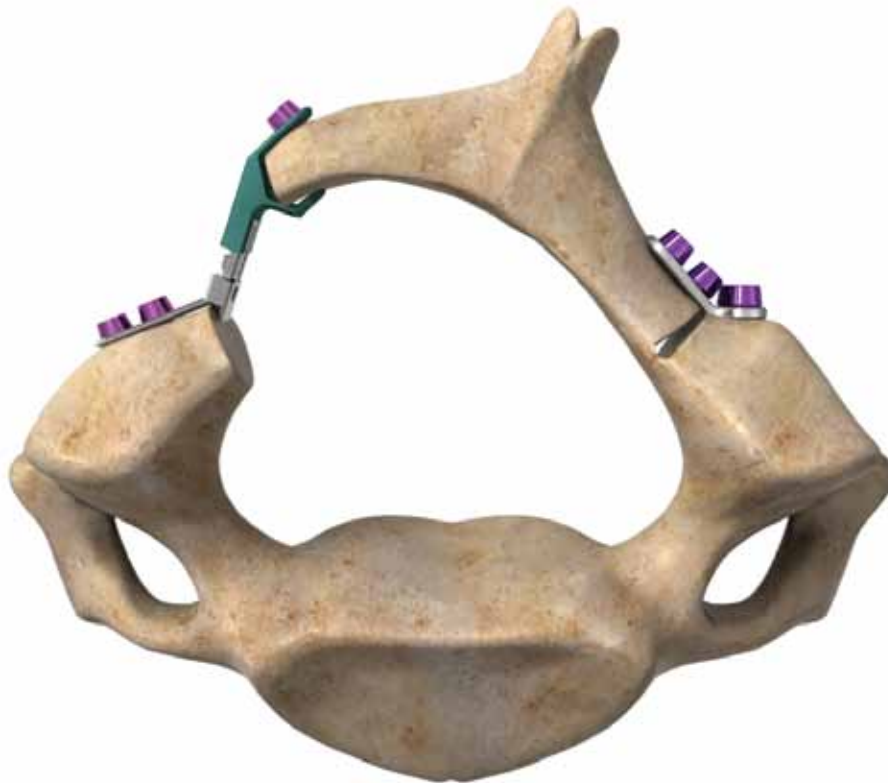


Escalate™ Laminoplasty System

Technical Monograph

- Streamlined efficiency
- Engineered for safety
- Control through expansion



System Overview



The Escalate Laminoplasty System is a comprehensive set of implants and instruments designed for a systematic approach to cervical laminoplasty procedures. The system features an

Expandable Laminoplasty Plate, a Base Laminoplasty Plate, Bone Screws for fixation, and a set of instruments to assist in implantation and removal of the device, if necessary.

Mechanical Testing

The Escalate Laminoplasty System provides a means by which the lamina may be opened to relieve cervical stenosis using a unique expandable plate. Escalate was designed to prevent lamina collapse.

The Escalate System was shown to be mechanically relevant in a series of tests designed to challenge its structural integrity. The Escalate System was compared to laminoplasty systems from Medtronic and Synthes. All systems were tested in accordance with the applicable ASTM standards.

Table of Contents

Prevention of Laminar Collapse	4
Prevention of Bone Screw Pullout	5

Prevention of Laminal Collapse

1. Design Challenge:

To design an implant that can adjust to a variety of heights and have enough strength to resist compressive loads.

2. Design Solution (Figure 1):

The triangular reinforced neck design of the Escalate Laminoplasty Plate is designed with increased rigidity of the mouth and greater lamina support. This feature was incorporated with consideration to the importance of maintaining an open lamina following the laminoplasty procedure.

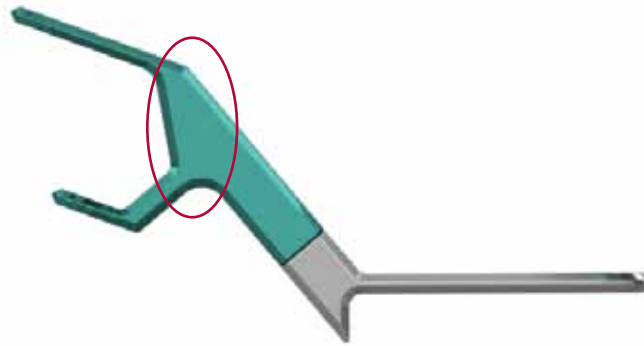


Figure 1
Escalate Laminoplasty Plate

3. Method (Figure 2):

The Laminoplasty Expandable Plate was expanded 12mm and its lateral mass and lamina mouth ends were attached to blocks of UHMWPE block. The lateral mass end UHMWPE block was pinned securely to a metal block and the metal block secured to the bottom of the test frame. A compressive load was applied at a rate of 10mm/minute until failure.

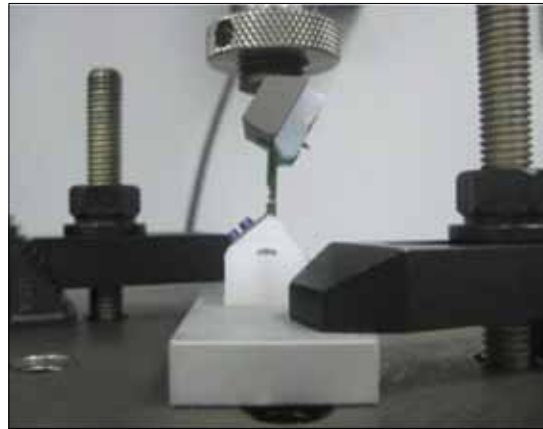


Figure 2
Escalate System Compressive Strength Testing Set-Up

4. Results (Figure 3):

- All values were normalized against the competitive component, denoted by 100%.^{*}
- The Escalate System was found to be 115% stronger in plate compressive strength than the Medtronic Lateral Hole Plate system.[†]

5. Conclusion:

The Escalate Plate was found to be more supportive than the comparable Medtronic plate when submitted to compressive loads.

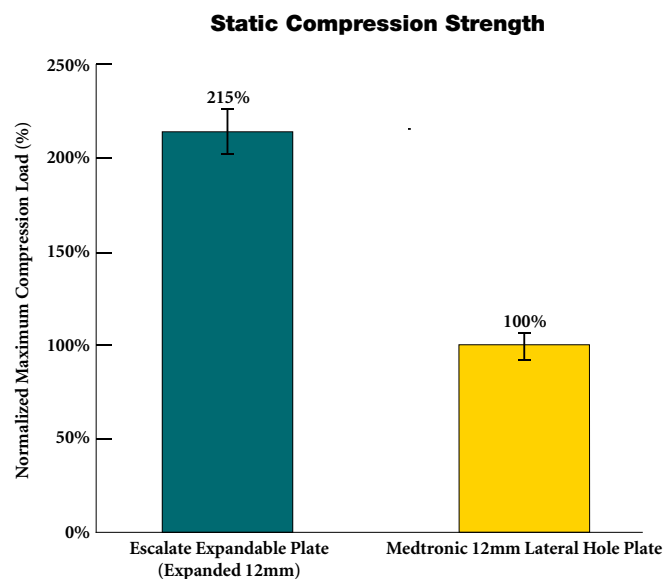


Figure 3
Laminoplasty Plate Compressive Strength

Data on file at Stryker Spine.

^{*}Report #: TREP0000025958

[†]Report #: TREP0000025961

Prevention of Bone Screw Pullout

1. Design Challenge:

To design a screw that is low profile and has the ability to resist pull out.

2. Design Solution:

By incorporating the well-known buttress thread design and promoting an environment that maximizes bone thread engagement, the Escalate bone screw is designed to increase resistance to implant backout and remain firmly in the lamina.

3. Method (Figure 4):

Testing followed ASTM F543-07 “Standard Specification and Test Methods for Metallic Medical Bone Screws.” Ø2mm self drilling bone screws were inserted into 20 pcf foam a depth of 5mm. A tensile load was applied to the bone screw at a rate of 5mm/minute until the screw released from the foam block.

4. Results (Figure 5):

- All values were normalized against the competitive component, denoted by 100%.*
- The Escalate bone screw was found to be 39.4% stronger than the Synthes ARCH bone screw.†

5. Conclusion:

Escalate withstood higher loads than the comparable Synthes screw when submitted to this force.

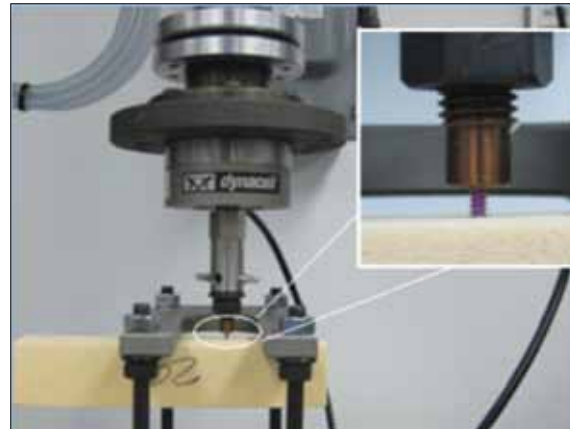


Figure 4
Escalate System Axial Pull Out Testing Set-Up

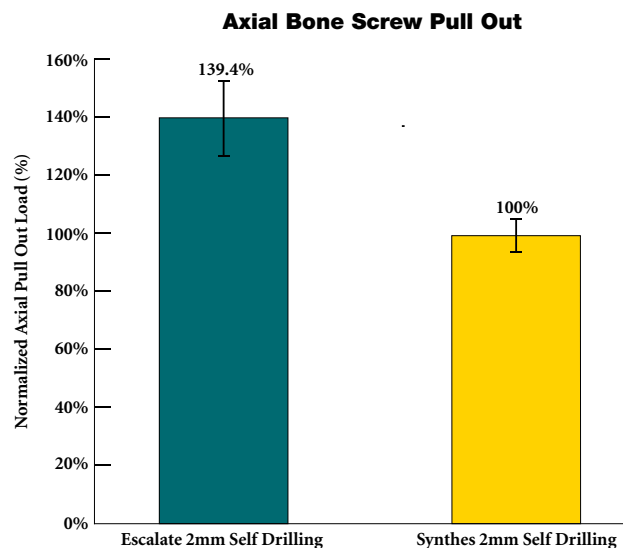


Figure 5
Axial Bone Screw Pull Out Resistance

Data on file at Stryker Spine.
*Report #: TREP0000025799
†Report #: TREP0000025894

Final Summary

The test results show that the mechanical strength of the Escalate Laminoplasty System exceeded the mechanical strength of the Medtronic and Synthes systems respectively when tested under the same conditions for:

Prevention of Laminar Collapse

Prevention of Bone Screw Pullout

Reconstructive

Hips
Knees
Trauma & Extremities
Foot & Ankle
Joint Preservation
Orthobiologics & Biosurgery

MedSurg

Power Tools & Surgical Accessories
Computer Assisted Surgery
Endoscopic Surgical Solutions
Integrated Communications
Beds, Stretchers & EMS
Reprocessing & Remanufacturing

Neurotechnology & Spine

Craniomaxillofacial
Interventional Spine
Neurosurgical, Spine & ENT
Neurovascular
Spinal Implants

US Operations

2 Pearl Court
Allendale, New Jersey 07401
Phone: +1 201 760 8000
Fax: +1 201 760 8108
Web: www.stryker.com

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: Escalate™, Stryker®. All other trademarks are trademarks of their respective owners or holders.

Literature Number: CVESCBR12090_US
SC/GS 10/12

Copyright © 2012 Stryker
Printed in USA