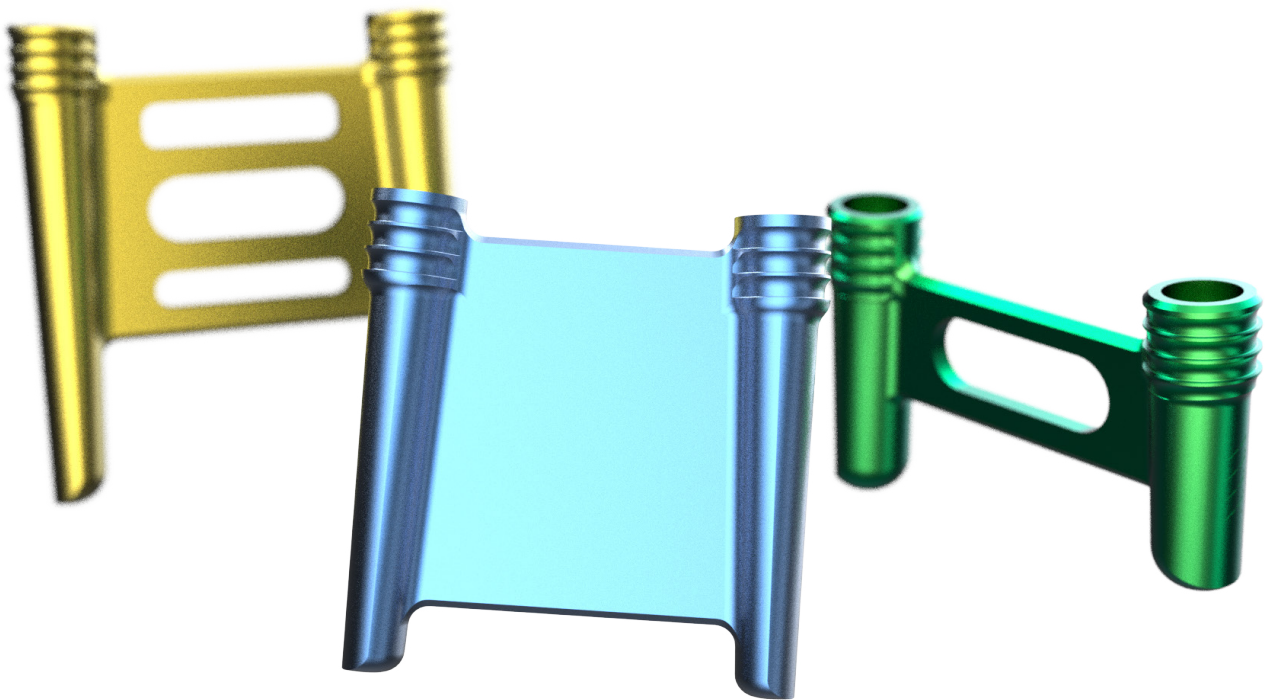


OSTEOTOMIES AND FRACTURE MANAGEMENT SURGICAL TECHNIQUE

Intraosseous Fixation System

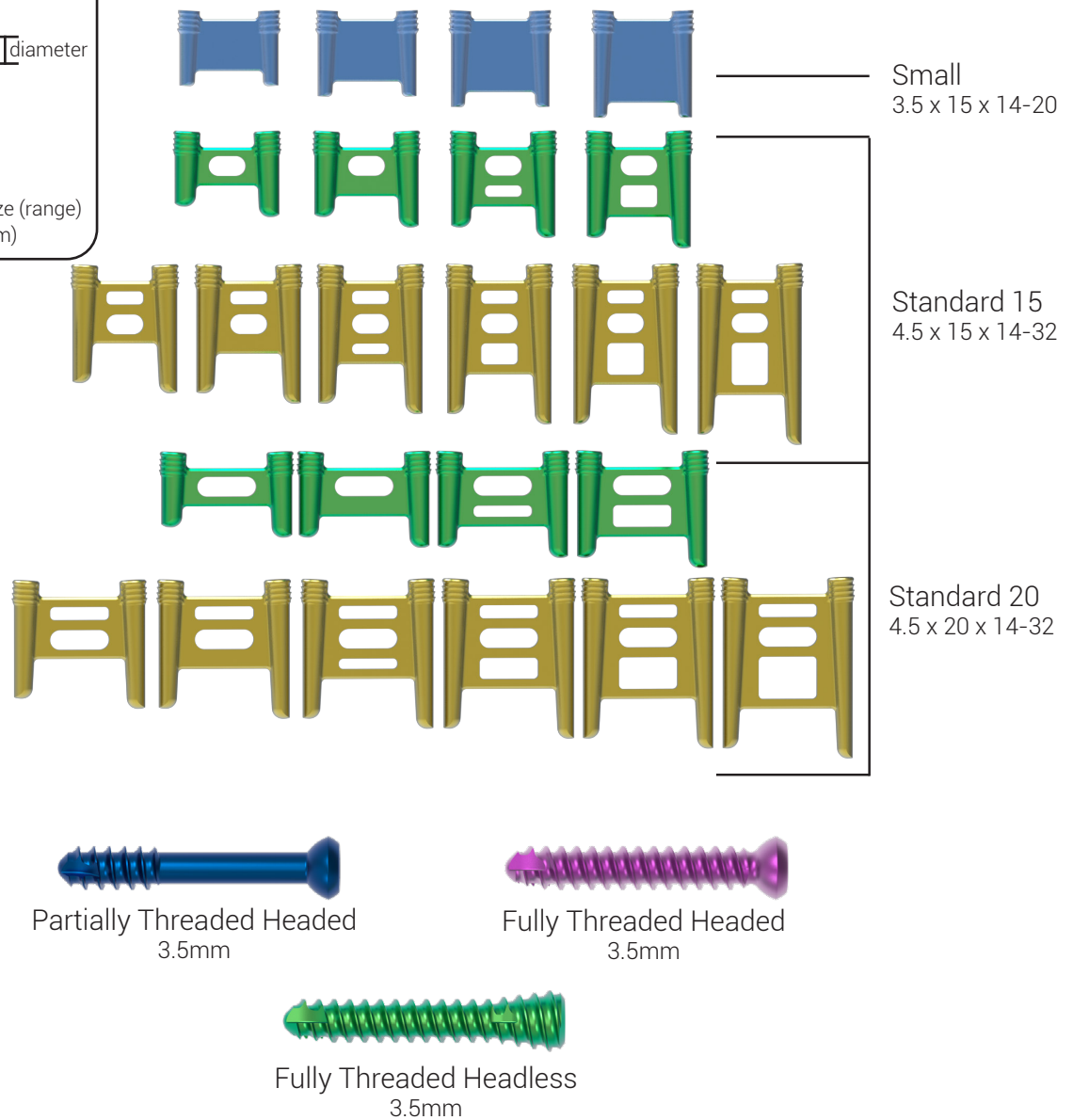
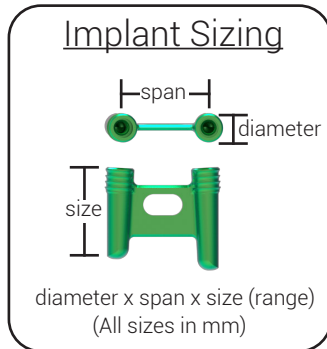


StealthFix

Contents

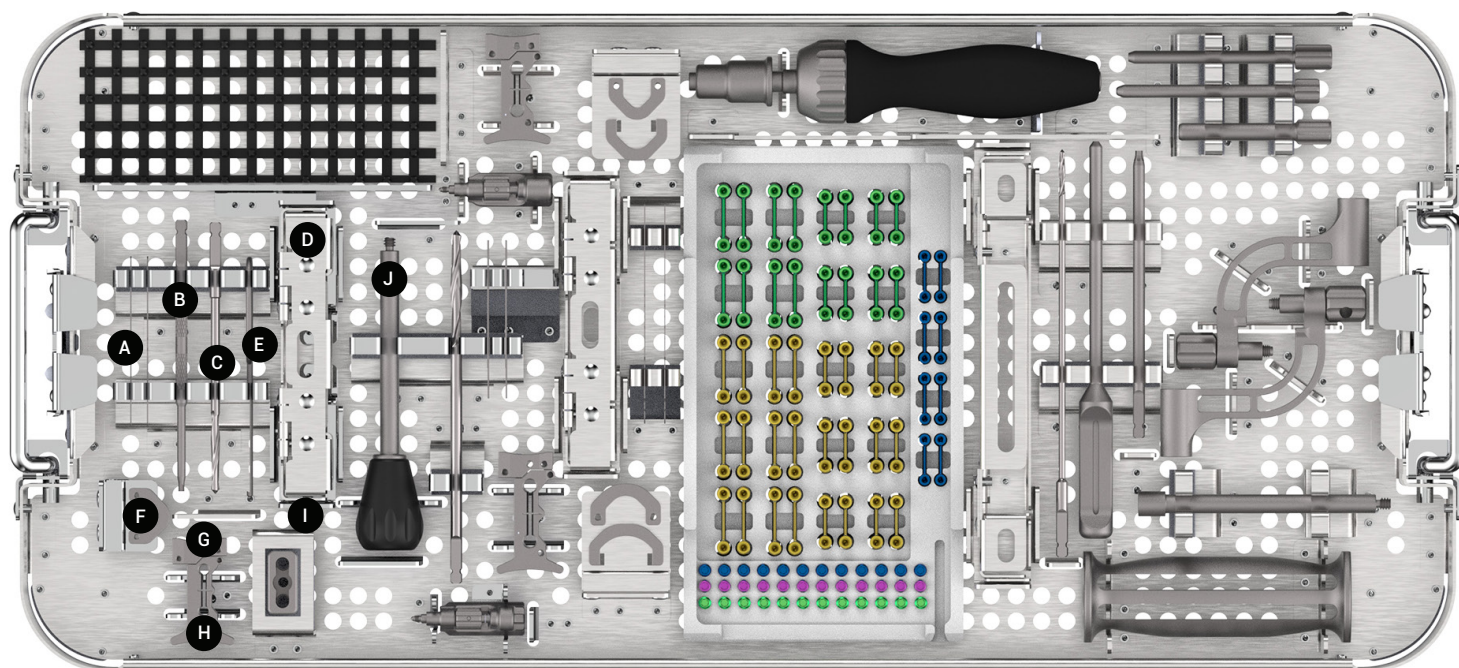
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10	Surgical Technique
10	Joint Preparation
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14	Implantation
15	Revision Technique (Implant Removal Only)
16	Ordering Information

Implant Identification



Diameter	Screw Type	Length (2mm increments)	Color
3.5mm	Partially Threaded Headed	16mm-38mm	Blue
3.5mm	Fully Threaded Headed	16mm-38mm	Magenta
3.5mm	Fully Threaded Headless	16mm-38mm	Green

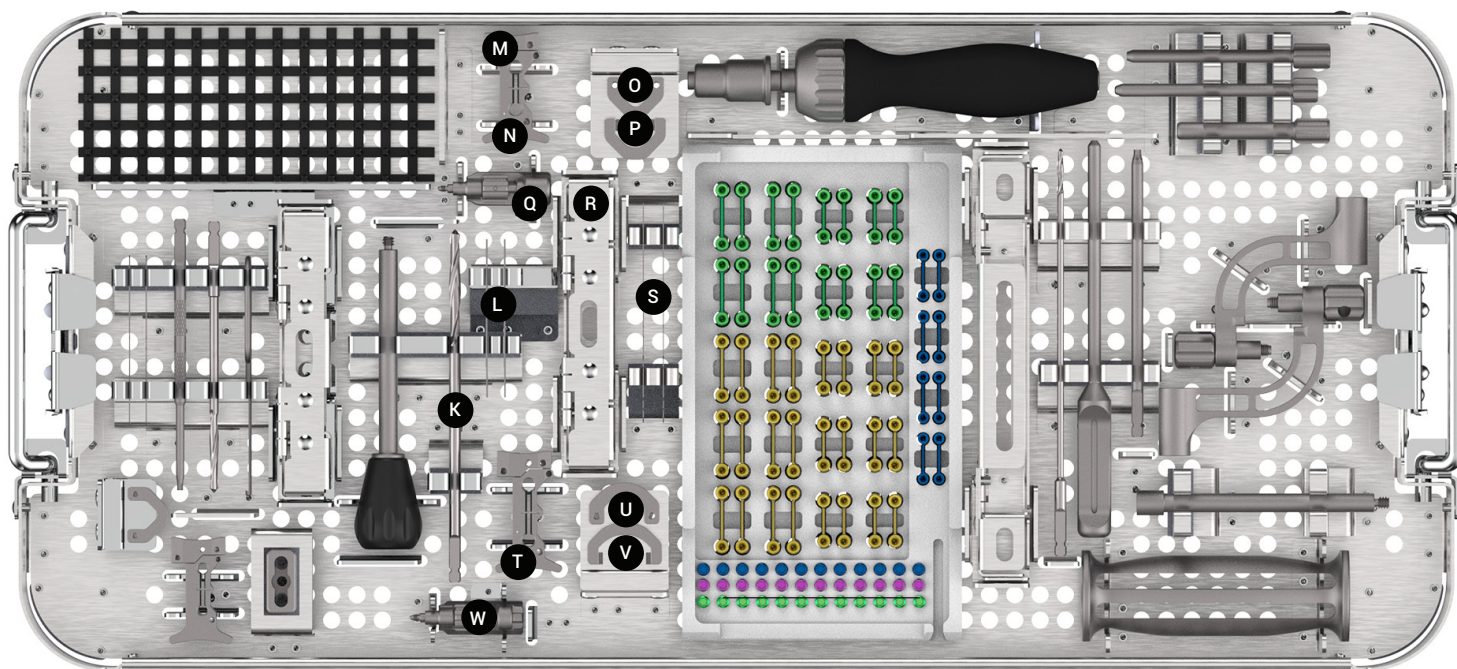
Set Definition - Instruments



Small/Universal Instruments

Reference	SKU	Description	QTY
A	SF1300	StealthFix Small Joint Gauge	2
B	SF5020	StealthFix Hex Driver 2.0mm	2
C	SF4335	StealthFix Post Drill 3.5mm	2
D	SF1001	K Wire 1.6mm X 100mm	4
E	SF1100	StealthFix Universal Post Depth Gauge	1
F	SF2301	StealthFix Small Position Guide	1
G	SF2412	StealthFix Guide Slide Small	1
H	SF2300	StealthFix Drill Guide 3.5mm X 15mm	1
I	SF3315	StealthFix Inserter 3.5mm	1
J	SF3110	StealthFix Impactor Long Handle	1

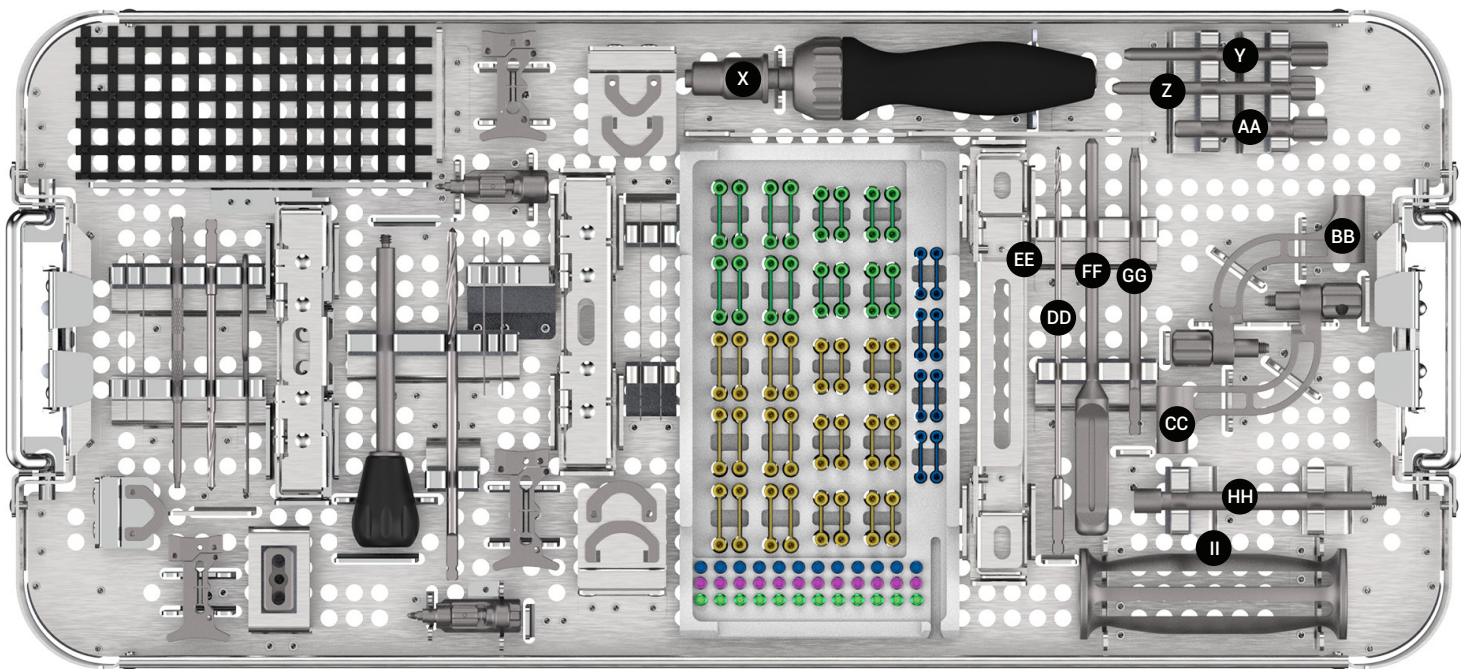
Set Definition - Instruments



Standard 15 & 20 Instruments

Reference	SKU	Description	QTY
K	SF4445	StealthFix Post Drill 4.5mm	2
L	SF6343	StealthFix Saw Blade, Stryker 1mm X 43 mm	2
M	SF2410	StealthFix Guide Slide 4.5mm	2
N	SF2400	StealthFix Drill Guide 4.5mm X 15mm	1
O	SF2420	StealthFix Saw Sleeve 4.5mm X 15mm	1
P	SF2401	StealthFix STD 15 Position Guide	1
Q	SF3415	StealthFix Inserter 4.5mm X 15mm	1
R	SF1002	K Wire 2.0mm X 100mm	6
S	SF1400	StealthFix Joint Gauge 4.5mm	2
T	SF2405	StealthFix Drill Guide 4.5mm X 20mm	1
U	SF2406	StealthFix STD 20 Position Guide	1
V	SF2425	StealthFix Saw Sleeve 4.5mm X 20mm	1
W	SF3420	StealthFix Inserter 4.5mm X 20mm	1

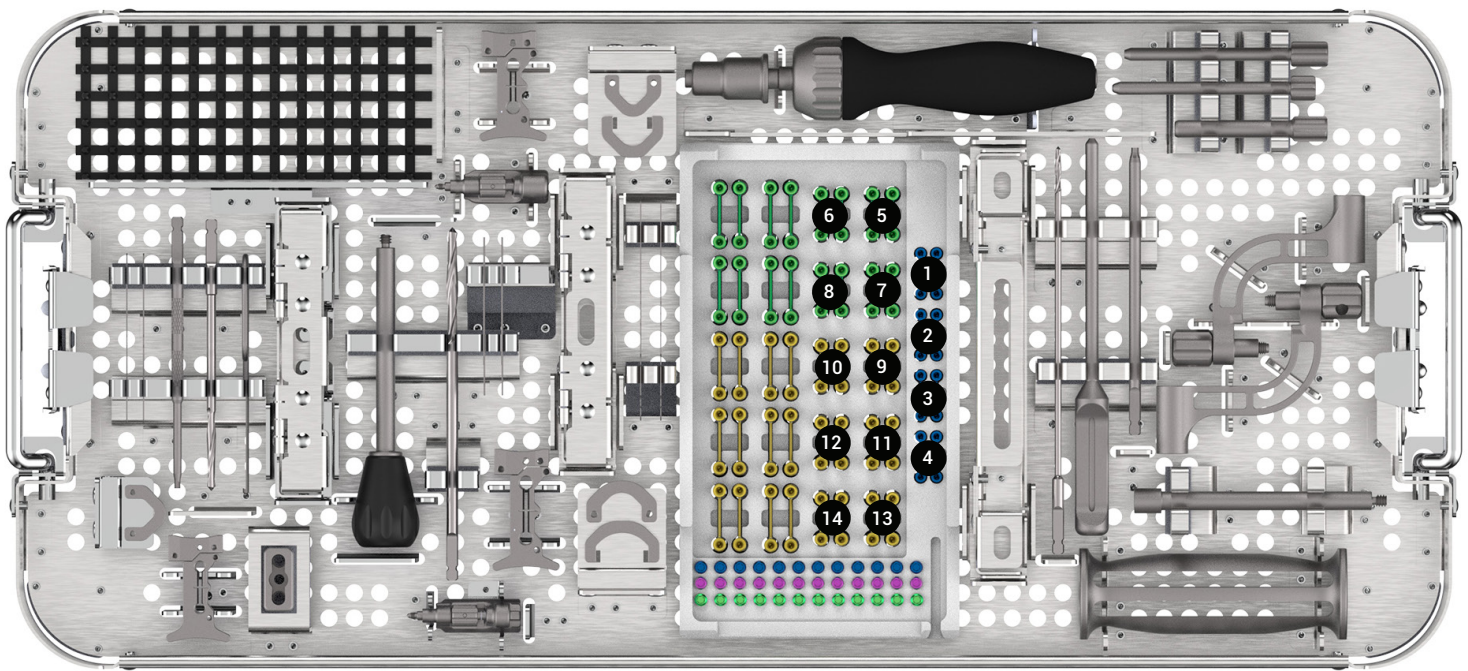
Set Definition - Instruments



Screw & Removal Instruments

Reference	SKU	Description	QTY
X	SF7800	StealthFix Ratcheting Handle	1
Y	SF2031	StealthFix Drill Sleeve	1
Z	SF2030	StealthFix K Wire Sleeve	1
AA	SF2032	StealthFix Screw Sleeve	1
BB	SF2014	StealthFix Targeting Guide Shallow	1
CC	SF2022	StealthFix Targeting Guide Deep	1
DD	SF4025	StealthFix Screw Drill 2.5mm	2
EE	SF1000	K-Wire 1.6mm X150mm	2
FF	SF1035	StealthFix Screw Depth Gauge	1
GG	SF5025	StealthFix Hex Driver 2.5mm	2
HH	SF7930	StealthFix Removal Rod, Small and Standard	1
II	SF7910	StealthFix Slap Hammer	1

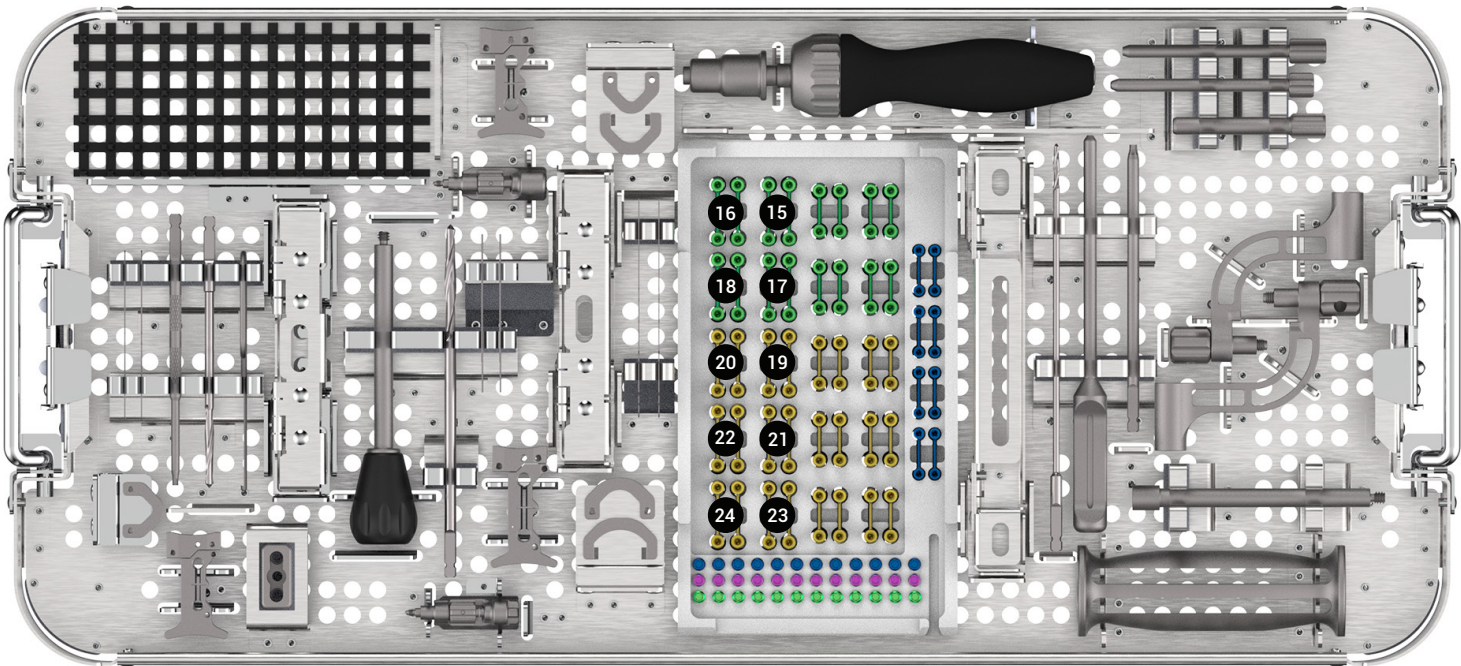
Set Definition - Implants



Small & Standard 15 Implants

Reference	SKU	Description	QTY
1	SF351514	StealthFix Ti Implant 3.5mm Post x 15mm Span x 14mm Long	2
2	SF351516	StealthFix Ti Implant 3.5mm Post x 15mm Span x 16mm Long	2
3	SF351518	StealthFix Ti Implant 3.5mm Post x 15mm Span x 18mm Long	2
4	SF351520	StealthFix Ti Implant 3.5mm Post x 15mm Span x 20mm Long	2
5	SF451514	StealthFix Ti Implant 4.5mm Post x 15mm Span x 14mm Long	2
6	SF451516	StealthFix Ti Implant 4.5mm Post x 15mm Span x 16mm Long	2
7	SF451518	StealthFix Ti Implant 4.5mm Post x 15mm Span x 18mm Long	2
8	SF451520	StealthFix Ti Implant 4.5mm Post x 15mm Span x 20mm Long	2
9	SF451522	StealthFix Ti Implant 4.5mm Post x 15mm Span x 22mm Long	2
10	SF451524	StealthFix Ti Implant 4.5mm Post x 15mm Span x 24mm Long	2
11	SF451526	StealthFix Ti Implant 4.5mm Post x 15mm Span x 26mm Long	2
12	SF451528	StealthFix Ti Implant 4.5mm Post x 15mm Span x 28mm Long	2
13	SF451530	StealthFix Ti Implant 4.5mm Post x 15mm Span x 30mm Long	2
14	SF451532	StealthFix Ti Implant 4.5mm Post x 15mm Span x 32mm Long	2

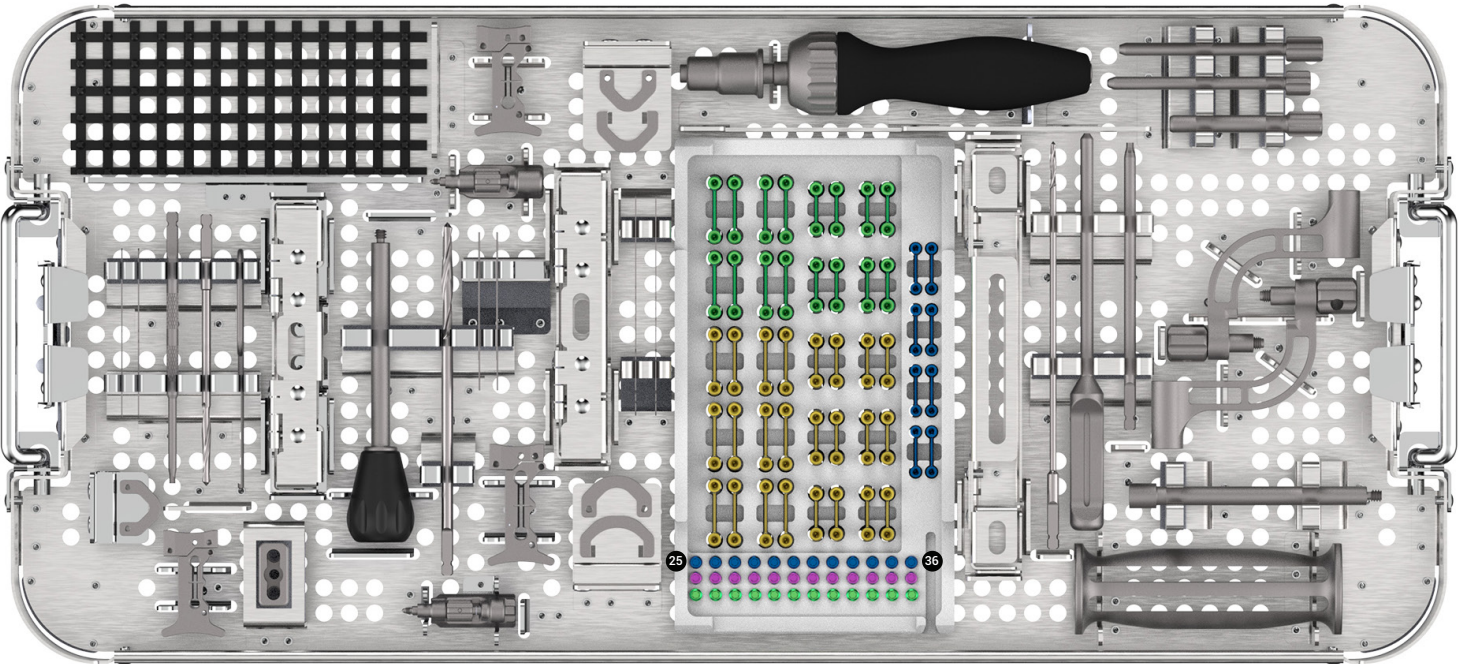
Set Definition - Implants



Standard 20 Implants

Reference	SKU	Description	QTY
15	SF452014	StealthFix Ti Implant 4.5mm Post x 20mm Span x 14mm Long	2
16	SF452016	StealthFix Ti Implant 4.5mm Post x 20mm Span x 16mm Long	2
17	SF452018	StealthFix Ti Implant 4.5mm Post x 20mm Span x 18mm Long	2
18	SF452020	StealthFix Ti Implant 4.5mm Post x 20mm Span x 20mm Long	2
19	SF452022	StealthFix Ti Implant 4.5mm Post x 20mm Span x 22mm Long	2
20	SF452024	StealthFix Ti Implant 4.5mm Post x 20mm Span x 24mm Long	2
21	SF452026	StealthFix Ti Implant 4.5mm Post x 20mm Span x 26mm Long	2
22	SF452028	StealthFix Ti Implant 4.5mm Post x 20mm Span x 28mm Long	2
23	SF452030	StealthFix Ti Implant 4.5mm Post x 20mm Span x 30mm Long	2
24	SF452032	StealthFix Ti Implant 4.5mm Post x 20mm Span x 32mm Long	2

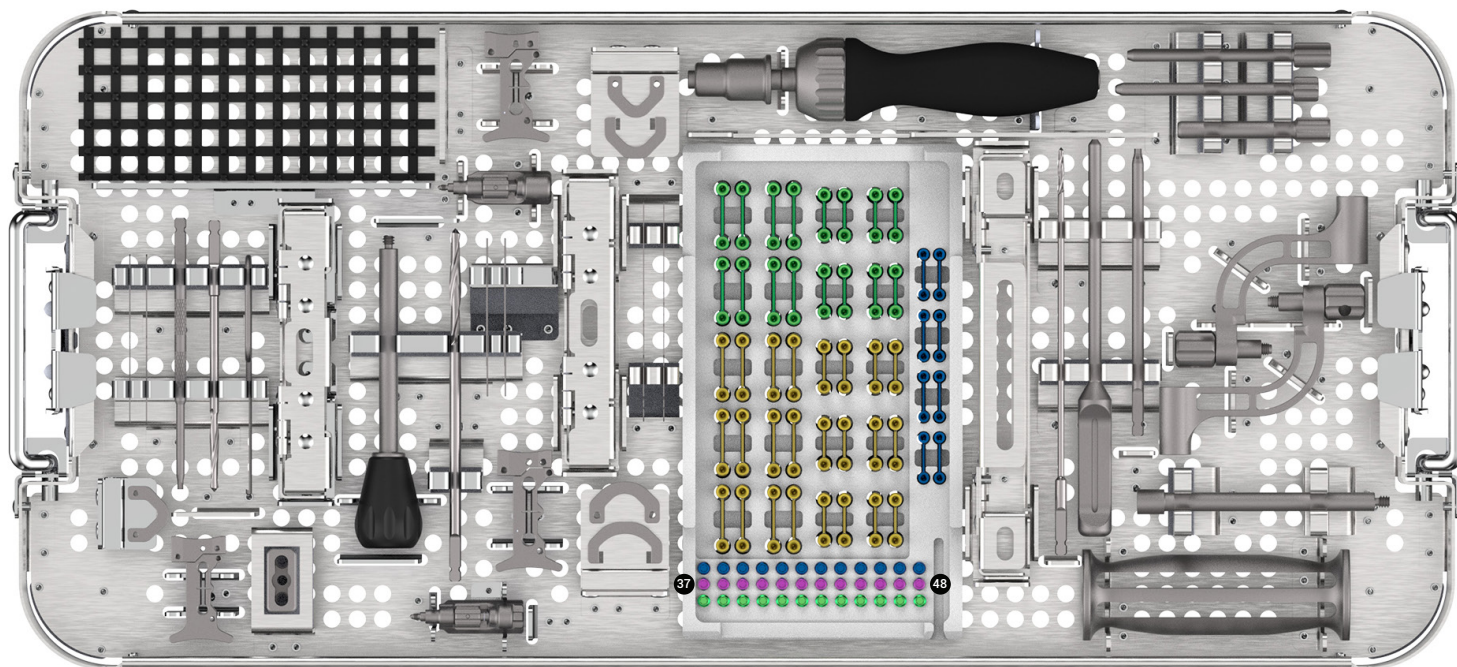
Set Definition - Implants



Screw Implants

Reference	SKU	Description	QTY
25	SF3516	StealthFix Lag Screw 3.5mm x 16mm	1
26	SF3518	StealthFix Lag Screw 3.5mm x 18mm	1
27	SF3520	StealthFix Lag Screw 3.5mm x 20mm	1
28	SF3522	StealthFix Lag Screw 3.5mm x 22mm	1
29	SF3524	StealthFix Lag Screw 3.5mm x 24mm	1
30	SF3526	StealthFix Lag Screw 3.5mm x 26mm	1
31	SF3528	StealthFix Lag Screw 3.5mm x 28mm	1
32	SF3530	StealthFix Lag Screw 3.5mm x 30mm	1
33	SF3532	StealthFix Lag Screw 3.5mm x 32mm	1
34	SF3534	StealthFix Lag Screw 3.5mm x 34mm	1
35	SF3536	StealthFix Lag Screw 3.5mm x 36mm	1
36	SF3538	StealthFix Lag Screw 3.5mm x 38mm	1

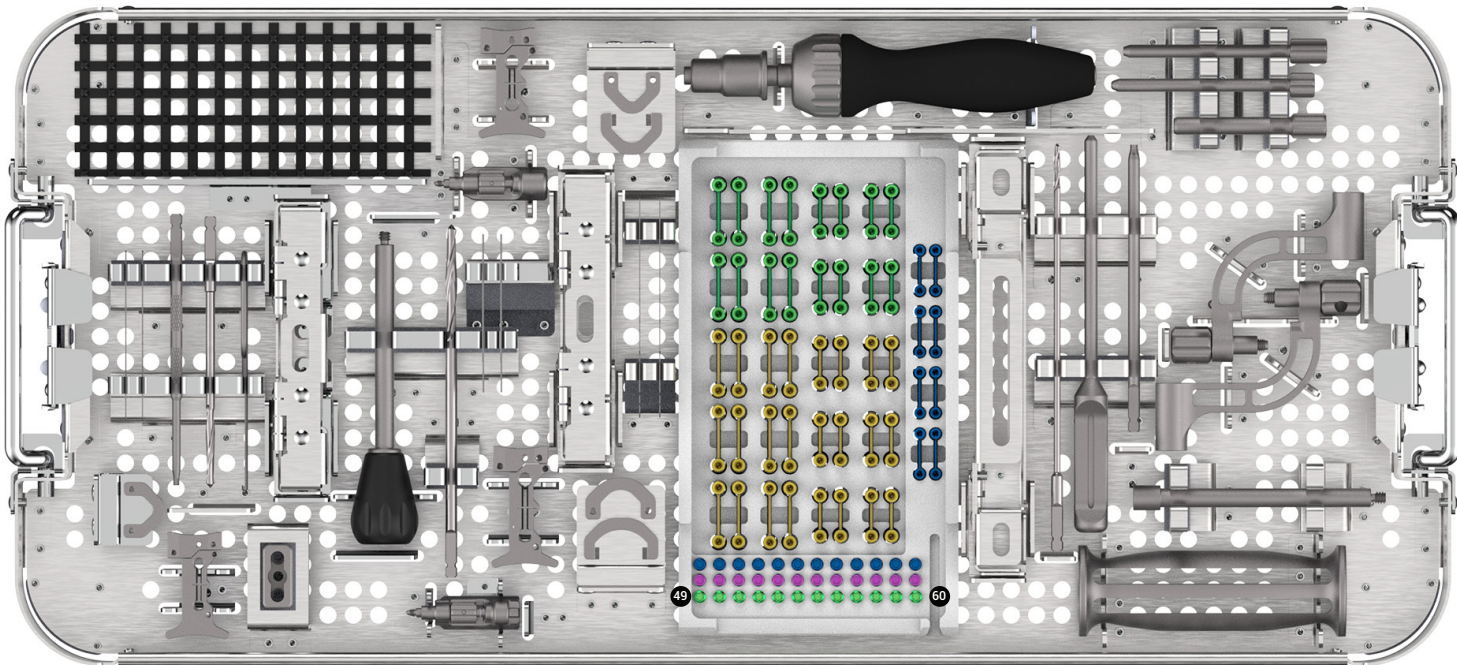
Set Definition - Implants



Screw Implants

Reference	SKU	Description	QTY
37	SF3616	StealthFix Fully Threaded Headed Screw Size 16	1
38	SF3618	StealthFix Fully Threaded Headed Screw Size 18	1
39	SF3620	StealthFix Fully Threaded Headed Screw Size 20	1
40	SF3622	StealthFix Fully Threaded Headed Screw Size 22	1
41	SF3624	StealthFix Fully Threaded Headed Screw Size 24	1
42	SF3626	StealthFix Fully Threaded Headed Screw Size 26	1
43	SF3628	StealthFix Fully Threaded Headed Screw Size 28	1
44	SF3630	StealthFix Fully Threaded Headed Screw Size 30	1
45	SF3632	StealthFix Fully Threaded Headed Screw Size 32	1
46	SF3634	StealthFix Fully Threaded Headed Screw Size 34	1
47	SF3636	StealthFix Fully Threaded Headed Screw Size 36	1
48	SF3638	StealthFix Fully Threaded Headed Screw Size 38	1

Set Definition - Implants



Screw Implants

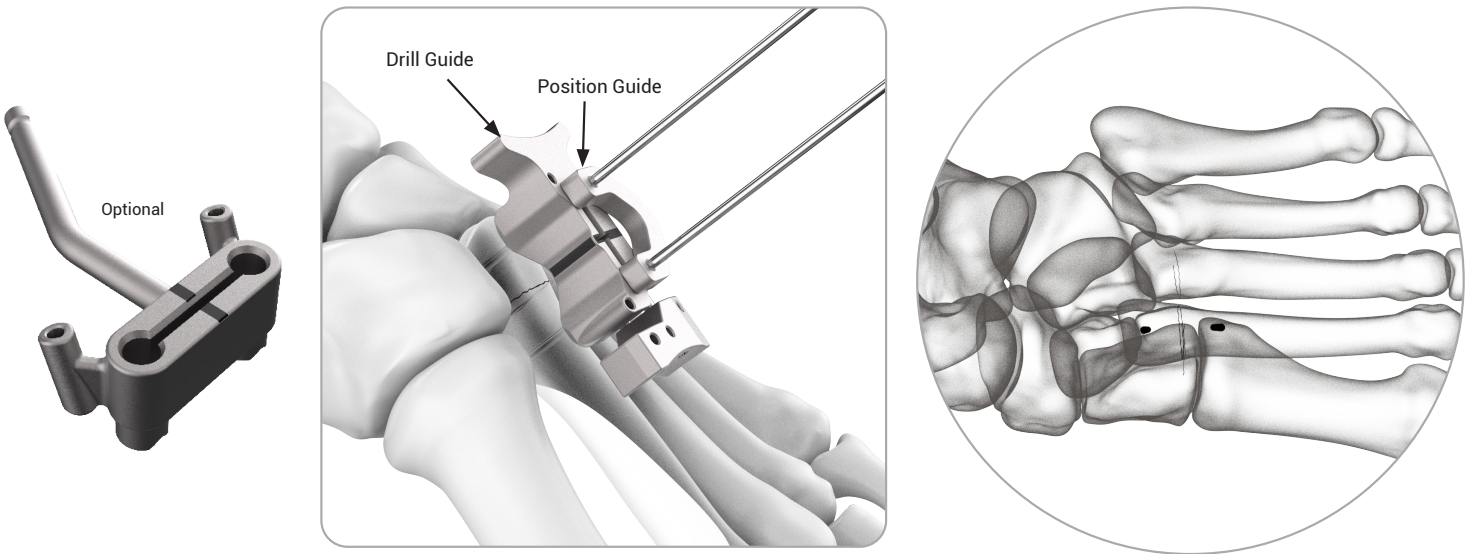
Reference	SKU	Description	QTY
49	SF3716	StealthFix Fully Threaded Headless Screw Size 16	1
50	SF3718	StealthFix Fully Threaded Headless Screw Size 18	1
51	SF3720	StealthFix Fully Threaded Headless Screw Size 20	1
52	SF3722	StealthFix Fully Threaded Headless Screw Size 22	1
53	SF3724	StealthFix Fully Threaded Headless Screw Size 24	1
54	SF3726	StealthFix Fully Threaded Headless Screw Size 26	1
55	SF3728	StealthFix Fully Threaded Headless Screw Size 28	1
56	SF3730	StealthFix Fully Threaded Headless Screw Size 30	1
57	SF3732	StealthFix Fully Threaded Headless Screw Size 32	1
58	SF3734	StealthFix Fully Threaded Headless Screw Size 34	1
59	SF3736	StealthFix Fully Threaded Headless Screw Size 36	1
60	SF3738	StealthFix Fully Threaded Headless Screw Size 38	1

Surgical Technique

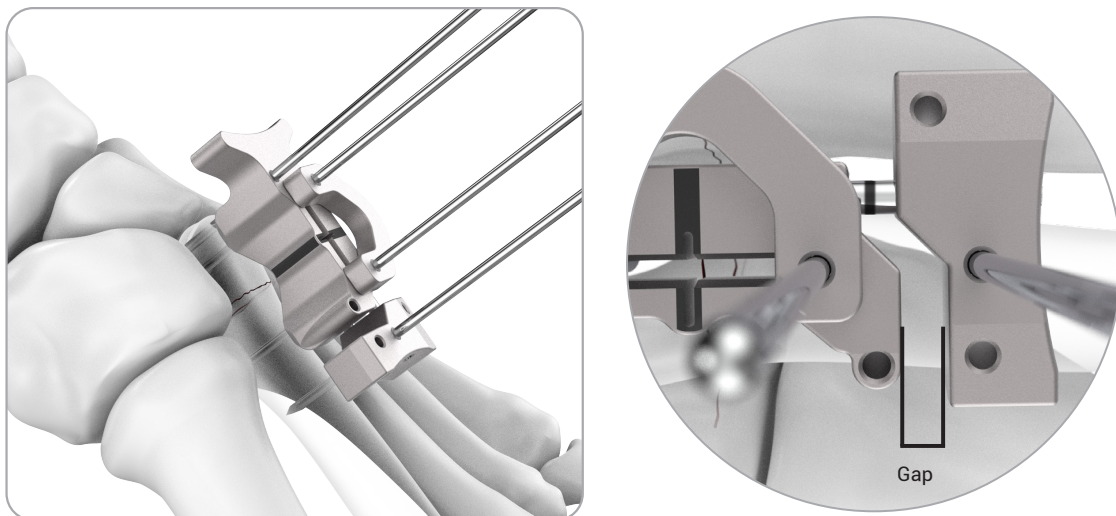
Joint Preparation

1. Place the Drill Guide and Position Guide assembly centered over the fracture or site of fusion. Using the K-Wire holes of the Position Guide place (2) 1.6mm/2.0mm K-Wires respectively to evaluate the final Implant post position. Check position using fluoroscopy. Adjustments can be made to optimize final implant position by removing one or both K-Wires and adjusting accordingly.

Optional: If joint reduction / compression is achieved from alternative instrumentation and/or methods the StealthFix low profile drill saw guide may be used in place of the drill guide. Prior to using the appropriate family low profile drill saw guide, ensure the joint is fully reduced and surfaces are opposed. The Joint Guide will not be utilized as the joint space is already compressed. Ensure final implant position is being verified using the Position Guide and omit steps 2, 4, and 5.



2. Fix the Drill Guide using a K-Wire near the finger rest. Temporarily fix the Drill Guide Slide using a K-Wire in one of the 3 holes. Ensure a gap is present between the Guide Slide and the Drill Guide prior to placing K-Wires.

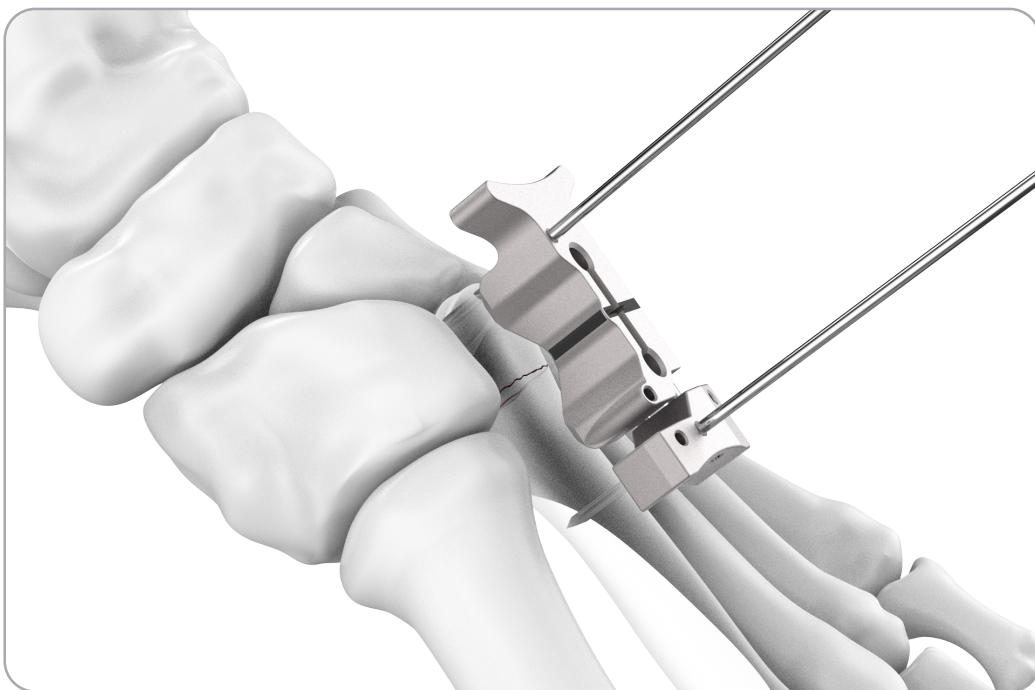


Surgical Technique

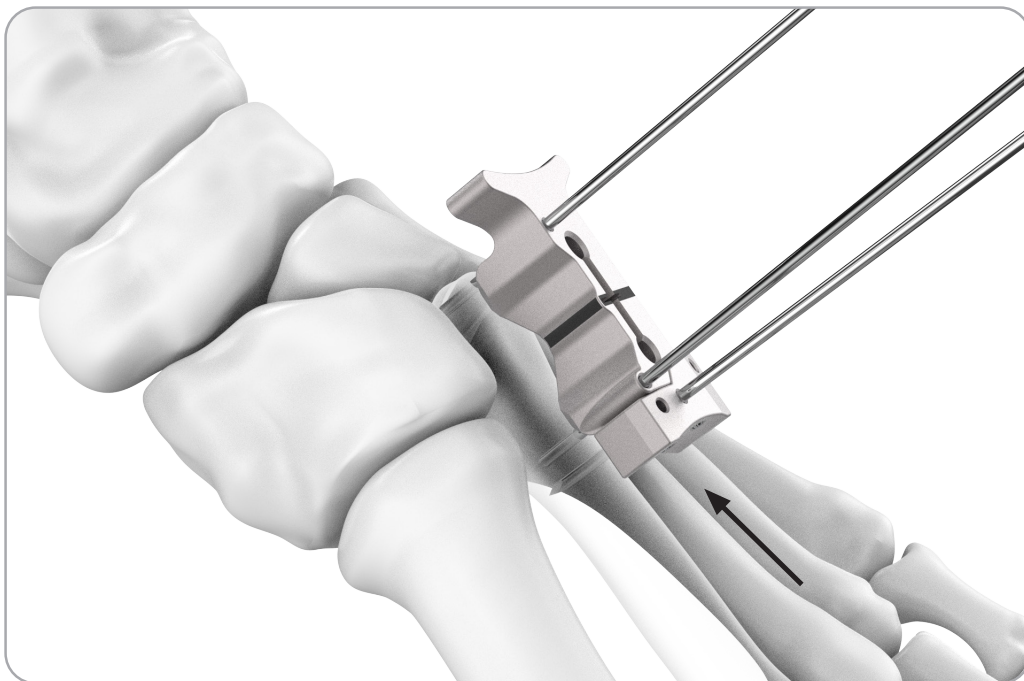
Joint Preparation

3. Remove all positioning instruments including, the Position Guide and 1.6mm K-Wires.

Optional: If the StealthFix low profile drill saw guide is used, fix the instrument using the indicated K-wire holes. The alternative compression device may be removed at this time if desired.



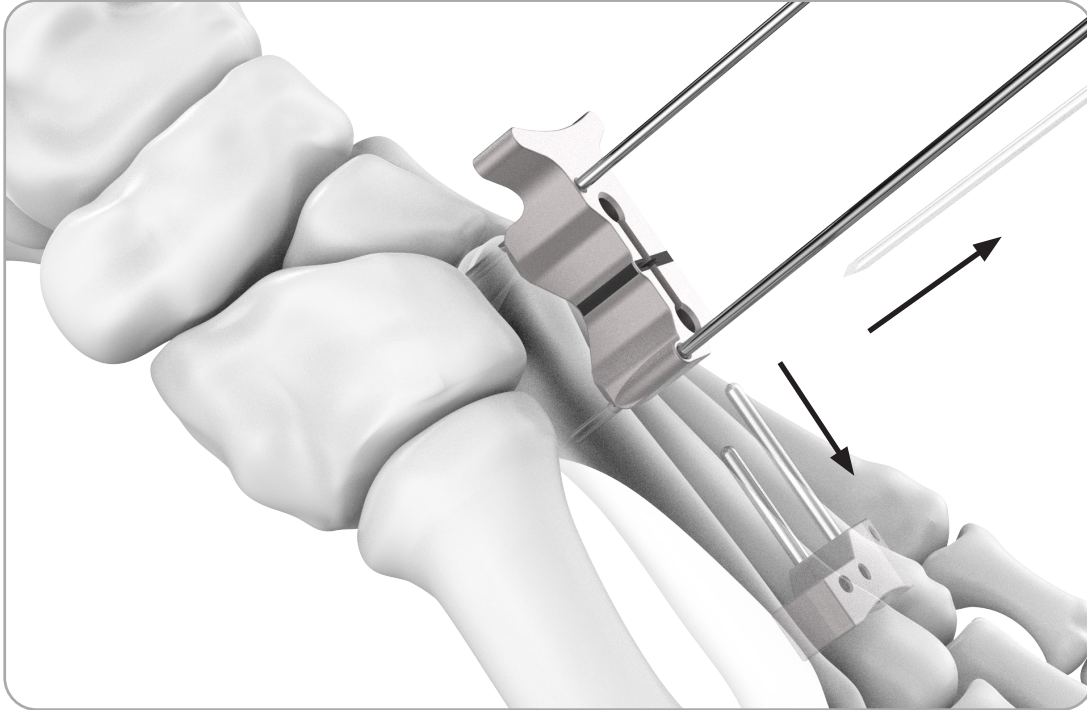
4. Hand compress the Drill Guide and Guide Slide until fracture site is closed. Lock position using a K-Wire in the second hole of the Drill Guide.



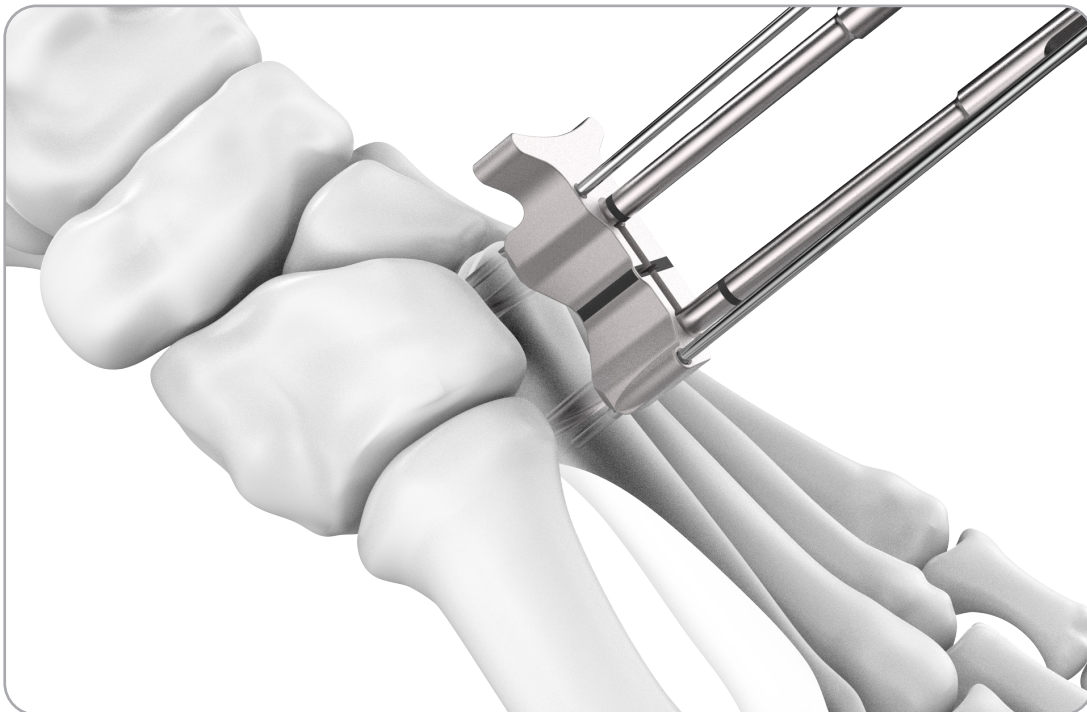
Surgical Technique

Joint Preparation

5. Once compression is locked into place, remove the Guide Slide K-Wire and Guide Slide from assembly.



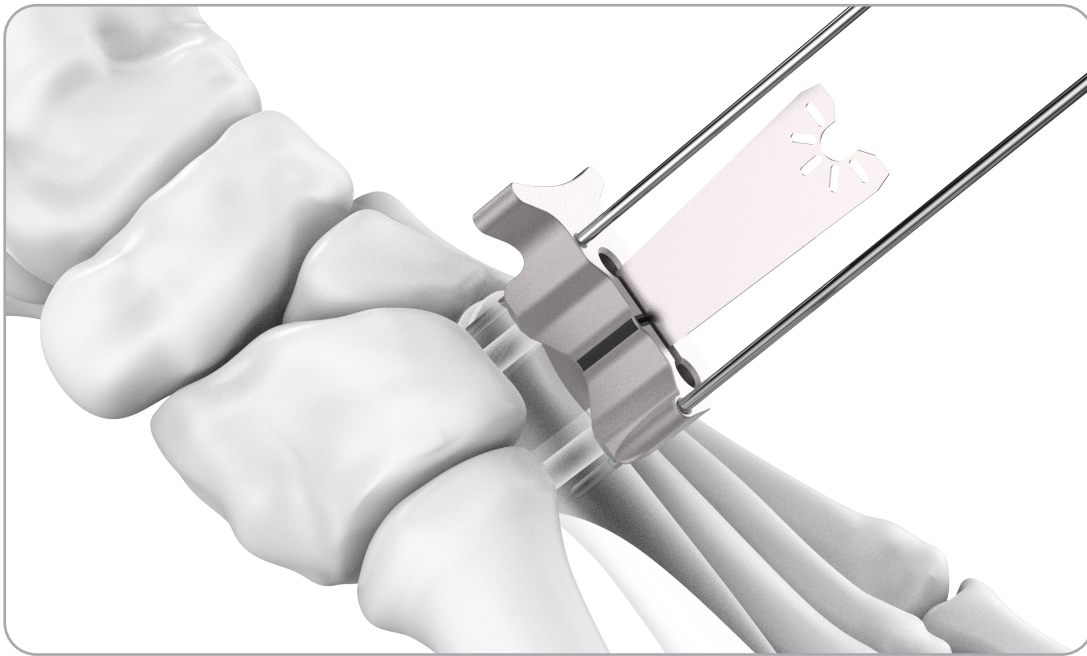
6. Using the corresponding size Drill, drill both post cavities. Drill through the far cortex or until the laser line marking.



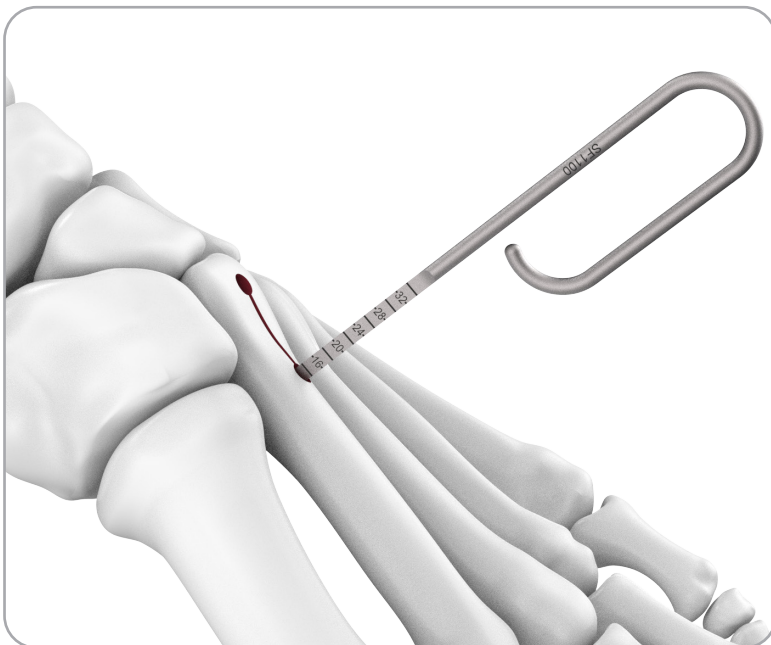
Surgical Technique

Resection & Depth Verification

7. Insert the corresponding size oscillating Saw Blade and remove material until the blade has bottomed out on the Drill Guide. Start the oscillating Saw Blade prior to contacting the bony anatomy.



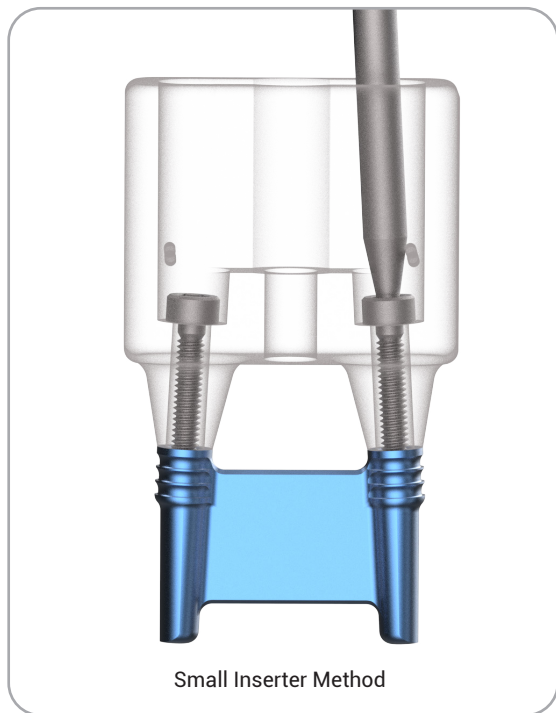
8. Remove K-Wires and preparation instruments. Verify implant size by placing the Depth Gauge into the distal hole, measuring the length of the prepared post cavity. For joints or fixation where the far cortex wall is not accessible, insert the Depth Gauge until it reaches the desired length for both post cavities. (Example: Calcaneocuboid Joint)



Surgical Technique

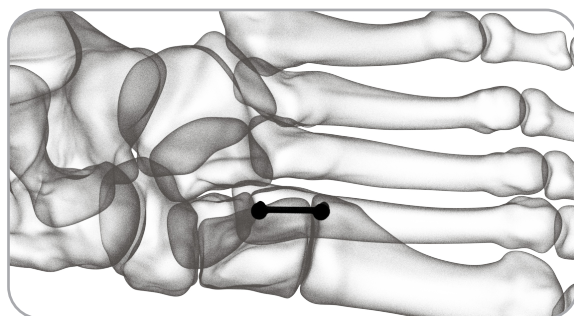
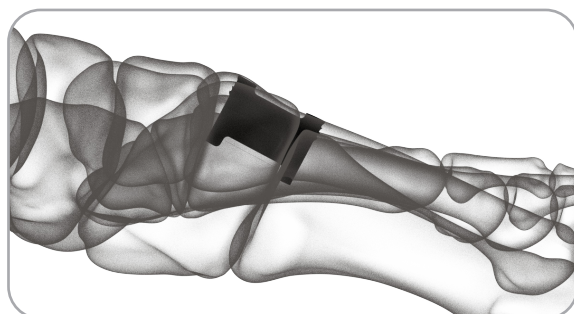
Implantation

9. Assemble the appropriate-sized implant to the Inserter. Then assemble the Impactor Handle to the Inserter.



10. Using a mallet, tamp the assembly until the Implant barbs are flush with the cortical bone surface. For Standard 15 and 20 family Implants ensure the shorter post is inserted in the distal post cavity.

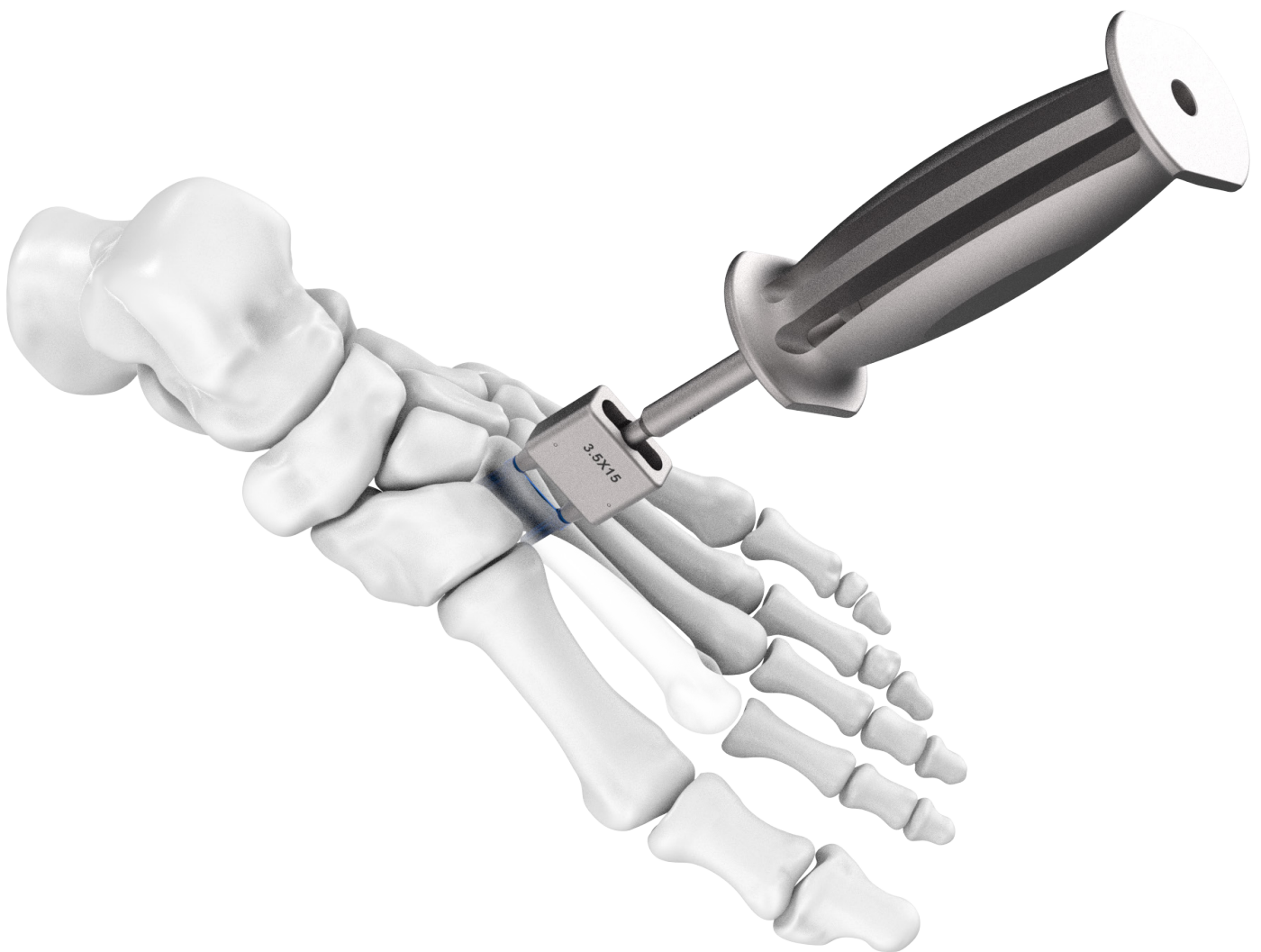
NOTE: Check Implant final position using fluoroscopy.



Revision Technique

(Implant Removal Only)

1. Locate and clear bone to gain access of the Implant post threads.
2. Insert the corresponding size Removal Rod through the Slap Hammer and thread into the Inserter.



Ordering Information

Part No.	Description
NON-STERILE IMPLANTS	
SF351514	StealthFix Ti Implant 3.5mm Post x 15mm Span x 14mm Long
SF351516	StealthFix Ti Implant 3.5mm Post x 15mm Span x 16mm Long
SF351518	StealthFix Ti Implant 3.5mm Post x 15mm Span x 18mm Long
SF351520	StealthFix Ti Implant 3.5mm Post x 15mm Span x 20mm Long
SF451514	StealthFix Ti Implant 4.5mm Post x 15mm Span x 14mm Long
SF451516	StealthFix Ti Implant 4.5mm Post x 15mm Span x 16mm Long
SF451518	StealthFix Ti Implant 4.5mm Post x 15mm Span x 18mm Long
SF451520	StealthFix Ti Implant 4.5mm Post x 15mm Span x 20mm Long
SF451522	StealthFix Ti Implant 4.5mm Post x 15mm Span x 22mm Long
SF451524	StealthFix Ti Implant 4.5mm Post x 15mm Span x 24mm Long
SF451526	StealthFix Ti Implant 4.5mm Post x 15mm Span x 26mm Long
SF451528	StealthFix Ti Implant 4.5mm Post x 15mm Span x 28mm Long
SF451530	StealthFix Ti Implant 4.5mm Post x 15mm Span x 30mm Long
SF451532	StealthFix Ti Implant 4.5mm Post x 15mm Span x 32mm Long
SF452014	StealthFix Ti Implant 4.5mm Post x 20mm Span x 14mm Long
SF452016	StealthFix Ti Implant 4.5mm Post x 20mm Span x 16mm Long
SF452018	StealthFix Ti Implant 4.5mm Post x 20mm Span x 18mm Long
SF452020	StealthFix Ti Implant 4.5mm Post x 20mm Span x 20mm Long
SF452022	StealthFix Ti Implant 4.5mm Post x 20mm Span x 22mm Long
SF452024	StealthFix Ti Implant 4.5mm Post x 20mm Span x 24mm Long
SF452026	StealthFix Ti Implant 4.5mm Post x 20mm Span x 26mm Long
SF452028	StealthFix Ti Implant 4.5mm Post x 20mm Span x 28mm Long
SF452030	StealthFix Ti Implant 4.5mm Post x 20mm Span x 30mm Long
SF452032	StealthFix Ti Implant 4.5mm Post x 20mm Span x 32mm Long

Ordering Information

Part No.	Description
NON-STERILE SCREWS	
SF3516	StealthFix Lag Screw 3.5mm x 16mm
SF3518	StealthFix Lag Screw 3.5mm x 18mm
SF3520	StealthFix Lag Screw 3.5mm x 20mm
SF3522	StealthFix Lag Screw 3.5mm x 22mm
SF3524	StealthFix Lag Screw 3.5mm x 24mm
SF3526	StealthFix Lag Screw 3.5mm x 26mm
SF3528	StealthFix Lag Screw 3.5mm x 28mm
SF3530	StealthFix Lag Screw 3.5mm x 30mm
SF3532	StealthFix Lag Screw 3.5mm x 32mm
SF3534	StealthFix Lag Screw 3.5mm x 34mm
SF3536	StealthFix Lag Screw 3.5mm x 36mm
SF3538	StealthFix Lag Screw 3.5mm x 38mm

Ordering Information

Part No.	Description
NON-STERILE SCREWS	
SF3616	StealthFix Fully Threaded Headed Screw Size 16
SF3618	StealthFix Fully Threaded Headed Screw Size 18
SF3620	StealthFix Fully Threaded Headed Screw Size 20
SF3622	StealthFix Fully Threaded Headed Screw Size 22
SF3624	StealthFix Fully Threaded Headed Screw Size 24
SF3626	StealthFix Fully Threaded Headed Screw Size 26
SF3628	StealthFix Fully Threaded Headed Screw Size 28
SF3630	StealthFix Fully Threaded Headed Screw Size 30
SF3632	StealthFix Fully Threaded Headed Screw Size 32
SF3634	StealthFix Fully Threaded Headed Screw Size 34
SF3636	StealthFix Fully Threaded Headed Screw Size 36
SF3638	StealthFix Fully Threaded Headed Screw Size 38
SF3716	StealthFix Fully Threaded Headless Screw Size 16
SF3718	StealthFix Fully Threaded Headless Screw Size 18
SF3720	StealthFix Fully Threaded Headless Screw Size 20
SF3722	StealthFix Fully Threaded Headless Screw Size 22
SF3724	StealthFix Fully Threaded Headless Screw Size 24
SF3726	StealthFix Fully Threaded Headless Screw Size 26
SF3728	StealthFix Fully Threaded Headless Screw Size 28
SF3730	StealthFix Fully Threaded Headless Screw Size 30
SF3732	StealthFix Fully Threaded Headless Screw Size 32
SF3734	StealthFix Fully Threaded Headless Screw Size 34
SF3736	StealthFix Fully Threaded Headless Screw Size 36
SF3738	StealthFix Fully Threaded Headless Screw Size 38

Ordering Information

Part No.	Description
NON-STERILE INSTRUMENTS	
SF1000	K-Wire 1.6mm X 150mm
SF1001	K Wire 1.6mm X 100mm
SF1002	K Wire 2.0mm X 100mm
SF1035	StealthFix Screw Depth Gauge
SF1100	StealthFix Universal Post Depth Gauge
SF1300	StealthFix Joint Gauge 3.5mm
SF1400	StealthFix Joint Gauge 4.5mm
SF2014	StealthFix Targeting Guide Shallow
SF2022	StealthFix Targeting Guide Deep
SF2030	StealthFix K-Wire Sleeve
SF2031	StealthFix Drill Sleeve
SF2032	StealthFix Screw Sleeve
SF2300	StealthFix Drill Guide 3.5mm X 15mm
SF2301	StealthFix Small Position Guide
SF2302	StealthFix Small Drill Saw Guide LowPro
SF2400	StealthFix Drill Guide 4.5mm X 15mm
SF2401	StealthFix STD 15 Position Guide
SF2402	StealthFix STD 15 Drill Saw Guide LowPro
SF2405	StealthFix Drill Guide 4.5mm X 20mm
SF2406	StealthFix STD 20 Position Guide
SF2407	StealthFix STD 20 Guide LowPro
SF2410	StealthFix Guide Slide 4.5mm
SF2412	StealthFix Guide Slide Small

Ordering Information

Part No.	Description
NON-STERILE INSTRUMENTS	
SF2420	StealthFix Saw Sleeve 4.5mm X 15mm
SF2425	StealthFix Saw Sleeve 4.5mm X 20mm
SF3110	StealthFix Impactor Long Handle
SF3315	StealthFix Inserter 3.5mm
SF3316	StealthFix STD Implant Tamp
SF3415	StealthFix Inserter 4.5mm X 15mm
SF3416	StealthFix STD Implant Tamp
SF3420	StealthFix Inserter 4.5mm X 20mm
SF4025	StealthFix Screw Drill 2.5mm
SF4335	StealthFix Post Drill 3.5mm
SF4445	StealthFix Post Drill 4.5mm
SF5020	StealthFix Hex Driver 2.0mm
SF5025	StealthFix Hex Driver 2.5mm
SF6343	StealthFix Saw Blade, Stryker 1mm X 43mm
SF7800	StealthFix Ratcheting Handle
SF7910	StealthFix Slap Hammer
SF7930	StealthFix Removal Rod, Small and Standard
SF8011	StealthFix Non-sterile Instrument Case
SF8012	StealthFix Non-sterile Instrument Lid
SF8013	StealthFix Non-sterile Implant Caddy
SF8014	StealthFix Non-sterile Implant Caddy Lid
SF8015	StealthFix Non-sterile 100mm K-wire Cage
SF8016	StealthFix Non-sterile 150mm K-wire Cage

This image shows a full page of white paper with horizontal blue or grey ruling lines, typical of notebook paper. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

INDICATIONS: The StealthFix Intraosseous Fixation System is indicated for fixation of bone fractures, fusions, or for bone reconstructions, including: (1) Arthrodesis in hand or foot surgery. (2) Mono or bi-cortical osteotomies in the foot or hand. (3) Fracture management in the foot or hand. (4) Distal or proximal metatarsal or metacarpal osteotomies. (5) Fixation of osteotomies for Hallux Valgus treatment such as scarf, chevron, etc.

CONTRAINDICATIONS: (1) Patient conditions including insufficient quantity or quality of bone and/or soft tissue. (2) Blood supply limitations and previous or active infections that may inhibit healing. (3) Surgical procedures other than for the indications listed. (4) Patients with conditions that limit their ability or willingness to follow postoperative care instructions. (5) Where material sensitivity is suspected, appropriate testing should be performed and sensitivity ruled out prior to implantation.

This material is intended for health care professionals. Distribution to any other recipient is prohibited. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert.

This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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The StealthFix System is manufactured using Ti-6Al-4V ELI.

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LIT-1596 Rev. 05

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