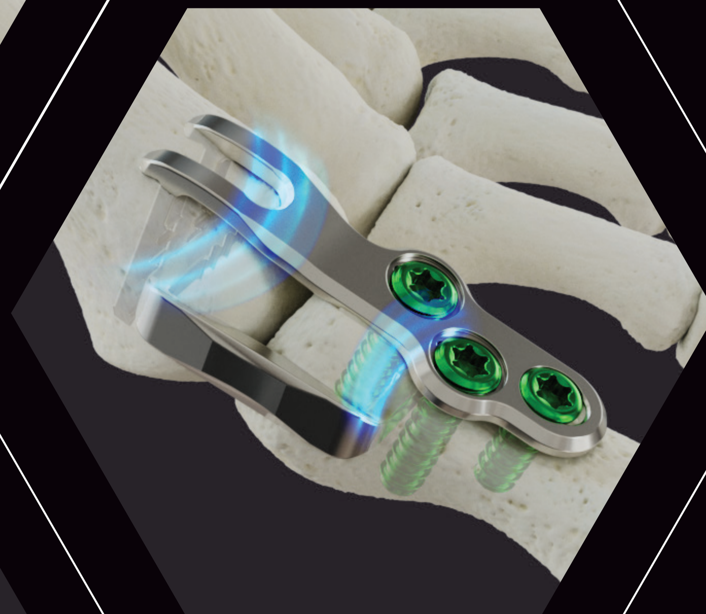
MEDLINE UNITE® FOOT & ANKLE

REFLEX® Nitinol Implant Systems

Intelligently designed implant systems.

VALUE ANALYSIS



What is nitinol?

Nitinol is a shape memory nickel–titanium alloy that provides continuous, dynamic compression at fusion sites through its superelasticity, allowing recovery of lost compression from bone resorption or micromotion—unlike traditional static plates and screws.[1] By adapting to physiologic loading, nitinol fixation reduces gapping, resists fatigue under cyclic stress, and maintains fixation over time while mitigating stress shielding.[2]

For hospitals and ASC settings, these benefits may support procedural objectives and may contribute to procedural efficiency and overall treatment value. Together, these characteristics position nitinol as a high value solution rather than a premium alternative.

The REFLEX® portfolio

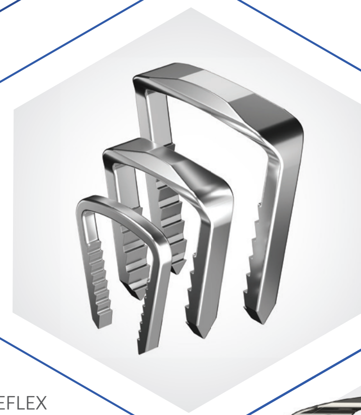
REFLEX® represents a major advancement in foot and ankle surgery, leveraging the benefits of nitinol across a portfolio of indication-specific implants supported by case start-to-finish instrumentation and thoughtfully designed tray layouts. Published biomechanical testing demonstrates that the REFLEX platform delivers reliable stability, gap recovery, and sustained compression across a range of foot and ankle procedures.[2,3]

REFLEX MINI, MAX, and **ULTRA** 2-leg staples provide low profile, continuous compression across a wide range of indications, while **REFLEX TETRA**®, a 4-leg staple, delivers dual plane fixation through patent pending targeting technology to deliver multiplanar stability, reproducible placement and construct versatility.

For enhanced construct strength, **REFLEX HYBRID** uniquely combines the dynamic compression of nitinol with the stability of a locking plate for MTP and Lapidus procedures.

Completing the system, the **REFLEX Nitinol Dynamic Disc** transforms a traditional static lag screw into a fully dynamic construct, providing continuous compression and gap recovery when used with cannulated screws.[3]

Together, the REFLEX portfolio offers a comprehensive fixation system that supports surgical efficiency, low profile implantation, and durable biomechanical performance under cyclic loading. More than 30 issued and pending patents across implants and instrumentation, combined with intuitive tray design, support procedural consistency and reproducibility across foot and ankle applications.

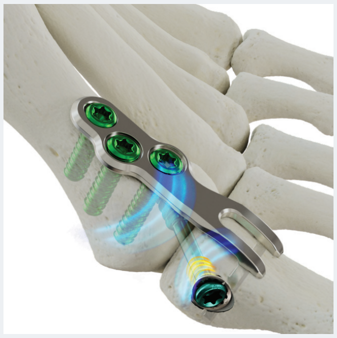


REFLEX MINI, MAX, AND ULTRA

REFLEX TETRA

REFLEX HYBRID

REFLEX NITINOL DYNAMIC DISC



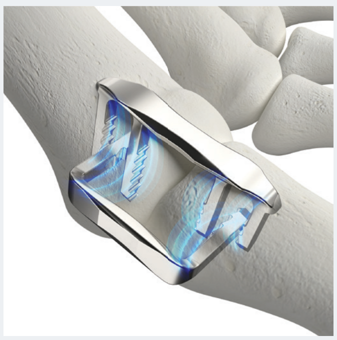
REFLEX HYBRID

showed both

42.5% GREATER ULTIMATE LOAD TO FAILURE

and

33.3% LESS GAPPING AT FAILURE[1]



Outperformed static plates and screws[2]

across:

- Compression retention
- Contact area
- Rigidity, and
- Torque after cyclic loading

REFLEX NITINOL DYNAMIC DISC

provides continuous compression with up to

4.0 mm GAP RECOVERY[3]

Clinical and biomechanical performance

Superior mechanical strength over static fixation

Across biomechanical studies, nitinol based dynamic constructs demonstrated higher load to failure and less gapping at failure than static titanium plates and screws. Notably, REFLEX HYBRID showed 42.5% greater ultimate load to failure and 33.3% less gapping at failure compared with a static locking titanium plate with a lag screw.[1]

Sustained compression and stability under cyclic loading

Dynamic nitinol constructs outperformed static plates and screws across compression retention, contact area, rigidity, and torque after cyclic loading, addressing a key failure mechanism of traditional fixation where compression rapidly decays post implantation.[2]

Gap recovery addresses bone resorption during healing

The REFLEX Nitinol Dynamic Disc provides continuous compression with gap recovery up to 4.0 mm, effectively maintaining mechanical engagement through bone resorption in the postoperative phase—something static fixation cannot achieve.[3]

Total cost of care analysis

How REFLEX impacts intraoperative costs

UNITE REFLEX emphasizes procedure efficiency through construct simplicity.

Fixation Construct	Typical Workflow Steps	Relative Time Burden
Staple	Drill → Pin → Staple	Lowest
Hybrid	Drill → Temp Fixation → Plate + 2 Screws	Moderate
Plate	Drill → Temp Fixation → Plate → ~5 Screws	Highest

Published analyses estimate average operating room costs of approximately $36 – $37 per minute in U.S. hospitals, with anesthesia costs averaging an additional $8.62 per minute, highlighting the financial impact of each additional minute of operative time.[4,5]

REFLEX Systems are thoughtfully organized with procedural workflow in mind. Features such as clear component identification, intuitive layouts, and comprehensive system configurations aim to simplify time and workflow.

How REFLEX impacts Sterile Processing Department (SPD) costs

UNITE REFLEX focuses on design to consolidate, not downsize.

- Case complete tray model
- Standardized tray configurations
- Fewer trays per case
- Streamlined reprocessing workflow

Aligned with published evidence showing tray consolidation and standardization reduce SPD errors, rework, and delays.[7–9]

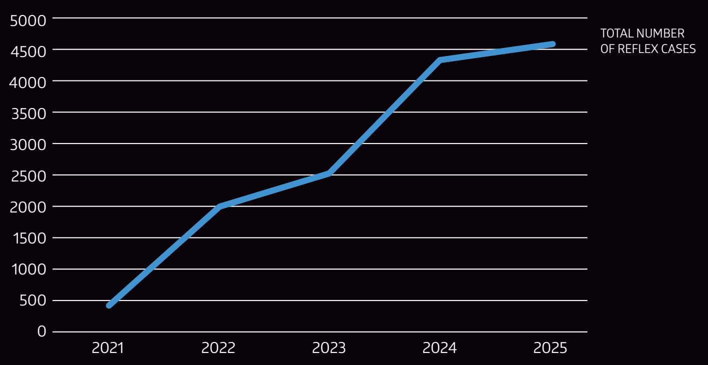
Published hospital and peer reviewed analyses show that sterile processing inefficiencies can drive over $1.5 million in annual cost exposure, while tray consolidation and standardization have demonstrated six figure annual savings per service line. By providing case complete fixation in fewer consolidated trays, UNITE REFLEX helps SPDs reduce rework, improve tray turnaround, and support reliable on time starts in high volume foot and ankle procedures—without sacrificing procedural completeness.[6–9]

How REFLEX impacts nonunion & revision costs

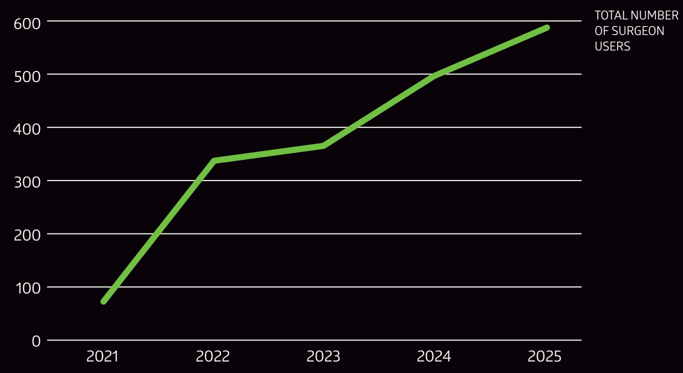
Economic analyses show that nonunion—across fracture and fusion procedures—can increase total cost of care by ~2.6 – 4.3x, adding tens of thousands of dollars in healthcare costs per patient and creating additional clinical and financial burden. By prioritizing stable, durable fixation intended to support consistent bone healing, the UNITE REFLEX system is designed to address a major downstream cost driver for hospitals.[10]

Year-by-year utilization and adoption

REFLEX year-by-year utilization



REFLEX year-by-year adoption



Indications for Use

Medline UNITE® REFLEX® Dynamic Discs

510(k) number: K211612

Indications for Use: The Medline UNITE® REFLEX® Dynamic Discs are indicated for use in bone reconstruction, osteotomies, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Discs are intended for single use only.

Medline UNITE® REFLEX® HYBRID Nitinol Implant System

510(k) number: K243888

Indications for Use: The Medline UNITE® REFLEX® HYBRID Nitinol Implants are intended to provide fixation for fractures, fusions or osteotomies of the bones of short (tarsals) and long (metatarsals, phalanges, distal tibia and fibula) bones comprising the foot and ankle such as: First metatarsal-cuneiform arthrodesis, First metatarsophalangeal arthrodesis, Talo-Navicular Fusion, Lisfranc arthrodesis, Scarf and Chevron osteotomies. Implants are intended for single use only. The Medline UNITE® Locking and Non-Locking Cortical Screws are indicated for use with the Medline UNITE® REFLEX® HYBRID Nitinol Implant. The Non-Locking Cortical Screws are also indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Medline UNITE® REFLEX® Nitinol Staple System

510(k) number: K210482

510(k) number: K231885

Medline UNITE® REFLEX® Nitinol Staple Kit

510(k) number: K232905

Indications for Use: The Medline UNITE® REFLEX® Nitinol Staples are intended to provide fixation for fractures, fusions or osteotomies of the bones of the hand and foot such as: First Metatarsal Cuneiform arthrodesis, First Metatarsophalangeal arthrodesis, Talonavicular Fusion, Lisfranc arthrodesis, Akin Osteotomy, Scarf and Chevron osteotomies. Staples are intended for single use only.

To schedule a case, contact your Medline UNITE Representative or visit medlineunite.com for more information.

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