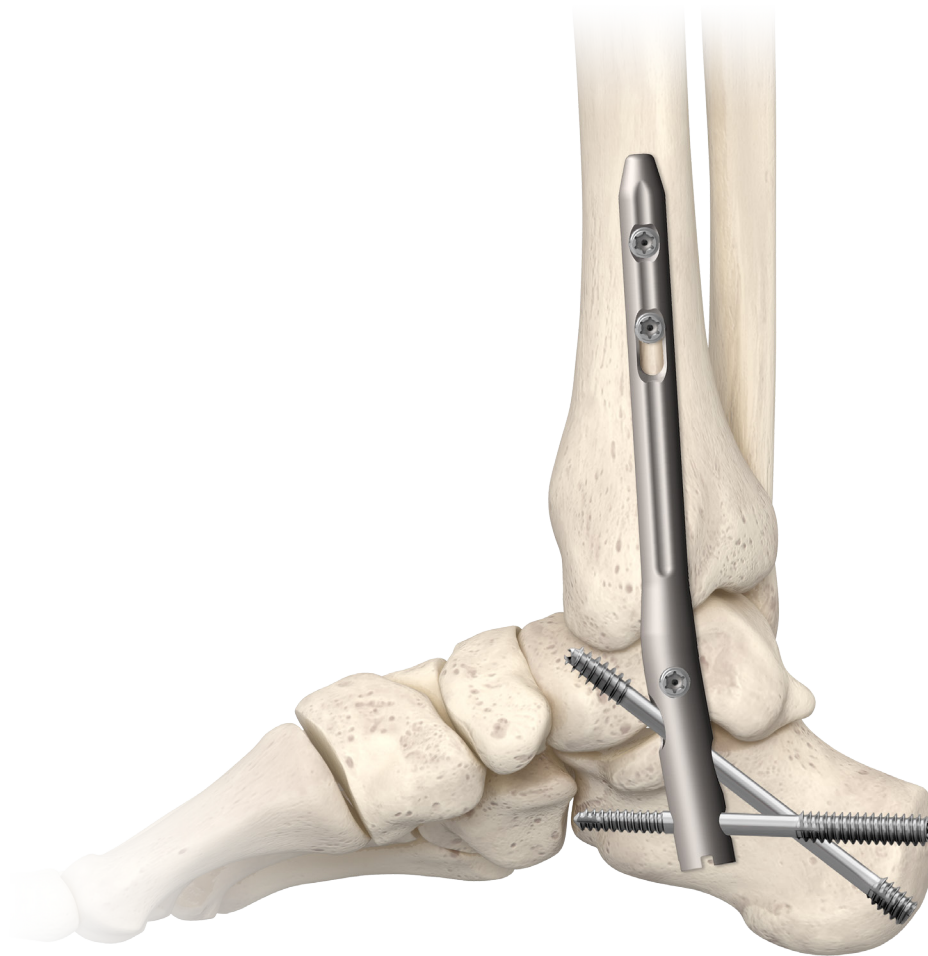


TriWay®

TibioTaloCalcaneal (TTC) Arthrodesis System



Solid Nail Construct
Multi-planar Fixation
Anatomical 7° Posterior Offset Nail



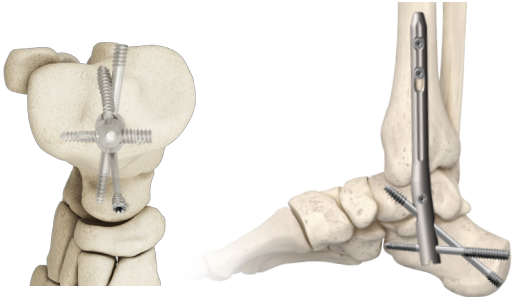
A GLOBAL EXTREMITY COMPANY

TriWay® TibioTaloCalcaneal Arthrodesis System

SYSTEM OVERVIEW / SPECIFICATIONS / DESIGN RATIONALE

IMPLANT SPECIFICATIONS

Solid Nail Construct



Multi-planar fixation

- Medio-lateral fixation
- Postero-anterior fixation
- Oblique screw in subtalar joint line with a slight valgus to match subtalar anatomical alignment

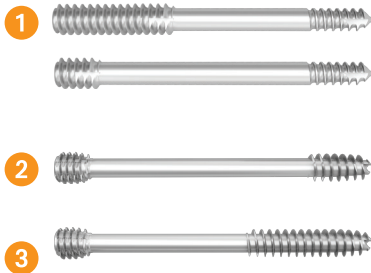
7° posterior offset Nail to calcaneocuboid joint line

- Designed for increased purchase in the calcaneus
- Straight Nail philosophy for bone preparation surgical steps

Anatomical Design

- Right & left versions
- 3 diameters (10-11-12mm)
- 3 lengths (160-200-250mm)

SCREWS DESIGN RATIONALE



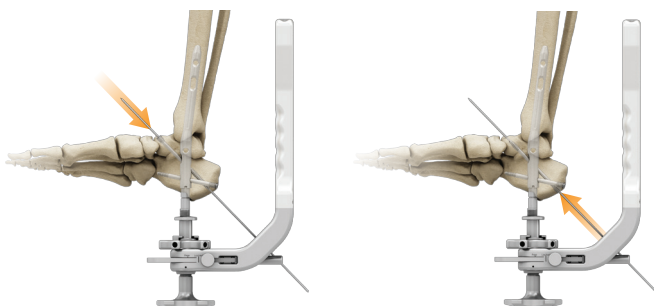
1 5.0 mm Cotter Screws

- Available in 25mm to 90mm lengths, 5mm increments
- For tibia, talus and calcaneus fixation
- Solid construct and works as a rod and allows for adequate fixation in bone
- No screw head impingement
- No screw thread / Nail impingement

6.5mm IBS C & C+ Screws

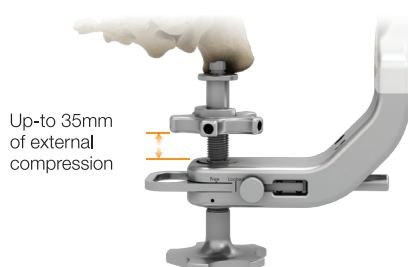
- Can be placed either with an anterior or posterior approach
- Compression screw provides subtalar compression
- When distal screws are placed first, there is no need to anticipate compression effect upon final position of the Nail
- Placed across the subtalar joint and through the Nail
- 6.5mm IBS C Screws: distal thread is 15mm long and is recommended when subtalar screw is preferred from posterior approach
- 6.5mm IBS C+ Screws: distal thread is 30mm long and is recommended when subtalar screw is preferred from anterior approach

INSTRUMENTATION DESIGN FEATURES



Independent Subtalar Compression Screw

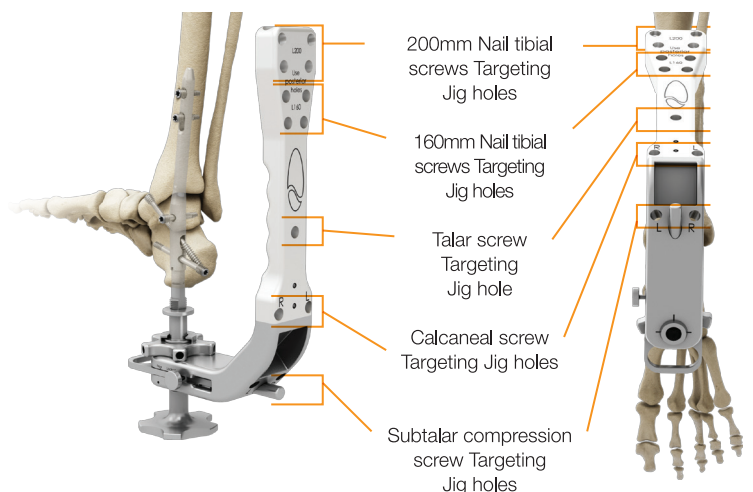
Anterior or posterior subtalar compression screw orientation



Up-to 35mm of external compression

Variable Compression

- when proximal screws are inserted first



Streamlined Instrumentation

ORDERING INFORMATION

TriWay® Arthrodesis Nails / Sterile

PART#	DESCRIPTION	RIGHT / LEFT
N20 ST101..	10mm Lg..	160mm..R
N20 ST201..	10mm Lg..	160mm..L
N20 ST102..	10mm Lg..	200mm..R
N20 ST202..	10mm Lg..	200mm..L
N20 ST111..	11mm Lg..	160mm..R
N20 ST211..	11mm Lg..	160mm..L
N20 ST112..	11mm Lg..	200mm..R
N20 ST212..	11mm Lg..	200mm..L
N20 ST113..	11mm Lg..	250mm..R
N20 ST213..	11mm Lg..	250mm..L
N20 ST121..	12mm Lg..	160mm..R
N20 ST221..	12mm Lg..	160mm..L
N20 ST122..	12mm Lg..	200mm..R
N20 ST222..	12mm Lg..	200mm..L
N20 ST123..	12mm Lg..	250mm..R
N20 ST223..	12mm Lg..	250mm..L

TriWay® Cotter Screws / Sterile

PART#	DESCRIPTION
N20 ST525...	5.0mm Lg.25mm
N20 ST530...	5.0mm Lg.30mm
N20 ST535...	5.0mm Lg.35mm
N20 ST540...	5.0mm Lg.40mm
N20 ST545...	5.0mm Lg.45mm
N20 ST550...	5.0mm Lg.50mm
N20 ST555...	5.0mm Lg.55mm
N20 ST560...	5.0mm Lg.60mm
N20 ST565...	5.0mm Lg.65mm
N20 ST570...	5.0mm Lg.70mm
N20 ST575...	5.0mm Lg.75mm
N20 ST580...	5.0mm Lg.80mm
N20 ST585...	5.0mm Lg.85mm
N20 ST590...	5.0mm Lg.90mm

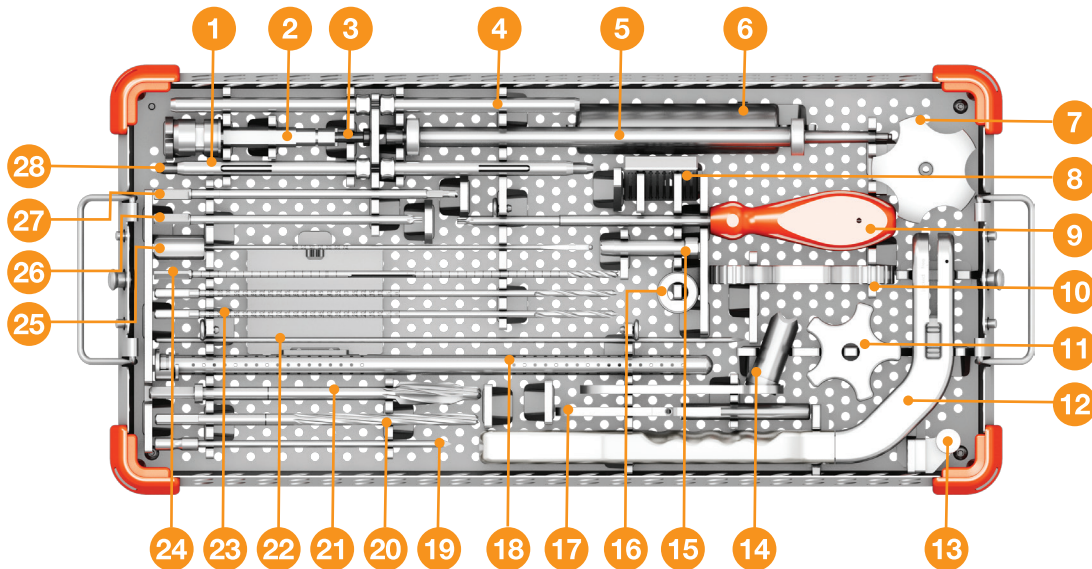
IBS® C 6.5mm Sterile Compression Screw

PART#	DESCRIPTION
S65 ST160 ...	6.5mm Lg. 60mm
S65 ST165 ...	6.5mm Lg. 65mm
S65 ST170 ...	6.5mm Lg. 70mm
S65 ST175 ...	6.5mm Lg. 75mm
S65 ST180 ...	6.5mm Lg. 80mm
S65 ST185 ...	6.5mm Lg. 85mm
S65 ST190 ...	6.5mm Lg. 90mm

IBS® C+ 6.5mm Sterile Compression Screw

PART#	DESCRIPTION
S65 ST560 ...	6.5mm Lg. 60mm
S65 ST565 ...	6.5mm Lg. 65mm
S65 ST570 ...	6.5mm Lg. 70mm
S65 ST575 ...	6.5mm Lg. 75mm
S65 ST580 ...	6.5mm Lg. 80mm
S65 ST585 ...	6.5mm Lg. 85mm
S65 ST590 ...	6.5mm Lg. 90mm

INSTRUMENT SET



PART NUMBER	DESCRIPTION	QUANTITY
1	N02 00013 Protecting Sleeve	2
2	N02 00003 Connector	1
3	N02 00004 Fixation Screw	1
4	N02 00008 Guide Guide for 2.0mm Dia K-wire	2
5	N02 00024 Slap Hammer Guide	1
6	N02 00025 Slap Hammer Mass	1
7	N02 00011 Hitting Plate	1
8	N02 00023 Tibio Talar Cutting Guide	1
9	G01 00411 T25 Screwdriver Cannulated (use over 2.0mm K-wire)	1
9	G01 01641 T25 Screwdriver Non Cannulated	1
10	G01 01391 "T" Handle For Medium Screwdriver	1
11	N02 00009 Compression Wheel	1
12	N02 00001 Targeting Jig	1
13	N02 00020 Index Lock	1
14	N02 00006 Soft Tissue Protector	1
15	N02 00019 Screw Extractor	1
16	N02 00010 Compression Sleeve	1

PART NUMBER	DESCRIPTION	QUANTITY
17	N02 00005 Index Tab	1
18	G01 40041 K-wire Tube	1
18	N02 00017 2.0mm Dia K-wire Lg 300mm	3
18	K10 NS200 2.5mm Dia K-wire Lg 200mm 1 Sharp Tip Non Sterile	1
18	K10 NS251 2.5mm Dia K-wire Lg 100mm 1 Sharp Tip Non Sterile	4
19	N02 00026 Trocar Tip 4.3mm Dia	1
20	N02 00027 7.0mm Dia Cannulated Drill	1
21	N02 00016 14.0mm Dia Cannulated Reamer	1
22	N02 00014 3.2mm X 350mm Guide Wire	2
23	N02 00015 4.3mm Non Cannulated Drill	2
24	G01 01651 4.3mm x 275mm Cannulated Drill (use over 2.0mm K-wire)	1
25	N02 00018 Depth Gauge	1
26	G01 01591 T25 Screwdriver Tip Cannulated K-wire 2.0mm (use over 2.0mm K-wire)	1
27	N02 00021 Screwhead Countersink	1
28	N02 00007 4.3mm Drill Guide	2

INDICATIONS

The TRIWAY® Nail Ankle Arthrodesis System is intended for use in tibiotalar calcaneal arthrodesis and treatment of trauma to the hindfoot and distal tibia. Examples include:

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
- Rheumatoid arthritis with severe deformity
- Revision of failed ankle arthrodesis with subtalar involvement or with insufficient talar body
- Revision of failed total ankle arthroplasty with subtalar intrusion
- Talar deficiency conditions, including avascular necrosis (requiring a tibiocalcaneal arthrodesis)
- Neuropathy or neuromuscular deformity or other neuromuscular disease with severe deformity or instability of the ankle, including Charcot foot
- Severe pilon fractures with trauma to the subtalar joint
- Malunited tibial pilon fractures

The addition of an IBS® 6.5mm Compression Screw through the subtalar joint and through the Nail is required.

CONTRAINDICATIONS

The implant should not be used in a patient who has currently, or who has history of:

- Acute or chronic, systemic inflammations,
- Active infections,
- Sensitivity/allergies to the implant materials.
- Bone pathologies that may compromise the rigidity of the implant fixation (examples include: osteoporosis, acute cystic developments, acute osteopenia, bone tumor, etc...)

Regulatory information

RECOMMANDATION

It is recommended to carefully read the instructions for use available in the package insert.

REIMBURSEMENT

Reimbursement may vary from country to country. Check with local authorities.

FABRICANT

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DOCUMENT

Référence : BR-DIG-TRIWAY-EN-122019

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

Always refer to the appropriate instructions for use for complete clinical instructions.

Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

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EC Classification (EC Directive MDD 93/42/EC):

Implant: CE Class IIb - CE2797

Instruments connected to a power driver: class IIa - CE2797

Instrument with measuring function: Class Im - CE2797

Other instruments: Class I - CE

BR-DIG-TRIWAY-EN-122019

PATENT PENDING



A GLOBAL EXTREMITY COMPANY

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