Test report

with validation data supplement

AC-161-20230503-Part-1-of-1
Date: May 03, 20230503
Rev. 000

Materials

- Dummy Model

Methods

- ASTM F2077-22 Spinal spacer axial compression (static)

Software build

Alfonso™ 20230503-1730

Customer

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Testing laboratory note: Reproductions of this test report shall be in full, unless with prior written approval by Lifespans. Results from this test report pertain only to the article(s) tested.

Background and objectives

ASTM F2077-22 is a standard test method used to evaluate the performance of non-biologic intervertebral body fusion devices (e.g., under FDA product code MAX, 21 CFR §888.3080) designed to promote arthrodesis or fusion at a given spinal motion segment. It is typically part of a battery of tests required to demonstrate that a study device is substantially equivalent to a legally marketed predicate device in a 510(k) premarket submission. Alfonso's particle-based model of ASTM F2077-22 can be used to quickly predict the likelihood that a candidate design will perform sufficiently without needing to produce and test a physical prototype.

Materials

The speed of sound c of each device material was calculated to set a theoretical upper bound of rate of motion for simulation according to the following equation (Eq. 1):

$$c = \sqrt{\frac{\left(K_f + \frac{4}{3}G_f\right)}{\rho}}$$

Where for each device material, K_f is the bulk modulus, G_f is the shear modulus, and ρ is the density (kg/m^3) of the material.

Table 1. Test devices and specifications provided by the customer

ID	Device description
1	Dummy Device 1 Filename: Dummy Device 1.stl Received: 20230502 SHA256SUM: 185bd5d958bd9103f40ea956f84445f57c9bf8080b61a95c55c9ccb031a7b2c7 • Intervertebral disc level: Lumbar • Intradiscal height (up to 20 mm to the nearest 200 μm): 7 • Implant lordosis angle (up to 80 degrees to the nearest 0.5 deg): 6 • Maximum pocket depth (up to 10 mm to the nearest 200 μm): 2 • Implant material elastic modulus in (GPa, default for Ti6Al4V = 104.8): 104.8 • Implant material tensile strength, yield (MPa, default for Ti6Al4V = 827): 827 • Implant material elongation at break (%, default for Ti6Al4V = 15): 15 • Implant material Poisson's ratio (default for Ti6Al4V = 0.342): 0.342 • Implant material speed of sound (m/s, calculated via Eq. 1) : 6059
1	Dummy Device 2 Filename: Dummy Device 2.stl Received: 20230502 SHA256SUM: ee9697554f880c73fee36e98f5fb0e8b9560c90c12bf0277ee5d383af028bb04 • Intervertebral disc level: Lumbar • Intradiscal height (up to 20 mm to the nearest 200 μm): 8 • Implant lordosis angle (up to 80 degrees to the nearest 0.5 deg): 6 • Maximum pocket depth (up to 10 mm to the nearest 200 μm): 2 • Implant material elastic modulus in (GPa, default for Ti6Al4V = 104.8): 104.8 • Implant material tensile strength, yield (MPa, default for Ti6Al4V = 827): 827 • Implant material elongation at break (%, default for Ti6Al4V = 15): 15 • Implant material Poisson's ratio (default for Ti6Al4V = 0.342): 0.342 • Implant material speed of sound (m/s, calculated via Eq. 1) : 6059

Methods

The published ASTM F2077-22 standard for static axial compression was used as a reference to construct a particle-based test setup in **Alfonso™**.[1] An illustration of the standard physical testing setup is shown in Figure 1 below.

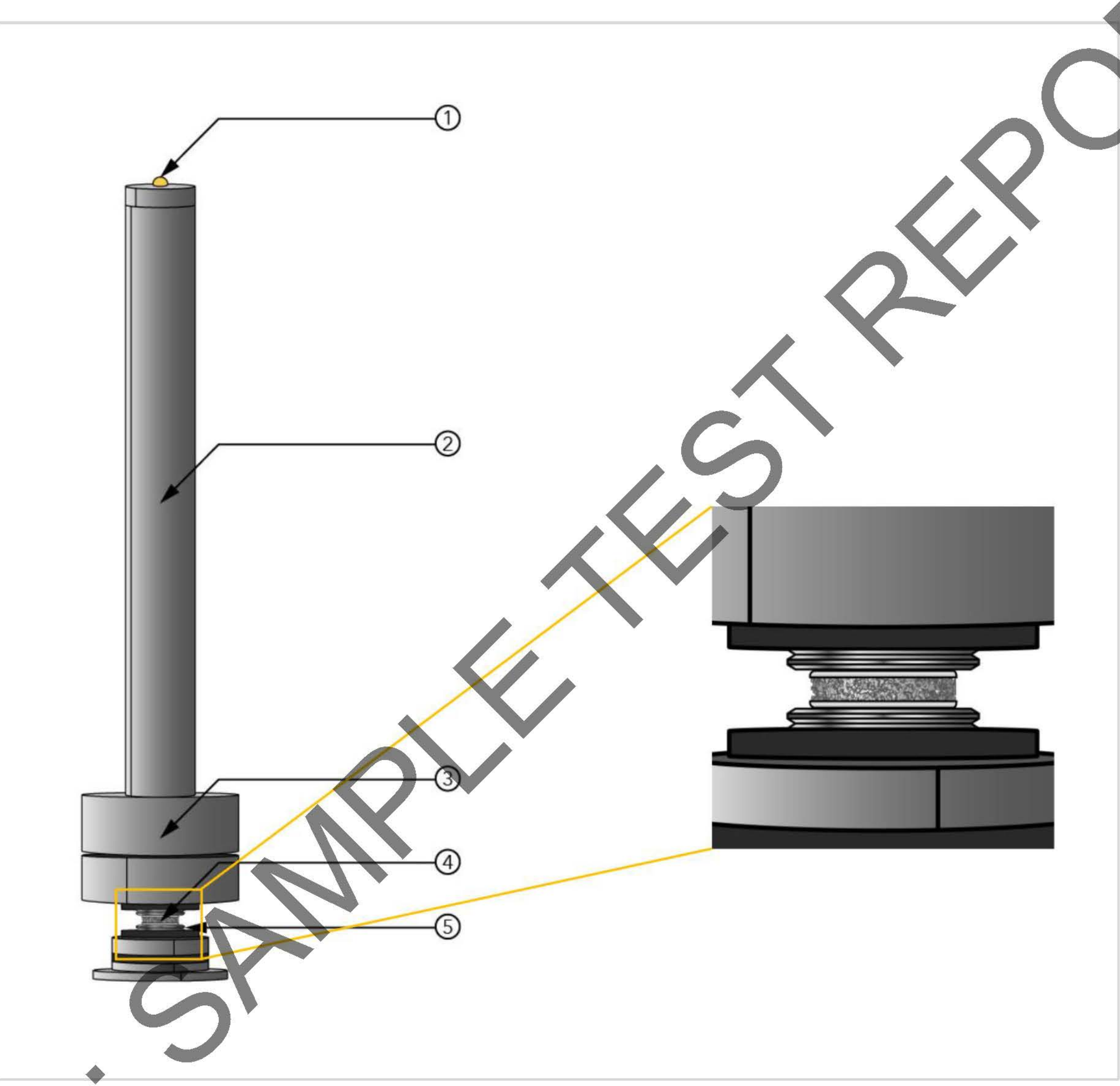

Figure 1. Example of a physical test setup: 1. Ball and socket bearing, 2. Metal pushrod, 3. Spherical bearing, 4. Implant, 5. Steel test block. Illustration by Eka Tjong

Preparation of the simulated testing model

Stereolithography models of the device(s) were provided by the customer and used to generate surface models of two conformal rigid testing blocks (Figure 2). These models were developed into particle-based models in Alfonso at a resolution of 182 µm per particle (see Figure 3 and [2] for further detail). A sensitivity analysis was conducted to determine the maximum uniaxial compression rate (5 m/s), below which there was no observable change in the force-displacement curve. This rate was also much less than the calculated speed of sound of the implant material (Table 1). Simulated static axial compression tests were then performed at this rate for all samples. Deviations between the simulated testing protocols and the published ASTM F2077-22 standard are summarized in Table 2. Note that models in Alfonso™ do not typically simulate the strain-rate dependent viscoelastic behaviors of materials for static tests; as physical static benchtop tests are usually conducted at very low rates of motion, we consider strain-rate components to be negligible.

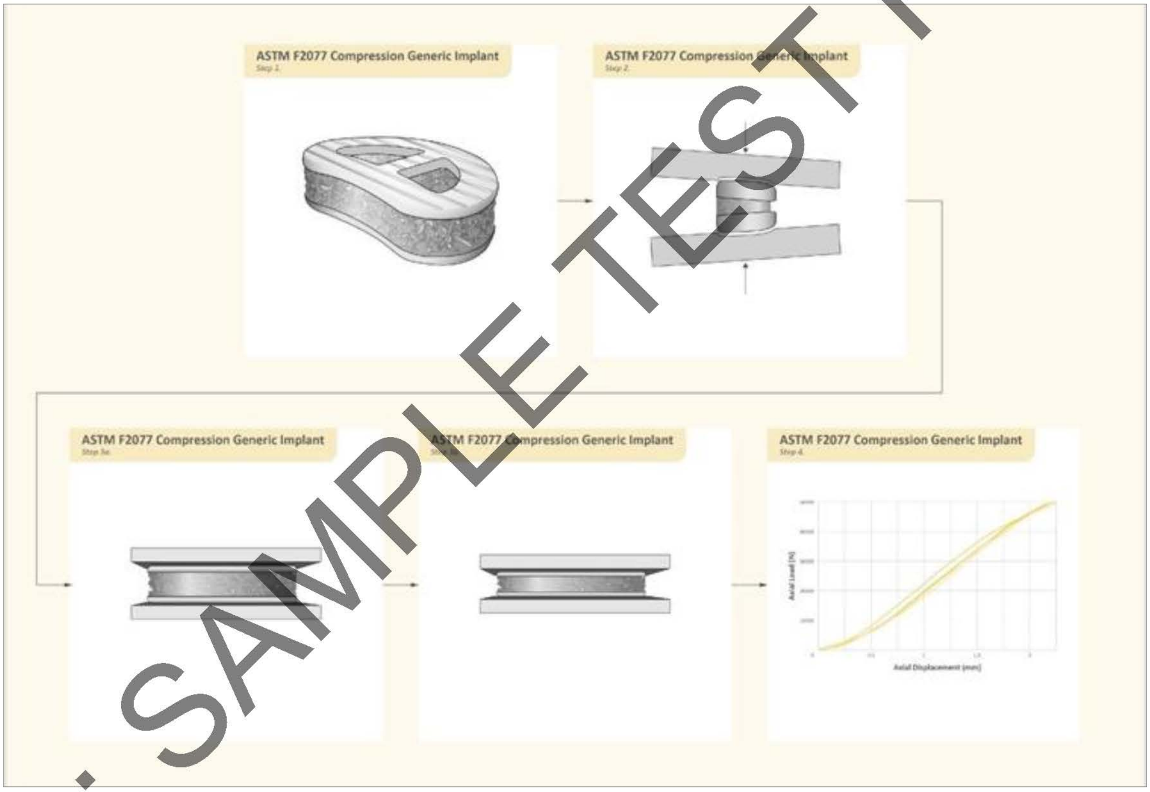

Figure 2. *Illustration of the overall ASTM F2077-22 static axial compression test simulation procedure in Alfonso™ Illustration by Eka Tjong*

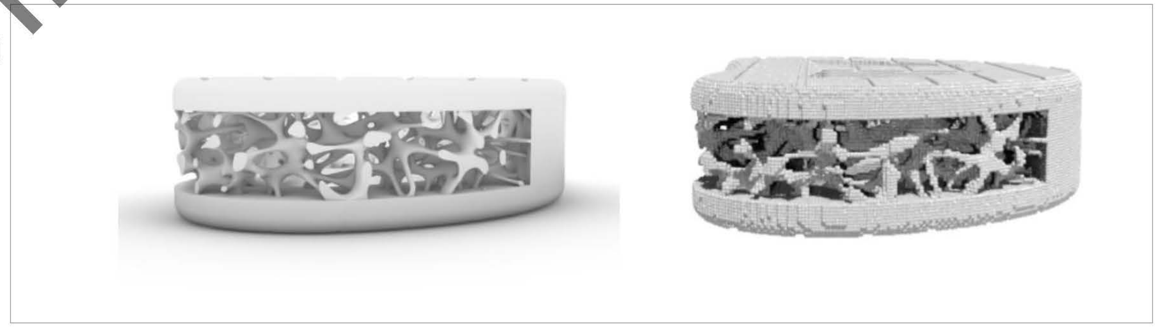

Figure 3. *Example STL to 182 µm particle model conversion for a representative 3D-printed spinal spacer device*

Table 2. Deviations between standard and simulated models

Test Setup Procedures / Parameters		**ASTM F2077-22 Static axial compression standard method**	**Simulation**
Test setup procedures	Load fixture	(1) Ball and socket joint; (2) Stainless-steel hollow pushrod D25 mm with one 25 mm radius concave spherical end, and other end having ball and socket joint. The length of the pushrod between the center of the ball-and-socket joint to the center of the spherical surface is to be a minimum of 38 cm; (3) Superior fixture with stainless steel sphere's diameter of at least 50 mm truncated to locate center at geometric center of intervertebral device	Load fixture was not simulated. For devices with a lordosis angle, the virtual superior and inferior test blocks are angled to match the lordosis angle.
	Load application	The actuator of the testing machine is connected to the pushrod by a minimal friction ball-and-socket joint or universal joint (that is, unconstrained in bending). The pushrod is connected to the superior fixture by a minimal friction sphere joint (that is, unconstrained in bending and torsion). The hollow pushrod should be of minimal weight to be considered as a "two-force" member. It thus applies to the intervertebral body fusion device assembly a resultant force directed along the pushrod's axis and located at the center of the superior fixture's sphere joint (the geometric center of the device being tested).	Virtual superior test block axially compressed the device at a specified rate of displacement. The joints were not modeled in the simulations.
	Metal block	Two metal blocks as superior and inferior fixtures. The blocks are to have surfaces that mate geometrically within the intervertebral device similar to how the device is intended to mate with vertebral end plates. The metal blocks may be reused if undamaged.	Two virtual rigid metal blocks as superior and inferior fixtures. For each device, two virtual metal blocks were generated with the pockets matching the cage's outer geometry with a maximum pocket depth as specified by the customer (Table 1). The same virtual metal blocks were used across all specimens of the same size.

Table 2. Deviations between standard and simulated models (continued)

Test Setup Procedures / Parameters		ASTM F2077-22 Static axial compression standard method	Simulation
	Initial intradiscal height	The straight-line distance along the *Z* axis between the unaltered simulated vertebral bodies. Shall be determined from vertebral body and disc morphometric data at the intended level of application. The intradiscal height should not reach zero before the onset of functional or mechanical failure. The user of this test method should select the intradiscal height that is appropriate for the device being tested. The initial intradiscal height shall be constant for all tests for an intervertebral body fusion device assembly of a given size.	Specified by the customer (Table 1)
	Sample size	Usually, n=5 minimum per case	n=1 per device
Parameters	Axial compression rate	No greater than 25 mm/min	5 m/s
	Data collection time interval	Not mentioned; suitable to continuously record load versus load fixture displacement	1 x 10^{-9} s
	Type of data	Load-displacement data, which will be used to calculate the yield displacement (mm), stiffness (N/mm), yield load (N), ultimate displacement (mm), and ultimate load (N).	Follows the ASTM F2077-22 standard
	End point	The load-displacement data is generated until functional or mechanical failure of the intervertebral body fusion device assembly is obtained.	Follows the ASTM F2077-22 standard
	Resolution (specific to simulation)	Not applicable	182 μm

The stiffness, yield load, yield displacement, ultimate load, and ultimate displacement were determined using the following method. A linear regression line was fitted to the initial linear portion of the load-displacement curve and the slope of this line was calculated as the stiffness of the device (K_d). The linear regression line was shifted by an offset displacement of 2% of the intradiscal height. The intersection of the offset linear regression line and the load-displacement curve determined the yield point. The ultimate load is the maximum load of the load-displacement curve.

Table 3. Parameters for calculating the results

ID	Device name	Range of force where stiffness is calculated (N)	Offset displacement (mm)
1	Dummy Device 1	8,000 to 18,000 N	0.25
2	Dummy Device 2	8,000 to 18,000 N	0.25

Results

Simulated test results for the device(s) provided by the customer are as follows:

(Note: **Click below to play the video** in the PowerPoint version of this test report)

*Simulations were conducted using a commercial, US FDA-cleared intervertebral body spinal fusion device; animation above is of a similar dummy device

Figure 4. *Video (top) and load-displacement graph (bottom) for static axial compression simulation ID 1.*

GRAPH

Figure 5. *Load-displacement graph for static axial compression simulation of specimen ID 1 with stiffness line, 2% offset line, yield load/displacement marker, and ultimate load/displacement marker.*

Table 4. Results of the static axial compression simulation(s)

ID	Device name	Stiffness, K_d (N/mm)	Yield load (N)	Yield displacement (mm)	Ultimate load (N)	Ultimate displacement (mm)
1	DEVICE_NAME	STIFFNESS	YIELD_LOAD	YIELD_DISPL	ULT_LOAD	ULT_DISPL
2	DEVICE_NAME	STIFFNESS	YIELD_LOAD	YIELD_DISPL	ULT_LOAD	ULT_DISPL

IMAGE OF FAILURE MODE

Figure 6. *Representative image showing the failure mode during the static axial compression simulation of specimen ID 1.*

The failure mode of specimen ID 1 was [DESCRIBE FAILURE MODE].

Conclusion

The devices were tested using an adapted form of ASTM F2077-22 static axial compression as particle-based models in Alfonso™, with resulting load-displacement curves and visualizations of the compression process recorded. The device with the highest stiffness was DEVICE_NAME, with a value of DEVICE_STIFFNESS. The device with the highest yield load was DEVICE_NAME, with a value of DEVICE_YIELD at DEVICE_YIELD_DISPLACEMENT.

References

[1] ASTM Standard F2077-22, 2022, "Standard Test Methods for Intervertebral Body Fusion Devices," ASTM International, West Conshohocken, PA, 2022,www.astm.org

[2] J. Oentaryo, R. Tharim, S. Kulper, and E. A. Ueda Boles, 'Validation of ASTM F2077 models in Alfonso™:Uniaxial compression of titanium spinal spacers', 2023, www.lifespans.net

Appendix A:

Notes on particle-based polyurethane foam models in *Alfonso*™

- Models of solid rigid polyurethane foam in Alfonso™ are generated with a randomized distribution of pores designed to mimic the generally isotropic structure of the physical material.
- Micro-CT scans of the corresponding physical materials for each foam grade are used as reference to ensure faithful reproduction of the true material structure.
- A review of the literature suggests that coarse model resolutions lead to stiffening when simulating porous compressible solids like bone or foam, though the effect size appears to decrease with porosity.[A. J. C. Ladd and J. H. Kinney, 'Numerical errors and uncertainties in finite-element modeling of trabecular bone', 1998.] To compensate for this effect, an iterative process is used to determine the appropriate material properties required for each simulated foam model to converge with the properties of the physical specimens, given the resolution used in each study.
- Using the stated material properties from the manufacturer as a starting point, a proprietary formula based on porosity is applied uniformly to the modulus, yield, and ultimate strength of each foam grade.
- In general, we do not scale material density (i.e., mass) in *Alfonso*™.
- "Resolution" (e.g., 50, 200, 500 µm) in *Alfonso*™ is typically equivalent to the diameter of the particles in the model, and thereby the minimum distance within which particles begin to interact. The degree of interaction between particles varies continuously as a function of their distance (e.g., in compression, particles repel more vigorously the closer they are to one another, while the reverse is true for tensile forces acting between "bonded" particles of the same object).
- Each particle represents a small volume of mass of an object in the analysis, the material properties of which (elastic modulus, yield, failure, hardening criteria, etc.) dictate the responses of particles to forces applied during analysis.
- While the initial positions of particles are typically spaced in discrete increments of the resolution (e.g., 200 µm), during analysis particles may continuously move in 3D space. For instance, a particle initially at (200, 200, 200) may move to (200.0034, 199.793403, 202.09809823462) during analysis.
- "Bonds" between particles in *Alfonso*™ are typically formed only at the initial time state, and then only between neighboring particles of the same object. Bonded particles resist both compression and tension, per the homogeneous or heterogenous properties of the material, until the stress or strain failure limits of the material are exceeded, and a crack is formed. Failed particles remain in analysis (e.g., as debris) and continue to interact with other particles, allowing phenomena such as compaction to be faithfully reproduced in *Alfonso*™.
- "Unbonded" particles that come into contact after analysis has begun (i.e., particles that move to within the minimum distance of interaction) will not form bonds and will only repel one another.
- (See [2] and "Beyond FEA: Particle-based simulation 101" at https://www.lifespans.net/publications for further discussion of the basics of mesh-free analysis)

Appendix B: Validation data supplement

(See attached whitepaper in the PDF version of this test report)