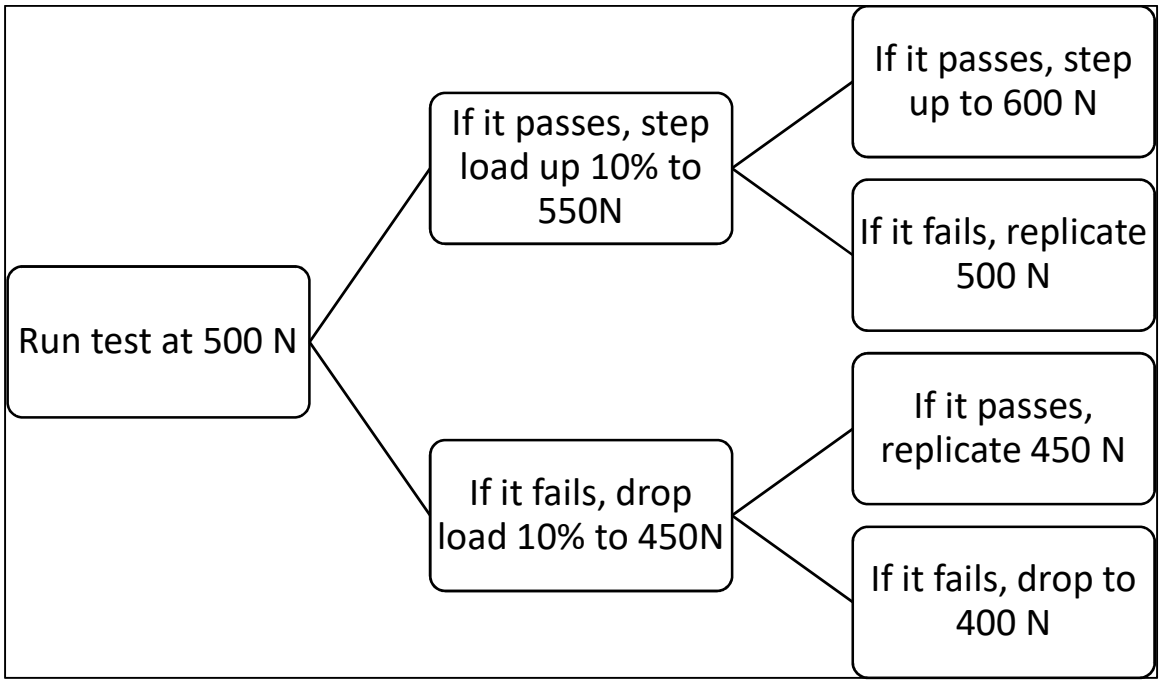
Test	Requirement ID	Requirement Summary	Test Strategy
Visual Inspection	TBD	Device shall be inspected visually and meet all inspection requirements.	Inspection criteria x, y, z are met and device can be tested.
Mass Analysis	TBD	Weigh device in accordance with TBD	Record pretest mass for comparison to post-test mass
Conditioning	TBD	Precondition at 50% ±5% Humidity and 22°C ±3° at ambient conditions for 24 hours	Confirm sample conditioning completion

Table 5: Example Test Method Procedure

Step	Action
01	Install sample into test frame
02	Align in accordance with figure x
03	Bring load applicator to approximately 0.1mm from contact
04	Start loading in displacement control at 0.1mm/sec
05	Observe for visual deformation and audible noise, record observations
06	Perform test until 5mm of displacement or ultimate force is reached
07	Remove and photograph specimen
08	Repeat

Table 6: Example Inspection Schedule

Inspection Interval	Inspection Frequency	Inspection/Test	Action
Pre-test	Single	Visual inspection	Discard sample if defects are detected
	Single	Microscopic inspection (10x magnification)	Discard sample if defects are detected
Test setup	Single	Device deployment inspection	Confirm parameters x, y, and z are met
	Single	Device mounting	Confirm parameters x, y, and z are met
	Single	Test equipment	Perform test in accordance with quality procedures
During testing	Daily, weekly, etc.	Endoscopic inspection (10x)	Observe for cracks or failures
	Every x number of cycles	Visual inspection	Observe for cracks or failures
Post-test	Single	Visual inspection	Record any observed surface deformities
	Single	Functional inspection	Confirm function of device



Example load selection flow chart for fatigue parameters

7. Acceptance Criteria

Outline the acceptance criteria and rationale for acceptance criteria, such as relevant regulatory requirements, product specifications, clinical inputs, prior data, predicate data, modeling inputs (e.g., finite element analysis), etc. Include definitions of pass/fail if applicable.

8. Exception or Deviation Conditions

Any exceptions, changes, or modifications to this test protocol shall be noted in the final test report.

9. Data Analysis and Documentation Requirements

A test report will be written documenting test results, analysis of results, discussion and conclusions drawn from the test results. *Specify how data will be analyzed and any statistical methods that will be used. The test may be a pass/fail test that requires no data analysis. Request raw data and images to be saved if needed. Specify the information and data that will be included in the test report. If using ASTM methodology, replicate the reporting section to align.*

10.References

Create bibliography of all pertinent references.

11.Revision History

Revision No.	Revision Description	Approved By	ECN #	Effective Date