

# Biomechanical Testing of the LDR ROI-A<sup>®</sup> ALIF Cage



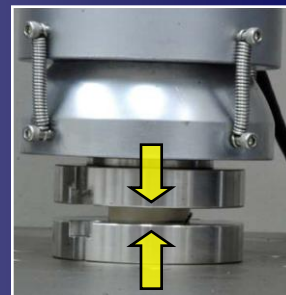
## Compression Testing

Testing per American Society for Testing and Materials (ASTM) Standard F2077-03, "Test Methods for Intervertebral Body Fusion Devices," conducted at Empirical Testing Corporation, Colorado Springs, Colorado.

Six ROI-A devices were tested in static axial compression to measure the 2% offset yield load (N) and peak load (N). The failure modes were also recorded. The static axial compression tests were conducted in displacement control at a rate of 0.2 mm/sec, collecting load and displacement data, until the device experienced a permanent deformation or gross failure occurred. The yield load is defined as the load above which the implant is permanently deformed. The peak load is defined as the highest load attained during the testing. All specimens experienced failure by anterior buckling. There were no unanticipated failure modes.

Subsequent dynamic axial compression testing was performed to 5 million cycles with no observed failure.

✓ The ROI-A survived compression loads greater than those that are expected to occur *in vivo*.



Yield Load:  
**22,704 N (5,104 lbs)**

Peak Load:  
**24,908 N (5,600 lbs)**



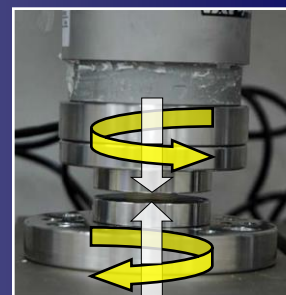
## Torsion Testing

Testing per ASTM Standard F2077-03, "Test Methods for Intervertebral Body Fusion Devices," conducted at Empirical Testing Corporation, Colorado Springs, Colorado.

Six ROI-A devices were tested in static torsion to measure yield torque (N-m) and peak torque (N-m). The failure modes were also recorded. The static torsion tests were conducted with a static axial compression preload of 500 N, in angular displacement control at a rate of 1°/sec, collecting torque and angular displacement data, until the device experienced a permanent deformation or reached approximately 90° of angular displacement. The yield torque is defined as the torque above which the implant is permanently deformed. The peak torque is defined as the highest value attained during the testing. All specimens experienced failure by the specimen permanently deforming. There were no unanticipated failure modes.

Subsequent dynamic torsion testing was performed to 5 million cycles with no observed failure.

✓ The ROI-A survived torsion loads greater than those that are expected to occur *in vivo*.



Yield Torque:  
**37.2 N-m (329 in-lbs)**

Peak Torque:  
**47.7 N-m (422 in-lbs)**



## Expulsion Testing

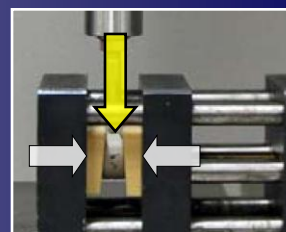
Testing per ASTM Draft Standard F-04.25.02.02, "Static Push-out Test Method for Intervertebral Body Fusion Devices," conducted at Empirical Testing Corporation, Colorado Springs, Colorado.

Six ROI-A devices were tested in static expulsion to measure the peak load to resist expulsion (N). The test blocks were Grade 15 (15 lb density per ASTM F1839) polyurethane foam. An axial preload of 450 N was placed on the device, then the device and fixtures were rotated 90° to test the expulsion resistance, as shown. A spherical point load was used to push against the device from posterior to anterior. The peak load is defined as the highest value attained during the testing.

The expulsion testing was repeated with six additional ROI-A devices with the VerteBRIDGE<sup>®</sup> Plating installed.

✓ The ROI-A resisted expulsion loads greater than those that are expected to occur *in vivo*.

**117% improvement in expulsion resistance with the VerteBRIDGE Plating installed.**



Peak expulsion load:

Implant alone  
**345 N (77.6 lbs)**

with VerteBRIDGE Plating  
**748 N (168.1 lbs)**