

## TECHNICAL BRIEF – TRUSS IMPLANT TECHNOLOGY EVALUATION OF FUSION

### QUICK FACTS

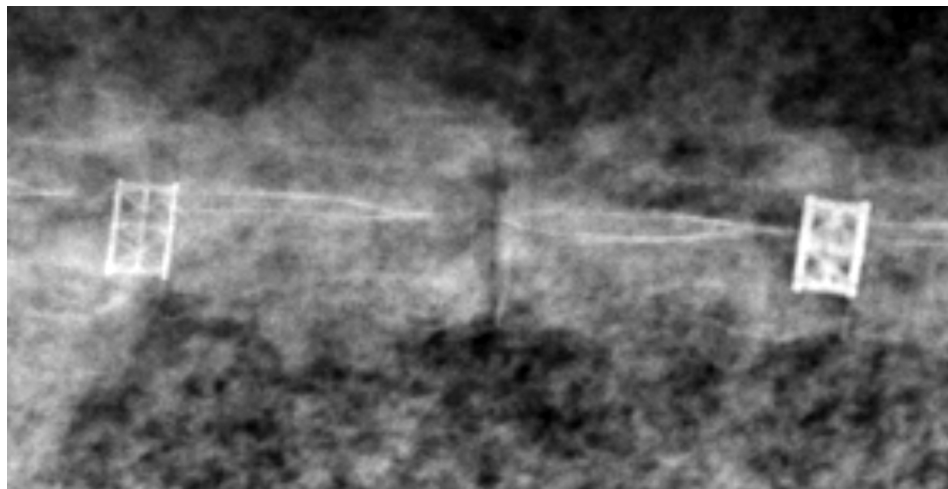
- The 4WEB® ASTS implants were evaluated for fusion in an ovine model.
- The ASTS implants had two different truss diameters: 0.75mm and 1.5mm.
- Regardless of strut diameter, bone was radiographically apparent within the center of both device types by 3 months.
- The median fusion score for the 0.75mm truss was 7.00 (highest possible value) at 3 months, while the 1.5mm truss group reached this value at 6 months.
- The results of this study are superior to fusion results reported for conventional designs.<sup>1,2,4</sup>

### PURPOSE

Evaluation of bone incorporation into the 4WEB® Anterior Spine Truss System™ (ASTS) evaluating different truss diameters (0.75mm, 1.50mm).

### PROTOCOL

- Ovine model – 18 mature sheep
- Implants with 0.75mm or 1.5mm truss diameters
- Both devices implanted into each sheep with equal distribution per level (L2-3 and L4-5)
- All implants packed with autograft
- Sacrifice 6 sheep at 3, 6 and 12 months
- Radiographic and histology fusion scores were calculated for each tissue slide at all time points as performed in similar studies<sup>1,2</sup>

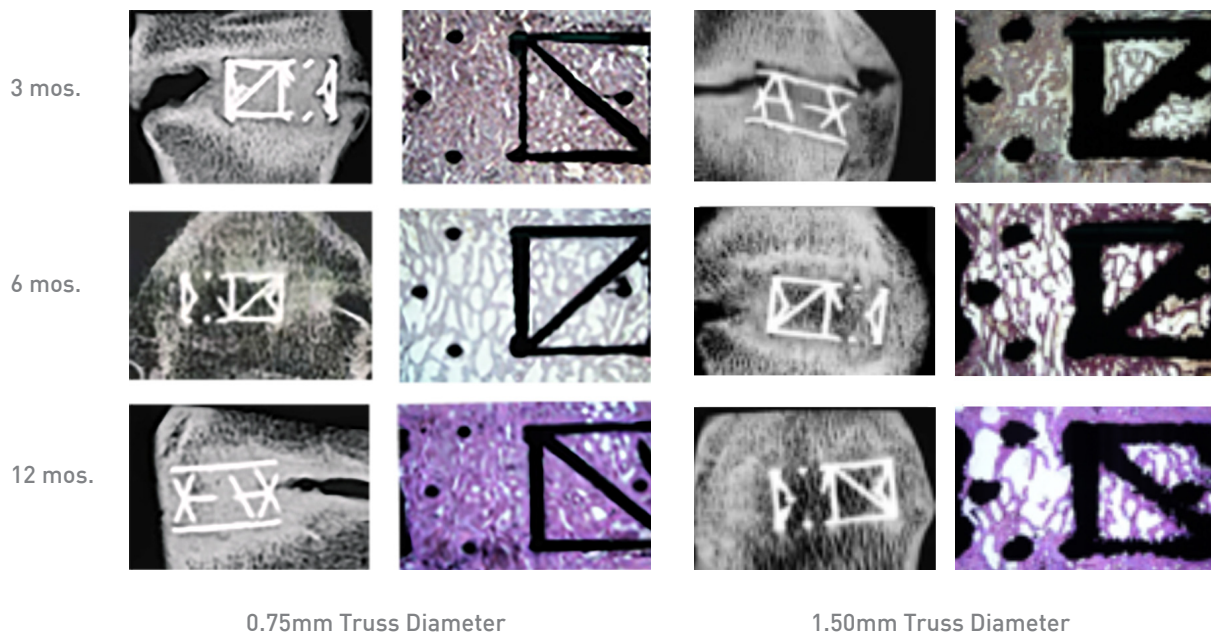


**Figure 1:** Radiograph of a spine harvested from a 6 month animal shows both implanted devices with the 0.75mm ASTS in place at the L3/L4 treated level (left) and the 1.5mm ASTS in place at the L2/L3-treated level (right).

As per independent radiographic assessment across all samples, bone was apparent within the cages and there was no evidence of structural collapse.

## PURPOSE

Clinical radiographs and slab radiographs showed trabecular bone present within the center of both devices by 3 months, and more extensive amounts of bone present in both groups at 6 and 12 months. Additionally, bone architecture was continuous within and adjacent to the ASTS implants.



**Figure:** Slab radiographs and histology slide sections show continuity of bone through, and adjacent to the 0.75mm and 1.50mm STS cage at 3, 6 and 12 months.

## SUMMARY

- Results show that the 4WEB ASTS implants can be designed to distribute strain in the range that promotes mechanobiological dynamic responses for stimulating bone on-growth, through-growth and implant fusion.<sup>3</sup>
- Bone was radiographically apparent within the center of both device types by 3 months.
- The results of this study are superior to fusion results reported for conventional interbody fusion implant designs.<sup>1,2,4</sup>

### REFERENCES:

1. Assad M, Jarzem P, Leroux MA, et al. Porous titanium-nickel for intervertebral fusion in a sheep model: Part 1. Histomorphometric and radiological analysis. *J Biomed Mater Res B Appl Biomater* 2003;64:107-20.
2. Sandhu HS, Toth JM, Diwan AD, et al. Histologic evaluation of the efficacy of rhbmp-2 compared with autograft bone in sheep spinal anterior interbody fusion. *Spine* 2002;27:567-75.
3. Caffrey JP, Cory E, Wong VW, Masuda K, Chen AC, Hunt JP, Ganey TM, Sah RL: Ex vivo loading of trussed implants for spine fusion induces heterogeneous strains consistent with homeostatic bone mechanobiology. *J Biomech*;2016;49,4090-4097.
4. Toth, JM, et al: Direct current electrical stimulation increases the fusion rate of spinal fusion cages. *Spine*, 2000;25(20):2580-2587.