

## Clinical Summary: Human Cadaver Studies

Four major clinical evaluations were conducted on human cadavers in support of FDA submission and approval for the NIO™. Two evaluations were conducted at the Central Morgue of Lima, Peru. One evaluation was conducted at the Georgia Health Sciences University cadaver lab and another evaluation was conducted at the New York Institute of Technology College of Osteopathic Medicine under the supervision of Dr. Bennett Futterman, M.D. All four studies were submitted to the FDA as part of validation and verification testing for the NIO. Discussed below are highlights from these studies.

### First-Attempt Success Rates as High as 98%<sub>2</sub>

Initial testing demonstrated an overall average success rate of 91.4% for the proximal tibia and 93.1% for the humeral head<sub>1</sub>. The New York Institute of Osteopathic Medicine conducted a 4th study, which established a proximal tibia success rate of over 98%<sub>2</sub>.

### Easily Tolerates Common User Errors

The study evaluated common user errors related to needle placement and found that even when placed up to 5cm from the correct insertion site, the NIO maintained an 85% success rate<sub>1</sub>.

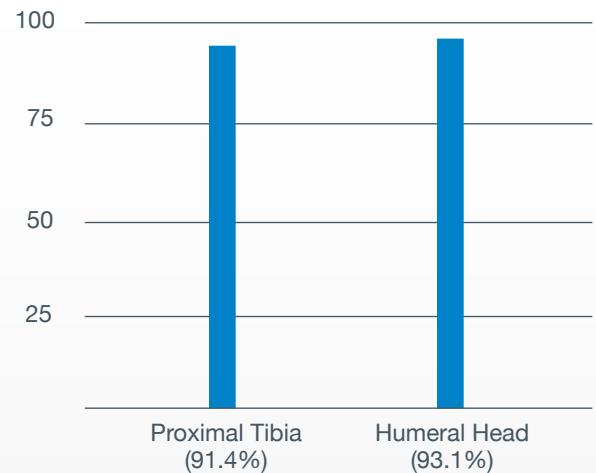
### Safe on the Bone

The NIO proved to be safe on the bone and resulted in zero incidence of bone fracture as observed by post-insertion X-rays<sub>3</sub>.

### Rapid Results with Remarkable Ease-of-Use

The average time of placement for the NIO was 18.3 seconds, with 10-second times achieved by trained personnel. Users reported an average ease-of-use rating of 8.5 on a scale of 1-10<sub>1</sub>.

NIO™ SUCCESS RATE (%)<sub>1</sub>



<sup>1</sup>NIO A.V Protocol.10, 2012.; NIO A.V Protocol.11, 2012; NIO A.V Protocol.13, 2013. <sup>2</sup>Flamm, Avram, and Bennett Futterman, MD. New York Institute of Technology College of Osteopathic Medicine. <sup>3</sup>Swisa, Einat. NIO-A.V.Report.09, Occurrence of Fractures in Bones. 2013.