

Nite Tibial Nail

Technical Data Sheet

Claw Technology

Dunitech leads innovational systems, and aims to supply options for the surgeons to excel at their expertise. Claws are a novelty solution on distal locking systems designed to support the orthopedic trauma community.

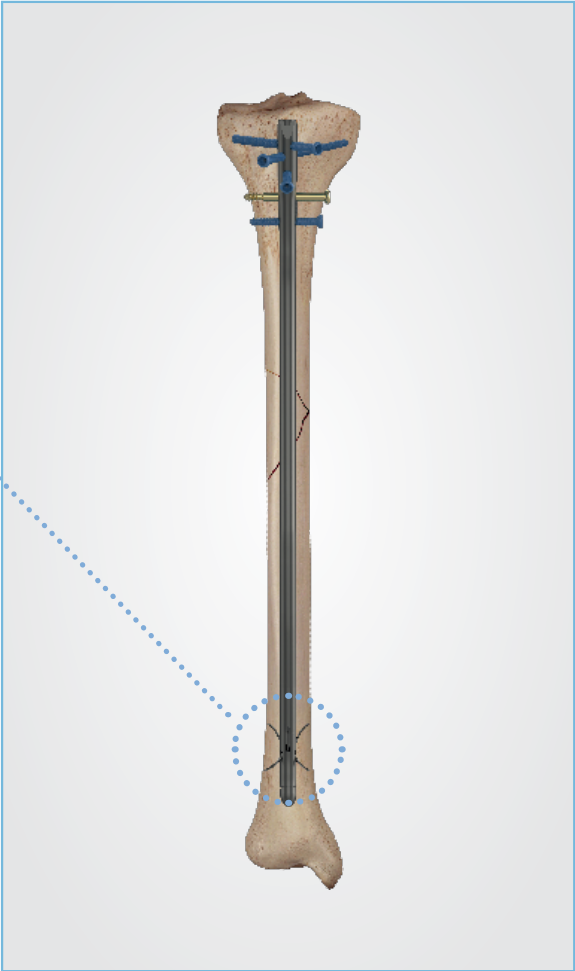
Claws are titanium pins that act as anchors to provide a stable fixation, as well as other superior operative parameters.

- ✓ *Claws are made from titanium, and mechanically deploy from within the nail.*
- ✓ *Claws penetrate through the cancellous bone, and anchor in the cortical bone.*

We focus on operative parameters that are vital for the success of the fracture treatment.

Dunitech's innovative devices allow healthcare professionals to reduce surgical time as well as the risk of pre- and postoperative complications.

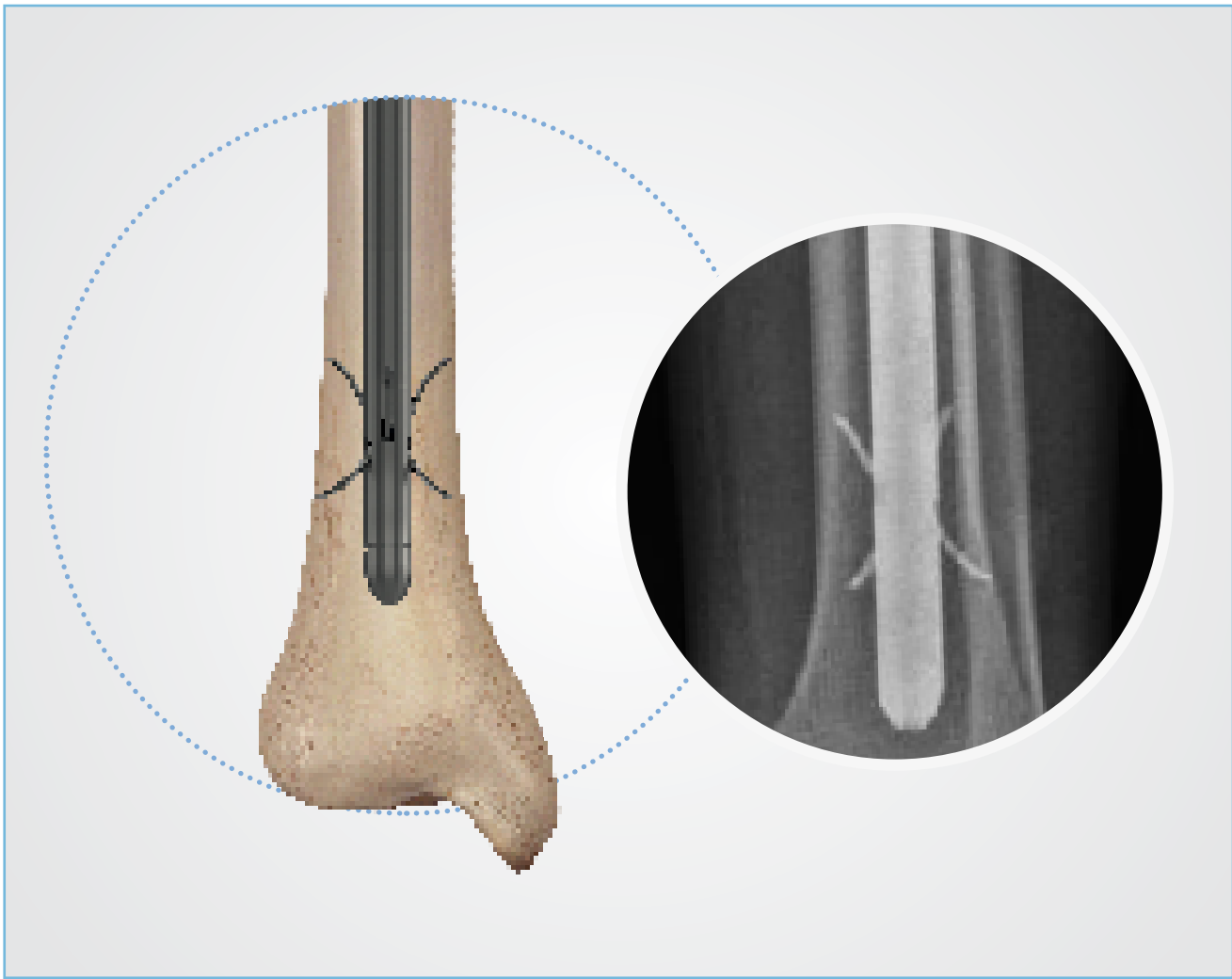
By eliminating the distal incisions, the Claws significantly reduce the radiation exposure and blood loss.



- ✓ ***Increased stability***
- ✓ ***Shorter operative time***
- ✓ ***Lower radiation exposure***
- ✓ ***Fewer incisions***
- ✓ ***Easy revision***
- ✓ ***No free-hand locking***
- ✓ ***Less bone removal***

Get Better Stability!

Six retractable Claws are designed to penetrate the cortex, and provide exceptional axial and rotational stability.



Less Radiation Exposure

Claws significantly reduce the radiation exposure of the team in the operating room by avoiding the need of targeting the distal hole, reaming and inserting a screw for distal locking.^{1,2}

Fewer Incisions

The nail is anchored by the Claws deployed from within the medullary canal. By avoiding extra incision, there will be fewer surgical scars, lower blood loss and shorter operative time while lowering the risk of infection.²

1. Çamurcu Y, Sofu H, Issin A, Koçkara N, Genç E, Çetinkaya M. Is talon tibial intramedullary nailing clinically superior compared to conventional locked nailing? Eklem Hastalik Cerrahisi. 2017 Dec;28(3):152-7.
2. Zehir S, Şahin E, Zehir R. Comparison of clinical outcomes with three different intramedullary nailing devices in the treatment of unstable trochanteric fractures. Ulus Travma Acil Cerrahi Derg 2015, Vol. 21, No. 6.

Nite Tibial Nail Indications

INDICATIONS

- Proximal extra-articular fracture
- Open and closed fractures of the tibial shaft
- Pathologic / impending pathologic fractures
- Malunions / nonunions

CONTRAINDICATIONS

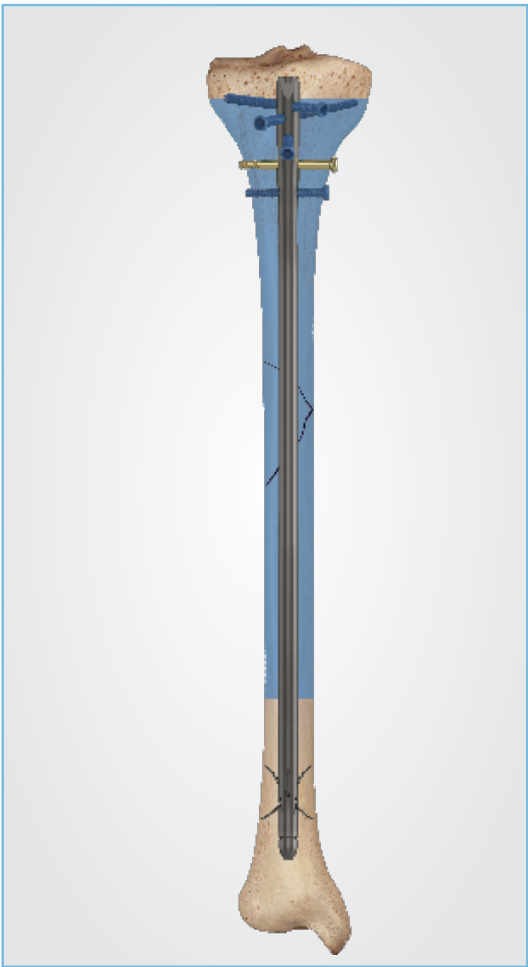
- In a leg with a total knee implant.
- Fractures of the distal third.

The following conditions may present an increased risk of implant failure. This list is not meant to be comprehensive. Physicians should use their clinical judgement when determining the appropriate implant and approach for a given patient.

- Infection
- Incomplete fusion of the epiphysis
- Cognitive and/or physical impairment that would lead to unacceptable risk of fixation failure
- Metal sensitivity or allergic reaction to foreign bodies
- Loss of bone stock or insufficient bone quality to support the device
- Obliterated or narrow medullary canal
- Obese patients
- In the same region as a pre-implanted screw plate
- In comminuted and/or intraarticular fractures
- In open fractures with inadequate soft tissue cover and/or with associated arterial injury

PRECAUTIONS

Nite Tibial Nail and accessories were not evaluated for safety and compatibility in the magnetic resonance (MR) environment and no tests for heating or migration were conducted for those products in MR environment.



Nite Tibial Nail Specifications

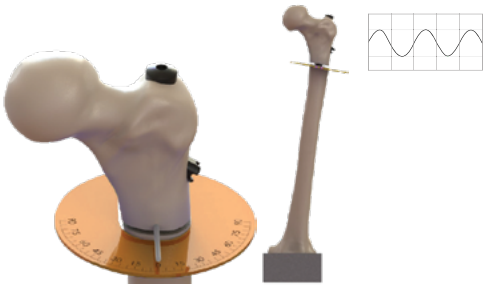
Material	Ti6Al4V ELI
Manufacturing Process	Machined from stock Material
Packaging	Double Package
Sterilization	Ethylene Oxide
Shelf Life	5 Years

Claws in Action

Claws are reliably retractable!

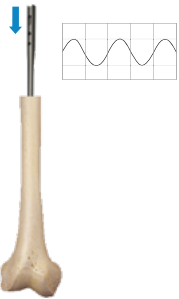
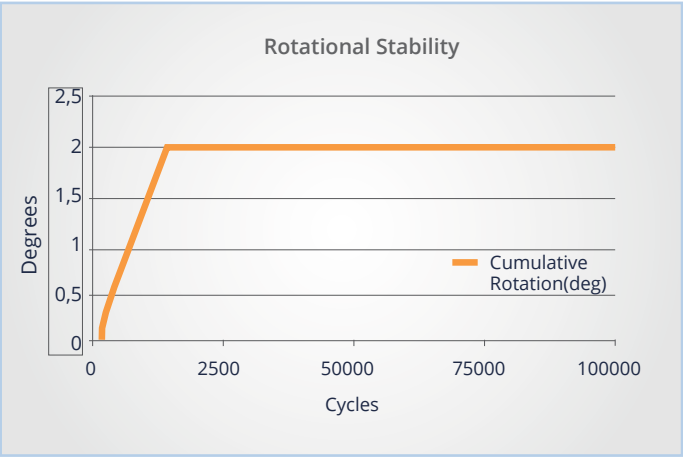
All Claws were **successfully retracted** after every test.

Conventional systems are subjected to screw breakage, screw head wear and drill bit breakage that may prevent the nail to be removed. Dunitech Claws are deployed within the nails from precise holes in a tight fit, preventing empty spaces for bone ingrowth.



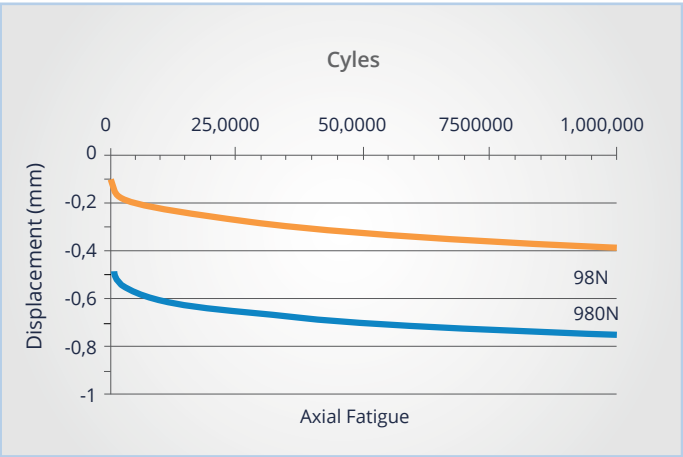
Rotational Stability

In unstable subtrochanteric fractures Claws provide superior rotational stability. After 10,000 cycles, the nail settled in and remained fixed until 100,000 cycles.



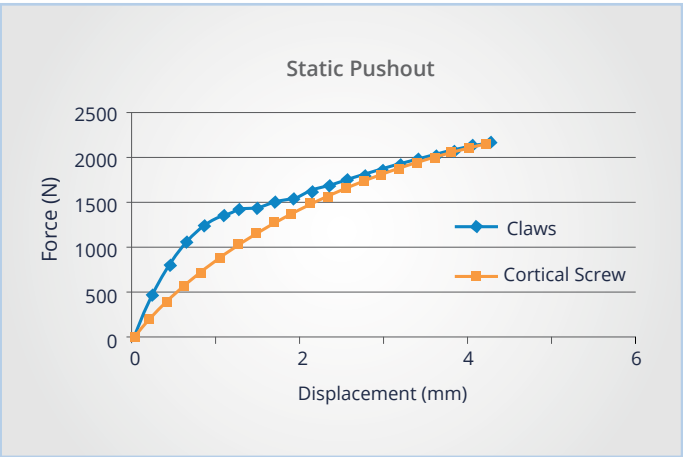
Claw's Axial Fatigue Strength

The average displacement observed at 1 million cycles was 0.74 mm.



Claw's Axial Static Strength

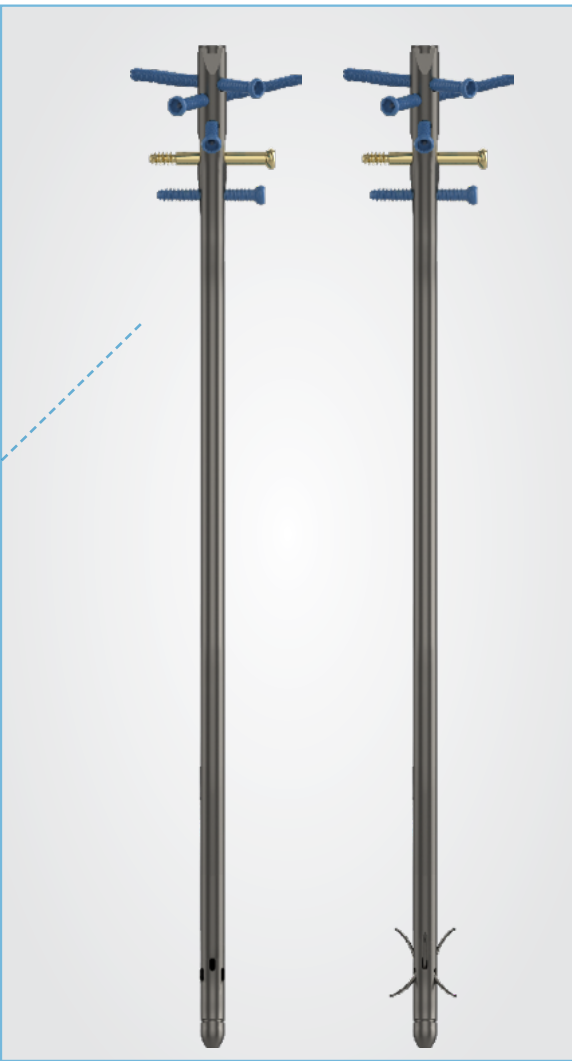
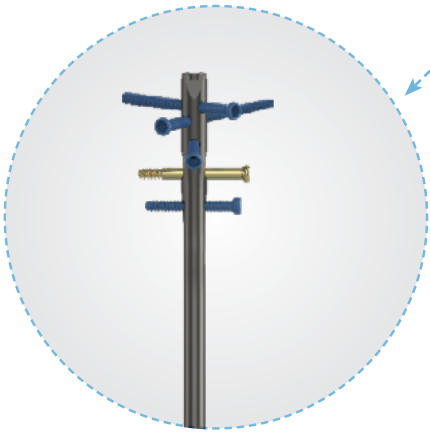
Claws resists to a higher force for a given displacement, compared to conventional stainless steel screws.



Nite Tibial Nail Specifications

NITE KEY FIGURES

- Nail Length: 270 mm to 375 mm in 15 mm increment
- Proximal Diameter: 11 mm
- Distal Diameter: 9 mm to 11 mm in 1 mm increment
- Distal Claw Maximum Span: 38 mm
- Compression Range: 7 mm
- End Cap Length: 0 mm to 10 mm in 5 mm increments Internal thread to secure the cap to the 5 mm Hex driver



COMPRESSION AND CORTICAL SCREWS' KEY FIGURES

- Length: 30 mm to 120 mm in 5 mm increment
- Diameter: 5 mm

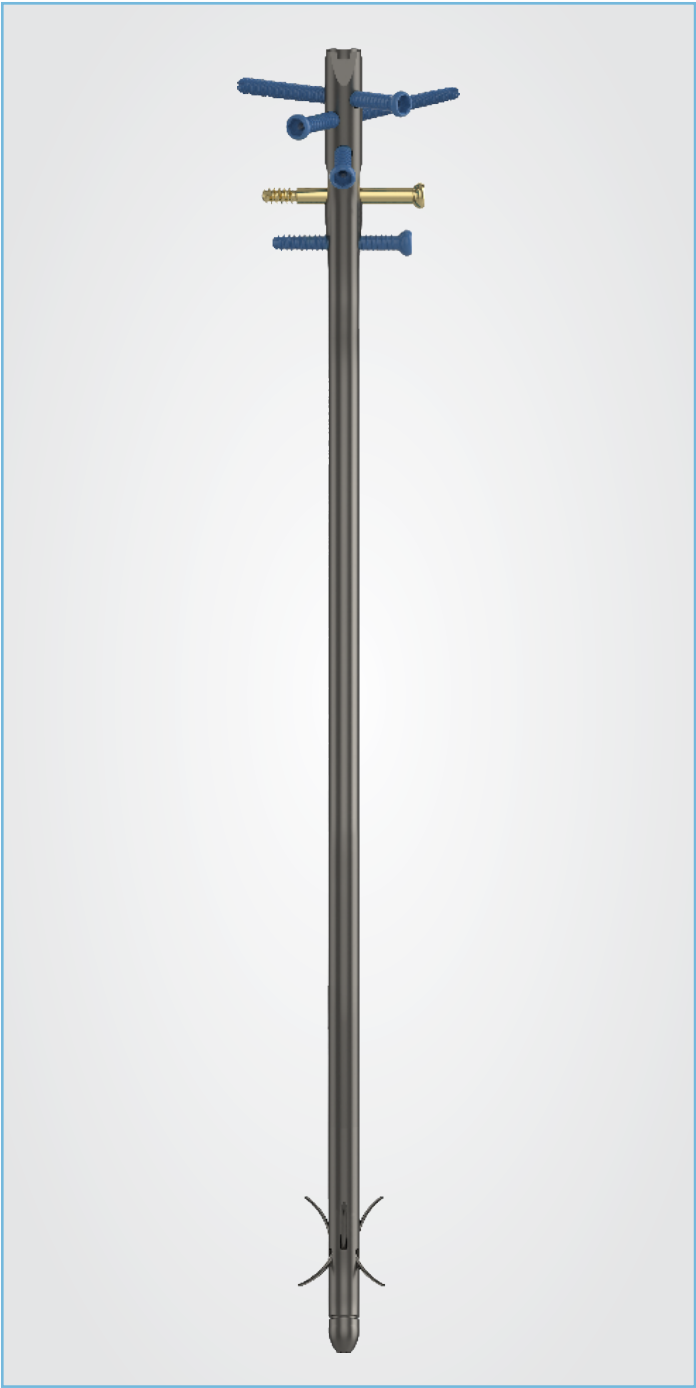
Internal thread to secure the screw to the 5 mm Hex Driver.

Compression Screw with threaded tip and 5 mm shaft to withstand compression load

Catalogue Information

Nite Tibial Nail

Distal Diameter	Lenght (mm)	Catalogue Code
9	270	NITE-C-09-270
9	285	NITE-C-09-285
9	300	NITE-C-09-300
9	315	NITE-C-09-315
9	330	NITE-C-09-330
9	345	NITE-C-09-345
9	360	NITE-C-09-360
9	375	NITE-C-09-375
10	270	NITE-C-10-270
10	285	NITE-C-10-285
10	300	NITE-C-10-300
10	315	NITE-C-10-315
10	330	NITE-C-10-330
10	345	NITE-C-10-345
10	360	NITE-C-10-360
10	375	NITE-C-10-375
11	270	NITE-C-11-270
11	285	NITE-C-11-285
11	300	NITE-C-11-300
11	315	NITE-C-11-315
11	330	NITE-C-11-330
11	345	NITE-C-11-345
11	360	NITE-C-11-360
11	375	NITE-C-11-375



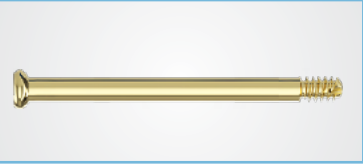
End Caps

Extension (mm)	Catalogue Code
0 (flush)	NITE-11-000
5	NITE-11-005
10	NITE-11-010
15	NITE-11-015



Cortical Screws

Diameter (mm)	Length (mm)	Catalogue Code
5	30	CORS-05-030
5	35	CORS-05-035
5	40	CORS-05-040
5	45	CORS-05-045
5	50	CORS-05-050
5	55	CORS-05-055
5	60	CORS-05-060
5	65	CORS-05-065
5	70	CORS-05-070
5	75	CORS-05-075
5	80	CORS-05-080
5	85	CORS-05-085
5	90	CORS-05-090
5	95	CORS-05-095
5	100	CORS-05-100
5	105	CORS-05-105
5	110	CORS-05-110
5	115	CORS-05-115
5	120	CORS-05-120



Compression Cortical Screws

Diameter (mm)	Length (mm)	Catalogue Code
5	30	COMS-05-030
5	35	COMS-05-035
5	40	COMS-05-040
5	45	COMS-05-045
5	50	COMS-05-050
5	55	COMS-05-055
5	60	COMS-05-060
5	65	COMS-05-065
5	70	COMS-05-070
5	75	COMS-05-075
5	80	COMS-05-080
5	85	COMS-05-085
5	90	COMS-05-090
5	95	COMS-05-095
5	100	COMS-05-100
5	105	COMS-05-105
5	110	COMS-05-110
5	115	COMS-05-115
5	120	COMS-05-120

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