Validation

Validation has been performed using device with outer diameter between 8 and and 10 mm. Please see the **Validation Whitepaper (PDF)** for a thorough description of the validation process and resulting data.

A full list of Alfonso publications can be found at **https://www.lifespans.net/publications**

Assumptions

The following **apply to our standard fixed-cost simulation model only.** We have built **custom tests** that overcome all of the limitations below; please contact us for an affordable quotation.

- **Resolution**
  In order to balance accuracy with cost of computation, we have limited our standard fixed-cost simulation model to a resolution of 200 μm/particle (see Fig 1 at right). This resolution is sufficient to reproduce the pull-out performance of many typical screws. Please note, however, that implant features smaller than 200 μm will be discarded during the STL to particle model conversion process.

- **Surface texture**
  We assume a smooth, machined surfaces by default for all implant surfaces. Surface textures with detail smaller than 200 μm are discarded.

- **Implant material**
  Implants are assumed to be rigid bodies in our standard simulation model.

- **Viscoelasticity**
  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 low rates of motion, we consider strain-rate components negligible.

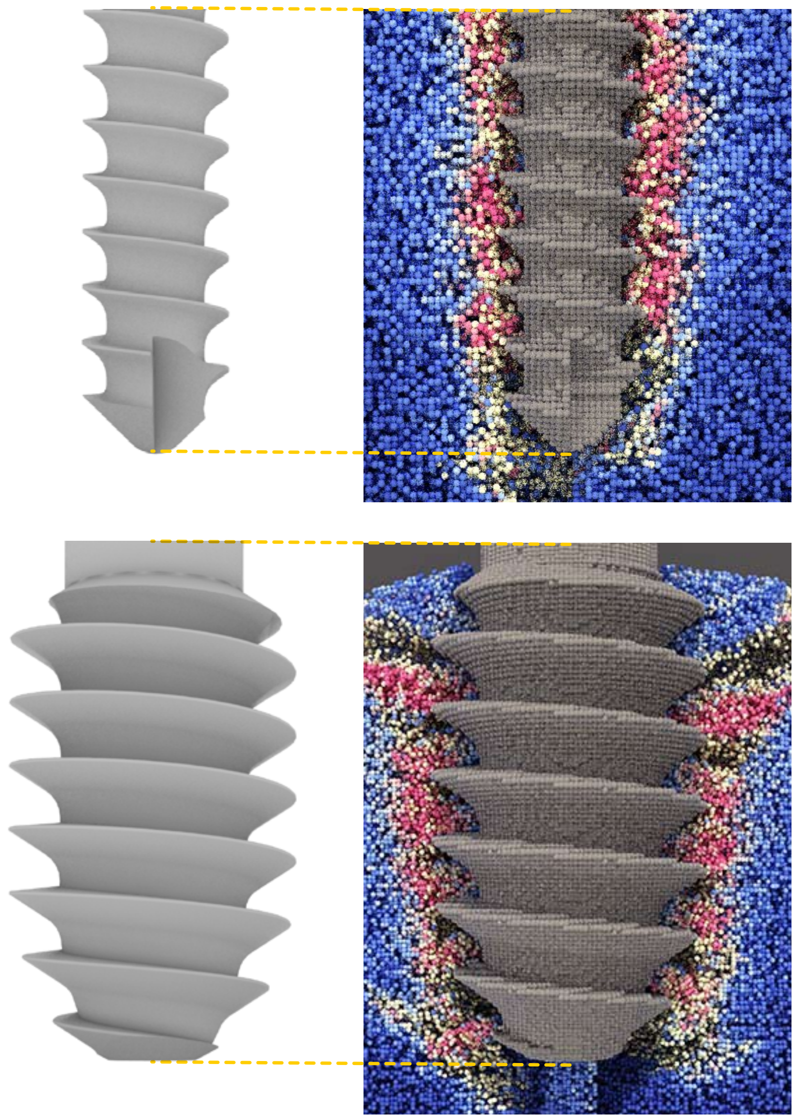

Figure 1. Example STL to 200 μm particle model conversion for screws with 4.5 mm (top) and 12.5 mm (bottom) diameters

- **Symmetry across YZ-plane**
  To reduce simulation costs we compute half of the simulation problem space (split across the YZ plane) and double the recorded pull-out force values. See P.3 of this document or our **Quick Start Guide**. If you have a highly asymmetric device, please contact us for a quotation.

Deviations from the ASTM standard

The table below provides a complete lists of the deviations from the ASTM standard of the physical and simulated tests conducted during development of our model. Please see the **Validation Whitepaper (PDF)** for a thorough description of the validation process and resulting data.

Table 1. Deviations between physical and simulated testing protocols and the published ASTM standard

Test Setup Procedures / Parameters		ASTM F1264-16 $^{\varepsilon 1}$ A1 Static four-point bend method	Physical test	Simulation
Test setup procedures	Spans and sizes of the rollers	For long, small-diameter, solid section IMFDs, smaller rollers and spans are adequate to measure the bending of the IMFD. Meanwhile, for hollow and open-section IMFDs, long spans and large-diameter rollers will minimize local artifacts at the load and support point as much as possible. Loading rollers should be the rolling type.	Follows the ASTM F1264-16 $^{\varepsilon 1}$ A1 standard to determine the spans and diameters of the rollers	Same spans and diameters of the rollers as the physical tests. Loading cylinders do not roll.
	Span between the two support rollers (L)	100 to 500 mm	156 mm	156 mm
	Span between the loading rollers (c)	No greater than L/3 Up to 167 mm	52 mm	52 mm
	Span from a load roller to the nearest support roller (s)	33 to 250 mm	52 mm	52 mm
	Diameter of the rollers	10 to 26 mm	12 mm	12 mm
	Load application	Equal loads are applied at each of the loading points (typically, a single load centered over the load points as shown in Error! Reference source not found.)	Follows the ASTM F1264-16 $^{\varepsilon 1}$ A1 standard	Follows the ASTM F1264-16 $^{\varepsilon 1}$ A1 standard
	Sample size	Usually, n=3 minimum per design	n=5 per design	n=1 per design
Parameters	Axial compression rate	No greater than 1 mm/s	0.1 mm/s	2.5 m/s
	Data collection time interval	Not mentioned; suitable to continuously record load versus load fixture displacement	Not mentioned	1×10^{-9} s

Deviations from the ASTM standard (continued)

Table 1. Deviations between physical and simulated testing protocols and the published ASTM standard

Test Setup Procedures / Parameters		ASTM F1264-16 $^{\varepsilon 1}$ A1 Static four-point bend method	Physical test	Simulation
	Type of data	Load–displacement data, which will be used to calculate the bending stiffness (N/mm) (the slope of the linear elastic region), 0.2% yield load (N), yield displacement (mm), bending moment to yield (Nm), and bending structural stiffness (Nm^2), mode of failure	Follows the ASTM F1264-16 $^{\varepsilon 1}$ A1 standard	Follows the ASTM F1264-16 $^{\varepsilon 1}$ A1 standard
	End point	Not mentioned	The load–displacement data are generated until the machine limit is reached or upon functional or mechanical failure of the intramedullary nail.	Up to the maximum displacement from the physical test
	Resolution (specific to simulation)	Not applicable	Not applicable	200 µm